



# Federal Register

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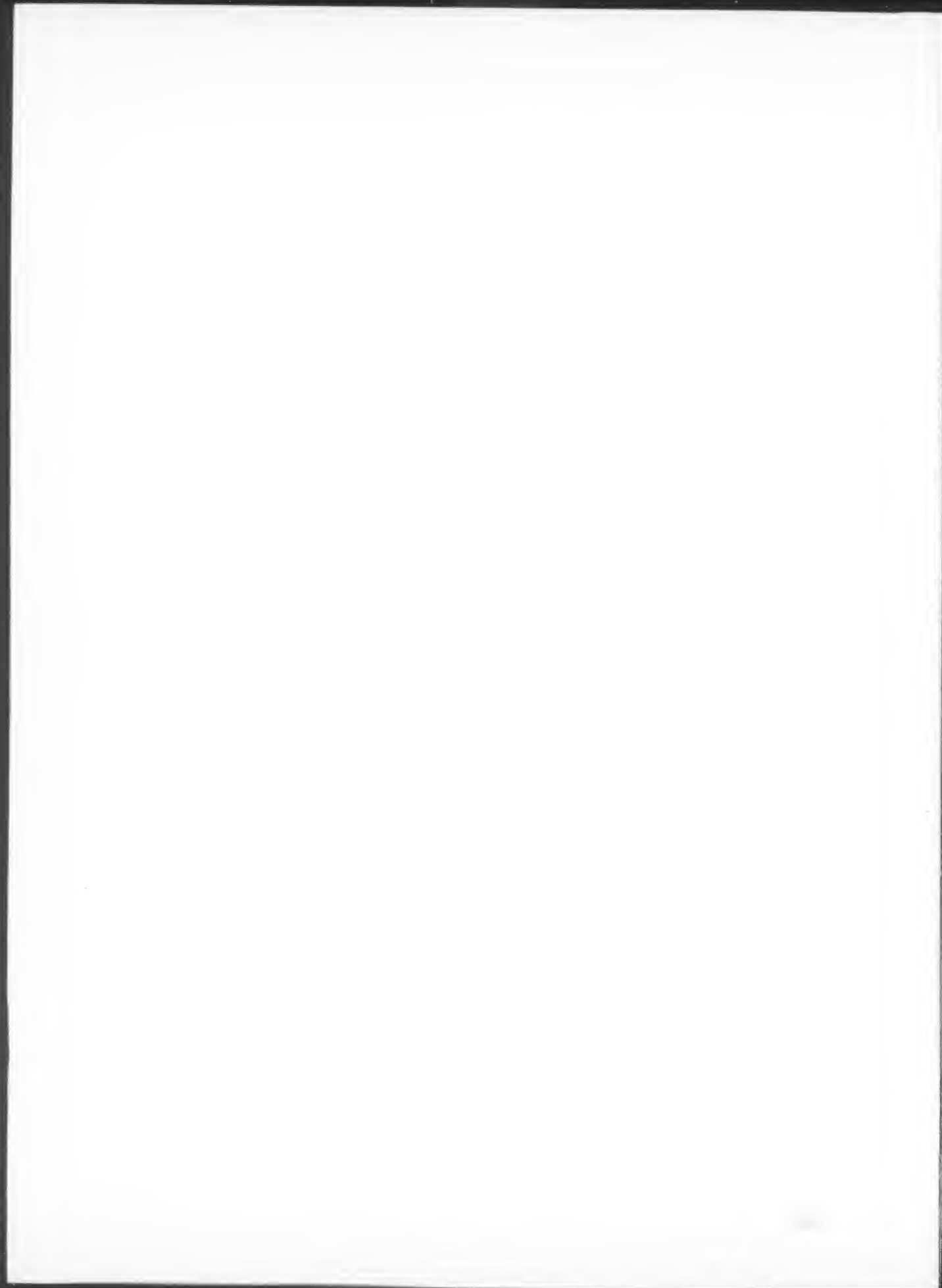
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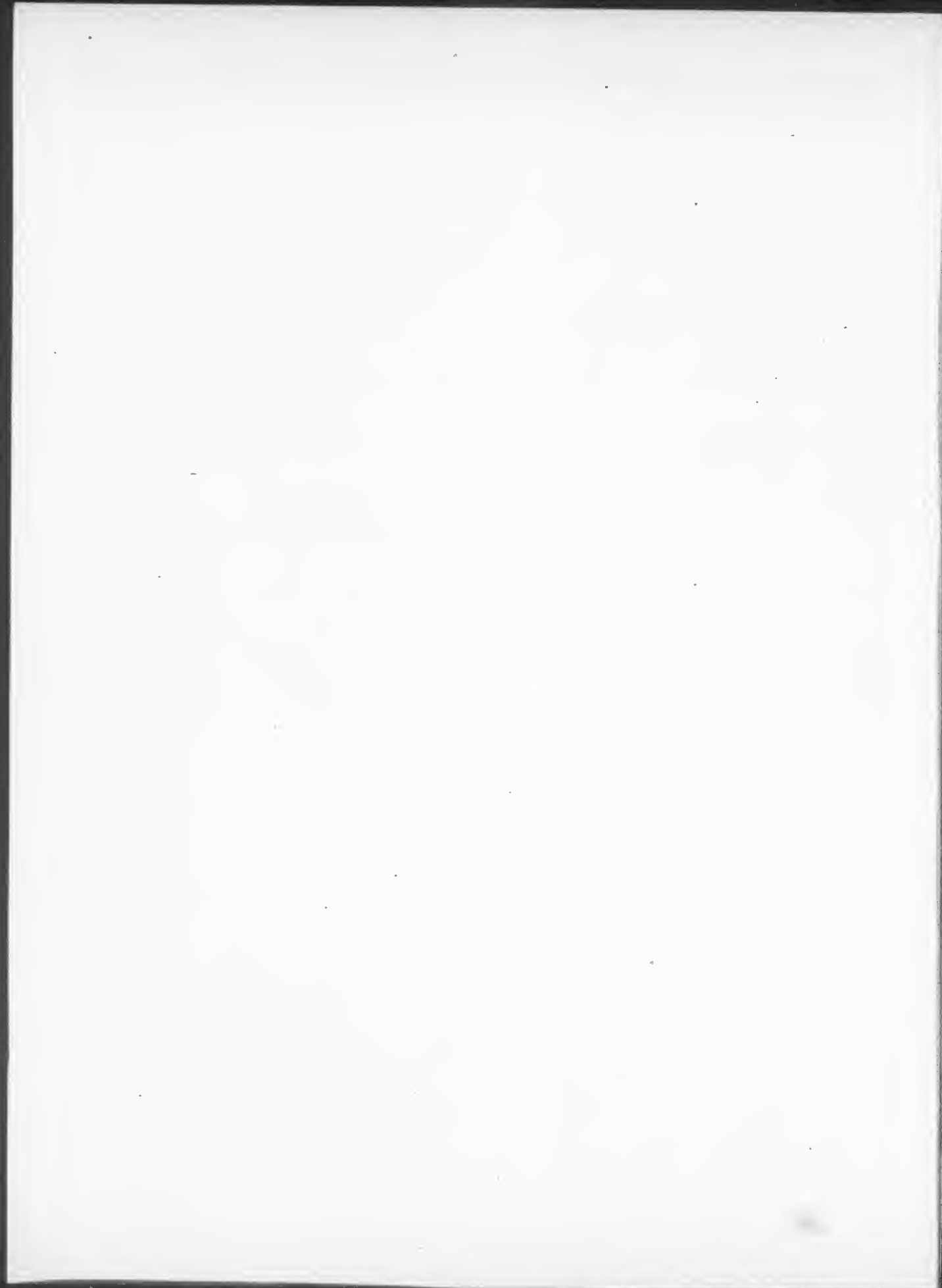
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## DEPARTMENT OF HOMELAND SECURITY

### 8 CFR Parts 328 and 329

[CIS No. 2479-09; DHS Docket No. DHS-2009-0025]

RIN 1615-AB85

### Naturalization for Certain Persons in the U.S. Armed Forces

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

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Department of Homeland Security (DHS) regulations by implementing a statutory amendment reducing from three years to one year the length of time a member of the United States Armed Forces has to serve to qualify for naturalization through service in the Armed Forces. In addition, this rule amends DHS regulations by implementing a statutory amendment to include as eligible for naturalization individuals who served or are serving as members of the Selected Reserve of the Ready Reserve of the U.S. Armed Forces during specified periods of hostility. This rule also amends the regulations to remove the requirement to submit Form G-325B, Biographic Information, with Form N-400, Application for Naturalization, for applicants applying for naturalization through service in the U.S. Armed Forces. By eliminating the Form G-325B requirement, the rule will reduce the response burden and amount of time it takes U.S. Armed Forces members to complete the paperwork required with a naturalization application.

**DATES:** This rule is effective February 18, 2010.

**FOR FURTHER INFORMATION CONTACT:** Kristie Krebs, Office of Field Operations, U.S. Citizenship and Immigration Services, Department of

Homeland Security, 111 Massachusetts Avenue, NW., 2nd Floor, Washington, DC 20529-2030; telephone number 202-272-1001. This is not a toll-free number. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at 800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Prior to November 24, 2003, aliens who served in the U.S. Armed Forces during peacetime were eligible for naturalization after serving honorably for an aggregate period of three years. See Immigration & Nationality Act (INA) sec. 328(a), 8 U.S.C. 1439(a) (2002) (amended (2003)); 8 CFR 328.2(a). Additionally, aliens who served in the U.S. Armed Forces during specific periods of hostilities were eligible for naturalization without having served for any particular length of time so long as the service was in active-duty status. See INA sec. 329(a), 8 U.S.C. 1440(a) (2002) (amended (2003)); 8 CFR 329.2(a).

On November 24, 2003, Congress amended these requirements in title XVII of the National Defense Authorization Act for Fiscal Year 2004 (NDAA), (Pub. L. 108-136, 117 Stat. 1392 (2003)), and made them effective as if enacted on September 11, 2001. The NDAA reduced from three years to one year the period of military service required to qualify for naturalization through service in the U.S. Armed Forces during peacetime. See INA sec. 328(a); 8 U.S.C. 1439(a) (2003); see also NDAA sec. 1701(c)(2). In addition, the NDAA extended the benefit of naturalization not only to individuals who served honorably in an active duty status during specified periods of hostilities, but also to individuals who have served honorably as members of the Selected Reserve of the Ready Reserve of the U.S. Armed Forces during such periods of hostilities. See INA sec. 329(a); 8 U.S.C. 1440(a) (2003); see also NDAA sec. 1702.

U.S. Citizenship and Immigration Services (USCIS) has been applying these statutory amendments since the law was enacted on November 24, 2003. This final rule updates the regulations to reflect these amendments. In addition, this rule removes an unnecessary paperwork requirement in

the naturalization application process for applicants with qualifying service in the U.S. Armed Forces.

##### II. Discussion

###### A. One Year or More of Military Service

Current regulations at 8 CFR 328.2(b) continue to list three or more years of service in the U.S. Armed Forces as an eligibility requirement for naturalization based on service in the U.S. Armed Forces. This final rule reduces the required number of years of service to one or more years in order to conform the regulations to the applicable statutory provision at section 328(a) of the INA, 8 U.S.C. 1439(a), as amended by the NDAA. See revised 8 CFR 328.2(b).

###### B. Service in the Selected Reserve of the Ready Reserve During Periods of Hostilities

USCIS regulations, 8 CFR 329.2(a), currently limit eligibility for naturalization based on service during specified periods of hostilities to those who served honorably in an active duty status in the U.S. Armed Forces. In conformance with the expansion of eligibility made by the NDAA (see section 329(a) of the INA, 8 U.S.C. 1440(a)), this final rule extends eligibility for naturalization to include those individuals who have served honorably in the U.S. Armed Forces either in an active duty status or as a member of the Selected Reserve of the Ready Reserve. See revised 8 CFR 329.2(a). In addition, this rule amends the title of 8 CFR part 329 to include service in the Selected Reserve of the Ready Reserve. Currently, the title only lists active duty service as a basis for naturalization where service occurred during specified periods of hostilities.

###### C. Elimination of Requirement to Submit Form G-325B

Applicants applying for naturalization based on service in the U.S. Armed Forces have been required to submit Form G-325B, Biographic Information, along with Form N-400, Application for Naturalization. See 8 CFR 328.4, 329.4(a). Prior to 2001, USCIS sent applicants' completed Forms G-325B to the Department of Defense (DoD) for background checks. As part of improvements to this process, DoD authorized the USCIS in 2001 to conduct these background checks.

Subsequently, USCIS determined that the information collected on Form N-400 (e.g., name, date of birth, Social Security number) was sufficient to perform the background checks. Therefore, USCIS discontinued sending Forms G-325B to DoD. Moreover, USCIS notes that it does not use the G-325B in its adjudication of Forms N-400, or for any other purpose.

Notwithstanding the discontinued use of Form G-325B, USCIS regulations continue to require applicants to submit the form with their naturalization applications. See 8 CFR 328.4 and 329.4(a). However, continuing to require Form G-325B would needlessly increase applicant response and USCIS processing times, as USCIS must issue a Request for Evidence and place the case on hold if the Form G-325B is not submitted with the Form N-400. Because the submission of a Form G-325B no longer serves a purpose in the adjudication process, this rule removes the Form G-325B submission requirement for applicants applying for naturalization under section 328 or 329 of the INA. See revised 8 CFR 328.4 and 329.4(a).

### III. Regulatory Requirements

#### A. Administrative Procedure Act

The Administrative Procedure Act (APA) provides that an agency may dispense with notice and comment rulemaking procedures when an agency is promulgating an interpretative rule, a general statement of policy, or a rule of agency organization, procedure, or practice. See 5 U.S.C. 553(b)(A). The elimination of the requirement to submit Form G-325B is procedural in nature and does not alter the substantive rights of affected naturalization applicants. Accordingly, DHS finds that this part of the rule is exempt from the notice and comment requirements under the APA at 5 U.S.C. 553(b)(A).

The APA provides that an agency may dispense with notice and comment rulemaking procedures when an agency, for "good cause," finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." See 5 U.S.C. 553(b)(B). This rule amends DHS regulations to conform with the changes made by the NDAA, reducing from three years to one year the amount of time a member of the U.S. Armed Forces has to serve to qualify for naturalization and extending the benefit of expedited naturalization to members of the Selected Reserve of the Ready Reserve. INA sec. 328(a), 329(a); 8 U.S.C. 1439(a), 1440(a). These requirements were mandated by statute and DHS has applied these

requirements since the law was enacted in 2003 (effective, with some exceptions, as if enacted on September 11, 2001). DHS views the act of promulgating this part of the rule as both ministerial and non-controversial. Accordingly, DHS finds that notice and comment is unnecessary and that this part of the rule is except from the notice and comment requirements under the APA at 5 U.S.C. 553(b)(B).

#### B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601-612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. When an agency invokes the good cause exception under the Administrative Procedure Act to make changes effective through an interim final or final rule, the RFA does not require an agency to prepare a regulatory flexibility analysis. DHS has determined in this final rule that good cause exists under 5 U.S.C. 553(b) to exempt this rule from the notice and comment. Therefore, a regulatory flexibility analysis is not required for this rule. However, DHS does expect that this rule will not have a significant economic impact on a substantial number of small entities because it affects only individuals.

#### C. Executive Order 12866

This rule is not a significant regulatory action as defined under Executive Order 12866, section 3(f), Regulatory Planning and Review. Thus it has not been reviewed by the Office of Management and Budget (OMB).

#### D. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### E. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996. See 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million

or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

#### F. Executive Order 13132: Federalism

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

#### G. Executive Order 12988: Civil Justice Reform

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

#### H. Paperwork Reduction Act of 1995 (PRA)

Under the Paperwork Reduction Act of 1995, Public Law 104-13, 109 Stat. 163 (1995), all Departments are required to submit to OMB, for review and approval, any reporting or recordkeeping requirements inherent in a rule. This rulemaking does not propose to impose any new reporting or recordkeeping requirements under the PRA.

OMB previously approved the use of forms G-325, G-325A, G-325B, and G-325C under the same OMB Control No. 1615-0008. Removing the requirement to submit Form G-325B will reduce the number of respondents and annual burden hours associated with OMB Control No. 1615-0008. Accordingly, USCIS will submit the Form OMB 83-C, Correction Worksheet, to OMB to reduce the annual number of respondents and annual burden hours.

#### List of Subjects

##### 8 CFR Part 328

Citizenship and naturalization, Military personnel, Armed Forces personnel, Application requirements, Residency requirements.

##### 8 CFR Part 329

Citizenship and naturalization, Military personnel, Armed Forces personnel, Application requirements. ■ Accordingly, chapter I of Title 8 of the Code of Federal Regulations is amended as follows:

**PART 328—SPECIAL CLASSES OF PERSONS WHO MAY BE NATURALIZED: PERSONS WITH 1 YEAR OF SERVICE IN THE UNITED STATES ARMED FORCES**

■ 1. The heading for part 328 is revised as set forth above.

■ 2. The authority citation for part 328 continues to read as follows:

Authority: 8 U.S.C. 1103, 1439, 1443.

■ 3. Section 328.2 is amended by revising paragraph (b) to read as follows:

**§ 328.2 Eligibility.**

\* \* \* \* \*

(b) Has served under paragraph (a) of this section for a period of 1 or more years, whether that service is continuous or discontinuous;

\* \* \* \* \*

■ 4. Section 328.4 is amended by revising the last sentence to read as follows:

**§ 328.4 Application.**

\* \* \* The application must be accompanied by Form N-426, Request for Certification of Military or Naval Service.

**PART 329—SPECIAL CLASSES OF PERSONS WHO MAY BE NATURALIZED: PERSONS WITH ACTIVE DUTY OR CERTAIN READY RESERVE SERVICE IN THE UNITED STATES ARMED FORCES DURING SPECIFIED PERIODS OF HOSTILITIES**

■ 5. The heading for part 329 is revised as set forth above.

■ 6. The authority citation for part 329 continues to read as follows:

Authority: 8 U.S.C. 1103, 1440, 1443; 8 CFR part 2.

■ 7. Section 329.2 is amended by revising paragraph (a) introductory text to read as follows:

**§ 329.2 Eligibility.**

\* \* \* \* \*

(a) Has served honorably in the Armed Forces of the United States as a member of the Selected Reserve of the Ready Reserve or in an active duty status in the Armed Forces of the United States during;

\* \* \* \* \*

■ 8. Section 329.4 is amended by revising the last sentence of paragraph (a) to read as follows:

**§ 329.4 Application and evidence.**

(a) Application. \* \* \* The application must be accompanied by

Form N-426, Request for Certification of Military or Naval Service.

\* \* \* \* \*

Janet Napolitano,  
Secretary.

[FR Doc. 2010-578 Filed 1-15-10; 8:45 am]

BILLING CODE 9111-97-P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. FAA-2010-0009; Directorate Identifier 2010-NE-01-AD; Amendment 39-16178; AD 2010-02-08]

RIN 2120-AA64

**Airworthiness Directives; Turbomeca Turmo IV A and IV C Turboshift Engines**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

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

During a maintenance inspection before the first flight of the day, an oil leak was found on an engine deck. A circumferential crack on the intermediate bearing return flexible pipe union (pipe part number 9 560 17 606 0) was identified as the origin of the leak. A similar oil pipe union crack was then reported at the same location on another engine, on the same pipe part number. This pipe part number was approved as Modification TU 233 in 2008.

Although such cracks have been detected and did not lead to an in-service event, the possibility exists that some additional cracks could occur and may not be detected before the potential complete rupture of the union.

We are issuing this AD to prevent a helicopter engine in-flight shutdown resulting in an emergency auto-rotation landing or accident.

**DATES:** This AD becomes effective February 3, 2010.

We must receive comments on this AD by February 18, 2010.

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

• **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.

• **Mail:** U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

• **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• **Fax:** (202) 493-2251.

Contact Turbomeca S.A., 40220 Tarnos, France; e-mail: [noria-dallas@turbomeca.com](mailto:noria-dallas@turbomeca.com); telephone 33 05 59 74 40 00, fax 33 05 59 74 45 15, or go to: <http://www.turbomeca-support.com>, for a copy of the service information identified in this AD.

**Examining the AD Docket**

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

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

**SUPPLEMENTARY INFORMATION:**

**Discussion**

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2009-0261-E, dated December 18, 2009 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

During a maintenance inspection before the first flight of the day, an oil leak was found on an engine deck. A circumferential crack on the intermediate bearing return flexible pipe union (pipe part number 9 560 17 606 0) was identified as the origin of the leak. A similar oil pipe union crack was then reported at the same location on another engine, on the same pipe part number. This pipe part number was approved as Modification TU 233 in 2008.

Although such cracks have been detected and did not lead to an in-service event, the possibility exists that some additional cracks could occur and may not be detected before the potential complete rupture of the union.

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

#### Relevant Service Information

Turbomeca has issued Alert Service Bulletin No. A249 72 0809, Version A, dated December 15, 2009. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

#### FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of EASA and is approved for operation in the United States. Pursuant to our bilateral agreement with EASA, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This AD requires, for Turmo IV A and Turmo IV C engines that have incorporated Turbomeca Modification TU 233, initial and repetitive visual inspections for the absence of oil leakage or seepage from the unions of the intermediate bearing return flexible pipes.

#### FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because failures of the flexible pipe unions, which if not corrected, could lead to an in-flight engine shutdown and a forced autorotation landing or accident. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

#### Interim Actions

These actions are interim actions and we may take further rulemaking actions in the future.

#### Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA-2010-0009; Directorate Identifier 2010-NE-01-AD"

at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477-78).

#### Authority for This Rulemaking

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

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

#### Regulatory Findings

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

For the reasons discussed above, I certify this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

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

Air transportation, Aircraft, Aviation safety, Safety.

#### Adoption of the Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**2010-02-08 Turbomeca:** Amendment 39-16178; Docket No. FAA-2010-0009; Directorate Identifier 2010-NE-01-AD.

#### Effective Date

(a) This airworthiness directive (AD) becomes effective February 3, 2010.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to Turbomeca Turmo IV A and IV C turboshaft engines that have incorporated Turbomeca Modification TU 233. These engines are installed on, but not limited to, Eurocopter SA 330F, G, or J PUMA helicopters.

#### Reason

(d) During a maintenance inspection before the first flight of the day, an oil leak was found on an engine deck. A circumferential crack on the intermediate bearing return flexible pipe union (pipe part number 9 560 17 606 0) was identified as the origin of the leak. A similar oil pipe union crack was then reported at the same location on another engine, on the same pipe part number. This pipe part number was approved as Modification TU 233 in 2008.

Although such cracks have been detected and did not lead to an in-service event, the possibility exists that some additional cracks could occur and may not be detected before the potential complete rupture of the union. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. We are issuing this AD to prevent a helicopter engine in-flight shutdown resulting in an emergency autorotation landing or accident.

**Actions and Compliance**

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

(1) Before the next flight after the effective date of this AD, and thereafter daily after the last flight of the day until further notice, visually inspect for absence of oil leakage or seepage from both unions of the intermediate bearing return flexible pipes, part number 9 560 17 606 0.

(2) If any oil leakage or seepage is found, disassemble the pipe and visually inspect the unions.

(3) If no crack is found, re-install the pipe.

(4) If any crack is found, remove the pipe from service and replace it.

(5) The actions required by paragraph (e)(1) of this AD may be performed by the owner/operator holding at least a private pilot certificate, and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9 and 91.417(a)(2)(v).

**FAA AD Differences**

(f) None.

**Alternative Methods of Compliance (AMOCs)**

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

**Related Information**

(h) Refer to MCAI Airworthiness Directive 2009-0261-E, dated December 18, 2009, and Turbomeca Alert Mandatory Service Bulletin No. A249 72 0809, Version A, dated December 15, 2009, for related information. Contact Turbomeca S.A., 40220 Tarnos, France; e-mail: [noria-dallas@turbomeca.com](mailto:noria-dallas@turbomeca.com); telephone 33 05 59 74 40 00, fax 33 05 59 74 45 15, or go to: <http://www.turbomeca-support.com>, for a copy of this service information.

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

**Material Incorporated by Reference**

(j) None.

Issued in Burlington, Massachusetts, on January 12, 2010.

**Peter A. White,**

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

[FR Doc. 2010-758 Filed 1-15-10; 8:45 am]

**BILLING CODE 4910-13-P**

**SECURITIES AND EXCHANGE COMMISSION****17 CFR Part 240**

[Release No. 34-61335; File No. S7-12-09]

RIN 3235-AK31

**Shareholder Approval of Executive Compensation of TARP Recipients**

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is adopting amendments to the proxy rules under the Securities Exchange Act of 1934 to set forth certain requirements for U.S. registrants subject to Section 111(e) of the Emergency Economic Stabilization Act of 2008. Section 111(e) of the Emergency Economic Stabilization Act of 2008 requires companies that have received financial assistance under the Troubled Asset Relief Program ("TARP") to permit a separate shareholder advisory vote to approve the compensation of executives, as disclosed pursuant to the compensation disclosure rules of the Commission, during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding. The amendments are intended to help implement this requirement by specifying and clarifying it in the context of the Federal proxy rules.

**DATES:** *Effective Date:* February 18, 2010.

**FOR FURTHER INFORMATION CONTACT:** John Harrington, Attorney-Adviser, or N. Sean Harrison, Special Counsel, Division of Corporation Finance, at (202) 551-3430, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-3628.

**SUPPLEMENTARY INFORMATION:** We are adopting new Rule 14a-20 and amendments to Schedule 14A<sup>1</sup> and Rule 14a-6<sup>2</sup> under the Securities Exchange Act of 1934 ("Exchange Act").<sup>3</sup>

**I. Background**

In July 2009, we published for public comment<sup>4</sup> proposed amendments to the proxy rules under the Exchange Act to set forth certain requirements for U.S. registrants subject to Section 111(e) of

the Emergency Economic Stabilization Act of 2008 ("EESA").<sup>5</sup>

Section 111(e) of the EESA, as amended by Section 7001 of the American Recovery and Reinvestment Act of 2009<sup>6</sup> on February 17, 2009, requires any entity that is a recipient of financial assistance under the Troubled Asset Relief Program ("TARP") to "permit a separate shareholder vote to approve the compensation of executives, as disclosed pursuant to the compensation disclosure rules of the Commission (which disclosure shall include the compensation discussion and analysis, the compensation tables, and any related material)."<sup>7</sup> Companies that have received financial assistance under the TARP are required to provide this separate shareholder vote during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding.<sup>8</sup> The shareholder vote required by Section 111(e) of the EESA is not binding on the board of directors of a TARP recipient, and such vote will not be construed as overruling a board decision or as creating or implying any additional fiduciary duty by the board.<sup>9</sup> The vote also will not be construed to restrict or limit the ability of shareholders to make proposals for inclusion in proxy materials related to executive compensation.<sup>10</sup>

<sup>5</sup> 12 U.S.C. 5221(e).

<sup>6</sup> Public Law 111-5, 123 Stat. 115 (2009).

<sup>7</sup> We do not believe this provision changes the Commission's rules for a smaller reporting company that is a TARP recipient under the EESA with respect to the compensation discussion and analysis ("CD&A") disclosure. Our compensation disclosure rules, as set forth in Item 402 of Regulation S-K [17 CFR 229.402], permit smaller reporting companies to provide scaled disclosure that does not include CD&A.

<sup>8</sup> Section 111 of the EESA defines this period not to include any period during which the Federal Government "only holds warrants to purchase common stock of the TARP recipient." See 12 U.S.C. 5221(a)(5).

<sup>9</sup> Section 111(e)(2) of the EESA [12 U.S.C. 5221(e)(2)].

<sup>10</sup> *Id.* Rule 14a-8 under the Exchange Act will continue to apply to shareholder proposals that relate to executive compensation. Rule 14a-8 provides shareholders with an opportunity to place a proposal in a company's proxy materials for a vote at an annual or special meeting of shareholders. Under this rule, a company generally is required to include the proposal unless the shareholder has not complied with the rule's procedural requirements or the proposal falls within one of the rule's 13 substantive bases for exclusion. To date, the staff of the Division of Corporation Finance has considered two requests in which TARP recipients requested the staff's concurrence that, given the shareholder advisory vote provision in Section 111(e) of the EESA, the companies could rely on Rule 14a-8(i)(9) [17 CFR 240.14a-8(i)(9)] (the exclusion for proposals that directly conflict with one of the company's own proposals) or Rule 14a-8(i)(10) [17 CFR 240.14a-8(i)(10)] (the exclusion for proposals that have been substantially implemented) to

Continued

<sup>1</sup> 17 CFR 240.14a-101.

<sup>2</sup> 17 CFR 240.14a-6.

<sup>3</sup> 15 U.S.C. 78a et seq.

<sup>4</sup> *Shareholder Approval of Executive Compensation of TARP Recipients*, Release No. 34-60218 (July 1, 2009) [74 FR 32474] (hereinafter, the "Proposing Release").

We received approximately 50 comment letters in response to the proposed amendments.<sup>11</sup> The respondents included business organizations, law firms and attorneys, investment firms, investor groups and many individuals. Most commenters expressed general support for the proposed amendments.<sup>12</sup> A few of these commenters expressed general support for the amendments, but also suggested certain changes or improvements on specific issues, as discussed more fully below.<sup>13</sup> Several other commenters only addressed specific aspects of the proposed amendments, such as the requirement to file a preliminary proxy statement as a consequence of the required vote, but did not express a viewpoint on the overall proposals.<sup>14</sup> One commenter argued that we should revise our proposals so that TARP recipients are not required to provide a mandatory annual advisory shareholder vote on executive compensation.<sup>15</sup>

More generally, many commenters expressed support for a requirement that all public companies permit an annual advisory vote on executive compensation.<sup>16</sup> Other commenters expressed opposition to mandatory "say on pay" for all public companies.<sup>17</sup> While we note these comments, the purpose of this rulemaking is limited to helping to implement the requirements of Section 111(e) of the EESA which

exclude from their proxy materials shareholder proposals that requested policies of holding annual shareholder advisory votes on executive compensation. The staff of the Division of Corporation Finance declined to concur with either request. See Bank of America Corp. (Mar. 11, 2009); CoBiz Financial Inc. (Mar. 25, 2009) (available at [http://www.sec.gov/divisions/corpfinc/cf-noaction/2009\\_14a-8.shtml](http://www.sec.gov/divisions/corpfinc/cf-noaction/2009_14a-8.shtml)).

<sup>11</sup> The public comments we received are available online at <http://www.sec.gov/comments/s7-12-09/s71209.shtml>.

<sup>12</sup> See, e.g., letters from California Public Employees' Retirement System ("CalPERS"), Calvert Group, Ltd. ("Calvert"), General Board of Pension and Health Benefits of the United Methodist Church ("UMC"), Northwest & Ethical Investments L.P., Sisters of Saint Francis of Philadelphia, United Brotherhood of Carpenters and Joiners of America ("UBCJA") and Walden Asset Management ("Walden").

<sup>13</sup> See, e.g., letters from CalPERS, UBCJA and Pax World Management Corp.

<sup>14</sup> See, e.g., letters from Cleary Gottlieb Steen & Hamilton LLP ("Cleary"), Mary K. Blasy, Esq. ("Blasy"), and Sullivan & Cromwell LLP ("S&C").

<sup>15</sup> See letter from Center for Capital Markets Competitiveness, U.S. Chamber of Commerce ("CCMC"). CCMC advocated a triennial vote with an opt-out provision for small and mid-size companies. However, as discussed below, Section 111(e)(1) of the EESA requires an annual vote and does not include opt-out provisions.

<sup>16</sup> See, e.g., letters from CalPERS, Calvert, Midwest Coalition for Responsible Investments and Walden.

<sup>17</sup> See, e.g., letters from The Center on Executive Compensation and UBCJA.

respect to TARP recipients. Therefore, these comments are beyond the scope of this rulemaking.

We have carefully considered the comments we received regarding the proposed amendments and are adopting new Rule 14a-20 and an amendment to Item 20 of Schedule 14A substantially as proposed with slight modifications to provide further clarity. In response to comments we received, we are also amending Rule 14a-6(a) under the Exchange Act so that TARP recipients required to provide a separate shareholder vote on executive compensation pursuant to Section 111(e)(1) of the EESA will not be required to file a preliminary proxy statement as a consequence of providing the required vote.

## II. Discussion of the Amendments

We are adopting substantially as proposed new Rule 14a-20 under the Exchange Act to help implement Section 111(e) of the EESA. Under Rule 14a-20, registrants that are "TARP recipients"<sup>18</sup> will be required to provide the separate shareholder vote to approve the compensation of executives, as required by Section 111(e)(1) of the EESA, in proxies solicited during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding. Rule 14a-20 clarifies that the separate shareholder vote required by Section 111(e)(1) of the EESA will only be required on a proxy solicited for an annual (or special meeting in lieu of the annual) meeting of security holders for which proxies will be solicited for the election of directors.<sup>19</sup>

We are making one modification to the proposed instruction to Rule 14a-20 in order to clarify its meaning. The purpose of the instruction remains, as

<sup>18</sup> Section 111(a)(3) of the EESA defines TARP recipient as "any entity that has received or will receive financial assistance under the financial assistance provided under the TARP." See 12 U.S.C. 5221(a)(3).

<sup>19</sup> As noted in the Proposing Release, the Commission agrees with the view previously expressed by the Division of Corporation Finance that a separate shareholder vote on executive compensation is required only with respect to an annual meeting of shareholders for which proxies will be solicited for the election of directors or a special meeting in lieu of such annual meeting. See Compliance and Disclosure Interpretations: American Recovery and Reinvestment Act of 2009 (Updated February 26, 2009), Question 1, available at <http://www.sec.gov/divisions/corpfinc/guidance/arrainterp.htm>. Although Section 111(e)(1) of the EESA refers to an annual "or other meeting of the shareholders," the subsection is titled "Annual Shareholder Approval of Executive Compensation." Rule 14a-20 is intended to result in TARP recipients conducting the required advisory vote annually in connection with the election of directors, with respect to which our rules call for disclosure of executive compensation.

proposed, to clarify that smaller reporting companies will not be required to provide a compensation discussion and analysis in order to comply with the requirements of Rule 14a-20.<sup>20</sup> As proposed, the instruction referenced the compensation of executives as disclosed pursuant to Item 402(m) through (r) of Regulation S-K.<sup>21</sup> Items 402(m) through (r) are the entire scaled compensation disclosure applicable to smaller reporting companies. However, paragraph (r) refers only to director compensation. As suggested by one commenter, we are revising the instruction to eliminate the reference to paragraph (r) in order to avoid the implication that the required vote relates to director compensation.<sup>22</sup> Other than this modification, we are adopting the instruction as proposed.

We are also adopting substantially as proposed an amendment to Item 20 of Schedule 14A that will be applicable to registrants that are TARP recipients and are required to provide a separate shareholder vote on executive compensation pursuant to Section 111(e)(1) of the EESA and Rule 14a-20. Pursuant to this amendment, such registrants will be required to disclose in the proxy statement that they are providing a separate shareholder vote on executive compensation pursuant to the requirements of the EESA, and to briefly explain the general effect of the vote. In response to a comment we received requesting clarification, we are adding the phrase "such as whether the vote is non-binding" to the end of the text of the amended Item 20 in order to provide an example of a type of disclosure that is required.<sup>23</sup>

As adopted, Item 20 will not require any additional disclosures by TARP recipients beyond those discussed above. Although a few commenters advocated additional disclosure requirements,<sup>24</sup> we believe the existing

<sup>20</sup> Several commenters expressed support for the proposed instruction clarifying that smaller reporting companies that are TARP recipients are not obligated to provide a compensation discussion and analysis. See, e.g., letters from Calvert, UBCJA and Ursuline Sisters of Tildonk. One commenter did not believe smaller reporting companies in general should be entitled to provide scaled compensation disclosure. See letter from CalPERS. Another commenter believed smaller reporting companies that are TARP recipients should provide a limited compensation discussion and analysis of at least 100 words. See letter from Phil Nicholas ("Nicholas"). As described above, we do not believe the EESA alters the disclosure obligations of smaller reporting companies pursuant to our existing rules regarding scaled disclosure. See note 7 above.

<sup>21</sup> 17 CFR 229.402(m)-(r).

<sup>22</sup> See letter from S&C.

<sup>23</sup> See letter from Davis Polk & Wardwell LLP ("Davis Polk").

<sup>24</sup> See letters from CalPERS (suggesting that TARP recipients should detail in the CD&A how receipt



compensation disclosure requirements of Item 402 of Regulation S-K should result in sufficient disclosure about TARP recipients' compensation policies and decisions to enable an informed vote on the compensation of executives.<sup>25</sup> We note in this connection that, under our existing rules, a TARP recipient must consider various disclosures regarding its participation in TARP. For example, a TARP recipient must consider whether the impact of TARP participation on compensation is required to be discussed in its CD&A in order to provide investors with material information that is necessary to an understanding of the company's compensation policies and decisions regarding named executive officers.<sup>26</sup>

As we indicated in the Proposing Release, we believe Rule 14a-20 and the amendment to Schedule 14A will afford registrants that are TARP recipients adequate flexibility to meet their obligations under Section 111(e) of the EESA.<sup>27</sup> At the same time, the

of TARP funds will affect executive compensation). The Value Alliance ("Value Alliance") (suggesting that required disclosures should include information on how receipt of TARP funds impacted compensation policies), Blasy (advocating for disclosure requirements related to EESA incentive compensation claw-back provisions), Jonathan Graf (commenting that CD&A should discuss key financial and risk decisions) and Jasim Haider (also expressing the view that CD&A should discuss significant financial and risk decisions).

<sup>25</sup> We also note that, on December 16, 2009, we approved certain amendments intended to improve our proxy disclosure requirements. See *Proxy Disclosure Enhancements*, Release No. 33-9089 (December 16, 2009). As part of this rulemaking, we approved amendments accelerating the reporting of shareholder vote results by moving the reporting requirement from the Exchange Act periodic reports to Form 8-K [17 CFR 249.308]. These amendments will apply to reporting results of the vote required by Section 111(e) of the EESA. This will help to address the concerns of commenters who stressed the importance of timely reporting of the shareholder vote on executive compensation. See, e.g., letter from CalPERS.

<sup>26</sup> See Item 402(b), (e) and (o) of Regulation S-K [17 CFR 229.402(b), (e) and (o)].

<sup>27</sup> Several commenters expressed support for the flexibility provided by the proposed rules and did not believe we should designate the specific language to be used by TARP recipients when presenting the required vote to shareholders. See, e.g., letters from Blasy, Davis Polk, UMC, UBCJA and Walden. On the other hand, two commenters suggested that we mandate the specific language to be used. See letters from S&C (proposing a standard form of resolution) and Value Alliance.

Consistent with the proposal, we are not requiring registrants to use any specific language or form of resolution in order to afford registrants that are TARP recipients some flexibility in how they present the required vote. However, as stated in Section 111(e)(1) of the EESA, the vote must be to approve "the compensation of executives, as disclosed pursuant to the compensation disclosure rules of the Commission (which disclosure shall include the compensation discussion and analysis, the compensation tables, and any related material)." As we indicated in the Proposing Release, we believe that a vote to approve a proposal on a

amendments, by helping to implement the requirements of Section 111(e) of the EESA in our proxy rules, should provide clarity for registrants that are TARP recipients regarding how they must comply with their obligations under Section 111(e) of the EESA. We also believe that this disclosure will provide investors with information that will help them to make informed voting decisions.

In the Proposing Release, we solicited comment on whether we should amend Rule 14a-6(a) under the Exchange Act so that registrants that are TARP recipients would not be required to file a preliminary proxy statement as a consequence of providing the required shareholder vote on executive compensation. In response to comments received and after further consideration of this issue, we are adopting an amendment to Rule 14a-6(a) under the Exchange Act to add the vote required for TARP recipients to the list of items that do not trigger a preliminary filing requirement.

Rule 14a-6 under the Exchange Act generally requires registrants to file proxy statements in preliminary form at least ten calendar days before definitive proxy materials are first sent to shareholders, unless the items included for a shareholder vote in the proxy statement are limited to matters specified in the rule.<sup>28</sup> During the time before final proxy materials are filed, our staff has the opportunity to comment on the disclosures, and registrants are able to incorporate the staff's comments in their final proxy materials. The matters that do not require filing of preliminary materials are various items that regularly arise at annual meetings, such as the election of directors, ratification of the selection of auditors, approval or ratification of certain employee benefits plans and shareholder proposals under Rule 14a-8.

We noted in the Proposing Release that, in light of the early stage of development of disclosures and the special policy considerations related to this required vote for TARP recipients,

different subject matter, such as a vote to approve only compensation policies and procedures, would not satisfy the requirements of Section 111(e)(1) of the EESA or Rule 14a-20.

Likewise, a shareholder proposal that asks the company to adopt a policy providing for periodic, non-binding shareholder votes on executive compensation in the future would not satisfy the requirement of Section 111(e) of the EESA or Rule 14a-20. Section 111(e) requires a vote to approve the compensation of executives. A vote to request a voting policy that would apply at future meetings would not satisfy the EESA or Rule 14a-20. See also note 10 above.

<sup>28</sup> 17 CFR 240.14a-6(a).

we thought it would be appropriate to provide the staff with the opportunity to comment on the disclosure before final proxy materials were filed. Some commenters agreed with that approach.<sup>29</sup> Other commenters who were opposed to a preliminary filing requirement generally argued that the burdens to TARP recipients and Commission staff would not be justified by the benefits of a preliminary filing requirement.<sup>30</sup> These commenters noted that a preliminary filing requirement would be unduly burdensome and amplify the already difficult timing and scheduling issues surrounding annual meetings. According to the commenters, the need to make a preliminary filing would require accelerated timelines and result in additional costs. Commenters also noted additional timing difficulties related to "notice and access" requirements under Rule 14a-16.<sup>31</sup> At the same time, the commenters argued that the disclosure provided in response to Item 20 of Schedule 14A as amended would be straightforward and unlikely to require staff intervention.<sup>32</sup> Therefore, these commenters asserted, the benefits to investors of a preliminary filing requirement would be limited. Overall, these commenters noted, an advisory vote on executive compensation of TARP recipients is similar to the other items specified in Rule 14a-6(a) that routinely arise at annual meetings and therefore should not trigger a preliminary filing requirement.<sup>33</sup>

After further consideration of this issue, we agree that a preliminary filing requirement is not necessary and are adopting an amendment to Rule 14a-6 accordingly. We agree with commenters that this item is similar to the other items specified in Rule 14a-6(a) that do not require a preliminary filing, and that the burdens of requiring a preliminary filing outweigh the potential benefits in this context. We note also that the staff is not precluded from providing an issuer with comments on the disclosure in a proxy statement after it has been filed in definitive form if the staff determines that to be appropriate in the circumstances.

<sup>29</sup> See letters from CalPERS, Calvert and Nicholas. See also letter from UMC (acknowledging that a preliminary filing may be beneficial to staff and some investors, but noting that a preliminary filing would be of limited value to the commenter).

<sup>30</sup> See letters from Cleary, Davis Polk and S&C. See also letter from UBCJA.

<sup>31</sup> 17 CFR 240.14a-16. See letters from Cleary and Davis Polk.

<sup>32</sup> See letter from Cleary.

<sup>33</sup> See letters from Davis Polk and S&C.

### III. Paperwork Reduction Act

#### A. Background

The final amendments contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995 ("PRA").<sup>34</sup> As discussed in the Proposing Release, we submitted the proposed amendments to the Office of Management and Budget ("OMB") for review in accordance with the PRA.<sup>35</sup> The title for the collection of information is:

"Schedule 14A" (OMB Control No. 3235-0059).

Schedule 14A was adopted under the Exchange Act and sets forth the disclosure requirements for proxy statements filed by U.S. issuers to help shareholders make informed voting decisions. The hours and costs associated with preparing, filing and sending the form constitute reporting and cost burdens imposed by each collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Compliance with the amendments by affected U.S. issuers will be mandatory. Responses to the information collections will not be kept confidential and there will be no mandatory retention period for the information disclosed.

As discussed in more detail above, we are adopting a new Rule 14a-20 under the Exchange Act and an amendment to Item 20 of Schedule 14A. Rule 14a-20 will help implement the requirement under Section 111(e)(1) of the EESA to provide a separate shareholder vote to approve the compensation of executives. Pursuant to the amendment to Item 20 of Schedule 14A, registrants required to provide a separate shareholder vote pursuant to Section 111(e) of the EESA and new Rule 14a-20 will be required to disclose the EESA requirement to provide such a vote and the general effect of the vote. In addition, we are adopting an amendment to Rule 14a-6(a) under the Exchange Act so that TARP recipients will not be required to file a preliminary proxy statement as a consequence of providing the required vote on executive compensation.

We published a notice requesting comment on the collection of information requirements in the Proposing Release and submitted these requirements to OMB for review in accordance with the PRA. Although we received many comment letters on the

proposed rule amendments, no commenter specifically mentioned the estimated effects of these proposed amendments on the collection of information requirements.<sup>36</sup>

Since we are adopting Rule 14a-20 and the amendment to Item 20 of Schedule 14A substantially as proposed, we are not changing the PRA burden estimates originally submitted to OMB. In addition, for the reasons discussed below, we are not revising our PRA burden estimates as a result of the amendment to Rule 14a-6(a).

#### B. Burden and Cost Estimates Related to the Amendments

We believe that Rule 14a-20 and the amendment to Schedule 14A will result in only a modest increase in the burden and cost of preparing and filing a Schedule 14A because they will not cause TARP recipients to collect or disclose any significant additional information. Section 111(e) of the EESA already increased the burdens and costs for registrants that are TARP recipients by requiring a separate shareholder vote on executive compensation and was already in effect during the 2009 proxy season. Our amendments address the EESA requirement in the context of the Federal proxy rules, thereby creating only an incremental increase in the burdens and costs for such registrants. We believe the amendments will remove uncertainty while still providing registrants that are TARP recipients adequate flexibility in complying with Section 111(e) of the EESA. For purposes of this analysis, we estimate the burden of disclosing the general effect of the vote pursuant to Item 20 of Schedule 14A and ensuring conformity with Rule 14a-20 when complying with Section 111(e)(1) of the EESA will be approximately one hour per year per registrant that is a TARP recipient. We do not believe the minor modifications that we are making to the proposed Rule 14a-20 and amendment Item 20 of Schedule 14A in response to comments will impact this estimated burden.

However, as a result of our amendment to Rule 14a-6(a), TARP recipients will no longer be required to file a preliminary proxy statement as a consequence of providing the required vote. The amendment to Rule 14a-6(a) does not change the substance of the information that must be collected and

disclosed in Schedule 14A, but it does eliminate an additional filing requirement. As discussed in greater detail below in the Cost-Benefit Analysis, we believe this amendment will benefit many TARP recipients, primarily by easing some of the timing challenges that can result from a requirement to prepare and file preliminary proxy materials in connection with an annual meeting. However, we do not believe the average paperwork burden will change as a result of the amendment to Rule 14a-6(a).

A requirement to file a preliminary proxy statement accelerates the time in which registrants must complete a Schedule 14A and creates the possibility that the filing could be subject to staff review before a definitive filing is made. A filer may incur additional paperwork burden if it changes its disclosure in the definitive proxy statement in response to staff comments. However, the staff does not review every preliminary proxy statement that is filed with the Commission and is not precluded from commenting on proxy materials filed in definitive form if the staff deems that to be appropriate under the circumstances. In addition, the amendment to Rule 14a-6(a) that we are adopting today does not necessarily eliminate the potential burdens associated with a preliminary filing requirement because any TARP recipient that presents an additional proposal to shareholders in its proxy materials that is not among the matters enumerated in Rule 14a-6(a) as amended will still be required to file a preliminary proxy statement. On balance, therefore, we do not believe that eliminating the requirement to file a preliminary proxy statement is likely to change the overall disclosure provided by TARP recipients with respect to the required vote on executive compensation, so we are not reducing our average PRA burden estimate.

We estimate there are approximately 275 registrants that are TARP recipients with outstanding obligations that would be subject to the final amendments.<sup>37</sup> Since we estimate that the rules we are adopting will result in an increased burden of one hour per year for each registrant that is a TARP recipient, the total annual PRA burden increase attributable to the final rules is 275 hours. For proxy statements, consistent with our customary assumptions, we

<sup>36</sup> We note that one commenter indicated that the additional burdens of a preliminary filing far outweigh any potential benefit of prior staff review. See letter from Cleary. As discussed above, we are amending Rule 14a-6 and, therefore, a TARP recipient will not be required to file a preliminary proxy statement as a consequence of providing the required vote.

<sup>37</sup> Our staff made this estimate from publicly-available information about TARP recipients. The estimate is based on the number of TARP recipients that are subject to our proxy rules and that have not repaid their TARP obligations as of November 6, 2009.

<sup>34</sup> 44 U.S.C. 3501 *et seq.*

<sup>35</sup> 44 U.S.C. 3507(d) and 5 CFR 1320.11.

estimate that 75% of the burden of preparation is carried by the company internally and that 25% of the burden is carried by outside professionals retained by the company to review corporate disclosure at an average cost of \$400 per hour.<sup>38</sup> The portion of the burden carried by outside professionals is reflected as a cost, while the portion of the burden carried by the company internally is reflected in hours. Based on the foregoing, we calculated the additional annual compliance burdens resulting from the final amendments at 206.5 hours (this is 75% of the total 275 hours in increased burden carried by the company internally) and \$27,500 (this is 25% of the total increased hourly burden carried by outside professionals and reflected as a cost). The current total annual burden hours and cost of Schedule 14A approved by the OMB is 555,683 hours and \$63,709,987. Giving effect to the incremental increases in burden hours and costs as a result of the final amendments, the total annual burden hours and cost of Schedule 14A will be approximately 555,889.5 hours and \$63,737,487.

#### IV. Cost-Benefit Analysis

We are sensitive to the costs and benefits of our rules. In this section, we examine the benefits and costs of the final amendments we are adopting today.<sup>39</sup>

In the Proposing Release, we requested that commenters provide views, supporting information and estimates on the benefits and costs that may result from adoption of the proposed amendments. No commenter expressly addressed the cost-benefit analysis in the Proposing Release. Some commenters cited certain benefits and costs of the proposed amendments in the course of making a variety of suggestions and observations. We discuss these comments throughout the release as applicable.

<sup>38</sup> We estimate an hourly rate of \$400 as the average cost for the service of outside professionals that assist in preparing and filing proxy statements and related disclosures with the Commission.

<sup>39</sup> The cost-benefit analysis in this section addresses the costs and benefits of the amendments. The analysis does not, however, address the costs and benefits of the requirement in Section 111(e)(1) of the EESA that TARP recipients conduct a separate shareholder vote on executive compensation. While the amendments set forth the manner in which registrants that are TARP recipients must implement this requirement when complying with the Federal proxy rules, such registrants are already subject to the provisions of Section 111(e)(1) of the EESA and thus we are only addressing the incremental costs and benefits of the amendments.

#### A. Benefits

We are adopting amendments to the Federal proxy rules to help implement the requirement in Section 111(e)(1) of the EESA that TARP recipients provide a separate shareholder vote to approve the compensation of executives. Under the amendments, this separate shareholder vote will be required when registrants that are TARP recipients solicit proxies during the period in which any obligation arising from financial assistance provided under the TARP remains outstanding, and the solicitation relates to an annual meeting (or a special meeting in lieu of an annual meeting) for which proxies will be solicited for the election of directors. Companies required to provide such a separate shareholder vote will also be required to disclose in their proxy statements the EESA requirement to provide such a vote, and to briefly explain the general effect of the vote. We are also amending Rule 14a-6(a) under the Exchange Act so that TARP recipients are not required to file a preliminary proxy statement as a consequence of providing the required vote on executive compensation.

We believe the amendments will benefit registrants that are TARP recipients by clarifying how they must comply with the requirements of Section 111(e)(1) of the EESA in the context of the Federal proxy rules. The amendments eliminate uncertainty that may have existed among TARP recipients and other market participants regarding what is necessary under the Commission's proxy rules when conducting a shareholder vote required under Section 111(e) of the EESA. In addition to these benefits, we believe the amendments allow TARP recipients adequate flexibility under the proxy rules to comply with the requirements of the EESA. By providing clarity while maintaining adequate flexibility, we believe the amendments will reduce the amount of management time and legal expenses necessary to ensure that registrants that are TARP recipients comply with their obligations under both the EESA and the Federal proxy rules. This should benefit TARP recipients and their shareholders.

The amendment to Rule 14a-6(a) will also benefit many TARP recipients. During the 2009 proxy season, TARP recipients were required to file preliminary proxy statements because the vote on executive compensation required by the EESA was not among the matters enumerated in Rule 14a-6(a) that do not trigger a preliminary filing requirement. Because a preliminary proxy statement must be filed at least 10

days prior to the date definitive copies are first sent or given to shareholders, registrants subject to a preliminary filing requirement must complete their materials on an accelerated basis. This can create costs and burdens, especially in conjunction with the scheduling and timing issues surrounding annual meetings. In addition, a preliminary filing requirement may make it more difficult for a registrant to achieve the cost savings possible under the "notice and access" model because a registrant must send shareholders a Notice of Internet Availability of Proxy Materials (and those materials must be available) at least 40 days prior to the meeting date unless the registrant relies on the "full set delivery" option.<sup>40</sup> By amending Rule 14a-6 so that TARP recipients are not required to file a preliminary proxy statement as a consequence of providing the required vote, we believe these costs may be avoided or lessened and thus the amendment will benefit many TARP recipients.

We believe the amendments will benefit investors by resulting in clear disclosure about the requirements of Section 111(e)(1) of the EESA as applied to Exchange Act registrants. When a separate shareholder vote on the compensation of executives is required by the EESA, Rule 14a-20 specifies and clarifies that requirement in the context of the Federal proxy rules. By doing so, we believe Rule 14a-20 should promote better compliance with the requirements of Section 111(e)(1) of the EESA when registrants that are TARP recipients conduct solicitations subject to our proxy rules. The amendment to Schedule 14A requires disclosure about the EESA requirement to provide a separate shareholder vote and the general effects of such a vote. Together, the amendments are intended to provide useful, comparable and consistent information to assist an informed voting decision when registrants that are TARP recipients present to investors the advisory vote on executive compensation required pursuant to Section 111(e)(1) of the EESA. The specification and clarification of the requirement in Rule 14a-20 will also help provide certainty about the nature of the TARP recipient's responsibility to hold the advisory vote, making it easier for companies to comply.

#### B. Costs

We believe the amendments will not add any significant costs for TARP recipients to those already created by the requirements of Section 111(e)(1) of the EESA and our proxy rules. The

<sup>40</sup> 17 CFR 240.14a-16.

amendments are intended to help implement the existing substantive EESA requirement in the context of the Federal proxy rules. While our amendment to Schedule 14A would require certain disclosures not explicitly required by EESA, we believe any incremental costs imposed by our amendments would be minimal. For purposes of the PRA, we estimated the total annual increase in incremental burden as a result of the amendments to be 275 hours.

There may be some costs to investors as a result of our amendment to Rule 14a-6(a). Because TARP recipients will no longer be required to file a preliminary proxy statement as a consequence of providing the required vote on executive compensation, Commission staff may not have the opportunity to review preliminary proxy materials before TARP recipients make definitive copies of these materials available to shareholders. Staff review of preliminary materials can benefit shareholders by helping to ensure that registrants comply with the Federal proxy rules and provide appropriate disclosure to shareholders. However, we do not believe the amendment to Rule 14a-6(a) will deprive investors of significant benefits. We believe that the rules we are adopting today, Rule 14a-20 and the amendment to Item 20 of Schedule 14A, provide clear guidance to TARP recipients regarding their obligations under the Federal proxy rules when subject to the requirements of Section 111(e) of the EESA. In addition, the staff does not review every preliminary proxy statement that is filed with the Commission and is not precluded from commenting on proxy materials filed in definitive form if the staff deems that to be appropriate under the circumstances.

#### V. Consideration of Impact on the Economy, Burden on Competition and Promotion of Efficiency, Competition and Capital Formation

Section 23(a)(2) of the Exchange Act<sup>41</sup> also requires us, when adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition. Section 23(a)(2) prohibits us from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. In addition, Section 3(f)<sup>42</sup> of the Exchange Act requires us, when engaging in rulemaking where we are required to consider or determine whether an action

is necessary or appropriate in the public interest, to also consider whether the action will promote efficiency, competition, and capital formation.

We believe the final amendments will benefit registrants that are TARP recipients and their shareholders by providing certainty regarding how registrants that are TARP recipients must comply with the EESA requirement to hold an advisory vote on executive compensation in the context of the Federal proxy rules, while maintaining adequate flexibility to comply with this requirement. The certainty should promote efficiency. The final amendments also will help ensure that shareholders receive disclosure regarding the required vote and the nature of a registrant's responsibilities to hold the vote under the EESA. The amendment to Rule 14a-6(a) will benefit many TARP recipients by reducing the burdens associated with a preliminary filing requirement. As discussed in greater detail above, we believe these benefits will be achieved without imposing any significant additional burdens on registrants that are TARP recipients or costs to their shareholders. We do not anticipate any effect on competition or capital formation. We do believe the rules will make compliance with EESA more efficient.

In the Proposing Release, we requested comment on whether the proposed amendments, if adopted, would impose a burden on competition. We also requested comment on whether the proposed amendments, if adopted, would promote efficiency, competition, and capital formation. We did not receive any comments directly responding to these requests.

#### VI. Regulatory Flexibility Act Certification

In Part VII of the Proposing Release, the Commission certified pursuant to Section 605(b) of the Regulatory Flexibility Act<sup>43</sup> that the proposed amendments to the Federal proxy rules would not have a significant economic impact on a substantial number of small entities. While the Commission encouraged written comments regarding this certification, no commenters responded to this request or indicated that the amendments as adopted would have a significant economic impact on a substantial number of small entities.

#### VII. Statutory Authority and Text of the Final Amendments

The amendments described in this release are being adopted under the

authority set forth in Section 111(e) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(e)) and Sections 14(a) and 23(a) of the Exchange Act (15 U.S.C. 78n(a) and 78w(a)).

#### List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

#### Text of the Amendments

■ For the reasons set out in the preamble, the Commission hereby amends title 17, chapter II, of the Code of Federal Regulations as follows:

#### PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The general authority citation for Part 240 is revised to read as follows:

**Authority:** 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z-2, 77z-3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78k-1, 78k, 78l-1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u-5, 78w, 78x, 78ll, 78mm, 80a-20, 80a-23, 80a-29, 80a-37, 80b-3, 80b-4, 80b-11, and 7201 *et seq.*, 18 U.S.C. 1350, and 12 U.S.C. 5221(e)(3), unless otherwise noted.  
\* \* \* \* \*

■ 2. Amend § 240.14a-6 by:

- a. Removing "and/or" from the end of paragraph (a)(5);
- b. Removing the period from the end of paragraph (a)(6) and in its place adding "; and/or"; and
- c. Adding paragraph (a)(7) immediately following paragraph (a)(6).

The addition reads as follows:

#### § 240.14a-6 Filing requirements.

(a) \* \* \*

(7) A vote to approve the compensation of executives as required pursuant to Section 111(e)(1) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(e)(1)) and § 240.14a-20.

\* \* \* \* \*

■ 3. Add § 240.14a-20 to read as follows:

#### § 240.14a-20 Shareholder approval of executive compensation of TARP recipients.

If a solicitation is made by a registrant that is a *TARP recipient*, as defined in section 111(a)(3) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(a)(3)), during the period in which any obligation arising from financial assistance provided under the *TARP*, as defined in section 3(8) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5202(8)), remains outstanding and the solicitation relates to an annual (or special meeting in lieu of the annual) meeting of security

<sup>41</sup> 15 U.S.C. 78w(a).

<sup>42</sup> 15 U.S.C. 78c(f).

<sup>43</sup> 5 U.S.C. 605(b).

holders for which proxies will be solicited for the election of directors, as required pursuant to section 111(e)(1) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(e)(1)), the registrant shall provide a separate shareholder vote to approve the compensation of executives, as disclosed pursuant to Item 402 of Regulation S-K (§ 229.402 of this chapter), including the compensation discussion and analysis, the compensation tables, and any related material.

**Note to § 240.14a-20:** TARP recipients that are smaller reporting companies entitled to provide scaled disclosure pursuant to Item 402(l) of Regulation S-K are not required to include a compensation discussion and analysis in their proxy statements in order to comply with this section. In the case of these smaller reporting companies, the required vote must be to approve the compensation of executives as disclosed pursuant to Item 402(m) through (q) of Regulation S-K.

■ 4. Amend § 240.14a-101 to add a sentence at the end of Item 20 to read as follows:

**§ 240.14a-101 Schedule 14A. Information required in proxy statement.**

#### SCHEDULE 14A INFORMATION

\* \* \* \* \*

Item 20. Other proposed action. \* \* \* Registrants required to provide a separate shareholder vote pursuant to section 111(e)(1) of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5221(e)(1)) and § 240.14a-20 shall disclose that they are providing such a vote as required pursuant to the Emergency Economic Stabilization Act of 2008, and briefly explain the general effect of the vote, such as whether the vote is non-binding.

\* \* \* \* \*

By the Commission.

Dated: January 12, 2010.

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-756 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## DEPARTMENT OF THE INTERIOR

### National Indian Gaming Commission

#### 25 CFR Part 514

RIN 3141-0001

#### Amendments to Various National Indian Gaming Commission Regulations; Correction

AGENCY: National Indian Gaming Commission.

**ACTION:** Correcting amendments.

**SUMMARY:** On July 27, 2009 (74 FR 36926), the National Indian Gaming Commission ("NIGC") published a final rule updating various NIGC regulations and streamlining procedures. On August 25, 2009 (74 FR 42275), NIGC extended the effective date of the changes made by the final rule to December 31, 2009. This publication corrects inadvertent errors left in § 514.1 of the final rule so that fees and fee statements are due on June 30th and December 31st of each calendar year, not on March 1st and August 1st as originally published.

**DATES:** *Effective Date:* This correction is effective on January 19, 2010.

**FOR FURTHER INFORMATION CONTACT:** Christopher White, Comptroller, at (202) 632-7003; fax (202) 632-7066 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:** Under the Indian Gaming Regulatory Act ("IGRA"), 25 U.S.C. 2701-2721, NIGC is funded through fees assessed on Class II and Class III gaming operations. Prior to the December 31, 2009 effective date of NIGC's final rule, "Amendments to Various National Indian Gaming Commission Regulations" (74 FR 36926), NIGC regulations required tribes to submit fees and fee statements four times per year. The prior regulations also required that the fees and fee statements be received at NIGC's Washington, DC headquarters no later than the last day of each quarter—March 31st, June 30th, September 30th, and December 31st of each calendar year.

The final rule amended 25 CFR 514.1 to require the payment of fees and submission of fee statements only twice each year, and it implemented the "mailbox" rule such that payments and submissions were timely if sent on or before their due dates.

Unfortunately, as published, the final rule contained incorrect due dates for fees and fee statements, giving them as March 1 and August 1 of each calendar year. This publication corrects § 514.1(c)(2), § 514.1(c)(6)(i), and § 514(d) so that the due dates for the submission of fees and fee statements read correctly as June 30th and December 31st of each calendar year. This correction makes no change to the adoption of the mailbox rule. Payments and submissions are still timely if sent on or before June 30th and December 31st of each calendar year.

The NIGC finds that it may make this correction without notice and public comment. The changes are few and ministerial, and they remove typographical errors so that the adopted regulations read correctly and reflect the

NIGC's intent. What is more, leaving the incorrect dates in place during a notice-and-comment period has the potential to prejudice Indian tribes and is therefore contrary to the public interest.

The incorrect final rule would make fees and fee statements due on March 1, 2010, a full four months (121 days) before the NIGC intended them to be due. Further, as a practical matter, NIGC could not propose an amended rule, receive and review comments, publish an amended final rule, and have that amended rule become effective before March 1. As a result, unless the final rule is corrected immediately, any failure by a tribe to submit fees by March 1 would be a technical violation of NIGC regulations and cause concern about the possibility, however remote, of a notice of violation and attendant fines and penalties.

Even though that outcome is unlikely, there is no need to artificially place tribes out of compliance with IGRA or to create a risk of adverse enforcement actions. An immediate ministerial change to three sentences will correct the NIGC's error, preserve tribal compliance with IGRA, and alleviate any concern about the possibility of enforcement actions.

#### List of Subjects in 25 CFR Part 514

Gambling, Indians—lands, Indians—tribal government, Reporting and recordkeeping requirements.

■ Accordingly, 25 CFR part 514 is corrected by making the following correcting amendments:

#### PART 514—FEES

■ 1. The authority citation for part 514 continues to read as follows:

**Authority:** 25 U.S.C. 2706, 2708, 2710, 2717, 2717a.

#### § 514.1 [Amended]

■ 2. Amend § 514.1 as follows:

■ a. Amend paragraph (c)(2) by correcting "March 1st and August 1st" to read "June 30th and December 31st".

■ b. Amend paragraph (c)(6)(i) by correcting "March 1st" to read "June 30th".

■ c. Amend paragraph (d) by correcting "March 1st and August 1st" to read "June 30th and December 31st".

Dated: January 12, 2010.

**George T. Skibine,**  
Acting Chairman.

[FR Doc. 2010-802 Filed 1-15-10; 8:45 am]

BILLING CODE 7565-01-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R09-OAR-2009-0350; FRL-9097-1]

**Revisions to the California State Implementation Plan, San Joaquin Valley Air Pollution Control District**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing approval of revisions to the San Joaquin Valley Air Pollution Control District portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on June 16, 2009 and concern volatile organic compound (VOC) emissions from coating of metal

parts, large appliances, metal furniture, motor vehicles, mobile equipment, cans, coils, organic solvent cleaning, and storage and disposal related to such operations. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** *Effective Date:* This rule is effective on February 18, 2010.

**ADDRESSES:** EPA has established docket number [EPA-R09-OAR-2009-0350] for this action. The index to the docket is available electronically at <http://www.regulations.gov> and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in

either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Nicole Law, EPA Region IX, (415) 947-4126, [law.nicole@epa.gov](mailto:law.nicole@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, "we," "us" and "our" refer to EPA.

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**I. Proposed Action**

On June 16, 2009 (74 FR 28467), EPA proposed to approve the following rules into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVAPCD .....	4603	Surface Coating of Metal Parts and Products .....	10/16/08	12/23/08
SJVAPCD .....	4604	Can and Coil Coating Operations .....	09/20/07	03/07/08
SJVAPCD .....	4612	Motor Vehicle and Mobile Equipment Coating Operations .....	09/20/07	03/07/08

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

**II. Public Comments and EPA Responses**

EPA's proposed action provided a 30-day public comment period. During this period, we received comments from the following party.

1. Sarah Jackson, Earthjustice; letter dated July 15, 2009 and received July 15, 2009.

After the close of the comment period, we also received comments from the following party.

2. Jim Sell, National Paint & Coatings Association; letter dated July 17, 2009 and received July 17, 2009.

The comments and our responses are summarized below. Although we are not obligated to address comments

submitted after the close of the comment period, we are addressing below the comments from both parties.

*Comment #1:* Earthjustice stated that Rule 4603 does not meet Reasonable Available Control Technology (RACT) requirements because it is not as stringent as EPA's 2008 Control Techniques Guidelines (CTG) for Miscellaneous Metal and Plastic Parts Coatings. The commenter noted that the limit for baked extreme performance coatings in the rule is less stringent than the limit in the CTG and that the rule exempts repair and touch-up operations, while the CTG recommends limits for those operations. The commenter stated that unavailability of the CTG during the period of rule development is "not an excuse for approving a rule that everyone acknowledges does not meet the minimum level of control currently considered for RACT." The commenter further stated that SJVAPCD adopted

Rule 4603 one month after EPA released the CTG.

*Response #1:* EPA's 2008 CTG for Miscellaneous Metal and Plastic Parts Coatings (2008 CTG) generally defines presumptive RACT for this activity nationwide. All requirements in Rule 4603 are equivalent to or more stringent than the recommendations in the 2008 CTG, except the VOC limit for baked extreme performance coatings and the exemption for repair and touch-up operations. As to the emission limit for baked extreme performance coatings, the VOC limit in Rule 4603 is 420 grams/liter (g/L) and the 2008 CTG recommends a VOC level of 360 g/L. We note that the difference between the two limits for this particular baked coating operation is relatively small, and that the rule contains VOC limits for four other coating categories that are more restrictive than the CTG recommendations for those operations, as shown below.

**VOC CONTENT LIMITS FOR SPECIALTY COATINGS, EXCEPT FOR LARGE APPLIANCE PARTS OR PRODUCTS, AND METAL FURNITURE—IN G/L**

[lbs/gallon]

Coating type	Rule 4603 VOC limit for baked coatings	CTG VOC limit for baked coatings	Rule 4603 VOC limit for air-dried coatings	CTG VOC limit for air-dried coatings
Camouflage .....	360 (3.0)	420 (3.5)	420 (3.5)	420 (3.5)
Extreme Performance .....	420 (3.5)	360 (3.0)	420 (3.5)	420 (3.5)
High Performance Architectural .....	420 (3.5)	740 (6.2)	420 (3.5)	740 (6.2)
Metallic Coating .....	360 (3.0)	420 (3.5)	420 (3.5)	420 (3.5)

At EPA's request, SJVAPCD staff examined recent inspection reports and notified us that only one facility in the SJV area uses extreme performance coatings. That facility operates by air drying and not baking.<sup>1</sup> As such, we are not aware of any baked coating operations in SJVAPCD that use extreme performance coatings. Additionally, SJVAPCD's RACT SIP analysis indicates that operators do not use special coatings for touch-up and repair operations. The same VOC-compliant coatings that are used in the fabrication process are used for touch-up and repair operations. As such, the emissions limit in Rule 4603 for baked extreme performance coatings and the exemption for repair and touch-up operations have no emissions impacts in the San Joaquin Valley (SJV) area.

EPA policy provides that SIP VOC rules may exceed the levels recommended in a CTG or contain limited exemptions if the total emissions in the area allowed under the SIP rule exceed the total emissions allowed by EPA's recommended emission levels by less than 5 percent.<sup>2</sup> In the absence of any extreme performance baked coating operations or special coatings for touch-up and repair operations in the SJV area, the total emissions allowed in the area under Rule 4603 are not greater than the total emissions allowed under the CTG levels and are permissible.

The commenter has provided no additional information about reasonably available control methods for these operations. Given that the VOC limits in Rule 4603 for this source category are generally more stringent than EPA's

CTG recommendations, and given the *de minimis* emission impacts of those rule elements that are less stringent than the CTG recommendations, we do not believe these elements of Rule 4603 constitute RACT deficiencies. See *NRDC v. EPA*, 571 F. 3d 1245, 1254 (DC Cir. 2009) (upholding EPA's case-by-case approach to RACT determinations).

Finally, regarding the comment that the 2008 CTG was released one month before SJVAPCD adopted the subject version of 4603, we note that SJVAPCD: (1) Was already far along in an extensive local process to develop this rule revision; (2) is allowed a year following EPA's issuance of the CTG to submit a rule that reflects current-day RACT for this source category; and (3) has since adopted a new version of Rule 4603 that contains emission limits for baked extreme performance coating and repair and touch-up operations consistent with the limits recommended in the 2008 CTG. We expect this version will be submitted to EPA for inclusion in the SIP in the near future.

*Comment #2:* Earthjustice further stated that Rule 4603 does not meet RACT requirements because it is not as stringent as other California district rules. Specifically, the commenter stated that the South Coast Air Quality Management District's (SCAQMD) rule has more stringent VOC limits for extreme high gloss coatings and does not exempt repair and touch-up coatings; that the Bay Area Air Quality Management District's (BAAQMD) rule has a more stringent VOC limit for baked metallic topcoats; and that Ventura County Air Pollution Control District's (VCAPCD) rule has more

stringent VOC limits for all air-dried coatings, baked extreme performance coatings, and baked and air-dried pretreatment wash primers. Earthjustice stated that the District "justifies the lack of stringency by claiming that other more stringent limits in its rule make up for the weaker limits," and that this assertion "has no factual or technical support." The commenter further stated the appropriate test is whether the limits in the rule represent reasonably available control technology, and that neither SJVAPCD nor EPA has explained why the more protective limits are not reasonable in SJVAPCD.

*Response #2:* State and local agencies rely heavily on CTGs to help define RACT when they are issued. When a CTG has not been issued for a category for many years, it is reasonable to consider whether RACT has evolved over time by examining analogous control requirements in other areas. For this source category, however, we have no information indicating that new control methods have become reasonably available since issuance of EPA's 2008 CTG. As such, we believe that the levels recommended in the 2008 CTG continue to reflect RACT level controls. Even upon an evaluation of the VOC limits in the other rules cited by the commenter, we have not identified any widely available and significantly more stringent requirements that compel us to reevaluate the limits in Rule 4603. The following table summarizes the more stringent requirements identified by the commenter.

Coating category	SJVAPCD VOC limit (g/L)	BAAQMD VOC limit (g/L)	SCAQMD VOC limit (g/L)	VCAPCD VOC limit (g/L)
Extreme high gloss (Air-dried) .....	420	420	340	420
Large appliance metallic topcoat (baked) .....	420	360	No limit	No limit.
Pretreatment wash primer (baked/air-dried) .....	420/420	420/420	420/420	275/340

In each case, the more stringent limit exists in only one other district, and we are not aware of the same limit having been adopted in any other area. We also note that extreme high gloss coatings, large appliance metallic topcoats, and pretreatment wash primers are relatively small source categories in the District. To our knowledge, the District has identified only one permitted facility that uses metallic surface coatings on

large appliances, but this facility uses powdered metallic coatings, which are not subject to the limits in Rule 4603.<sup>3</sup>

*Comment #3:* Earthjustice stated that Rule 4604 does not meet RACT because it is not as stringent as other California district rules. Specifically, the commenter stated that neither the BAAQMD's nor Sacramento Metro AQMD's (SMAQMD) rules exempt facilities using fewer than 55 gallons per

year, while Rule 4604 exempts these sources. Also, Earthjustice stated that Rule 4604 exempts necker lubricants, stripping of cured materials, and cleaning solvent for lab and research, while SCAQMD's rule has limits for these categories, and that the District has provided no analysis to support its claim that these categories are insignificant. Lastly, the commenter stated that SMAQMD's rule has more

<sup>1</sup> See e-mail correspondence dated July 23, 2009, between Nicole Law (EPA) and Joven Nazareno (SJVAPCD).

<sup>2</sup> See *Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations*, EPA Office

of Air Quality Planning and Standards, May 25, 1988, at 2-2 and Attachment 2; Memorandum from Andrew Steckel, Rulemaking Office Chief, to Rulemaking Office, EPA Region IX, "Screening

Analysis for 5% De Minimis Determinations for Coating Rules," December 4, 2002.

<sup>3</sup> See phone conversation dated August 4, 2009, between Nicole Law (EPA) and Joven Nazareno (SJVAPCD).

stringent limits for the cleaning of 3-piece can sheet coaters. In sum, Earthjustice stated that EPA should disapprove and require the District to revise Rule 4604.

**Response #3:** First, EPA's long-standing national policy allows for exemptions from RACT limits for "low-use" coatings at sources that use small quantities for intermittent or specialty-type operations.<sup>4</sup> The policy states that an exemption based on a plantwide cutoff of 55 gallons per rolling 12-month period for all low-use coatings in the aggregate used at a facility is reasonable, and may be approved into a SIP, provided the 55-gallon plantwide limit is accompanied by good recordkeeping requirements and is federally enforceable. The exemption in section 4.1 of Rule 4604 for stationary sources that use 55 gallons or less in the aggregate of coatings and cleaning solvent per rolling 12-month period, together with the recordkeeping requirements of the rule (see section 6.1), are consistent with this policy.

Second, as to the commenter's objection to the exemptions in Rule 4604 for necker lubricants, stripping of certain cured materials, and cleaning in laboratory tests and analyses, we note that EPA's 2006 CTG for Industrial Cleaning Solvents (2006 CTG) specifically identifies "stripping of cured inks, coatings, and adhesives" and "research and development laboratories" among the categories that State and local agencies may consider for exclusion from RACT requirements.<sup>5</sup> Moreover, contrary to the commenter's assertion, SCAQMD's RACT rule for this source category exempts the use of cleaning solvents for stripping of cured materials and for cleaning in laboratory tests and analyses.<sup>6</sup> Specifically, SCAQMD's Rule 1125 (Metal Container, Closure, and Coil Coating Operations) requires that all solvent cleaning operations be carried out pursuant to Rule 1171 (Solvent Cleaning Operations), which in turn exempts solvent cleaning in research and development laboratory tests from the VOC limits of the rule, and exempts solvent cleaning for "stripping of cured coatings, cured ink, or cured adhesives"

from all requirements of the rule.<sup>7</sup> These exemptions are consistent with the recommendation provided in EPA's 2006 CTG.<sup>8</sup> The commenter has provided no additional information about reasonably available control methods for these operations and we are not aware of more stringent RACT measures for them.

Finally, as to the commenter's assertion that SMAQMD's rule for this source category has more stringent VOC limits for cleaning of 3-piece can sheet coaters, we note first that it is not clear which VOC limit(s) the commenter is referring to. In the absence of more specific information, we assume the commenter based its assertion on the information provided in SJVAPCD's 2009 RACT SIP, which indicates that SMAQMD's Rule 452 contains a 25 g/L limit for 3-piece can sheet coaters.<sup>9</sup> Specifically, however, SMAQMD's Rule 452 prohibits the use of solvents that contain more than 25 g/L VOCs for "cleanup of container assembly equipment, including slitters, bodymakers, beadlers, end seamers, flangers, and testers, excluding side seam spray application equipment."<sup>10</sup> It is not clear that this language includes 3-piece can sheet coaters. Nonetheless, to the extent the commenter intended to assert that a 25 g/L VOC limit should apply to cleaning of 3-piece can sheet coating operations in the SJV area, we disagree.

According to the SJVAPCD staff report for Rule 4604, currently there are no effective cleaning solvents for can sheet coaters that meet a 25 g/L VOC content limit. The SJVAPCD staff report notes that SCAQMD's Rule 1177 contains a 25 g/L VOC limit for cleaning of 3-piece can sheet coaters but that this 25 g/L limit is not achieved in practice because all operations in SCAQMD that are required to comply with the limit use VOC capture and control systems.<sup>11</sup> Given the commenter has provided no information to support its assertion that lower-VOC solvents for cleaning of 3-piece can sheet coaters are reasonably available and we are not otherwise aware of such information, we conclude that the VOC limits for this activity in Rule 4604 represent RACT.

**Comment #4:** Earthjustice stated that Rule 4612 does not meet RACT because

it is not as stringent as other California district rules. The commenter asserted generally that Rule 4612 "has limits on precoat and topcoat-metallic iridescent coatings that are less stringent than Bay Area, South Coast, and Sacramento rules," and that neither the District's RACT SIP nor EPA's technical support document explains the significance of these sources or whether the more protective limits are reasonable in SJVAPCD. The commenter concluded by stating that "[w]ithout this analysis, EPA has no rational basis for approving this rule as satisfying the RACT requirement."

**Response #4:** We note initially that the commenter's assertion is stated only generally and does not specify which more stringent limits it is referring to. In the absence of more specific information, we assume the commenter based its assertions on the information provided in SJVAPCD's 2009 RACT SIP, which indicates that VOC limits in BAAQMD's Rule 8-45 and SMAQMD's Rule 459 for "precoat" coatings are more stringent than corresponding limits in Rule 4612, and that a VOC limit in SCAQMD's Rule 1151 for "topcoat-metallic/iridescent" coatings is more stringent than the corresponding limit in Rule 4612.<sup>12</sup> Our review of the specific limits in these rules indicates that this information is not correct.

First, Rule 4612 does not contain VOC limits specific to "precoat" coatings. The rule does, however, contain a VOC limit of 250 g/L for "primer" coatings and a limit of 660 g/L for "pretreatment" coatings.<sup>13</sup> We note that the definition of "primer"<sup>14</sup> in Rule 4612 is identical to the definition in the California Air Resources Board's 2005 Suggested Control Measures for Automotive Coatings (CARB 2005 SCM), which includes "precoat" coatings in the "primer" category.<sup>15</sup> The 2005 CARB SCM recommends a VOC limit of 250 g/L for primer coatings.<sup>16</sup> It defines "pretreatments" coatings separately<sup>17</sup>

<sup>12</sup> See 2009 RACT SIP, SJVAPCD, April 16, 2009, at pp. 4-242.

<sup>13</sup> See SJVAPCD Rule 4612, section 5.1.

<sup>14</sup> Rule 4612 defines "primer" as follows: "any coating, which is labeled and formulated for application to a substrate to provide a bond between the substrate and subsequent coats, corrosion resistance, a smooth substrate surface, or resistance to penetration of subsequent coats, and on which a subsequent coating is applied. Primers may be pigmented." Rule 4612 at section 3.29.

<sup>15</sup> See *Suggested Control Measure for Automotive Coatings*, CARB, October 2005 (CARB 2005 SCM), Appendix D at D-5.

<sup>16</sup> See CARB 2005 SCM at section 4.1 (Coating Limits).

<sup>17</sup> The CARB 2005 SCM defines "pretreatment coating" as "any coating that contains a minimum of one-half (0.5) percent acid by weight and not more than 16 percent solids by weight necessary to

<sup>4</sup> See Memorandum from G.T. Helms, Chief, EPA Ozone/Carbon Monoxide Programs Branch, to Air Branch Chiefs, Regions I-X, "Exemption for Low-Use Coatings," August 10, 1990.

<sup>5</sup> See *Control Techniques Guidelines: Industrial Cleaning Solvents*, EPA Office of Air Quality Planning and Standards, September 2006, EPA-HQ-OAR-2006-0535, at pp. 8-9.

<sup>6</sup> See SCAQMD Rule 1125 at section (c)(5) (referencing SCAQMD Rule 1171 for solvent cleaning operations); SCAQMD Rule 1171 at sections (g)(2)(G) and (g)(3)(B).

<sup>7</sup> *Ibid.*

<sup>8</sup> See footnote 5, *supra*.

<sup>9</sup> See *Reasonably Available Control Technology (RACT) Demonstration for Ozone State Implementation Plans (SIP)*, SJVAPCD, April 16, 2009 (2009 RACT SIP), at pp. 4-194.

<sup>10</sup> See SMAQMD Rule 452 at section 303.2.

<sup>11</sup> See SJVAPCD Final Staff Report for Rules 4603-4607, 4612, 4653, 4661, 4662, 4663, 4684, September 20, 2007, at pp. 10-11.



and recommends a VOC limit of 660 g/L for these coatings.<sup>18</sup> In its 2009 RACT SIP submittal, however, SJVAPCD compared the VOC limit in Rule 4612 for "pretreatment" coatings (660 g/L) to the VOC limits in BAAQMD's and SMAQMD's rules for "precoat" coatings (580 g/L and 600 g/L, respectively), suggesting that BAAQMD's and SMAQMD's rules contain more stringent VOC limits for the same coating activities.<sup>19</sup>

We believe this comparison was inaccurate. A more appropriate evaluation would have been to compare the VOC limits for primer coatings in SJVAPCD's Rule 4612 to the corresponding limits for primer coatings in BAAQMD's and SMAQMD's rules, and to also compare the VOC limits for pretreatment coatings among the same rules. The limit for primer coatings in SJVAPCD's Rule 4612 (250 g/L) is equivalent to the limits for primer coatings in BAAQMD's Rule 8-45 and SMAQMD's Rule 459, and to the recommended limit in the CARB 2005 SCM for Automotive Coatings.<sup>20</sup> The limit for pretreatment coatings in Rule 4612 (660 g/L) is equivalent to the limits for pretreatment coatings in BAAQMD's Rule 8-45 and to the recommended limit in CARB's 2005 SCM for Automotive Coatings, and is more stringent than the limit for "pretreatment wash primers" in SMAQMD's Rule 459 (780 g/L).<sup>21</sup> To the extent that the limit for "primer" coatings in SJVAPCD Rule 4612 covers "precoat" coating activities, consistent with the CARB 2005 SCM recommendations, SJVAPCD's Rule 4612 is more stringent than many other district rules that provide a separate, higher VOC limit for precoat coatings.<sup>22</sup> As such, we disagree with the commenter's assertion that BAAQMD's and SMAQMD's rules contain more stringent VOC limits for precoat coatings than SJVAPCD's Rule 4612.

Similarly, Rule 4612 does not contain VOC limits specific to "topcoat-metallic/iridescent" coatings. It does, however,

contain a limit of 420 g/L for "color coating,"<sup>23</sup> which is defined to include metallic/iridescent color coatings.<sup>24</sup> The definition of "color coating" in Rule 4612 is identical to the definition in the CARB 2005 SCM, which also includes metallic/iridescent color coatings.<sup>25</sup> The CARB 2005 SCM recommends a VOC limit of 420 g/L for color coatings.<sup>26</sup>

In its 2009 RACT SIP, SJVAPCD erroneously compared the limit in Rule 4612 for both color coatings and topcoat-metallic/iridescent coatings (420 g/L) with a 340 g/L limit in SCAQMD's Rule 1151 for the same coating activities.<sup>27</sup> SCAQMD's Rule 1151 contains a 340 g/L VOC limit for metallic-iridescent topcoats for certain vehicles that was effective between December 12, 1998 and July 1, 2008.<sup>28</sup> This requirement, however, expired as of July 1, 2008, at which time the requirements of Rule 1151, Appendix A became effective.<sup>29</sup> These currently-effective provisions establish a 420 g/L VOC limit for "color coating," which is now essentially defined identically to the definition in SJVAPCD's Rule 4612 and in the CARB 2005 SCM.<sup>30</sup>

As such, to the extent the commenter intended to argue that the limit for topcoat-metallic/iridescent coatings in SJVAPCD's Rule 4612 is less stringent than the corresponding limit in SCAQMD's Rule 1151, we disagree. The VOC limit for topcoat-metallic/iridescent coatings, which are included in "color coatings," in SJVAPCD's Rule 4612 is equivalent to both the corresponding limit in SCAQMD's Rule 1151 and to the recommended limit in the CARB 2005 SCM.

The commenter has provided no information to support its assertion that lower-VOC coatings for primer, pretreatment, and/or color coating (including topcoat-metallic/iridescent coating) activities are reasonably available in the SJV area and we are otherwise aware of no such information. Accordingly, we conclude that the limits in Rule 4612 represent RACT levels of control.

*Comment #5:* The National Paint & Coatings Association (NPCA) stated that the revisions to Rule 4603 that EPA proposed to approve have not been adopted by the District and that the VOC limits for two subcategories in the Pleasure Craft Coatings category are too low to allow for effective coatings. NPCA also stated that the VOC limits for pleasure craft coatings that ultimately appeared in EPA's 2008 CTG on Miscellaneous Metal and Plastic Parts Coatings were not mentioned in EPA's proposed CTG, and that the regulated communities were, therefore, not given the opportunity to comment and make recommendations on these limits. NPCA recognized that CTGs are not formal rulemakings and thus are not governed by notice and comment rulemaking requirements, but nonetheless stated that EPA should reevaluate the efficacy of the CTG recommendations in this case, given the absence of thorough public review and comment.

Lastly, NPCA noted that USEPA is conducting a comprehensive technology review of pleasure craft coatings for purposes of setting NESHAP emission limits and stated that the resulting data will provide a more current and thorough understanding of RACT for these coating operations. NPCA requested that EPA "not approve the pleasure craft coating aspects of SJVAPCD's SIP" during the pendency of this rulemaking process.

*Response #5:* NPCA's comments address revisions to Rule 4603 that have not yet been submitted for approval into the SIP. As such, NPCA's comments are not relevant to this action. Our action today is limited to the version of Rule 4603 that the District adopted and submitted to EPA for SIP approval on December 23, 2008. This version of Rule 4603 does not contain the VOC limits for pleasure craft coatings recommended in the 2008 CTG.

### III. EPA Action

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving these rules into the California SIP.

### IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet

provide surface etching and is labeled and formulated for application directly to bare metal surfaces to provide corrosion resistance and adhesion." CARB 2005 SCM at section 3.23.

<sup>18</sup> See CARB 2005 SCM at section 4.1 (Coating Limits).

<sup>19</sup> See 2009 RACT SIP, SJVAPCD, April 16, 2009 at pp. 4-242.

<sup>20</sup> See SJVAPCD Rule 4612 at section 5.1; BAAQMD Rule 8-45-301; SMAQMD Rule 459 at section 301; CARB 2005 SCM at section 4.1 (Coating Limits).

<sup>21</sup> See SMAQMD Rule 459 at section 301.1.

<sup>22</sup> See e.g., SMAQMD Rule 459 at section 301.1, which establishes a 250 g/L VOC limit for primer coatings and a separate 600 g/L VOC limit for precoat coatings; see also CARB 2005 SCM at Appendix D, D-4 and D-5.

<sup>23</sup> See SJVAPCD Rule 4612 at section 5.1.

<sup>24</sup> See SJVAPCD Rule 4612 defines "color coating" as follows: "any pigmented coating, excluding adhesion promoters, primers, and multi-color coatings, that requires a subsequent clear coating and which is applied over a primer, adhesion promoter, or color coating. Color coatings include metallic/iridescent color coatings." Section 3.15.

<sup>25</sup> See CARB 2005 SCM at section 3.12.

<sup>26</sup> See CARB 2005 SCM at section 4.1 (Coating Limits).

<sup>27</sup> See 2009 RACT SIP, SJVAPCD, April 16, 2009, at pp. 4-242.

<sup>28</sup> See SCAQMD Rule 1151 at section (c)(1)(A), Table 1.

<sup>29</sup> See SCAQMD Rule 1151, Appendix A.

<sup>30</sup> See SCAQMD Rule 1151, Appendix A, sections (c)(12) and (d)(1), Table A.

the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. *For that reason, this action:*

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
  - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
  - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
  - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
  - Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
  - Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
  - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
  - Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
  - Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.
- The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 22, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

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

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

Dated: December 3, 2009.

**Laura Yoshii,**

*Acting Regional Administrator, Region IX.*

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

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

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

#### Subpart F—California

- 2. Section 52.220 is amended by adding paragraphs (c)(354) (i)(E)(9) and (10) and (c)(364)(i)(A)(3) to read as follows:

#### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*  
 (354) \* \* \*  
 (i) \* \* \*  
 (E) \* \* \*

(9) Rule 4604, "Can and Coil Coating Operations," adopted on September 20, 2007.

(10) Rule 4612, "Motor Vehicle and Mobile Equipment Coating Operations-

Phase II," adopted on September 20, 2007.

\* \* \* \* \*

(364) \* \* \*  
 (i) \* \* \*  
 (A) \* \* \*

(3) Rule 4603, "Surface Coating of Metal Parts and Products," adopted on October 16, 2008.

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2005-0051]

#### 44 CFR Part 206

RIN 1660-AA44

### Special Community Disaster Loans Program

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) is amending its Special Community Disaster Loan Program regulations to establish loan cancellation provisions. The Special Community Disaster Loan Program, and these cancellation provisions, apply to communities in the Gulf Coast region who received Special Community Disaster Loans following Hurricanes Katrina and Rita. The period for new Special Community Disaster Loan eligibility closed at the end of fiscal year 2006. This final rule establishes procedures and requirements for Special Community Disaster Loan recipients to apply for cancellation of their loan as authorized by the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007. This final rule does not cancel all Special Community Disaster Loans, nor does it apply to loans made under FEMA's Community Disaster Loan program which is governed under separate regulations. This rule also finalizes the 2005 Special Community Disaster Loan Program interim rule.

**DATES:** This final rule is effective March 22, 2010.

**ADDRESSES:** Copies of this final rule, the 2005 interim Rule, the 2009 notice of proposed rulemaking, all public comments received, and supplementary information (if any) are available electronically on the Federal

eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) in Docket ID: FEMA-2005-0051. The regulatory docket is also available for inspection at the Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street, SW., Washington, DC 20472.

**FOR FURTHER INFORMATION CONTACT:**

James A. Walke, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington DC 20472-3300, or call (202) 646-2751, or e-mail [james.walke@dhs.gov](mailto:james.walke@dhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Federal Emergency Management Agency's (FEMA) Community Disaster Loan (CDL) Program for local governments began in 1974. The program provides funding to help communities that, due to a presidentially-declared disaster, have incurred a significant loss in revenue that hinders the community's ability to provide essential municipal services such as public schools, sanitation, fire and police services. The CDL program is governed by regulations at 44 CFR part 206 subpart K. See 44 CFR 206.360.

After the catastrophic damage caused by Hurricanes Katrina and Rita in 2005, communities in Louisiana, Texas, Mississippi, and Alabama experienced severely depleted tax bases, but a remaining need to provide essential services such as a police force, medical care, public education, and firefighting. The costs to provide these services are not eligible for funding from FEMA under the Public Assistance Program or any other FEMA grant or assistance program.

Due to the unusual circumstances facing these communities, Congress passed the Community Disaster Loan Act of 2005, Public Law 109-88 (Oct. 7, 2005) (2005 Act). The 2005 Act authorized FEMA to loan up to \$1 billion to communities that had sustained revenue losses due to the disaster. Loans that FEMA issued under the 2005 Act are referred to as "Special Community Disaster Loans" (Special CDLs). Special CDLs and FEMA's regulations governing the issuance of Special CDL's, (44 CFR 206.370-206.377), only apply to communities affected by Hurricanes Katrina and Rita.

The eligibility requirements and procedures for Special CDLs provided under the 2005 Act are similar to those of the CDL program. Special CDLs, however, are different in three aspects: (1) The \$5 million limit on individual loans found in the CDL program was

removed; (2) the Special CDLs could only be used to assist local governments in providing essential service[s]; and (3) the loan cancellation provision of section 417(c)(1) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), which was applicable to CDLs, was not applicable to Special CDLs. On October 18, 2005, FEMA published an interim rule to implement the provisions of the 2005 Act. See 70 FR 60443; also 44 CFR 206.370-206.377. The interim rule took immediate effect and only authorized FEMA to approve Special CDLs during fiscal year (FY) 2005 or FY 2006. Accordingly, FEMA is no longer authorized to grant new Special CDLs.

After FEMA published the interim rule, Congress passed the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006, Public Law 109-234 (June 15, 2006) (2006 Act), which appropriated funds to support \$371,733,000 in loan authority in addition to the loans authorized under the 2005 Act. Special CDLs provided under the 2006 Act included three additional limitations: (1) The maximum loan amount was increased to 50 percent of the applicant's operating budget during the fiscal year of the disaster (FY 2005); (2) the loan analysis could only consider "tax revenue" losses and not "other revenues" as permitted in the 2005 Act; and (3) applicants were required to demonstrate actual loss in tax revenues of 25 percent or greater. Like the 2005 Act, the 2006 Act also specifically stated that the loan cancellation provision of section 417(c)(1) of the Stafford Act did not apply. Under the authority of the 2005 and 2006 Acts, FEMA approved 152 Special CDLs, totaling \$1,270,501,241, to 109 eligible applicants in Mississippi and Louisiana.

On May 25, 2007, Congress passed The U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110-28, section 4502(a), Public Law 110-28, section 4502(a), 119 Stat. 2061 (2007 Act). The 2007 Act provided FEMA the discretionary authority to cancel Special CDLs, but that authority is limited by the language in section 417(c)(1) of the Stafford Act. See 42 U.S.C. 5184. FEMA's discretionary authority to cancel Special CDLs is identical to the agency's authority to cancel loans issued under the CDL program. FEMA's procedures and criteria for cancellation of CDLs are set forth at 44 CFR 206.366. FEMA has found these provisions to be successful in providing the information necessary to determine whether

cancellation of a CDL is appropriate. FEMA similarly has determined that these processes and criteria should apply to the process for cancellation of Special CDLs. Therefore, on April 3, 2009, FEMA published a notice of proposed rulemaking that proposed to revise the regulations established in the interim rule to include the same cancellation requirements and procedures for the Special CDL program as FEMA has been using for the CDL program. See 74 FR 15228.

Pursuant to FEMA's statutory authority under the 2007 Act, FEMA may cancel " \* \* \* all or any part of [a Special CDL] to the extent that revenues of the local government during the three full fiscal year period following the major disaster are insufficient to meet the operating budget of the local government, including additional disaster-related expenses of a municipal operation character." 42 U.S.C. 5184(c). As required by statute, FEMA's decision must be based on the revenues of the local government during the three-full-fiscal-year period following the major disaster. In the proposed rule, FEMA established that the Federal government's "fiscal year" typically runs from October 1 to September 30, and that FEMA would modify the three-year period to reflect the 36 calendar months following the disaster for governments that operate under a different fiscal year. FEMA also proposed to define the term "operating budget" as actual revenues and expenditures of the local government as published in the official financial statements of the local government.

Furthermore, since the purpose of the Special CDL program is not to underwrite pre-disaster budget or deficits of the local government, FEMA proposed that such deficits carried forward would reduce any amounts otherwise eligible for loan cancellation. Therefore, expenditures would be reduced accordingly for purposes of evaluating any request for loan cancellation if the transfer is from an operating funds account to a capital funds account, or if operating funds are used for other than routine maintenance purposes, or non-disaster related expenditures are increased (except increases due to inflation, the annual operating budget or operating statement). Additionally, FEMA proposed that the tax and other revenue rates or the tax assessment valuation of undamaged property in effect at the time of the disaster would be used without reduction for purposes of computing revenues received.

As the statute authorizes FEMA to cancel "all or any part" of a Special CDL,

FEMA proposed to cancel a part of a loan as opposed to the entire loan where the application for cancellation reflects that the applicant's revenues are insufficient to repay the entire loan but sufficient to repay a portion of the loan. If FEMA were to determine that all or a part of an applicant's Special CDL should be cancelled, the proposed rule stated that the amount of principal would be cancelled and the related interest forgiven. FEMA further proposed that the determination concerning loan cancellation would specify that any uncancelled principal and related interest must be repaid according to the terms and conditions of the promissory note; if repayment would constitute a financial hardship, then the local government would be required to submit a repayment schedule to FEMA for review, providing a plan for settling the indebtedness on a timely basis.

FEMA also proposed that, although a loan or cancellation of a loan would not reduce or affect other disaster-related grants or other disaster assistance, FEMA would not approve any Special CDL cancellation that would result in a duplication of benefits to the applicant. Finally, as proposed, if FEMA denies an Application for Loan Cancellation, in whole or in part, the applicant would be allowed to appeal and to submit any additional information in support of the application within 60 days of the date the application is denied. The decision of the Assistant Administrator on appeal would be final.

## II. Changes From the Proposed Rule

FEMA made five substantive changes to the regulatory text in response to the 68 comments received by FEMA on the proposed rule. (A discussion of the comments received on the proposed rule, the 2005 interim rule, and FEMA's responses to those comments, is in section IV below.) Further, as a result of these five substantive changes, FEMA redesignated the paragraphs in 44 CFR 206.376 to accommodate the new regulatory text.

First, FEMA has revised 44 CFR 206.376(c)(4) to allow the transfer of *ad valorem* property tax revenues under certain conditions. The proposed rule contained a restriction that a transfer from an operating fund for debt service (*i.e.*, principal and interest payment on bonded indebtedness, capital leases, or other debt for capital expenditures which is paid for through property tax levies) would be excluded from allowable expenditures in the operating budget calculation. This exclusion was proposed because the use of the loan funds was limited to the provision of

essential services, and the regulations clearly prohibited the use of the funds for capital expenses under the regulations. See 44 CFR 206.371(f). However, one commenter noted that the loss of tax revenue in non-operating funds will require the reallocation of *ad valorem* tax resources from operations to debt service and retirement obligation funding. In evaluating this comment, FEMA realized that this type of transfer may be legitimate if required by law. Excluding the transfers from expenditures in the operating budget calculation may result in an operating surplus instead of a deficit (when making a loan cancellation determination) if such transfers were allowed as a legitimate expenditure.

To account for this situation, in this final rule, FEMA has revised 44 CFR 206.376(c)(4) to allow the transfer of *ad valorem* property tax revenues under certain conditions. If a local government or other entity that received a Special CDL has property tax revenues affected by the disaster, FEMA will consider the impact of the loss of property tax revenue in Debt Service or Pension Funds (non-operating funds) if all of the following conditions are met: (1) The entity experienced a loss of property tax revenue as a result of the disaster and the assessed value during the three years following the disaster, in the aggregate, is less than the pre-disaster assessed value; (2) the entity has a property tax cap limitation on the ability to raise property taxes post-disaster; and (3) the property taxes are levied through the General Operating Fund and transfers for obligations mandated by law are made to fund Debt Service or Pension Obligations which result in the entity experiencing a reduction of property tax revenues in the General Fund. If all three conditions are met, the amount of property taxes that are transferred to other funds for Debt Service or Pension Obligations funding will not be excluded from the calculation of the operating budget or from expenditures in calculation of the operating deficit, to the extent that the property tax revenues in the General Fund are less than the property tax revenues were pre-disaster.

Third, FEMA added definitions for the terms "revenues" and "operating expenses" which were critical, but undefined, terms in the proposed rule. See 44 CFR 206.376(b). For cancellation purposes, these definitions will be used to determine if the applicant experienced a deficit during the three full fiscal years following the disaster. For additional guidance, non-governmental applicants may choose to refer to the standards established by the

Financial Accounting Standards Board (FASB). Governmental applicants may choose to refer to the general accounting standards established by the Government Accounting Standards Board (GASB) and published by the Government Finance Officers Association (GFOA). The FASB and GASB provide general accounting principles that are not controlled or required by FEMA.

Fourth, the language in the proposed rule at 44 CFR 206.376(d)(4) proposed that the initial review of an application for cancellation was to be conducted by the Assistant Administrator of the Disaster Assistance Directorate or designee. The proposed rule also stated that should the local government seek reconsideration, it could submit additional information in support of the application within 60 days. The reconsideration was to be made by the Assistant Administrator for the Disaster Assistance Directorate. Although, in practice, the Assistant Administrator for the Disaster Assistance Directorate had delegated the initial determination responsibility for CDL cancellation to the Director of the Public Assistance Division, this delegation was not apparent in the proposed regulation. As a result, FEMA received comments requesting that a different person determine the appeal than the person who makes this initial decision. In response to those comments, FEMA revised the regulatory text to specify that the Director of the Public Assistance Division makes the initial determination. Although a revision to the regulatory text will not change FEMA's actual procedure for reviewing and adjudicating appeals of cancellation determinations, in this final rule the language at 44 CFR 206.376 (f) clearly places the initial determination decision with the Director of the Public Assistance Division.

Fifth, FEMA received a comment noting that the proposed rule lacked a timeline for the review and processing of applications for cancellation. The commenter requested a time period in which FEMA will conduct its review and make its initial determination regarding loan cancellation. In response to this request, FEMA revised 44 CFR 206.376(f), to add a new paragraph (f)(1) which provides that once all required and requested information has been provided by the applicant including non-reimbursed disaster related expenses, the Director of the Public Assistance Division will complete the initial evaluation within 60 days.

Finally, FEMA realized that the language of the proposed regulatory text did not align with the language of the

preamble of the proposed rule with respect to how the three-fiscal-year period in 44 CFR 206.376(a)(3) is calculated. Compare the proposed 44 CFR 206.376(a)(3) at 74 FR 15235 with 74 FR 15230, bottom of first column. The 36-month period referenced in the proposed regulatory text was intended to prevent communities from revising their fiscal years during the evaluation period to artificially extend their evaluation period beyond the traditional 36-month period of three fiscal years. However, the explanation in the preamble describing how FEMA would calculate the three-full-fiscal-year period did not make it into the proposed regulatory text. The preamble explained that the Federal fiscal year begins on October 1st and for those governments that operate under a different fiscal year, FEMA would modify the three-year period to reflect the 36 calendar months following the disaster. To align the regulatory text with the preamble, language has been added to paragraph 206.376(b)(3) to clarify that at the local government's discretion, the three-fiscal-year period following the disaster is either a 36-month period beginning on September 1, 2005 or the 36 months of the local government's fiscal year as established before the disaster.

### III. FEMA's Process for Reviewing Applications

When reviewing the comments received on the proposed rule, FEMA realized that applicants for cancellation would benefit from a concise explanation of the steps FEMA will follow in its internal review process. When reviewing applications, FEMA will review the operating budgets for the three full fiscal years following the disaster. The budgets of the General Fund, Special Revenue Funds of an operating nature, and Enterprise Funds of an operating nature will be reviewed. Revenues from the Special CDL will be excluded from the revenues considered in this analysis. Further, debt service payments and capital expenditures will be excluded from the operating budget calculations per the regulations. Next, revenues will be compared to expenses for all funds noted above to determine if there is an operating deficit. If there is no operating deficit, then loan cancellation will not be approved. If there is an operating deficit for the three full fiscal years following the disaster, then revenue losses will be reviewed. If the revenue losses are great enough to offset the entire amount of the Special CDL, then no further work will be done, and the loan will be canceled and all accrued interest forgiven. If the revenue losses are not enough to offset the loan,

then FEMA will review the applicant's unreimbursed disaster-related expenses. If the revenue loss and unreimbursed disaster related expenses do not offset the entire amount of the loan, then any remaining principal that is not offset, and the associated accrued interest will be due at the end of the five-year term of the loan. The amount of the loan that is offset will be canceled, and the related interest forgiven.

For these cancellation procedures to provide the greatest benefit, loan recipients should submit their Application for Loan Cancellation before the expiration date of their loan. This will allow FEMA to cancel all or part of the loan if appropriate, and to forgive all related interest before loan repayment commences. If the loan recipient applies for and is granted cancellation before the expiration date of its Special CDL, then all interest on the amount of the loan that is cancelled would be forgiven regardless of the date that the loan amount was dispersed or the date that loan cancellation is granted.

### IV. Discussion of the Public Comments Received

#### A. The 2005 Interim Rule

FEMA published an interim rule in 2005 which created the Special CDL program. FEMA solicited public comment on those interim regulations and received one comment. The commenter questioned FEMA's determination that recreation districts did not provide "essential services" as provided for in the 2005 Act, and therefore would not be eligible to receive a loan under the 2005 Act. The commenter stated that since recreation districts were considered subdivisions of a State, they should qualify as "essential services."

Upon review of this comment, FEMA re-evaluated the eligibility of recreation districts under the 2005 Act in light of the limited funding available to address priority needs of local governments. The 2005 funds were limited to \$1 billion, and all \$1 billion was provided to eligible applicants with many of the applicants receiving only a portion of the funds for which they were eligible due to a lack of available funds. In making its award determinations, FEMA prioritized services, finding the needs of a police force, medical care, public education, and firefighting, as examples, to be more "essential" than the services provided by a recreation district. Because there were more than enough applicants who met the eligibility criteria to utilize the complete amount of the limited available funding, FEMA

did not grant loans to recreation districts under the 2005 Act. The 2006 Act, on the other hand, provided additional available funds, but the eligibility requirements were more restrictive. Only a small fraction of those eligible for the 2005 Act funds were eligible for the 2006 Act funds. No recreation districts applied for the 2006 Act funds. Had they applied and been eligible for the 2006 Act funds, FEMA would have considered them for funding.

#### B. The 2009 Notice of Proposed Rulemaking

FEMA published a notice of proposed rulemaking on April 3, 2009 that proposed to revise the interim rule by adding cancellation procedures. See 74 FR 15228. The proposed rule also included a proposed Paperwork Reduction Act collection of information. Comments on the proposed rule were due on or before June 2, 2009. FEMA received 68 comments on the proposed rule from a wide and diverse representation of the public affected by the proposed rule. Commenters included members of Congress, States, cities, parishes, public and private non-profit service providers, public and private organizations, utilities, a school board, and individual citizens. The substantive comments received, and FEMA's responses thereto, are as follows:

##### 1. General Comments

Nearly every comment expressed general support for the cancellation of Special CDLs. Commenters see the action as aiding in disaster recovery by reducing the tax burden on the local population. Further, the commenters recognized that relieving this financial burden would increase communities' ability to provide vital services to the communities' residents. Only one commenter opposed the rule. However, the opposing commenter's rationale alleged an improper use of funds for cars, boats and trips in lieu of repairing one's property and referenced disapproval of FEMA's activities related to the housing of individuals for almost four years after the disaster. Based on this rationale, FEMA believes this commenter misconstrued the intent of the proposed rule, which does not provide assistance to individuals and households.

##### 2. Small Business Administration Loans

Twenty-nine comments sought cancellation of Small Business Administration (SBA) loans and/or mortgages for individual homeowners or business owners. These requests are

outside the scope of this rulemaking and FEMA's authority. FEMA has forwarded these comments to the SBA.

### 3. Increase in Market Values

After the disaster, the Gulf region realized severe inflation in costs to maintain a workforce (increased salaries and employee benefits); obtain materials, insurance, and equipment; and house evacuees from other areas. Had the disaster not occurred, these costs would likely not have been incurred to the extent that existed in the post-Katrina environment. One hospital representative commented that they experienced a 695 percent increase in the cost of nursing contract labor in calendar year 2006 as compared to 2005 because of the loss of staff. Five commenters requested that FEMA consider the increased costs of workforce maintenance, obtaining materials, insurance and equipment, and housing evacuees as disaster-related expenses, thereby considering increased expenditures on regular and disaster-related budget items when evaluating loan cancellation.

Although non-disaster related expenses may not be considered, the three-year operating budget used for calculation purposes takes into account any increase in expenditures based upon local labor and other economic conditions. Expenditures will be reviewed for reasonableness and FEMA may request demonstration by the local authority that conditions existed to cause an increase in expenditures above the normal inflation rate as a result of the disaster. As proposed in 44 CFR 206.376(a)(4), increases due to inflation will not be reduced for purposes of evaluating a loan cancellation request. Therefore FEMA will apply disaster-related costs at their actual incurred expense.

Two commenters stated that loan recipients are experiencing post-event needs and incurring non-reimbursable expenses which, while not directly covered by the Stafford Act, are a result of post-effect conditions such as increased homelessness, and law enforcement/code enforcement issues. The commenters recommended that all post-Katrina and Rita expenditures be considered disaster-related under proposed 44 CFR 206.376(a)(4) because of the nature of the disaster and its scope of devastation.

The examples provided by the commenters would be characterized as disaster-related expenses of a municipal operation character, and therefore eligible for consideration. Unless otherwise indicated, all expenditures in the adopted operating budgets will be

assumed to be related to carrying out the essential services of the local government, and would therefore be considered disaster-related expenses of a municipal operation character.

One commenter stated that applicants were required to have at least a 25 percent decrease in operating revenues to receive the Special CDL funds, but that operating expenditures were not considered. Another commenter noted that it experienced a growth in some specific revenues, but the growth was strictly attributable to the significant purchases made by its citizens to recover their losses, and the commenter has seen its operating expenditures grow roughly 24 percent. These commenters requested that FEMA take into consideration the gap between a decrease in operating revenues with a limited decrease or even an increase in operating expenditures.

The Special CDL Program was designed to provide loans based upon post-disaster estimated revenue losses, not expenditures. Therefore, the first test for cancellation of a Special CDL is to determine whether there is an operating deficit. If expenditures exceeded revenues during the three-full-fiscal-year period (which would create an operating deficit), then loan cancellation may be possible. If a cumulative three fiscal year operating deficit exists, FEMA will consider revenue losses and/or unreimbursed disaster-related expenditures in determining how much of the loan may be cancelled.

### 4. Treatment of Property Values

Three commenters were concerned that the proposed rule would create an unnecessary burden on the applicants to determine which properties were or were not physically damaged by the storms. They noted that properties which may not have been physically damaged by the storms may have experienced a drop in property value in revenue evaluation. One city requested an agreement by FEMA that the entire city was damaged or destroyed, and recommended the creation of a threshold for establishing that an entire community has been damaged, rather than going from structure to structure. Another commenter suggested that FEMA not seek to determine if revenue decreases are associated with assessed property value decline related to the disaster, or to general market conditions.

Revenue loss calculations will use actual property taxes collected. See 44 CFR 206.374(b)(2). Property tax revenues are considered on an aggregate basis, not an individual property

assessment basis, so FEMA expects the impact on the revenues will be properly reflected in the financial statements, based upon actual property tax collection. Furthermore, because property tax revenues are considered on an aggregate basis, applicants will not need to make a property by property determination as feared by the commenters. Finally, unless provided information to the contrary, FEMA will assume that any assessed property value decline during the three full fiscal years after the disaster was related to the disaster, and not to general market conditions, as market conditions themselves were severely affected by the disaster during that period of time.

One commenter alleged that the use of post-disaster reassessment of property values will show a false economic increase to property assessment values. However, if one is using actual tax revenues collected, and applying them to actual expenditures incurred, FEMA does not agree that there would be a false increase. For purposes of determining loan cancellation, FEMA uses actual tax revenues collected, and the actual inability of an applicant to meet its operating budget. The post-disaster reassessment of property values is not used to determine eligibility for cancellation. It is the taxes received based on those revised property values, along with all other revenues, compared to the expenses incurred in the operating budget which then results in either an operating surplus or deficit.

Finally, one commenter stated that some State constitutions provide for the mandatory reappraisal and valuation at least every four years of all property that is subject to taxation. According to the commenter, that reappraisal and valuation requirement is designed to result in local governments receiving the same amount of ad valorem taxes received before the reassessment. The commenter advised that rates are therefore established to yield the same amount of tax revenue collected in the prior year. So, although rates may go down, actual tax revenues may not decrease.

FEMA uses actual tax revenues in making its determination of an operating deficit. FEMA expects the reassessment will have no impact on the calculation of the operating deficit since no revenues will be lost as a result of this process. Regardless of whether the applicant's revenues remained constant, increased, or decreased, if those revenues were insufficient to meet its operating expenses during the three full fiscal years after the event, then the applicant may be eligible for cancellation.

## 5. Appeals Process

FEMA proposed in the NPRM, 44 CFR 206.376(d)(4), that if the Assistant Administrator of the Disaster Assistance Directorate, or designee disapproved, in whole or in part, an Application for Loan Cancellation, the applicant could submit additional information in support of its application within 60 days of the date of the disapproval notice. The application and any new information would then be considered by the Assistant Administrator for the Disaster Assistance Directorate (Assistant Administrator) on appeal. Any decision made by the Assistant Administrator on the additional information would be final. Four commenters requested that this process be revised so that a different person determines the appeal than the person who makes the initial decision.

In response to these comments, FEMA has revised the regulatory text explaining the appeals process. The proposed language mirrored the CDL cancellation appeal text and said that the Assistant Administrator or designee could make the initial decision. In practice, the Director of the Public Assistance Division has been fulfilling this duty. The Director of the Public Assistance Division therefore makes the initial decision, and the Assistant Administrator reviews the Director of the Public Assistance Division's decision, and any additional information, to make the final agency decision on the request. Although a revision to the regulatory text will not change FEMA's actual procedure for reviewing and adjudicating appeals of cancellation determinations, the revised language at 44 CFR 206.376(f) clearly vests the initial determination decision with the Director of the Public Assistance Division.

## 6. Extent of Cancellation

The proposed rule explained that the cancellation authority provided to FEMA in the 2007 Act authorized FEMA to cancel all or a part of a Special CDL if a certain threshold is met. Congress did not provide FEMA with the blanket authority to cancel all Special CDLs. Seven commenters, however, requested blanket cancellation. Several noted that it would be the least complicated and most beneficial method; others opined that since FEMA considered it as an alternative in the rule FEMA therefore has implied authority to do so; and another asserted that because of the differences in the funding and eligibility requirements between the CDL and Special CDL programs, there should be

a difference in the requirements for cancellation.

FEMA does not have the legal authority to unilaterally cancel all Special CDLs. As some commenters noted, FEMA did consider whether it had the authority to cancel all loans when drafting the proposed rule, but after careful consideration, concluded that it lacks the statutory authority to issue a blanket cancellation. Furthermore, it is not in FEMA's discretion to apply a different threshold for cancellation of Special CDLs than CDLs. The 2007 Act clearly noted that the cancellation provisions of section 417 of the Stafford Act were to apply to the cancellation of Special CDLs. Section 417 of the Stafford Act only allows FEMA to cancel all or a part of a community's loans if "revenues of the local government during the three-full-fiscal-year period following the major disaster are insufficient to meet the operating budget of the local government, including additional disaster-related expenses of a municipal operation character." See 42 U.S.C. 5184(c)(1).

Therefore, when considering requests for cancellation, each loan will be considered on a case-by-case basis. FEMA will cancel all or a part of an applicant's Special CDL based on a review of actual losses and/or increased expenditures, and will cancel all or a part of a Special CDL if that applicant's budget results in an operating deficit.

One commenter noted that if blanket forgiveness is not possible, FEMA should amend the program to offer further deferrals, forgiveness of interest accrual in the meantime, and/or individual consideration for partial forgiveness or further deferral if justified.

FEMA does provide for deferral. If an applicant does not qualify for full or partial cancellation, the remaining debt may be paid over the remaining five-year period in accordance with the terms and conditions of the Promissory Note. See 44 CFR 206.376(f). The regulations also provide that if repayment will constitute a financial hardship, the applicant can submit a repayment schedule to FEMA for review. That time schedule would establish the applicant's plan for settling the indebtedness on a timely basis. See *Id.* Further, the term of a Special CDL may be extended by the Assistant Administrator for the Disaster Assistance Directorate, and he or she may defer payments of principal and interest for up to five years. See 44 CFR 206.377(b)(1) and (4). If such deferment should occur, however, interest will continue to accrue. See 44 CFR

206.377(b)(4). Also, in unusual circumstances involving financial hardship, the Assistant Administrator for the Disaster Assistance Directorate may also provide an additional period of time, beyond the extension allowed in 44 CFR 206.377(b), to repay the indebtedness. The conditions on this hardship extension are contained in 44 CFR 206.377(c).

Finally, one commenter noted that some communities prudently spread out the use of their eligible loan amounts. As a result, the commenter alleged that forgiveness should be for the total loan amount for which the jurisdiction qualified, regardless of any remaining balances which may be available at the time the application for forgiveness is submitted.

Although FEMA applauds wise financial management by communities, it finds that accommodating the commenter's suggestion would not be wise financial management by the Federal Government. A loan recipient may only use the loaned funds to assist in providing essential services, not to finance capital improvements or the repair or restoration of damaged facilities, or to pay the nonfederal share of any Federal program. See 44 CFR 206.371(f). To ensure that the level and frequency of periodic payments are justified, and to ensure that funds are appropriately received and disbursed, all loan recipients must show a need and must establish necessary accounting records before they may draw down funds. See 44 CFR 206.375. As communities continue to recover, at some point they are not going to be able to show a need to draw down additional funds.

To ensure appropriate management of funds, forgiveness of loans will be based on the amounts qualified for, and actually drawn down, and for which the applicant qualifies for cancellation of the loan under these regulations. Any outstanding principal and interest balance on a Special CDL after the review for cancellation will still be due and payable within the five-year time frame, unless extended by FEMA if requested by the applicant. Cancellation will not prevent a loan recipient from continuing to draw down funds, however. If a loan recipient has unused loan funds available, and they ultimately draw down those funds after the initial cancellation review, a separate cancellation review will be required before the Promissory Note expires (including any extensions provided under the authority of these regulations). If cancellation of those additional funds is not requested, or if FEMA does not deem those additional

funds eligible for cancellation, the new loan amount will have to be repaid.

#### 7. Time Period Considered

As previously noted, section 417 of the Stafford Act allows for all or a part of a Special CDL to be canceled if the revenues of the local government "during the three-full-fiscal-year period following the major disaster" are insufficient to meet its operating budget. FEMA received nine comments requesting that FEMA adjust the three-fiscal-year period. See 44 CFR 206.371(h).

One commenter requested that the three-year period (or longer) commence after the last FEMA appeal from the disaster is complete or after the last Project Worksheet is closed out, whichever is later. Not only does FEMA lack the legal authority to make the change as requested, but to do so would significantly delay any cancellation determination. The current approach allows loan recipients to more quickly request and receive cancellation of their loans, if they have an operating deficit caused by disaster-related revenue losses or increases in expenditures due to unreimbursed disaster-related expenditures. Disasters often remain open for many years, (e.g., the Northridge Earthquake declaration has been open since January 1994) and it is not expected that the disasters declared as a result of Hurricanes Katrina and Rita will close faster than the norm. Requiring loan recipients to wait the several years for all Project Worksheets to close or all appeals to be resolved would pose an undue hardship on those who seek cancellation of their Special CDL. FEMA believes the three-year period is adequate and, in most cases, will be more favorable to applicants.

Noting the long duration of disasters, one commenter stated that the full economic impact of public assistance work may not be known until the storm is closed out. The commenter advised that their sales tax revenues, which are a part of the General Fund receipts, declined nearly 17 percent this year and are predicted to fall another 10 percent in the coming fiscal year. Although the rule focuses only on the three full fiscal years immediately following the event, the commenter asserted that the effects are only now being felt, in the fourth year, and the commenter predicts that it will worsen in the fifth and possibly sixth year, before a stabilization of revenues is realized. Four commenters asserted that in the initial two years after the storm, sales tax revenues were extraordinarily inflated because of replacement and rebuilding purchases. As sales tax diversions normalize in the

coming years, commenters fear future operating deficits that were initially offset by these replacement purchases might ensue. Further, several commenters suggested a six-year or simply "longer" evaluation period be considered. Another commenter sought a longer evaluation period while allowing for immediate application for cancellation for those local governments who can document adequate revenue shortfalls at this time.

If sales tax revenues are declining as significantly as suggested, it is likely that an operating deficit occurred within the three-year period, which will result in an evaluation of all revenue losses and a review of unreimbursed disaster-related expenditures, if applicable. Even if FEMA had the legal authority to extend the period, which it does not, the longer it is extended, the greater the likelihood that the loss would be unrelated to the disaster (e.g., due to the nationwide economic downturn).

Similarly, one commenter noted that some states' ad valorem taxes are paid in arrears, meaning that tax revenues may not have been impacted in 2005 or 2006, but may have reduced significantly in 2007 and following. The commenter found three years to be insufficient. Although FEMA recognizes the impact that the ad valorem tax structure of some states could put them at a disadvantage, FEMA has attempted to apply as liberal an interpretation of its statutory authority as possible, and determined that it does not have the authority to shift the three-year period. The statutory language states "during the three full fiscal year period following the major disaster." See 42 U.S.C. 5184(c)(1). The language of the statute explicitly requires FEMA to consider only the three full fiscal years immediately after the major disaster, therefore FEMA cannot revise the regulation in response to this comment.

Two commenters asserted that because of the difference in applicants' fiscal years, some may be at a disadvantage if FEMA automatically applies a 36-month period for calculating the three full fiscal years. As an example, one commenter's fiscal year is from July 1 to June 30, so the commenter asserted that their review period would commence July 1, 2006; 10 months after the disaster. The commenters expressed concern that at that point some improvement in financial conditions should have already occurred beyond the conditions that existed immediately after the disaster. The commenters requested that an applicant be given the option of basing its cancellation request upon its fiscal year or a 36-month period

commencing on the first full month after the disaster.

In reviewing the proposed rule in light of this comment, FEMA realized that the proposed language of the regulatory text does not align with the language in the preamble of the proposed rule. Compare proposed 44 CFR 206.376(a)(3) at 74 FR 15235 with 74 FR 15230, bottom of first column. The 36-month period referenced in the proposed regulatory text was intended to prevent applicants from revising their fiscal years during the evaluation period to artificially extend their evaluation period beyond the traditional 36-month period of three fiscal years. However, the explanation in the preamble describing how FEMA would calculate the three-full-fiscal-year period did not make it into the proposed regulatory text. The preamble explained that the Federal fiscal year begins on October 1st and for those applicants that operate under a different fiscal year, FEMA would modify the three-year period to reflect the 36 calendar months following the disaster. Since Hurricane Katrina made landfall on August 29, 2005, allowing a 36-month period to begin immediately thereafter would place the beginning of the calculation on September 1, 2005.

Both of these commenters noted that allowing applicants to start with September 1, 2005, instead of their fiscal year start, would ensure that the extraordinary expenses and lost revenue incurred immediately after the event are fully taken into consideration. The regulatory text that would implement this change, however, was unintentionally omitted from the proposed rule. As a result, language has been added to paragraph 206.376(b)(3) to clarify that at the local government's discretion, the three-fiscal-year period following the disaster is either a 36-month period beginning on September 1, 2005, or the 36 months of the local government's fiscal year as established before the disaster. Should applicants elect the 36-month period beginning September 1, 2005, FEMA will prorate the revenues and expenses for the partial years. For example, if a city's fiscal year runs from January 1 through December 31, FEMA will apply one third of the city's fiscal year 2005 budget, all of its fiscal years 2006 and 2007 budgets, and two thirds of its fiscal year 2008 budget.

#### 8. Rules for Cancellation—General

Three commenters requested that FEMA align the accounting methods for the consideration of revenues and expenditures for the purpose of loan cancellation with the accounting



methods for loan eligibility to reduce subjective interpretations during the evaluation process and prevent any extreme changes in FEMA determinations.

FEMA will apply the same accounting methods in its review of applications for cancellation of Special CDLs as it applied to applications for the loans themselves. To provide clarity, in this final rule FEMA added definitions for the terms "revenues" and "operating expenses" to 44 CFR 206.376(b). In addition, for further guidance, non-governmental applicants may choose to refer to the standards established by the FASB and governmental applicants may choose to refer to the general accounting standards established by the GASB. These standards boards provide general accounting principles that are not controlled or required by FEMA.

Although FEMA will apply the same accounting methods, it will not apply the same criteria to applications for cancellation as applied to loan applications. This is because unlike the application stage where estimates are made because actual future budget data are not available, actual expenditures are known during the cancellation stage. The actual expenditure data provide a much more accurate presentation of a community's budget than estimates.

Further, FEMA is unable to use the same criteria for eligibility for the loan, as the criteria established by statute were not the same for all Special CDLs. To qualify for the Special CDLs issued under the authority of the 2005 Act, applicants were required to demonstrate that they had suffered substantial loss (*i.e.*, 5 percent) of tax and other revenues, whereas the 2006 Act further defined "substantial" by requiring at least a 25 percent loss of only tax revenues. The Special CDL issuance criteria also differed. The 2005 Act established loan amounts based upon the lesser of 25 percent of the operating budget, or the projected revenue loss and unreimbursed disaster-related expense. The Special CDLs issued under the 2006 Act, however, established loan amounts at 50 percent of the operating budget.

Just showing a loss, however, does not prove that a local government's revenues are insufficient to meet its operating budget as required by section 417 of the Stafford Act. To make this determination, the cancellation reviewer will first determine if there is an operating deficit, regardless of the projected revenue losses at the time the Special CDL was issued. The accounting procedures for cancellation use the same governmental accounting principles, but the calculation of the

operating deficit is expanded to include all revenue sources affected by the disaster so that the full picture of the financial condition of the local government is considered. This computation may result in revenue losses being realized that are greater than what was initially projected at the time of loan application. Reviewing all revenues affected by the disaster is expected to generally favor the applicant during the loan cancellation review process.

Two commenters were in favor of the rule as proposed and encouraged FEMA to provide equal treatment to the Gulf Coast communities and forgive Special CDLs under the same rules as CDLs are forgiven in other States for other storms. Three commenters, however, recommended that FEMA create new, different regulatory requirements for cancellation of Special CDLs because of the special circumstances related to this disaster. One of those commenters asserted that Special CDLs are not contemplated under section 417(c)(1) of the Stafford Act, so FEMA has the discretion to choose other methods for cancellation. All three commenters asserted that new, more flexible regulatory requirements should be established that maximize the possibility for cancellation for each individual recipient.

FEMA agrees that it should be as flexible and least restrictive as possible when establishing the procedures for cancellation. However, contrary to the one commenter's assertion, the 2007 Act explicitly ordered FEMA to apply section 417 of the Stafford Act when considering Special CDLs for cancellation. *See* 42 U.S.C. 5184. Therefore, the underlying statutory requirement that FEMA only forgive all or a part of those loans if, during the three-full-fiscal-year period following the event, revenues of the local government are insufficient to meet its operating budget, applies. The Special CDL program was created to assist communities in providing essential functions to their residents. Therefore, forgiveness should not be provided because a community would be inconvenienced by the requirement to repay the debt, but because it actually cannot do so and continue to provide those essential functions. This need is apparent when a community's revenues are insufficient to meet its operating budget.

As discussed throughout this preamble, FEMA has attempted to broadly construe its statutory authority and provide as much flexibility in the process as possible. However, FEMA has been using the existing procedures

for CDL cancellation since 1990, and has found them to be an efficient and accurate method of determining when revenues of a local government are insufficient to meet its operating budget. These procedures were successfully applied after other major hurricanes, including but not limited to hurricanes Andrew (1992) and Marilyn (1995).

Since each jurisdiction was not equally impacted by hurricanes Katrina and Rita, each loan cancellation application should be considered on its own merits. To ensure fairness, each applicant's request for cancellation will be reviewed individually to determine if the loan may be cancelled. Since each application for cancellation is considered individually, the evidence for cancellation eligibility will be unique to each applicant. If the magnitude of damage resulting from hurricanes Katrina and Rita resulted in a cumulative operating deficit during the three-full-fiscal-year period following the disaster, then Special CDL applicants will receive loan forgiveness based upon the revenues actually lost, up to the amount of the loan. If the revenue loss is not sufficient to cancel the entire loan, then FEMA will consider unreimbursed disaster-related expenses to offset the loan. If, after considering both revenue losses and unreimbursed disaster-related expenses, the entire loan is not cancelled, any remaining principal that was not cancelled along with associated accrued interest must be repaid at the end of the loan term, including any extensions, if approved.

One commenter asserted that FEMA should apply all expenses of the applicant in its evaluation, and not assess whether the expense is disaster-related. The commenter explained that all expenditures were made in accordance with local and state law governing the use of public funds, thus they were necessary and appropriate to meet the needs of the citizenry and/or constituents of the local government. While that may be true, the purpose of the Special CDL was to help local governments recover from losses associated with Hurricanes Katrina and Rita. Therefore, any losses due to an increase in expenditures must also be related to Hurricanes Katrina or Rita.

Three commenters suggested that FEMA provide cancellation in those situations where a cumulative operating deficit is not realized, or consider the operating deficit as a secondary criterion if an applicant's cumulative post-disaster revenue shortfall is less than the outstanding balance of the loan. One commenter encouraged FEMA to compare pre-storm revenue

projections to post storm actual revenues as the primary criteria for determining eligibility for partial or complete cancellation. In particular, the commenter requested that FEMA use the schedule of historic and projected revenues provided by loan recipients when they applied for the Special CDL.

FEMA's statutory authority only allows loans to be canceled if the local government's revenues are insufficient to meet its operating budget. See 42 U.S.C. 5184(c)(1). When actual operating revenues are not sufficient to meet actual operating expenditures, an operating deficit occurs. Therefore, for FEMA to cancel a loan, the applicant must first have an operating deficit. FEMA does not have the authority to waive this requirement.

If a local government has the financial ability to maintain its operating budget, the surplus should go to repay its debts. To the extent possible, Federal funds which were provided with the expectation of repayment should be repaid if the borrower has the assets available to repay them. Further, projected revenues versus actual revenues should not be used in lieu of actual revenues applied to actual costs because the latter provides a more accurate representation of an applicant's true financial status. The purpose of cancellation is to assist those communities that, due to the disaster, have incurred a revenue loss of such a magnitude that they no longer have sufficient funds to operate. These loans were provided to ensure that essential services would continue to be provided in the aftermath of the disaster. Therefore, cancellation should be provided when repayment of the debt would cause the community to no longer have the budget available to provide these essential services; not simply to provide a replacement for lost revenue.

Finally, one commenter was concerned that any increase in expenditures for the Special CDL recipients will be benchmarked to pre-Katrina levels. However, FEMA already reviewed the pre-Katrina operating budgets at the time the loan was made. When considering applications for cancellation, FEMA will review post-Katrina budgets for reasonableness but will assume that any costs in the operating budget are disaster-related unless otherwise noted.

#### 9. Today's Economy

Four commenters noted that loan recipients are now finding themselves in a deep recession, although 2009 figures will not be considered for cancellation. They stated that a three-

year qualifying snapshot as outlined in the proposed rule might unfairly disqualify certain loan recipients for loan cancellation. Another commenter asserted that requiring loan recipients to repay is in direct conflict with what President Obama and Congress are trying to accomplish with the economic stimulus package. Finally, another commenter urged FEMA to consider the effectiveness of simultaneously collecting Special CDL repayments from recovering communities and distributing funds appropriated by the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) to the same communities. The commenter encouraged FEMA to consider forgiveness as a component of the Nation's economic recovery effort.

The Special CDL Program was established to help communities affected by Hurricanes Katrina and Rita recover from revenue losses due to the disaster, not revenue losses for any other reason. The operating deficit and revenue loss/increased expenditures must be related to Hurricanes Katrina or Rita as required by 44 CFR 206.371(h). Further, unlike the ARRA, the Special CDL program was designed to replace lost revenues to continue essential services of an operating character, not provide capital funding for public works projects. The ARRA stimulus funding is provided for different reasons under separate authority, and is generally used for capital projects, which are not eligible costs under the Special CDL program. Therefore, these comments are outside the scope of this rulemaking.

#### 10. Documentation for Consideration

The proposed rule in 44 CFR 206.376(c), set out specific documents and data that are to be submitted in a community's Application for Loan Cancellation. Four commenters encouraged FEMA to allow for the submittal of additional documentation, above and beyond what is required by regulation, to support an application for loan forgiveness. One commenter specifically cited the GAO report: "Hurricane Katrina: Trends in Operating Results of Five Hospitals in New Orleans Before and After Hurricane Katrina." One commenter mentioned the value of original revenue projections, and said that FEMA should allow applicants to file this information with the application, not only during an appeal. Another argued that the rule should not limit information source documents to the publicly available financial statements of the local government. That commenter asserted that all sources of data should be considered in the local government's

application for cancellation as there is a great deal of variation among the local governments.

Applicants may submit any supporting documentation they believe supports an operating deficit, a disaster-related loss in revenue, or an increase in disaster-related unreimbursed expenditures. Furthermore, the application may include a narrative presentation to supplement the financial material accompanying the application and to present any extenuating circumstances for FEMA's consideration. See 44 CFR 206.376(e)(2). However, FEMA suggests that applicants not submit additional supporting documentation, outside of that required initially by FEMA, until they are notified by FEMA that they do not qualify for cancellation of all or part of the loan. Such notification is provided to each applicant in writing after FEMA has reviewed the financial statements, budgets, revenues, and if applicable, the unreimbursed disaster-related expenditures of the applicant; and made a determination that they do or do not qualify for cancellation under the regulations. If the applicant wishes to appeal that decision, additional supporting documentation may be submitted to FEMA at that time.

With respect to the audited financial statements and operating budgets of the local government, these are used because they will reflect the financial condition of the local government and its ability to repay the loan. Should a community choose to do so, it may submit other underlying documentation to support the information in the audited financial statements, provided it can be tracked into the financial system that was audited.

#### 11. Use of Official Financial Statements

Six commenters were concerned with FEMA's use of official financial statements. One was concerned that "additional disaster-related expenses of a municipal operation character" might not be reflected in official financial statements. Another was concerned that using official financial statements instead of actual cash expenditures might overstate the actual financial health of an applicant in the aftermath of a disaster.

Assuming the entity accounts for all expenditures through their accounting system, the official financial statements reflect the financial health of the applicant in accordance with generally accepted accounting principles; therefore their use is most appropriate. All expenses of an applicant should be included in the official financial statements. Although details of

unreimbursed disaster-related expenditures may not be reflected in the official financial statements, specifically, FEMA will ask applicants to identify such detailed information in the accounting system that may be eligible for consideration during the Special CDL cancellation process.

When making cancellation determinations, three commenters urged FEMA to also consider the revenue projections and other materials that were reviewed and accepted during the loan application process (5 year budgets, etc.), to take into account the overall loss of revenues that the applicant incurred as a result of the hurricanes.

Although FEMA based eligibility for the Special CDLs on revenue projections, it did so only because actual data were not available. Now that the statutorily-mandated three-fiscal-year period has passed, actual data exist. The official financial statements show the actual operating results, which will show whether or not the applicant actually experienced a loss of revenues and incurred an operating deficit. Because FEMA is limited to evaluating the data from the three full fiscal years after the disaster, projected data for that period would be less accurate and the consideration of projected data for a period thereafter is outside the scope of the authority provided in section 417 of the Stafford Act. Further, revenue losses as a result of the hurricane are part of the basis for determining an operating deficit. It is possible that other revenues not affected by the hurricane could offset the losses of revenues affected by the disaster, but if that were true, then there would be no operating deficit unless expenditures increased dramatically and the applicant had unreimbursed disaster-related expenses great enough to offset the loan. Therefore, FEMA made no change to this final rule based on the commenter's request.

One commenter noted that some cities are required by their state constitution to have a balanced budget. The commenter advised that this may have resulted in loan recipients reducing expenditures to match their decreased revenues. FEMA's acceptance of actual financial statements without a review of reduced expenditures that were made to match revenues would, the commenter stated, result in a distorted picture of the financial condition of the applicant. To remedy this, the commenter recommended that expenditures have a component of expenses not incurred, and therefore services not provided, as a result of the reduced revenues.

The Special CDL program was intended to provide loans that would replace estimated lost revenues as a result of the disaster. The loan proceeds were to be used to provide essential services that could otherwise not be provided due to the loss of those revenues. It would be difficult, if not impossible, for FEMA to determine which expenses, if any, were not incurred or services not provided as a result of the disaster, as the decision to fund services are made by the local authorities. In addition, the constitutional requirements for a balanced budget of state or local governments and the allocation of resources at the local level are outside the authority of FEMA. In calculating the operating budget, FEMA excludes the Special CDL proceeds which may create an operating deficit for many applicants that otherwise may not show an operating deficit in their own financial statements.

One commenter noted that some applicants may be required to prepare their budgets on a cash basis, so the budget-to-actual comparisons in the official financial statements are presented on a cash basis, the fund financial statements presented on a modified accrual basis and the government-wide financial statements prepared on a full accrual basis. In calculating the cumulative operating deficit from the official financial statements of the local government, the commenter asked, whether the applicant should begin with the statement of activities in the government-wide financial statements or the statement of revenues, expenditures, and changes in fund balance in the fund financial statements or the statement of revenues, expenditures, and changes in fund balances—budget and actual.

The operating budget used in the loan cancellation calculation is based upon the required supplementary budget schedules for all operating funds with revenues affected by the disaster, contained in the Comprehensive Annual Financial Report (CAFR). The operating budget schedules will be adjusted to exclude capital expenditures, debt service payments, or capital lease payments for equipment or buildings for purposes of calculating the operating budget at the time of cancellation review. Use of the statement of revenues, expenditures, and fund balance-budget and actuals may include funds which are of a non-operating nature. Such funds would not qualify for use of the Special CDL proceeds, and therefore, should not be used as the basis for Special CDL cancellation.

## 12. Documentation Required

One commenter stated that in the initial months after the storm, cities faced many challenges and in many cases did not track "un-reimbursed expenses", which may include, for example, police protection to FEMA trailer parks. Because of this, the commenter requested that FEMA consider expenses without supporting documentation.

If an applicant needs to identify unreimbursed disaster-related expenditures in order to cancel more of the loan, FEMA will work with the applicant to develop methods to identify and calculate unreimbursed disaster-related expenditures. However, without documentation, FEMA will not consider such undocumented unreimbursed disaster-related expenses for purposes of loan cancellation. FEMA applies the requirements of Office of Management and Budget (OMB) Circular A-129 "Policies for Federal Credit Programs and Non-Tax Receivables" to the management of its loan programs. OMB Circular A-129 is available electronically at <http://www.whitehouse.gov/omb/rewrite/circulars/a129/a129rev.html>. Although OMB Circular A-129 does not specifically address the unusual circumstance of the cancellation of Federal loans, it does require Federal Departments (including the Department of Homeland Security, of which FEMA is a component) to "follow sound financial practices in the design and administration of their credit programs," and loan documentation is required for the extension of credit. See OMB Circular A-129, Appendix A, paragraphs II.2 and III.A.2. Further, FEMA and government-wide regulations such as those at 44 CFR Part 13 and 2 CFR Part 215 require cost documentation to support reimbursement of funds in its grant programs, including documentation to support reimbursement of costs incurred for the response to and recovery from hurricanes Katrina and Rita under the Public Assistance program. Requiring the documentation of costs and revenues to justify the cancellation of a loan is a sound financial practice, is consistent with management of other programs, and is not changed in this final rule.

## 13. Definition of "Revenues"

The proposed rule contained no definitions for the terms "revenues" or "operating expenses." Two commenters sought definitions for these terms, and further, requested that FEMA define these terms to have the meaning

ascribed to them by the GASB and as discussed in the "Blue Book" by the GFOA except to the extent expressly modified in these regulations. Another commenter stated that the proposed rule focused only on property assessments and related taxes; the commenter encouraged FEMA to allow revenues from all sources, including sales taxes and in some cases, the relationship between local revenues and state revenues.

The individual comment highlighted the need for the definitions sought by the other two commenters. All sources of revenues will be considered in FEMA's cancellation calculation procedures, provided the entity has a cumulative operating deficit. To ensure applicants and FEMA apply consistent professional standards and common terminology to these words, the regulation has been revised to add definitions for these terms at 44 CFR 206.376(b). These definitions align with the usage of those terms by the GASB and GFOA.

Three commenters requested that one-time funds such as grants, awards, waivers, settlements and insurance proceeds, which are non-recurring, not be considered revenue when FEMA reviews a community's budget for loan cancellation. These one-time income surges, the commenters asserted, could overstate the run-rate of revenues to the local government.

Revenue calculations for cancellation review will use actual post-disaster revenue minus actual post-disaster expenditures to determine if an operating deficit exists. Federal grants, for example, received to fund operating programs are offset by expenditures for those grants, and should have no impact on the operating deficit. Grants and other one-time revenues received by the community that are not related to the Special CDL program, will be included if they represent revenues sought by the government and received to offset expenses of an operating character. Insurance proceeds directly related to the disaster must be included as revenue if they are reimbursing expenses of an operating character, or disaster-related expenses. Special CDL proceeds, however, will be excluded. By matching such revenues against operating expenses, FEMA expects the net effect will have no impact on the operating deficit.

Another commenter requested that FEMA clarify the term "revenues" to include revenues from traditional sources existing before the disaster. The commenter provided the example of a prison facility whose closing resulted in the loss of revenue to a sheriff and tax

collector's office, and requested that revenues after the disaster be compared to revenues before the disaster, including the consideration of the loss of its traditional revenue sources.

In response to this comment, FEMA added a definition of the term "revenue" in 44 CFR 206.376(b)(2). During the cancellation review process, all revenues during the three-full-fiscal-year period will be reviewed, including those from traditional sources existing before the disaster. These actual revenues will be compared to the actual expenditures during that period to determine eligibility for cancellation.

Two commenters noted that many loan recipients have pledged their revenues as the security for bonds. They encouraged FEMA to exclude from "revenues" those that are received by a local government, but are not available for the payment of operating expenses by law or contract.

Any revenues that are dedicated to non-operating expenditures, such as debt service or capital expenditures are excluded on both the revenue and expenditure side of the budget calculation to determine the net eligible operating budget. As for whether the entity has these funds available for the repayment of the loan, each entity knew of commitments of operating revenues that were pledged at the time the loan was made. Further, each applicant signed a collateral security agreement at the time it was granted the Special CDL, pledging future revenues to be used to repay the loan, if necessary.

Two commenters requested that FEMA consider pre-disaster budgets and/or financial statements to determine base revenue and expenditure levels for comparison against post-disaster levels to establish a more realistic and accurate shortfall. Although FEMA does consider the pre-disaster budgets and financial statements in base revenues at the time the loan is made, the shortfall, if any, must be from actual revenues lost.

One commenter requested that the "revenues" included in the "operating budget" submitted for cancellation consideration be adjusted to remove any increased tax revenues resulting from a voluntary increase in millage rates or other fees (ex: An airport's airline fees) during the applicable three-full-fiscal-year period following the disaster. FEMA uses actual tax and other revenues received during the three-full-fiscal-year period in calculating the operating deficit and ultimately possible cancellation of the Special CDL. Further, property tax revenues are considered in the aggregate for purposes of calculating the cumulative three-year operating deficit. To ensure an accurate

review of the entity's ability to meet its operating budget, if the local government increases taxes or adds new fees or raises existing fees, the actual revenues received during the three-full-fiscal-year period following the disaster will be included in the loan cancellation calculation of operating revenues.

Finally, one commenter asked if the terminal and landing fees of a regional airport will have an impact on the forgiveness of its loan. If the regional airport qualified for a Special CDL, those revenues will be considered in the calculation for cancellation. If the regional airport was part of a larger governmental entity and treated as an enterprise fund, the impact fees will still be considered. The impact on the loan forgiveness will be determined by whether or not there is (1) a cumulative operating deficit; (2) whether there was a loss of revenues during the three-year period; and (3) if there are any unreimbursed disaster-related expenditures which offset all or part of the loan.

#### 14. Definition of "Disaster-Related Expenses"

In the proposed rule at 44 CFR 206.376(b)(1), FEMA defined disaster-related expenses of a municipal operation character as those expenses incurred "for general government purposes, including but not limited to police and fire protection, trash collection, collection of revenues, maintenance of public facilities, flood and other hazard insurance." Because of the insertion of new definitions at new (b), and the expansion of the regulatory text on revenue calculation procedures in new (c), the subparagraph on disaster-related expenses was redesignated to 44 CFR 206.376(d) The redesignation is not a substantive change.

Several commenters sought revisions to this definition to include additional expenditures. Two commenters sought to include expenditures associated with debt service. One of those commenters stated that operating losses incurred because of Hurricane Katrina caused it to default on its debt covenant compliance. As a result, its covenant compliance threshold was increased; it was required to engage consultants to conduct a review of operations and make recommendations to improve operations; and was required to file a mortgage on all of the entity's equipment and properties. Another commenter requested that FEMA revise the definition of expenses not only to include debt service, but also major repairs, rebuilding, replacement or reconstruction of public facilities or

other capital projects, intra-governmental services, special assessments, trust and agency fund operations.

Another commenter urged FEMA to also consider the following expenses when evaluating an application for cancellation: The cost of maintaining a workforce, the cost of drainage work and the replacement of streets and roadways for which communities had to borrow or use their own funds, code enforcement expenditures (additional staffing, legal costs, and demolitions needed to accommodate the code enforcement department), insurance expenses, and finally legal and consultant fees incurred to deal with FEMA appeals and FEMA paperwork processing. Two other commenters inquired as to the eligibility of legal fees, asserting that such fees are not eligible for reimbursement under project applications or any other Federal program.

For the reasons explained below, FEMA made no changes to the disaster-related expenses at 44 CFR 206.376(d) based on these comments. Labor costs for code enforcement and insurance expense increases due to the disaster are reflected in an applicant's post-disaster operating budgets and actual expenditures. The Special CDL program is intended to cover expenses of an operating nature in the budget. Therefore, capital expenditures for drainage work and street repairs are ineligible uses for Special CDL funds but may be eligible for reimbursement under another Federal program. Debt service is also generally incurred for capital expenditures. Although debt service is not considered an operating expense which provides essential government services, if the applicant can demonstrate that the debt service is related to debt assumed to cover normal operating expenditures, then the applicant may include the related interest on the debt as an unreimbursed disaster-related expenditure. Debt service used for capital expenditures, however, is not eligible for consideration.

Major repairs, rebuilding, replacement or reconstruction of public facilities damaged by the disaster are likely to be eligible under the Public Assistance program, which is a FEMA grant program separate from the Special CDL program. Eligible applicants should have applied for and received grant funds to reimburse these costs under the Public Assistance program. Intra-governmental services, (*i.e.*, an Internal Service Fund such as a Fleet Maintenance Fund or Central Purchasing Services), of an operating

character were eligible for consideration in the original loan application and will be included in the subsequent review for loan cancellation. See 44 CFR 206.376(d)(2).

With respect to legal fees, if the expenditure is disaster-related, and not reimbursable through any other Federal or State program, or not covered by insurance, FEMA may consider such expense as an unreimbursed disaster-related expenditure. If the attorneys' fees are incurred as a regular operating expenditure, the attorneys' fees will be included in the operating budget and will be part of the calculation of an operating deficit or surplus.

Disaster-related expenses that are not reimbursed through any other program will be included to determine if the entity incurred an operating deficit for the three-full-fiscal-year period following the disaster. If revenue losses are insufficient to offset the full amount of the loan at the time of loan cancellation review, unreimbursed disaster-related expenses that are of a municipal operating character as defined in the regulations may be used to offset principal of the loan. If there is any balance of the loan after revenue losses and unreimbursed disaster-related expenses are considered, the remaining balance will remain due in accordance with the terms and conditions of the Promissory Note.

One commenter sought inclusion of the local government's cost share of assistance provided by FEMA under the Stafford Act's Public Assistance program. The Federal cost share for both Louisiana and Mississippi for the disasters declared as a result of Hurricanes Katrina and Rita was adjusted to 100 percent. See 70 FR 70086 (November 21, 2005) for Louisiana; and 71 FR 41228 (July 20, 2006) and 72 FR 34704 (June 25, 2007) for Mississippi. Therefore there should have been no cost share incurred by the local governments during that time.

Finally, one commenter requested that unfunded needs to basic services be taken into consideration as the reduction in operating budgets after Hurricane Katrina demanded that expected services were cut but still left a void that needed to be filled. The Special CDL program is not intended to supplant the decisions of the local government in determining what constitutes "basic services." However, unless applicants indicate that revenues were lost or expenses increased due to other non-Hurricane Katrina or Rita related factors, FEMA will assume that any operating deficit occurred during the three-year period is related to Hurricanes Katrina or Rita.

#### 15. Definition of "Operating Budget"

For loan application, the "operating budget" is that document or documents approved by an appropriating body, which contains an estimate of proposed expenditures, other than capital outlays for fixed assets for a stated period of time and the proposed means of financing the expenditures. See 44 CFR 206.374(b)(2). Two commenters recommended that the operating budget consist of a pro forma budget constructed from the revenues of the character and to the extent permitted by law to be used to pay operating expenses and not otherwise required by contract to be used for another purpose, and expenditures actually incurred during the applicable period, together with an adjustment to expenditures (increase) to reflect the level of expenditures required during the applicable period to allow for adequate performance of its governmental functions at the levels reflected in the last full fiscal year before the disaster.

The Special CDL Program was not designed to fund estimated expenditures, but rather the loan amounts were based on estimated lost revenues, established by historical data three years prior to the disaster and a projection of lost revenues three years after the disaster. Any revenues that are dedicated to non-operating expenditures, such as debt service or capital expenditures are excluded on both the revenue and expenditure side of the budget calculation to determine the net eligible operating budget. As for repayment of the loan, each loan recipient knew of commitments of operating revenues that were pledged at the time the loan was made. Further, each applicant signed a collateral security agreement pledging future revenues to be used to repay the loan, if necessary.

Another commenter noted that some revenue streams may be dedicated to specific purposes by the taxpayers and may not be spent in other areas. As a result, revenue growth in one area cannot be used to supplement losses in other areas. The commenter encouraged FEMA to take this into account when reviewing applications for cancellation. Another commenter requested that FEMA allow a cancelled debt requirement to substitute for lost revenues that will never be replaced.

Any revenues that are dedicated to non-operating expenditures, such as debt service or capital expenditures are excluded on both the revenue and expenditure side of the budget calculation to determine the net eligible operating budget, so FEMA expects

there will be no effect on the calculation of the operating deficit. However, if the debt service or pension payments are mandated by law and the entity has a property tax cap limitation by law, FEMA has modified the regulations to review that situation and its impact on the calculation of the operating deficit. See 44 CFR 206.376(c)(4)(ii). Debt payments, whether cancelled or paid, are not included in the operating budget calculation.

One commenter asserted that FEMA's interpretation of the term "operating budget" basically eliminates most, if not all, local governments from consideration for any sort of loan cancellation because, unlike the Federal Government, local governments are prohibited by law from operating at a deficit. The commenter stated that they reduce expenditures to the extent of incoming revenues regardless of pre-disaster revenue levels or the revenue amounts budgeted at the time of the disaster.

The purpose of cancellation is to assist those communities that have incurred a loss due to the disaster to ensure that they can continue providing essential services; that loss must first be evident in an operating deficit. FEMA understands that some states require balanced budgets, but that issue is outside the scope of FEMA's authority with regard to loan cancellation. In calculating the operating budget FEMA excludes the Special CDL itself, which may result in an operating deficit for many communities who otherwise were required by law to have a balanced budget, if other revenues were not adopted to cover either the loss of revenues or increased expenditures as a result of the disaster.

Another commenter advised that before the disaster, cities had planned for infrastructure repair and improvement projects that were put on hold. The commenter noted that in the mean-time these projects have been continually deteriorating, and the costs to complete the work have increased. In addition, the number of households decreased, resulting in lower annual revenues, while the amount of waste produced per consumer has increased, causing an additional strain on the budget. The commenter requested that FEMA focus on cash flow, as opposed to a supposed surplus indicated on the city's published financial statements. One commenter stated that operating budgets and audits (which are generally modified accrual audits) may not show the unfunded and deferred maintenance issues communities continue to struggle with as a result of Hurricane Katrina. Another commenter simply requested

that FEMA consider expenditures that were deferred by local governments because money was not available.

The Special CDL program is not intended to provide funding for unfunded or deferred maintenance issues, but rather to replace lost revenues as a result of the disaster. Capital expenditures have traditionally been excluded costs for the CDL program. The Special CDL program was created to assist those who demonstrated a need for Federal financial assistance to provide essential services. Because capital projects are not part of the Special CDL program, the impact of deferring projects is unrelated, and the timing and funding of projects is a local decision outside the scope of FEMA's authority. The official financial statements should reflect all costs of the entity. The operating budget used in the calculation is the required supplementary budget schedule, excluding capital expenditures, debt service payments, or capital lease payments for equipment or buildings.

Finally, one commenter advised that accounting adjustments required by the advent of GASB 34 are on the full accrual basis, but one of the major distortions created by the entity-wide accrual basis is that capital projects are not expensed, but cost is allocated over time. The commenter sought clarification that the term "operating budget as shown on our published financial statements" means the Budgetary Comparison Schedule included in the Required Supplementary Information of its published financial report.

The operating budget used in the loan cancellation calculation is the required supplementary budget schedule, found in the Supplementary Information Section of the Comprehensive Annual Financial Report (CAFR) which is the official financial statement of the government. The calculation, for purposes of loan cancellation, excludes capital expenditures, debt service payments, or capital lease payments for equipment or buildings.

#### 16. Statutory Criteria for Cancellation

Several commenters sought changes to FEMA's statutory authority for cancellation. Although FEMA is unable to provide cancellation outside the authority provided in the 2007 Act, FEMA has attempted to interpret its authority in as broad and flexible manner as possible.

One commenter stated that if a local government's deficit is retained as an eligibility criterion, the unfunded need of the local government should be included for the purpose of determining

deficits. If unmet needs are not considered, the commenter said, the local government's reward for conservative management would be to repay their Special CDL, while less fiscally conservative local governments would be rewarded with cancellation. To reward conservative financial management, the commenter encouraged FEMA to look solely at revenues in determining eligibility for cancellation.

FEMA's authority is to cancel the loans of communities whose revenues are insufficient to meet their operating expenses, not simply those who have experienced a loss in revenue. Further, such a calculation may not be in the community's best interest. If an operating deficit exists, then revenue losses may offset only part of a loan. If FEMA looked solely at revenues, then the cancellation may not be total because unreimbursed disaster-related expenditures would not be included in the calculation. When reviewing applications for cancellation, unless applicants indicate that revenues were lost or expenses increased due to other non-Hurricane Katrina or Rita related factors, FEMA will assume that any operating deficit occurred during the three-year period is Hurricane Katrina or Rita related.

Along the same line, another commenter stated that sound fiscal policy before the disaster that allows a community to retain good reserves should not be compromised and reserves depleted to fund the payback of this loan. With respect to reserve balances, these do not play a role in the calculation of the loan cancellation. Further, local governments pledged their future revenues to pay the loan. This pledge was not contingent upon the retention of a certain amount of reserve.

Another commenter declared that organizations that effectively manage expenditures could potentially be adversely impacted, while those that are less effective at managing expenses could enjoy the benefits of full forgiveness. Without proper actual documentation of revenues and expenditures for a particular applicant, FEMA cannot confirm the accuracy of the commenter's statement. Each loan cancellation application will be evaluated independently and this cannot be assumed. According to one commenter, the proposed rule said that for communities that have not exhibited reasonable financial recovery after three years, cancellation may be appropriate subject to the limitations of section 417(c) of the Stafford Act. However, FEMA disagrees with the commenter

because section 417 reiterates the aforementioned three-full-fiscal-year rule. The commenter suggested that a more appropriate determining factor may be whether or not a local government can prove that it has not "exhibited reasonable financial recovery" after three years even if it did not actually meet the requirement of cumulative operating deficits in the first three years after recovery. Two other commenters reiterated this position, but added that FEMA should require the community to also demonstrate that repayment of the loan will adversely impact the community's long-term recovery.

The authority in section 417 of the Stafford Act authorizes FEMA to cancel loans of communities who are able to show an operating deficit "during the three full fiscal year period following the major disaster." As a result, the Special CDL regulations require that the entity have a cumulative operating deficit during the three full fiscal years following the disaster to qualify for cancellation of all or part of the loan. If no operating deficit exists, then FEMA determines that the community has exhibited reasonable financial recovery for purposes of this program. The statute does not authorize FEMA to cancel loans based on the finances of a community after that three-fiscal-year period.

#### 17. Reimbursement

In the proposed rule at 44 CFR 206.376(a)(4), any transfers from operating accounts to capital fund accounts (for other than routine maintenance purposes) will be reduced from the operating budget for purposes of evaluating any request for loan cancellation. In this final rule, proposed 44 CFR 206.376(a)(4) was re-designated as 44 CFR 206.376(c)(3) without further change. One commenter requested that there be some recognition for capital expenditures that cannot be recovered through the FEMA Public Assistance grant program project worksheet damage assessments or other revenue sources. As an example, the commenter stated that the project worksheet includes the anticipated insurance proceeds an organization would receive from property insurance. These insurance proceeds are often tied up in litigation for long periods of time and recoveries reduced by the cost of litigation. To cover these gaps pending settlement of litigation, the commenter explained, organizations may need to transfer resources from operating funds to capital funds.

Transfers from operating accounts to capital fund accounts are not allowed by

FEMA as part of the operating budget calculation because Special CDL funds may not be used for capital expenditures. See 44 CFR 206.371(a). However, interest paid on money borrowed to pay amounts FEMA does not advance towards completion of approved projects under the Public Assistance grant program is an eligible unreimbursed disaster-related expenditure.

Another commenter noted that FEMA Public Assistance grants reimburse governments for expenses, meaning that the expenses must first be paid by the community before they can receive FEMA funds. So, although they will eventually receive these expenditures, the commenter asserted, the costs are a drain on the General Fund operating budget and cripple continuing essential operations. The commenter believes that repaying Special CDLs will further worsen the situation.

Although the commenter is correct that the Public Assistance grant program works on a system of reimbursements, FEMA reimburses approved funds on project worksheets within a short period of time. Entities do not languish for long periods of time with reimbursable expenses on their books. If an entity borrowed money while waiting for FEMA reimbursement, the accrued interest related to that loan is an eligible unreimbursed disaster-related expenditure. While it would be easier for communities to pay their expenses without being required to repay their Special CDL, each applicant signed a collateral security agreement at the time the initial loan was made stating they would utilize resources of the local government to ensure repayment of the loan. Such commitment extends until the loan is either cancelled or repaid.

Finally, one commenter asked if a Special CDL recipient would be penalized for moving funding from a pertinent operating expenditure to another. In response, if an expense is an operating expense budgeted for one purpose, but utilized for another operating purpose, there is no "penalty" for such transfer:

#### 18. Loss of Tax Revenue

One commenter requested that FEMA consider the loss of tax revenue in non-operating funds, as they may require the reallocation of ad valorem tax resources from operations to debt service and retirement obligation funding.

As proposed in 44 CFR 206.376(c)(3), a transfer from an operating fund for debt service (*i.e.*, principal and interest payment on bonded indebtedness, capital leases, or other debt for capital expenditures which is paid for through

property tax levies) is generally excluded from allowable expenditures in the operating budget calculation. However, such a transfer could be appropriate for inclusion in a loan cancellation determination if the transfer is required by law. Excluding such a transfer from expenditures in the operating budget calculation may result in an operating surplus instead of a deficit.

To account for this situation, FEMA has revised the rule to allow the transfer of ad valorem property tax revenues. See 44 CFR 206.376(c)(4). If a Special CDL recipient has property tax revenues affected by the disaster, FEMA will consider the impact of the loss of property tax revenue in Debt Service or Pension Funds (non-operating funds) if all of the following conditions are met: (1) The entity experienced a loss of property tax revenue as a result of the disaster and the assessed value during the three years following the disaster, in the aggregate, is less than the pre-disaster assessed value; (2) the entity has a property tax cap limitation on the ability to raise property taxes post-disaster; and (3) the property taxes are levied through the General Operating Fund and transfers for obligations mandated by law are made to fund Debt Service or Pension Obligations which result in the entity experiencing a reduction of property tax revenues in the General Fund. If all three conditions are met, the amount of property taxes that are transferred to other funds for Debt Service or Pension Obligations funding will not be excluded from the calculation of the operating budget or from expenditures in calculation of the operating deficit, to the extent that the property tax revenues in the General Fund are less than they were pre-disaster.

Another commenter asked simply what impact the ad valorem tax would have on the forgiveness of one's loan. In response, if a loss of revenues from reduced property taxes results in a cumulative operating deficit, then it is possible that all or part of the loan may be cancelled.

#### 19. Form 90-5

One commenter requested that if the Application for Loan Cancellation Form 90-5 (the form used for cancellation applications for CDLs) is used, FEMA should ask for budget revenue in line 6 and actual revenue in line 7 instead of one entry combining the two. The commenter explained that this is because the language in proposed 44 CFR 206.376(a)(1) references a budget, which is a forward projection, as opposed to actual revenues and

expenditures. The commenter does not believe that both of these can be addressed in a single line.

FEMA re-designated proposed 44 CFR 206.376(a)(1) as 44 CFR 206.376(a) in this final rule for ease in reading. FEMA has not revised the application form in response to this comment. When filling out the form, applicants should enter on line 6 the annual operating budget for each of the years specified on line 6. This form should be completed for each operating fund that had revenues affected by the disaster (*i.e.*, General Operating Funds, Special Revenue Funds of an operating nature, and Enterprise Funds), and then summarized on one form in total. On line 7, enter the total actual revenues including the proceeds of the Special CDL. FEMA will subtract the Special CDL funds received from the actual revenues in determining the operating deficit. Actual expenditures are required to be entered on line 8 for "normal" non-disaster related expenditures (*i.e.*, regular operating costs), and line 9 is for disaster-related expenses. This method should result in the submission of four forms at the maximum: 1 for General Fund, 1 for Special Revenue Funds, 1 for Enterprise Funds and 1 summary.

Another commenter requested that when developing and evaluating the application form, FEMA take into consideration that local government entities and private non-profit entities operate differently. Further, the commenter encouraged FEMA to recognize that some entities may properly enter "not applicable" relative to some inquiries, such as levying or collecting taxes, so that those entities are not unfairly disadvantaged.

FEMA will consider the operating differences between a local government and a non-governmental entity, such as a hospital, in the cancellation evaluation. If no property taxes are levied or collected by a non-profit entity, there will be no impact to the applicant if they enter "not applicable" to the question on property taxes, in determining loan cancellation eligibility.

#### 20. Other Sources of Funds

School districts benefitted from an influx of Federal funding after Hurricane Katrina using aid from the Department of Education to get schools back in operation. According to one commenter, now that those funds are no longer available, school districts are only now realizing the full extent of their revenue shortfalls. Further, State education funding to these districts is also decreasing because of decreased enrollments. The commenter alleged

that requiring school districts to repay these loans could create budget deficits.

The effect of funding from the Department of Education (DOEd) on the Special CDL Program is outside the scope of FEMA's authority. If the DOEd funding is not adequate to cover all revenues affected by the disaster during the three-year period following the disaster, and the school district has an operating deficit as a result of other revenue losses or reduced enrollment resulting in revenue losses, then it may qualify for loan cancellation. As for repayment of the loan, each entity knew of commitments of operating revenues that were pledged at the time the loan was made. Further, each applicant signed a collateral security agreement pledging future revenues to be used to repay the loan, if necessary.

Two commenters asked, when calculating a cumulative operating deficit, whether FEMA-reimbursed expenses should be deducted from the actual revenues and expenditures of the local government as published in the official financial statements of the local government.

FEMA does not believe FEMA-reimbursed expenses should be deducted from the actual revenues and expenditures of the local government as published in the official financial statements of the local government. The expenditures incurred that are of an operating nature, even if reimbursed by FEMA through the Special CDL program, the Public Assistance Program, or some other program should not be excluded. However, FEMA staff will exclude the Special CDL proceeds from the revenues as part of the calculation. Further, funds received from a FEMA program that were applied to operating costs should not hurt the applicant's bottom line as those revenues should be canceled out by the incurred cost.

Finally, one commenter asked if insurance proceeds could be excluded from calculation of the operating deficit. Insurance proceeds that were received to address business interruption or to reimburse the entity for expenditures of an operating nature must be included as revenue since the insurance proceeds were used to cover expenses of an operating nature.

#### 21. Deadlines

One commenter noted that the proposed rule does not provide a timeline for FEMA to conduct its reviews and make determinations for loan cancellation. The commenter requested that the final rule include such timelines as well as FEMA's timeline for reviewing appeals.

As has traditionally been done in the CDL program, once an applicant submits an application for cancellation, FEMA performs an initial review and either approves the request or informs the applicant that the application is insufficient, and provides applicants an opportunity to provide additional documentation to support its request for cancellation. In this initial determination, FEMA attempts to be as flexible as possible in considering additional documentation to support cancellation. However, the timeline for review is not indefinite, and applicants must provide the information as quickly as possible during the appeals process so the loan cancellation determination can be finalized. Limiting the applicant's time during which it can provide additional supporting information and engage in a dialogue with FEMA staff would provide a disservice to the applicant.

To protect the applicant's flexibility, while ensuring that FEMA will issue its determination in a timely manner, in response to the comment, FEMA revised 44 CFR 206.376(f) to provide that once all required and requested information has been provided by the applicant including un-reimbursed disaster related expenses, the Director of the Public Assistance Division will make a cancellation determination within 60 days. The term "required" represents that information explicitly required by the regulations (*e.g.*, financial reports, and tax rates established in 44 CFR 206.376(e)). The term "requested" relates to information such as invoices and purchase orders FEMA may seek from the applicant in support of the applicant's stated unreimbursed disaster-related expenditures.

#### 22. Outside the Scope

FEMA received several comments that, although substantive, were outside the scope of this rulemaking. One commenter encouraged FEMA to incorporate a formula in the Stafford Act for the designation of a "catastrophic disaster" to differentiate those disasters of more devastating impact from the existing category of major disaster. Another commenter requested that the CDL program revert to a grant program as it was when it originated in 1970. Finally, one commenter felt that rather than singling out one area or local jurisdiction, there should be a loan cancellation program for all taxpayers who suffer hardship from floods and storms. This commenter stated that forgiveness should not be limited to the debts of cities, towns, counties and parishes, but provided to the individuals as well, and should



alleviate mortgage and SBA debt. Each of these comments is outside the scope of this rulemaking and would require a change to the Stafford Act to implement. FEMA does not have the authority to change the Stafford Act.

#### IV. Statutory and Regulatory Review

##### A. Executive Order 12866

In the April 2009 proposed rule, FEMA stated that this rule is an economically significant regulatory action because it is expected to have an annual effect on the economy of more than \$100 million, and materially alter the budgetary impact of the Special CDL Program. 74 FR 15231. The purpose of this final rule is to address comments and finalize the 2005 interim rule that established the Special CDL program, and further revise those regulations to implement cancellation provisions that were proposed in the April 2009 notice of proposed rulemaking. Those cancellation provisions are authorized by the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110-28, section 4502(a), Public Law 110-28, section 4502(a), 119 Stat. 2061 (2007 Act). Pursuant to that authority, FEMA shall cancel " \* \* all or any part of [a] Special Community Disaster Loan to the extent that revenues of the local government during the three full fiscal year period following the major disaster are insufficient to meet the operating budget of the local government, including additional disaster-related expenses of a municipal operation character." See 42 U.S.C. 5184. The cancellation provisions apply only to Special CDLs. CDLs, which are issued as a separate program, are not affected by this rule. Consequently, this rule will only affect those local governments in the Gulf Coast region who received Special CDLs following Hurricanes Katrina and Rita and will not have any impact on local governments that do not have a Special CDL.

In this rule, FEMA is establishing the application requirements communities would be required to follow to apply for cancellation of their Special CDL. Although it also finalizes the application requirements for the issuance of loans, these loans are statutorily limited to communities affected by hurricanes Katrina and Rita, and FEMA was only authorized to approve loans during fiscal years 2005 and 2006. Therefore, FEMA is no longer authorized to grant new Special CDLs, and the only substantive change effected by this final rule is the establishment of cancellation procedures.

In establishing cancellation procedures, FEMA used the procedures established for the CDL program. The Special CDL program and the CDL program share the same cancellation authority (Section 417 of the Stafford Act), and FEMA has been using the cancellation procedures for the CDL program since 1990. FEMA has found the cancellation procedures for the CDL program to be successful in providing the information necessary to determine whether cancellation is appropriate. Based on this success, FEMA proposed to apply the same provisions for the Special CDL program.

In response to the proposed rule, FEMA received several comments seeking blanket cancellation of the loans, with no application required. The blanket cancellation of loans is outside the scope of FEMA's authority. The text of the authorizing statute shows that Congress did not automatically cancel these loans, but allows for partial or full forgiveness of community disaster loan repayments if, after three years, local revenue remains insufficient to meet operating expenses.

Among other suggestions for revision of the regulations, FEMA received comments seeking the consideration of additional costs (such as the increase in market values) and exclude certain sources of revenue (such as insurance proceeds). Commenters also sought the consideration of estimated expenses and revenues, in lieu of the proposed method of reviewing an applicant's actual expenses and revenues to determine if it experienced an actual operating deficit in the three full fiscal years after the event. FEMA evaluated these comments and discusses each of them in the discussion of the comments section, Section III of this final rule. In the end, FEMA has revised the rule as a result of public comments, to make five substantive changes.

First, transfers from an operating fund for debt service are allowed for the transfer of ad valorem property tax revenues under certain conditions See 44 CFR 206.376(c)(4). Second, FEMA added definitions for the terms "revenues" and "operating expenses." See 44 CFR 206.376(b). Third, the title of the individual who makes FEMA's initial determination on the application for cancellation has been clarified to remove the appearance that the same individual who makes the initial determination also makes the determination on appeal See 44 CFR 206.376(f). Fourth, FEMA revised 44 CFR 206.376(f), to add a new paragraph (f)(1) which provides that once all required and requested information has been provided by the applicant

including un-reimbursed disaster related expenses, the Director of the Public Assistance Division will complete the initial evaluation within 60 days. And, finally, FEMA added language that at the local government's discretion, the three-full-fiscal-year period following the disaster is either a 36-month period beginning on September 1, 2005, or the 36 months of the local government's fiscal year as established before the disaster. See 44 CFR 206.376(c)(2).

These revisions create no change in the overall impact of this rule. The overall impact of this rule is the cost to the applicant to apply for the cancellation, as well as the impact on the economy of potentially forgiving all Special CDLs and any related interest and costs. The burden on the public is low with respect to new administrative requirements associated with submitting the Application for Loan Cancellations. As explained in the proposed rule, FEMA estimates that the annual estimated cost to submit the Application for Loan Cancellation will be \$4,850.32. FEMA issued 152 Special CDLs totaling \$1,270,501,241 to 109 eligible applicants in Mississippi and Louisiana. The application period for these loans has closed, so no new loans can be granted under this program. If all 152 loan recipients apply for and are found eligible for full cancellation under this rule, up to \$1,270,501,241, plus any applicable interest and costs, could be forgiven.

The maximum total economic impact of this rule, therefore, is approximately \$1.3 billion (conservatively assuming that all funds awarded will be drawn down, and exclusive of any interest that may also be forgiven). However, without knowing the dollar amounts or even the number of loans that will be cancelled, it is impossible to predict the amount of the economic impact of this rule with any precision. Although the impact of the rule could be spread over multiple years as applications are received, processed, and loans cancelled, the total economic effects of a specific loan cancellation would only occur once, rather than annually.

##### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), FEMA has considered whether this final rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and

governmental jurisdictions with populations of less than 50,000.

FEMA certifies under 5 U.S.C. 605(b) that this final rule would not have a significant economic impact on a substantial number of small entities. Section 601(5) defines small governmental jurisdictions as governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000. This final rule would affect the following entities, some of which might be small entities: The 109 eligible applicants devastated by Hurricanes Katrina and Rita located in Mississippi and Louisiana that received Special CDLs authorized in the 2005 and 2006 Acts. This final rule will not impose any additional requirements on local governments that do not have Special CDLs.

As stated previously, the potential for loan cancellation under the proposed procedures would not have a negative impact on any loan applicant as any funds cancelled will have a positive beneficial effect on the State and local governments by reducing ongoing operating expenses and debt related to the loan. FEMA previously explained that State and local governments that choose to seek loan cancellation consideration will need to spend a minimal amount of staff time preparing the required application. Such a minimal staffing burden is not considered to be a significant economic impact. Consequently, this final rule would not have a significant economic impact on a substantial number of small entities.

#### C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This rule is excluded from the Unfunded Mandates Reform Act as provisions in proposed or final Federal regulations that require compliance with accounting and auditing procedures with respect to grants or other money or property provided by the Federal Government, and those that provide for emergency assistance or relief at the request of any State, local, or tribal government or any official of a State, local, or tribal government. See 2 U.S.C. 1503.

#### D. Federalism

Pursuant to Executive Order 13132, FEMA has determined that this action will not have a substantial direct effect on the States, or the relationship

between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications. Eligible applicants who applied for Special CDLs, or who received Special CDLs and choose to apply for loan cancellation do so voluntarily. State policymaking discretion is not affected.

#### E. National Environmental Policy Act

FEMA's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) at 44 CFR 10.8(d)(2)(ii) categorically exclude the preparation, revision, adoption of regulations, directives, manuals, and other guidance documents related to actions that qualify for categorical exclusions. The changes in this final rule constitute actions that qualify for the following categorical exclusions: the enforcement of existing Federal regulations, and the involvement in emergency and disaster response and recovery activities under section 417 of the Stafford Act. See 44 CFR 10.8(d)(2)(iv) and 10.8(d)(2)(ix)(K). This rulemaking will not have a significant effect on the human environment and, therefore, neither an environmental assessment nor an environmental impact statement is required.

#### F. Paperwork Reduction Act of 1995

In the October 19, 2005 Interim Rule (at 70 FR 60442; also 44 CFR 206.370–206.377), FEMA determined that implementation of the Interim Rule would be subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). FEMA submitted with the interim rule two information collection requests to OMB for review and clearance in accordance with the review procedures of the PRA. OMB approved the requested revision of the collection entitled "Application for Community Disaster Loan (CDL) Program and the Special Community Disaster Loan (SCDL) Program," which was assigned OMB Control Number 1660–0083 and expires on June 30, 2012. This final rule does not contain any changes that would affect that currently approved collection.

In this final rule, FEMA is finalizing the Special CDL regulations published in the Interim Rule and implementing the cancellation provisions outlined in the 2007 Act as applied to loans issued under the 2005 and 2006 Acts. As previously stated, FEMA intends to apply the cancellation procedures already existing under the CDL program as outlined in 44 CFR 206.360 through

206.367. It is intended that applicants seeking cancellation of a Special CDL will use the Application for Loan Cancellation and its associated forms, if applicable, already approved by OMB under OMB Control Number 1660–0082, which expires on January 31, 2010.

Collection 1660–0082 uses FEMA Form 90–5, Application for Loan Cancellation, which has an annual number of respondents of one (the number of communities who apply for cancellation of a Community Disaster Loan under the existing procedures in 44 CFR 206.366). With this Final Rule, applicants seeking cancellation of a Special Community Disaster Loan will use the same form submitted for Community Disaster Loans. FEMA therefore seeks to amend that existing collection to increase the number of respondents to 153. This number reflects the one Community Disaster Loan cancellation application already received annually under the Community Disaster Loan program, and the potential 152 applications for cancellation of Special Community Disaster Loans allowed in this rule.

Accordingly, in the proposed rule, FEMA published a 60-day notice seeking a revision to the already existing collection of OMB Control Number 1660–0082, FEMA Form 90–5, to include the cancellation of Special CDLs. FEMA received no public comments in response to the 60-day notice. Section 3507(d) of the PRA and 5 CFR 1320.11 require Federal agencies to submit new and revised collections of information to OMB for review. FEMA will submit the appropriate request to OMB for approval, with a copy of this rule. FEMA invites the general public to comment on the collection of information.

#### Collection of Information:

Title: Application for Community Disaster Loan Cancellation.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0082.

Form Numbers: FEMA Form 90–5.

Abstract: Local governments may submit an Application for Loan Cancellation through the Governor's Authorized Representative to the FEMA Regional Administrator prior to the expiration date of the loan. FEMA has the authority to cancel repayment of all or part of a Community Disaster Loan or a Special Community Disaster Loan to the extent that a determination is made that revenues of the local government during the three fiscal years following the disaster are insufficient to meet the operating budget of that local government because of disaster-related

revenue losses and additional unreimbursed disaster-related municipal operating expenses. Operating budget means actual revenues and expenditures of the local

government as published in the official financial statements of the local government.

*Affected Public:* State, local or tribal governments.

*Number of Respondents:* 153.  
*Frequency of Response:* 1 per year.  
*Hour Burden per Response:* 1 hour.  
*Estimated Total Annual Burden Hours:* 153 hours.

TABLE A-12—ESTIMATED ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Form name/form No.	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total annual burden (in hours)	Avg. hourly wage rate	Total annual respondent cost
State, local and Tribal Government.	Application for Loan Cancellation/ FEMA Form 90-5 (under 44 CFR 206.366 as currently approved by OMB).	1	1	1	1	\$31.91	\$31.91
State, local and Tribal Government.	Application for Loan Cancellation/ FEMA Form 90-5 (under 44 CFR 206.376, the change associated with this rule).	152	1	1	152	31.91	4,850.32
Total .....	.....	153	.....	.....	153	.....	4,882.23

*Estimated Cost:* \$0. There are no start-up, operational or other costs associated with this information collection in addition to the burden hour cost noted in the table above.

*Comments:* Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer, Department of Homeland Security/ FEMA, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974. Comments must be submitted on or before February 18, 2010. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646-3347 or e-mail address: [FEMAInformation-Collections@dhs.gov](mailto:FEMAInformation-Collections@dhs.gov).

#### G. Executive Order 12630, Taking of Private Property

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

#### H. Executive Order 12988, Civil Justice Reform

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

#### I. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Because no Special Community Disaster Loans were made to Indian Tribal Governments, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. This rule would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs—housing and community development, Housing; Insurance, Intergovernmental relations, Loan programs—housing and community development, Natural resources, Penalties, Reporting and recordkeeping requirements.

Accordingly, the Interim Rule published on October 18, 2005 (70 FR 60443), is adopted as a final rule with the following changes:

#### PART 206—FEDERAL DISASTER ASSISTANCE

1. The authority citation for part 206 continues to read as follows:

**Authority:** 42 U.S.C. 5121–5206; 6 U.S.C. 101; 6 U.S.C. 311–321; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; E.O. 12673, 54 FR 12571, 3 CFR, 1989 Comp., p. 214; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

2. In § 206.370 revise paragraphs (a) and (b) to read as follows:

#### § 206.370 Purpose and scope.

(a) *Purpose.* Sections 206.370 through 206.377 provide procedures for local governments and State and Federal officials concerning the Special Community Disaster Loans program under section 417 of the Stafford Act (42 U.S.C. 5184), the Community Disaster Loan Act of 2005, Public Law 109–88, and the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006, Public Law 109–234.

(b) *Scope.* Sections 206.370 through 206.377 apply only to Special Community Disaster Loans issued under the Community Disaster Loan Act of 2005, Public Law 109–88, and the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006, Public Law 109–234.

3. In § 206.371, revise the last sentence of paragraph (f), revise

paragraph (g) and add new paragraph (h) to read as follows:

**§ 206.371 Loan program.**

\* \* \* \* \*

(f) \* \* \* Neither the loan nor any cancelled portion of the loans may be used as the non-Federal share of any Federal program, including those under the Stafford Act.

(g) *Relation to other assistance.* Any Special Community Disaster Loans including cancellations of loans made under this subpart shall not reduce or otherwise affect any commitments, grants, or other assistance provided under the authority of the Stafford Act or this part.

(h) *Cancellation.* The Director of the Public Assistance Division shall cancel repayment of all or part of a Special Community Disaster Loan to the extent that he/she determines that revenues of the local government during the three full fiscal years following the disaster are insufficient to meet the operating budget of that local government because of disaster-related revenue losses and additional unreimbursed disaster-related municipal operating expenses.

■ 4. In § 206.372 revise paragraphs (a), (c), (d) and (e) to read as follows:

**§ 206.372 Responsibilities.**

(a) The local government shall submit the financial information required by FEMA in the application for a Community Disaster Loan or other format specified by FEMA and comply with the assurances on the application, the terms and conditions of the Promissory Note, the application for loan cancellation, if submitted, and §§ 206.370 through 206.377. The local government shall send all loan application, loan administration, loan cancellation, and loan settlement correspondence through the Governor's Authorized Representative (GAR) and the FEMA Regional Office to the Director of the Public Assistance Division.

\* \* \* \* \*

(c) The Regional Administrator or designee shall review each loan application or loan cancellation request received from a local government to ensure that it contains the required documents and transmit the application to the Director of the Public Assistance Division. He/she may also submit appropriate recommendations to the Director of the Public Assistance Division.

(d) The Director of the Public Assistance Division or a designee, shall execute a Promissory Note with the local government and shall administer

the loan until repayment or cancellation is completed and the Promissory Note is discharged.

(e) The Director of the Public Assistance Division shall approve or disapprove each loan request, taking into consideration the information provided in the local government's request and the recommendations of the GAR and the Regional Administrator. The Director of the Public Assistance Division shall approve or disapprove a request for loan cancellation in accordance with the criteria for cancellation in these regulations.

\* \* \* \* \*

■ 5. In § 206.374, add a sentence at the end of paragraph (b)(2) to read as follows:

**§ 206.374 Loan application.**

\* \* \* \* \*

(b) \* \* \*  
(2) \* \* \* For loan cancellation purposes, FEMA interprets the term "operating budget" to mean actual revenues and expenditures of the local government as published in the official financial statements of the local government.

\* \* \* \* \*

■ 6. Add § 206.376 to read as follows:

**§ 206.376 Loan cancellation.**

(a) FEMA shall cancel repayment of all or part of a Special Community Disaster Loan to the extent that the Director of the Public Assistance Division determines that revenues of the local government during the three-full-fiscal-year period following the disaster are insufficient, as a result of the disaster, to meet the operating budget for the local government, including additional unreimbursed disaster-related expenses of a municipal operating character.

(b) *Definitions.* For loan cancellation purposes,

(1) "Operating budget" means actual revenues and expenditures of the local government as published in the official financial statements of the local government.

(2) "Revenue" means any source of income from taxes, fees, fines, and other sources of income, and will be recognized only as they become susceptible to accrual (measurable and available).

(3) "Three-full-fiscal-year period following the disaster" means either a 36-month period beginning on September 1, 2005, or the 36 months of the applicant's fiscal year as established before the disaster, at the applicant's discretion.

(4) "Operating expenses" means those expenses and expenditures incurred as

a result of performing services, including salaries and benefits, contractual services, and commodities. Capital expenditures and debt service payments and capital leases are not considered operating expenses. Under accrual accounting, expenses are recognized as soon as a liability is incurred, regardless of the timing of related cash flows.

(c) *Revenue Calculation procedures.*

(1) If the tax rates and other revenues or the tax assessment valuation of property which was not damaged or destroyed by the disaster are reduced during the three full fiscal years subsequent to the major disaster, the tax rates and other revenues and tax assessment valuation factors applicable to such property in effect at the time of the major disaster shall be used without reduction for purposes of computing revenues received.

(2) At the applicant's discretion, the three-full-fiscal-year period following the disaster is either a 36-month period beginning on September 1, 2005 or the 36 months of the applicant's fiscal year as established before the disaster. If the applicant's fiscal year is changed within the 36 months immediately following the disaster, the actual period will be modified so that the required financial data submitted covers an inclusive 36-month period. Should the applicant elect the 36-month period beginning September 1, 2005, FEMA will prorate the revenues and expenses for the partial years based on the applicant's annual financial statements.

(3) If the local government transfers funds from its operating funds accounts to its capital funds account, utilizes operating funds for other than routine maintenance purposes, or significantly increases expenditures which are not disaster related, except increases due to inflation, the annual operating budget or operating statement expenditures will be reduced accordingly for purposes of evaluating any request for loan cancellation.

(4) Notwithstanding paragraph (c)(3) of this section, the amount of property taxes that are transferred to other funds for Debt Service or Pension Obligations funding will not be excluded from the calculation of the operating budget or from expenditures in calculation of the operating deficit, to the extent that the property tax revenues in the General Fund are less than they were pre-disaster. FEMA will consider the impact of the loss of property tax revenue in Debt Service or Pension Funds (non-operating funds) if all of the following conditions are met:

(i) The entity experienced a loss of property tax revenue as a result of the

disaster and the assessed value during the three years following the disaster, in the aggregate, is less than the pre-disaster assessed value;

(ii) the entity has a property tax cap limitation on the ability to raise property taxes post-disaster; and

(iii) the property taxes are levied through the General Operating Fund and transfers for obligations mandated by law are made to fund Debt Service or Pension Obligations which result in the entity experiencing a reduction of property tax revenues in the General Fund.

(5) It is not the purpose of this loan program to underwrite pre-disaster budget or actual deficits of the local government. Consequently, such deficits carried forward will reduce any amounts otherwise eligible for loan cancellation.

(6) The provisions of this section apply to all Special Community Disaster loans issued from the dates of enactment of Public Law 109-88 and Public Law 109-234.

(d) *Disaster-related expenses of a municipal operation character.* (1) For purposes of this loan, unreimbursed expenses of a municipal operating character are those incurred for general government purposes, including but not limited to police and fire protection, trash collection, collection of revenues, maintenance of public facilities, flood and other hazard insurance.

(2) Disaster-related expenses do not include expenditures associated with debt service, any major repairs, rebuilding, replacement or reconstruction of public facilities or other capital projects, intragovernmental services, special assessments, and trust and agency fund operations. Disaster expenses which are eligible for reimbursement under project applications or other Federal programs are not eligible for loan cancellation.

(3) Each applicant shall maintain records including documentation necessary to identify expenditures for unreimbursed disaster-related expenses. Examples of such expenses include but are not limited to:

(i) Interest paid on money borrowed to pay amounts FEMA does not advance toward completion of approved Project Applications.

(ii) Unreimbursed costs to local governments for providing usable sites with utilities for mobile homes used to meet disaster temporary housing requirements.

(iii) Unreimbursed costs required for police and fire protection and other community services for mobile home parks established as the result of or for use following a disaster.

(iv) The cost to the applicant of flood insurance required under Public Law 93-234, as amended, and other hazard insurance required under section 311, Public Law 93-288, as amended, as a condition of Federal disaster assistance for the disaster under which the loan is authorized.

(4) The following expenses are not considered to be disaster-related for Special Community Disaster Loan purposes:

(i) The local government's share for assistance provided under the Stafford Act including flexible funding under section 406(c)(1) of the Act (42 U.S.C. 5172).

(ii) Improvements related to the repair or restoration of disaster public facilities approved on Project Applications.

(iii) Otherwise eligible costs for which no Federal reimbursement is requested as a part of the applicant's disaster response commitment, or cost sharing as specified in the FEMA-State Agreement for the disaster.

(iv) Expenses incurred by the local government which are reimbursed on the applicant's Project Application.

(e) *Cancellation application.* A local government which has drawn loan funds from the U.S. Treasury may request cancellation of the principal and related interest by submitting an Application for Loan Cancellation through the Governor's Authorized Representative to the Regional Administrator prior to the expiration date of the loan.

(1) Financial information submitted with the application shall include the following:

(i) Annual Operating Budgets for the fiscal year of the disaster and the three subsequent fiscal years;

(ii) Annual Financial Reports (Revenue and Expense and Balance Sheet) for each of the above fiscal years. Such financial records must include copies of the local government's annual financial reports, including operating statements and balance sheets and related consolidated and individual presentations for each fund account. In addition, the local government must include an explanatory statement when figures in the Application for Loan Cancellation form differ from those in the supporting financial reports.

(iii) The following additional information concerning annual real estate property taxes pertaining to the community for each of the above fiscal years:

(A) The market value of the tax base (dollars);

(B) The assessment ratio (percent);

(C) The assessed valuation (dollars);

(D) The tax levy rate (mils);

(E) Taxes levied and collected (dollars).

(iv) Audit reports for each of the above fiscal years certifying to the validity of the Operating Statements. The financial statements of the local government shall be examined in accordance with generally accepted auditing standards by independent certified public accountants. The report should not include recommendations concerning loan cancellation or repayment.

(v) Other financial information specified in the Application for Loan Cancellation.

(2) *Narrative justification.* The application may include a narrative presentation to supplement the financial material accompanying the application and to present any extenuating circumstances which the local government wants the Director of the Public Assistance Division to consider in rendering a decision on the cancellation request.

(f) *Determination.* (1) The Director of the Public Assistance Division will make a cancellation determination within 60 days of the date the applicant submits all required and requested information, including documentation in support of un-reimbursed disaster related expenses.

(2) If, based on a review of the Application for Loan Cancellation and FEMA audit, the Director of the Public Assistance Division determines that all or part of the Special Community Disaster Loan funds should be canceled, the amount of principal canceled and the related interest will be forgiven. The Director of the Public Assistance Division's determination concerning loan cancellation will specify that any uncanceled principal and related interest must be repaid in accordance with the terms and conditions of the Promissory Note, and that, if repayment will constitute a financial hardship, the local government must submit for FEMA review and approval, a repayment schedule for settling the indebtedness on a timely basis. Such repayments must be made to the Treasurer of the United States and be sent to FEMA, Attention: Office of the Chief Financial Officer.

(3) A loan or cancellation of a loan does not reduce or affect other disaster-related grants or other disaster assistance. However, no cancellation may be made that would result in a duplication of benefits to the applicant.

(4) The uncanceled portion of the loan must be repaid in accordance with § 206.377.

(5) *Appeals.* If an Application for Loan Cancellation is disapproved, in

whole or in part, by the Director of the Public Assistance Division, the local government may submit any additional information in support of the application within 60 days of the date of disapproval. The decision by the Assistant Administrator for the Disaster Assistance Directorate on the additional information is final.

■ 7. Amend § 206.377 by revising the first sentence of the introductory text in paragraph (b), adding a new sentence at the end of paragraph (b)(2), revising paragraph (b)(4) and revising (c)(2) to read as follows:

**§ 206.377 Loan repayment.**

\* \* \* \* \*

(b) *Repayment*: To the extent not otherwise cancelled, loan funds become due and payable in accordance with the terms and conditions of the Promissory Note. \* \* \*

\* \* \* \* \*

(2) \* \* \* If any portion of the loan is cancelled, the interest amount due will be computed on the remaining principal with the shortest outstanding term.

\* \* \* \* \*

(4) The Assistant Administrator for the Disaster Assistance Directorate may defer payments of principal and interest until FEMA makes its final determination with respect to any Application for Loan Cancellation which the borrower may submit. However, interest will continue to accrue.

\* \* \* \* \*

(c) \* \* \*

(2) The principal amount shall be the original uncancelled principal plus related interest less any payments made.

\* \* \* \* \*

Dated: January 12, 2010.

**W. Craig Fugate,**  
Administrator, Federal Emergency  
Management Agency.

[FR Doc. 2010-925 Filed 1-15-10; 8:45 am]

BILLING CODE 9110-10-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 648**

[Docket No. 0809251266-81485-02]

RIN 0648-XT61

**Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer**

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

**ACTION:** Temporary rule; quota transfer.

**SUMMARY:** NMFS announces that the State of North Carolina is transferring a portion of its 2009 commercial summer flounder quota to the Commonwealth of Virginia. By this action, NMFS adjusts the quotas and announces the revised commercial quota for each state involved.

**DATES:** Effective December 17, 2009, through December 31, 2009.

**FOR FURTHER INFORMATION CONTACT:** Sarah Heil, Fishery Management Specialist, 978-281-9257.

**SUPPLEMENTARY INFORMATION:** Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The final rule implementing Amendment 5 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP), which was published on December 17, 1993 (58 FR 65936), provided a mechanism for summer flounder quota to be transferred from one state to another. Two or more states, under mutual agreement and

with the concurrence of the Administrator, Northeast Region, NMFS (Regional Administrator), can transfer or combine summer flounder commercial quota under § 648.100(d). On September 13, 2005, NMFS published the final rule to amend the regulations implementing the Summer Flounder, Scup, and Black Sea Bass FMP to address late-season circumstances that necessitate a state quota transfer (70 FR 53969). This rule specified that such late-season quota transfers could be approved, even if the transfer request is made in the subsequent fishing year, and would be valid for the fishing year for which the request is made. The Regional Administrator is required to consider the criteria set forth in § 648.100(d)(3) in the evaluation of requests for quota transfers or combinations.

In response to unforeseen circumstances late in the 2009 fishing year, North Carolina has agreed to transfer 24,548 lb (11,134.79 kg) of its 2009 commercial quota to Virginia to cover the summer flounder landings of three vessels granted safe harbor in Virginia, due to vessel damage and stormy weather, on December 17, 2009, and December 18, 2009. The Regional Administrator has determined that the criteria set forth in § 648.100(d)(3) have been met. The revised quotas for calendar year 2009 are: North Carolina, 2,854,494 lb (1,294,777 kg); and Virginia, 2,371,022 lb (1,075,477 kg).

**Classification**

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: January 12, 2010.

**Emily H. Menashes,**

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

[FR Doc. 2010-817 Filed 1-13-10; 4:15 pm]

BILLING CODE 3510-22-S

# Proposed Rules

Federal Register

Vol. 75, No. 11

Tuesday, January 19, 2010

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

## OFFICE OF PERSONNEL MANAGEMENT

### 5 CFR Part 293

RIN 3206-AM05

#### Personnel Records

**AGENCY:** U.S. Office of Personnel Management.

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** The U.S. Office of Personnel Management (OPM) is proposing to amend the regulations governing disposition of Official Personnel Folders of Federal employees to clarify the roles and responsibilities of OPM and Federal agencies.

**DATES:** Comments must be received on or before March 22, 2010.

**ADDRESSES:** Send or deliver written comments to, Tanya Bennett, Records Manager, Office of Chief Information Officer, Office of Personnel Management, 1900 E Street, NW., Room 7439, Washington, DC 20415-8200; by e-mail to [tanya.bennett@opm.gov](mailto:tanya.bennett@opm.gov); by fax to (202) 606-1719.

**FOR FURTHER INFORMATION CONTACT:** Tanya Bennett by telephone at (202) 606-4054, by fax at (202) 606-1719, or by e-mail at [tanya.bennett@opm.gov](mailto:tanya.bennett@opm.gov).

**SUPPLEMENTARY INFORMATION:** The U.S. Office of Personnel Management (OPM) is proposing to amend part 293 of title 5, Code of Federal Regulations (Personnel Records) to clarify agency responsibilities concerning Official Personnel Folders (OPFs) of employees in the civil service.

Section 293.303, currently encapsulated "Ownership of folder," provides that OPFs are under the "jurisdiction and control" of and are "part of the records of" OPM. The language of the current version of § 293.303 has caused confusion with respect to the allocation of costs for the storage and physical transfer of OPFs. The National Archives and Records Administration (NARA), which stores OPFs when the subjects are not

employed by the Federal Government, has informed OPM that it adopted the position that it lacks authority to bill any agency other than OPM for costs associated with OPFs because it believed that the language of 5 CFR 293.303 precluded any other solution. This interpretation has caused the cost of OPF transfers initiated by other agencies to be shifted to OPM. For example, any time an agency requests that NARA send the agency the OPF of an applicant for an agency position, OPM is billed. Sometimes, the same file is returned and requested more than once by the same agency in connection with the same personnel action. As long as the cost is borne by OPM, however, an entity has no incentive to make requests judiciously, *i.e.*, obtain all necessary information at once.

The purpose of the proposed amendments is to clarify OPM's and agencies' roles with respect to OPFs and permit a more rational allocation of the costs associated with the movement of OPFs. The use of the term "ownership" and the reference to "jurisdiction and control of OPM" in 5 CFR 293.303 were intended to summarize OPM's Governmentwide authority to standardize practices and procedures for the establishment and maintenance of the OPF, not to minimize the responsibilities of other agencies with respect to the maintenance and use of OPFs.

*To clarify the intended meaning of its regulations, OPM proposes the following specific changes to the regulations:*

- In section 293.303, we propose to change the heading from "Ownership of the folder" to "The roles of the Office and custodians" to revise and clarify the text of the section. "Ownership of the folder" will be deleted as the title of this section because its use has had confusing implications as to what entity should be responsible for ancillary costs associated with the OPF.

- In section 293.303, we also propose to delete the phrase "under the jurisdiction and control of" to eliminate confusion about the meaning of this clause. This section now specifies that the role of the Office is to develop regulations, practices and procedures for the establishment, maintenance, and transfer of OPFs. Additionally, several subsections have been proposed to specify the role of custodians.

- In section 293.102, we propose to add a definition of the term "custodian," to be consistent with the revisions to section 293.303 summarized above.

- In section 293.307, which addresses the disposition of folders of former Federal employees, we propose to add paragraphs (c) and (d) to clarify responsibility for costs associated with the disposition of OPFs of former employees.

#### Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

#### Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

#### List of Subjects in 5 CFR Part 293

Government employees, Privacy, Records.

U.S. Office of Personnel Management.

**John Berry,**  
Director.

Accordingly, OPM proposes to amend part 293 of title 5, Code of Federal Regulations, as follows:

#### PART 293—PERSONNEL RECORDS

1. The authority citation for part 293 is revised to read as follows:

**Authority:** 5 U.S.C. 552, 552a, 1103, 1104, 1302, 2951(2), 3301, and 4315; E.O. 12107 (December 28, 1978), 3 CFR 1954-1958 Comp.; 5 CFR 7.2; E.O. 9830; 3 CFR 1943-1948 Comp.

#### Subpart A—Basic Policies on Maintenance of Personnel Records

2. In § 293.102, add a definition of *Custodian* in alphabetical order to read as follows:

#### § 293.102 Definitions.

\* \* \* \* \*

*Custodian* means an agency in physical possession of an Official Personnel Folder. The custodian is responsible for the maintenance and disposition of the Folder and the costs associated with maintenance and disposition until after the Folder has been transferred to and accepted at the National Personnel Records Center. The custodian carries out its responsibilities

with respect to the Folder in accordance with regulations, practices, and procedures promulgated or published by the Office of Personnel Management.

\* \* \* \* \*

### Subpart C—Official Personnel Folder

3. Revise § 293.303 to read as follows:

#### § 293.303 The roles of the Office and custodians.

(a) The OPF of each employee in a position subject to civil service rules and regulations and of each former employee who held such a position is part of the records of the Office of Personnel Management (the Office). The Office has Governmentwide responsibility for developing regulations, practices and procedures for the establishment, maintenance, and transfer of OPFs.

(b) An agency is the legal custodian of an employee's OPF during the period of the employee's employment at that agency. An agency is responsible for the establishment of the OPF for a new appointee or a new employee for whom no OPF has previously been established and is similarly responsible for the maintenance of a previously existing OPF during the period any new appointee or employee remains in the agency's employ. An agency is also the custodian of an OPF it requests from the National Personnel Records Center (NPRC) for any other temporary use, during the period the agency holds the OPF and until the OPF is returned to the NPRC.

(c) Once an employee separates from federal service, the agency must transfer the OPF to the NPRC in accordance with established procedures for maintaining OPFs as indicated in OPM's Guide to Personnel Recordkeeping.

(d) Once NPRC has approved the transfer, the Office is the legal custodian of the OPF and is responsible for the destruction date established for the file pursuant to the National Archive and Records Administration's General Records Schedule unless another agency requests the OPF from the NPRC in the interim. In the event another agency requests the OPF from the NPRC, that agency becomes the custodian from the date that the OPF is transmitted by the NPRC until the date that the NPRC receives the OPF back from the agency.

4. Amend § 293.307 by adding new paragraphs (c) and (d) as follows:

#### § 293.307 Disposition of folders of former Federal employees.

\* \* \* \* \*

(c) Agencies are responsible for all costs associated with the establishment

and maintenance of OPFs, and transfer of OPFs to the National Personnel Records Center.

(d) Agencies are responsible for all costs associated with agency-initiated requests for OPFs or services from the National Personnel Records Center.

[FR Doc. 2010-809 Filed 1-15-10; 8:45 am]

BILLING CODE 6325-39-P

## FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

### 5 CFR Part 1631

#### Availability of Records

**AGENCY:** Federal Retirement Thrift Investment Board.

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** The Federal Retirement Thrift Investment Board (Agency) proposes to amend its regulations on availability of records to establish the manner of service for administrative subpoenas issued by the Agency and to delegate authority to the Agency's General Counsel to issue administrative subpoenas. These changes implement section 107 of the Thrift Savings Plan Enhancement Act of 2009, which gave the Agency authority to issue subpoenas *duces tecum* in order to carry out the Agency's functions.

**DATES:** Comments must be received on or before February 18, 2010.

**ADDRESSES:** You may submit comments using one of the following methods:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Office of General Counsel, Attn: Thomas Emswiler, Federal Retirement Thrift Investment Board, 1250 H Street, NW., Washington, DC 20005.

- *Hand Delivery/Courier:* The address for sending comments by hand delivery or courier is the same as that for submitting comments by mail.

- *Facsimile:* Comments may be submitted by facsimile at (202) 942-1676.

The most helpful comments explain the reason for any recommended change and include data, information, and the authority that supports the recommended change. We will post all substantive comments (including any personal information provided) without change (with the exception of redaction of SSNs, profanities, *et cetera*) on [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:** Laurissa Stokes at 202-942-1645.

**SUPPLEMENTARY INFORMATION:** The Agency administers the Thrift Savings Plan (TSP), which was established by the Federal Employees' Retirement System Act of 1986 (FERSA); Public Law 99-335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401-79. The TSP is a tax-deferred retirement savings plan for Federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

#### Issuance of Subpoenas

Section 107 of the Thrift Savings Plan Enhancement Act of 2009 ("the Act"), Public Law 111-31 (123 Stat. 1776, 1853) (codified at 5 U.S.C. 8480) authorizes the Agency to issue administrative subpoenas to compel production of designated books, documents, records, electronically stored information, or tangible things. This proposed regulation would establish three means by which the Agency may serve an administrative subpoena: (1) Certified or registered mail, return receipt requested, (2) fax or electronic transmission, provided the subpoenaed party gives prior approval, or (3) personal delivery at the principal place of business or the last known residential address of the subpoenaed party. This proposed regulation would also delegate authority to the General Counsel to issue administrative subpoenas.

The Agency, like other financial institutions, has been the subject of fraudulent withdrawals from its participants' accounts. The Agency anticipates using its subpoena authority to obtain information necessary to prevent or investigate fraudulent or otherwise improper routing of participants' money to financial institutions. The Agency, therefore, needs an expeditious means to obtain information from financial institutions to which participants' money is transferred. Prompt action and cooperation from financial institutions is the best way to recover or deter fraudulent or improper routing of participants' money.

Allowing the use of several alternative means to accomplish service is intended to facilitate expeditious cooperation between the Agency and financial institutions in an effort to prevent or investigate fraudulent withdrawals and transfers. Delegation to the General Counsel of the authority to issue administrative subpoenas is intended to expedite the issuances of subpoenas,



e.g. by removing the need for the staff of the Office of General Counsel to seek Executive Director approval for issuances that are routine or urgent.

#### Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will affect Federal employees and members of the uniformed services who participate in the Thrift Savings Plan, which is a Federal defined contribution retirement savings plan created under the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99-335, 100 Stat. 514, and which is administered by the Agency. Although it will also occasionally require financial institutions to provide information, such entities rarely constitute small entities. Additionally, this regulation provides the Agency with no new authority; it merely provides guidance on existing statutory authority.

#### Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

#### Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501-1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of \$100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under section 1532 is not required.

#### Submission to Congress and the General Accounting Office

Pursuant to 5 U.S.C. 810(a)(1)(A), the Agency submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before publication of this rule in the **Federal Register**. This rule is not a major rule as defined at 5 U.S.C. 804(2).

#### List of Subjects in 5 CFR Part 1631

Government employees, Courts, Freedom of information.

#### Gregory T. Long,

*Executive Director, Federal Retirement Thrift Investment Board.*

For the reasons stated in the preamble, the Agency proposes to amend 5 CFR chapter VI as follows:

### PART 1631—AVAILABILITY OF RECORDS

1. Remove the existing authority citation for part 1631.

#### Subpart A—[Amended]

2. Add an authority citation to subpart A of part 1631 to read as follows:

**Authority:** 5 U.S.C. 552.

#### Subpart B—[Amended]

3. Add an authority citation to subpart B of part 1631 to read as follows:

**Authority:** 5 U.S.C. 552.

4. Add subpart C to subpart 1631 to read as follows:

#### Subpart C—Administrative Subpoenas

Sec.

- 1631.40 Subpoena authority.
- 1631.41 Production of records.
- 1631.42 Service.
- 1631.43 Enforcement.

#### Subpart C—Administrative Subpoenas

**Authority:** 5 U.S.C. 8480.

#### § 1631.40 Subpoena authority.

The Executive Director or General Counsel may issue subpoenas pursuant to 5 U.S.C. 8480. The General Counsel may delegate this authority to a Deputy General Counsel, Associate General Counsel, or Assistant General Counsel.

#### § 1631.41 Production of records.

A subpoena may require the production of designated books, documents, records, electronically stored information, or tangible materials in the possession or control of the subpoenaed party when the individual signing the subpoena has determined that production is necessary to carry out any of the Agency's functions.

#### § 1631.42 Service.

(a) *Return of service.* Each subpoena shall be accompanied by a Return of Service certificate stating the date and manner of service and the names of the persons served.

(b) *Methods of service.* Subpoenas shall be served by one of the following methods:

- (1) Certified or registered mail, return receipt requested to the principal place of business or the last known residential address of the subpoenaed party.
- (2) Fax or electronic transmission to the subpoenaed party or the subpoenaed party's counsel, provided the subpoenaed party gives prior approval.
- (3) Personal delivery at the principal place of business or residence of the subpoenaed party during normal business hours.

#### § 1631.43 Enforcement.

Upon the failure of any party to comply with a subpoena, the General Counsel shall request that the Attorney General seek enforcement of the subpoena in the appropriate United States district court.

[FR Doc. 2010-769 Filed 1-15-10; 8:45 am]

BILLING CODE 6760-01-P

### FEDERAL DEPOSIT INSURANCE CORPORATION

#### 12 CFR Part 327

RIN 3064-AD56

#### Incorporating Employee Compensation Criteria Into the Risk Assessment System

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Advance notice of proposed rulemaking (ANPR).

**SUMMARY:** The FDIC is seeking comment on ways that the FDIC's risk-based deposit insurance assessment system (risk-based assessment system) could be changed to account for the risks posed by certain employee compensation programs. Section 7 of the Federal Deposit Insurance Act (FDI Act) sets forth the risk-based assessment authorities underlying the FDIC's deposit insurance system. The FDIC seeks comment on all aspects of this ANPR.

**DATES:** Comments must be submitted on or before February 18, 2010.

**ADDRESSES:** You may submit comments on the advance notice of proposed rulemaking by any of the following methods:

- *Agency Web Site:* <http://www.FDIC.gov/regulations/laws/federal/propose.html>. Follow the instructions for submitting comments on the Agency Web Site.
- *E-mail:* [Comments@FDIC.gov](mailto:Comments@FDIC.gov). Include RIN #3064-AD56 on the subject line of the message.

• *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

• *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

**Instructions:** All comments received will be posted generally without change to <http://www.fdic.gov/regulations/laws/federal/propose.html>, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:**

Marc Steckel, Associate Director, (202) 898-3618, Rose Kushmeider, Acting Section Chief, (202) 898-3861, Daniel Loneragan, Counsel, (202) 898-6971, or Sheiklia Kapoor, Senior Attorney, (202) 898-3960.

**SUPPLEMENTARY INFORMATION:****I. Background**

Section 7 of the FDI Act requires the FDIC to establish a risk-based assessment system that incorporates statutory and other factors determined to be relevant in assessing the probability that the Deposit Insurance Fund (DIF) will incur a loss from the failure of an insured depository institution. In accordance with this mandate, the FDIC is exploring whether and, if so, how to incorporate employee compensation criteria into the risk-based assessment system. The FDIC does not seek to limit the amount which employees are compensated, but rather is concerned with adjusting risk-based deposit insurance assessment rates (risk-based assessment rates) to adequately compensate the DIF for the risks inherent in the design of certain compensation programs. By doing this, the FDIC seeks to provide incentives for institutions to adopt compensation programs that align employees' interests with the long-term interests of the firm and its stakeholders, including the FDIC. Such incentives would also seek to promote the use of compensation programs that reward employees for internalizing the firm's focus on risk management.

This initiative is intended to be a complementary effort to the supervisory standards being developed both domestically and internationally to address the risks posed by poorly designed compensation programs. While supervisory standards are set to define the minimum standards that all institutions must meet, the FDIC seeks to use the deposit insurance assessment system to provide incentives for institutions to meet higher standards, should they choose to do so. Using the deposit insurance assessment system in this way does not mandate institutions to adopt higher standards, but instead would broaden and improve the regulatory approach to addressing compensation issues by providing institutions with an incentive to choose to exceed base supervisory standards.

In the wake of the global financial crisis that began in 2007, public, academic, and government attention has been directed toward the compensation practices of financial institutions—especially the largest, most complex, financial organizations—with particular

focus on whether compensation practices contributed to the excessive build-up of risk that precipitated the crisis. A review of work by academics, consulting groups and others indicates a broad consensus that some compensation structures misalign incentives and induce imprudent risk taking within financial organizations.<sup>1</sup> Some poorly designed compensation structures reward employees based on short-term results without full consideration of the longer-term risks to the firm. In so doing, they fail to align individual incentives with those of the firm's other stakeholders, including shareholders and the FDIC.

Excessive and imprudent risk taking remains a contributing factor in financial institution failures and losses to the DIF, and to some extent these losses can be attributed to the incentives provided by poorly designed compensation programs. Section 7 of the FDI Act requires the FDIC to account for these risks to the DIF when setting risk-based assessment rates. This ANPR seeks comment on a variety of issues that will be considered in this effort.

While there is general agreement that certain compensation programs misalign incentives and increase risk, the proposals to address these problems differ. In sum, identifying the risks posed is easier than identifying the most appropriate solution to address them. Recommendations include mandated stock purchases, performance look-back periods, and bonus clawbacks. Other recommendations focus on the benefits of improving the effectiveness of compensation committees, or on the benefits of shareholders' "say-on-pay."

<sup>1</sup> See, e.g., Lucian Bebchuk, Alma Cohen, and Holger Spamann, "The Wages of Failure: Executive Compensation at Bear Stearns and Lehman 2000-2008," *Yale Journal on Regulation* (forthcoming) (<http://www.law.harvard.edu/faculty/bebchuk/pdfs/BCS-Wages-of-Failure-Nov09.pdf>); Carl R. Chen, Thomas L. Steiner, and Ann Marie Whyte, "Does Stock Option-Based Executive Compensation Induce Risk-Taking? An Analysis of the Banking Industry," *Journal of Banking & Finance*, 30, pp. 915-945 (2006); Alon Raviv and Yorain Landskroner, "The 2007-2009 Financial Crisis and Executive Compensation: Analysis and a Proposal for a Novel Structure," (NYU finance working paper) (<http://archive.nyu.edu/handle/2451/28105>); Jonathan R. Macey and Maureen O'Hara, "Corporate Governance of Banks," *FRBNY Economic Policy Review*, 9, pp. 91-107 (2003); and Valentine V. Craig, "The Changing Corporate Governance Environment: Implications for the Banking Industry," *FDIC Banking Review*, 16, pp. 121-135 (2004). In addition, the Federal banking agencies addressed compensation in the Interagency Statement on Meeting the Needs of Creditworthy Borrowers, issued November 12, 2008. Specifically, this interagency statement notes that poorly designed management compensation policies can "create perverse incentives" that may jeopardize the institution's health.

**Legal Framework**

Section 7 of the Federal Deposit Insurance Act (FDI Act, 12 U.S.C. 1817) sets forth the risk-based assessment authorities underlying the FDIC's deposit insurance system. It requires that a depository institution's deposit insurance assessment be based on the probability that the DIF will incur a loss with respect to that institution, the likely amount of the loss, and the revenue needs of the DIF. 12 U.S.C. 1817(b)(1)(C). Employee compensation programs have been cited as a contributing factor in 35 percent of the reports prepared in 2009 investigating the causes of insured depository institution failures and the associated losses to the DIF.

The FDIC's Board of Directors is required to set risk-based assessments for insured depository institutions in such amounts as it determines to be necessary or appropriate. 12 U.S.C. 1817(b)(2)(A). The Board of Directors must, in setting risk-based assessments, consider the estimated operating expenses of the DIF, the estimated case resolution expenses and income of the DIF, the projected effects of the payment of assessments on the capital and earnings of insured depository institutions, the risk factors listed at 12 U.S.C. 1817(b)(1)(C), and any other factors the Board determines to be appropriate. 12 U.S.C. 1817(b)(2)(B). The FDIC believes the risks presented by certain employee compensation programs are an appropriate factor for the Board to consider when setting risk-based assessments.

In some cases, an institution's risk profile can be affected by holding company and affiliate activities. For example, employees of a parent holding company may be responsible for making decisions or taking actions that will have a material effect on the insured depository institution. In this scenario, the control of significant risks affecting the insured depository institution resides outside the institution, but in the event of failure, the costs associated with the risk will be borne by the DIF. In another example, an employee may have dual responsibilities—to the insured depository institution and to the parent holding company or affiliate—and thus be partly compensated under a contract with a parent company or affiliate. The FDIC is seeking comment on how these types of risks should be accounted for when setting an institution's risk-based assessment.

The Board of Directors may establish separate risk-based assessment systems for large and small members of the DIF. 12 U.S.C. 1817(b)(1)(D). However, no

insured depository institution may be barred from the lowest-risk category solely because of size. 12 U.S.C. 1817(b)(2)(D). Any changes made to the risk-based assessment system would be subject to this constraint.

The FDIC views the contemplated changes to the risk-based assessment system as separate from and complementary to recent supervisory initiatives to address compensation issues. Unlike supervisory standards, which set a floor below which the insured depository institution cannot operate, the contemplated standards used for determining risk-based assessment rates would be voluntary. The risk-based assessment system is therefore designed to provide incentives for institutions to adopt standards that exceed supervisory minimum standards. The existing risk-based assessment system provides a variety of incentives for institutions to achieve lower risk-based assessment rates by exceeding supervisory minimum standards. The FDIC views the contemplated approach as consistent with the existing approach whereby the deposit insurance system is used to provide incentives for risk management practices that exceed supervisory minimum standards, while stopping short of mandating higher standards.

## II. Methodology

Certain compensation programs can increase losses to the DIF as they provide incentives for employees of an institution to engage in excessive risk taking which can ultimately increase the institution's risk of failure. In 2009 there were 49 Material Loss Reviews completed that addressed the factors contributing to the losses resulting from financial institution failures—17 of these reports (35 percent) cited employee compensation practices as a contributing factor. Therefore, the FDIC is seeking to identify criteria upon which to base adjustments to the risk-based assessment system in order to correctly price and assess the risks presented by certain compensation programs. These criteria would be organized to provide either a "meets" or "does not meet" metric, which would then be used to adjust an institution's risk-based assessment rate.

### *Description of the FDIC's Goals*

The FDIC's goals include:

- Adjusting the FDIC's risk-based assessment rates to adequately compensate the DIF for the risks presented by certain compensation programs.
- Using the FDIC's risk-based assessment rates to provide incentives

for insured institutions and their holding companies and affiliates to adopt compensation programs that align employees' interests with those of the insured depository institution's other stakeholders, including the FDIC.

- Promoting the use of compensation programs that reward employees for focusing on risk management.

In assessing institutions for the risks posed by certain compensation programs, the FDIC seeks to develop criteria that are straightforward and require little additional data to be collected. The criteria should allow the FDIC to determine whether an institution has adopted a compensation system that either meets a defined standard or does not. The FDIC does not seek to impose a ceiling on the level of compensation that institutions may pay their employees. Rather, the criteria should focus on whether an employee compensation system is likely to be successful in aligning employee performance with the long-term interests of the firm and its stakeholders, including the FDIC. In this manner any adjustment to the risk-based assessment system should complement supervisory initiatives to ensure that institutions have compensation policies that do not encourage excessive risk taking and that are consistent with the safety and soundness of the organization.

Compensation programs that meet the FDIC's goals may include the following features:

1. A significant portion of compensation for employees whose business activities can present significant risk to the institution and who also receive a portion of their compensation according to formulas based on meeting performance goals should be comprised of restricted, non-discounted company stock. Such employees would include the institution's senior management, among others. Restricted, non-discounted company stock would be stock that becomes available to the employee at intervals over a period of years. Additionally, the stock would initially be awarded at the closing price in effect on the day of the award.
2. Significant awards of company stock should only become vested over a multi-year period and should be subject to a look-back mechanism (e.g., clawback) designed to account for the outcome of risks assumed in earlier periods.
3. The compensation program should be administered by a committee of the Board composed of independent directors with input from independent compensation professionals.

Under the approach contemplated above, the FDIC could conclude that firms that are able to attest that their compensation programs include each of the features listed above present a decreased risk to the DIF, and therefore would face a lower risk-based assessment rate than those firms that could not make such attestation. Alternatively, the FDIC could conclude that firms that cannot attest that their compensation programs include each of these features present an increased risk to the DIF, and therefore would face a higher risk-based assessment rate than those firms that do make such attestation.

## III. Request for Comments

The FDIC requests comment on all aspects of the proposal to incorporate employee compensation criteria into the FDIC's risk-based assessment system, including comments on the FDIC's stated goals and the features of compensation programs that meet such goals. In particular, the FDIC invites comment on the following:

1. Should an adjustment be made to the risk-based assessment rate an institution would otherwise be charged if the institution could/could not attest (subject to verification) that it had a compensation system that included the following elements?

a. A significant portion of compensation for employees whose business activities can present significant risk to the institution and who also receive a portion of their compensation according to formulas based on meeting performance goals would be comprised of restricted, non-discounted company stock. The employees affected would include the institution's senior management, among others. Restricted, non-discounted company stock would be stock that becomes available to the employee at intervals over a period of years. Additionally, the stock would initially be awarded at the closing price in effect on the day of the award.

b. Significant awards of company stock would only become vested over a multi-year period and would be subject to a look-back mechanism (e.g., clawback) designed to account for the outcome of risks assumed in earlier periods.

c. The compensation program would be administered by a committee of the Board composed of independent directors with input from independent compensation professionals.

2. Should the FDIC's risk-based assessment system reward firms whose compensation programs present lower

risk or penalize institutions with programs that present higher risks?

3. How should the FDIC measure and assess whether an institution's board of directors is effectively overseeing the design and implementation of the institution's compensation program?

4. As an alternative to the FDIC's contemplated approach (see q. 1), should the FDIC consider the use of quantifiable measures of compensation—such as ratios of compensation to some specified variable—that relate to the institution's health or performance? If so, what measure(s) and what variables would be appropriate?

5. Should the effort to price the risk posed to the DIF by certain compensation plans be directed only toward larger institutions; institutions that engage only in certain types of activities, such as trading; or should it include all insured depository institutions?

6. How large (that is, how many basis points) would an adjustment to the initial risk-based assessment rate of an institution need to be in order for the FDIC to have an effective influence on compensation practices?

7. Should the criteria used to adjust the FDIC's risk-based assessment rates apply only to the compensation systems of insured depository institutions? Under what circumstances should the criteria also consider the compensation programs of holding companies and affiliates?

8. How should the FDIC's risk-based assessment system be adjusted when an employee is paid by both the insured depository institution and its related holding company or affiliate?

9. Which employees should be subject to the compensation criteria that would be used to adjust the FDIC's risk-based assessment rates? For example, should the compensation criteria be applicable only to executives and those employees who are in a position to place the institution at significant risk? If the criteria should only be applied to certain employees, how would one identify these employees?

10. How should compensation be defined?

11. What mix of current compensation and deferred compensation would best align the interests of employees with the long-term risk of the firm?

12. Employee compensation programs commonly provide for bonus compensation. Should an adjustment be made to risk-based assessment rates if certain bonus compensation practices are followed, such as: Awarding guaranteed bonuses; granting bonuses that are greatly disproportionate to

regular salary; or paying bonuses all-at-once, which does not allow for deferral or any later modification?

13. For the purpose of aligning an employee's interests with those of the institution, what would be a reasonable period for deferral of the payment of variable or bonus compensation? Is the appropriate deferral period a function of the amount of the award or of the employee's position within the institution (that is, large bonus awards or awards for more senior employees would be subject to greater deferral)?

14. What would be a reasonable vesting period for deferred compensation?

15. Are there other types of employee compensation arrangements that would have a greater potential to align the incentives of employees with those of the firm's other stakeholders, including the FDIC?

#### *Paperwork Reduction Act*

At this stage of the rulemaking process it is difficult to determine with precision whether any future regulations will impose information collection requirements that are covered by the Paperwork Reduction Act ("PRA") (44 U.S.C. 3501 *et seq.*). Following the FDIC's evaluation of the comments received in response to this ANPR, the FDIC expects to develop a more detailed description regarding incorporating employee compensation criteria into the risk assessment system, and, if appropriate, solicit comment in compliance with PRA.

Dated at Washington, DC, this 12th day of January 2010.

By order of the Board of Directors,  
Federal Deposit Insurance Corporation.

**Robert E. Feldman,**  
*Executive Secretary.*

[FR Doc. 2010-718 Filed 1-15-10; 8:45 am]

BILLING CODE 6714-01-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2010-0040; Directorate Identifier 2008-NM-203-AD]

RIN 2120-AA64

#### **Airworthiness Directives; Sicma Aero Seat 88xx, 89xx, 90xx, 91xx, 92xx, 93xx, 95xx, and 96xx Series Passenger Seat Assemblies, Installed on Various Transport Category Airplanes**

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

**ACTION:** Notice of proposed rulemaking (NPRM).

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

Cracks have been found on seats [with] backrest links P/N (part number) 90-000200-104-1 and 90-000200-104-2. These cracks can significantly affect the structural integrity of seat backrests.

Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

**DATES:** We must receive comments on this proposed AD by March 5, 2010.

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

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

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Sicma Aero Seat, 7, Rue Lucien Coupet, 36100 ISSOUDUN, France; telephone 33 (0) 2 54 03 39 39; fax 33 (0) 2 54 03 39 00; e-mail:

*customerservices@sicma.zodiac.com*;  
Internet: <http://www.sicma.zodiac.com/en/>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

#### **Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the

regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:**

Jeffrey Lee, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (781) 238-7161; fax (781) 238-7170.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA-2010-0040; Directorate Identifier 2008-NM-203-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We have lengthened the 30-day comment period for proposed ADs that address MCAI originated by aviation authorities of other countries to provide adequate time for interested parties to submit comments. The comment period for these proposed ADs is now typically 45 days, which is consistent with the comment period for domestic transport ADs.

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

**Discussion**

The Direction Generale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, has issued French Airworthiness Directive 2001-613(AB), dated December 12, 2001 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

Cracks have been found on seats [with] backrest links P/N (part number) 90-000200-104-1 and 90-000200-104-2. These cracks can significantly affect the structural integrity of seat backrests.

Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The required actions include a general visual inspection for cracking of backrest links;

replacement with new, improved links if cracking is found; and eventual replacement of all links with new, improved links.

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

**Relevant Service Information**

Sicma Aero Seat has issued Service Bulletin 90-25-013, Issue 3, dated December 19, 2001, including Annex 1, Issue 1, dated June 26, 2001. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

**FAA's Determination and Requirements of This Proposed AD**

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

**Differences Between This AD and the MCAI or Service Information**

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

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

**Costs of Compliance**

Based on the service information, we estimate that this proposed AD would affect about 611 seats on 4 products of U.S. registry. We also estimate that it would take about 1 work-hour per seat to comply with the basic requirements of this proposed AD. The average labor rate is \$80 per work-hour. Required parts would cost about \$0 per seat. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage

for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$48,880, or \$80 per seat.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

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

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

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

**Sigma Aero Seat:** Docket No. FAA-2010-0040; Directorate Identifier 2008-NM-203-AD.

**Comments Due Date**

(a) We must receive comments by March 5, 2010.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to Sigma Aero Seat 88xx, 89xx, 90xx, 91xx, 92xx, 93xx, 95xx, and 96xx series passenger seat assemblies identified in Annex 1, Issue 1, dated June 26, 2001, of Sigma Aero Seat Service Bulletin 90-25-013, Issue 3, dated December 19,

2001, that have backrest links having part numbers (P/Ns) 90-000200-104-1 and 90-000200-104-2; and that are installed on, but not limited to, the airplanes identified in Table 1 of this AD, certificated in any category. This AD does not apply to Sigma Aero Seat series 9140, 9166, 9173, 9174, 9184, 9188, 9196, 91B7, 91B8, 91C0, 91C2, 91C3, 91C4, 91C5, 9301, and 9501 passenger seat assemblies.

**TABLE 1—CERTAIN AFFECTED MODELS**

Manufacturer	Model
Airbus	A300 Airplanes.
Airbus	A310, A318, A319, A320, A321, A330-200 and A330-300 Series Airplanes.
ATR—GIE Avions de Transport Régional	ATR42-200, -300, -320, and -500 Airplanes.
ATR—GIE Avions de Transport Régional	ATR72-101, -201, -102, -202, -211, -212, and -212A Airplanes.
The Boeing Company	727, 727C, 727-100, 727-100C, 727-200, and 727-200F Series Airplanes.
The Boeing Company	737-100, -200, -200C, -300, -400, -500, -600, -700, -700C, -800, -900, and -900ER Series Airplanes.
The Boeing Company	747-100, 747-100B, 747-100B SUD, 747-200B, 747-200C, 747-200F, 747-300, 747-400, 747-400D, 747-400F, 747SR, and 747SP Series Airplanes.
The Boeing Company	757-200, -200PF, -200CB, and -300 Series Airplanes.
The Boeing Company	767-200, -300, -300F, and -400ER Series Airplanes.
The Boeing Company	777-200, 777-300, 777-300ER, 777-200LR, and 777F Series Airplanes.
Bombardier, Inc	CL-600-1A11 (CL-600), CL-600-2A12 (CL-601), and CL-600-2B16 (CL-601-3A, CL-601-3R, and CL-604) Airplanes.
Bombardier, Inc	CL-600-2B19 (Regional Jet Series 100 & 440) Airplanes.
Bombardier, Inc	CL-600-2C10 (Regional Jet Series 700, 701, & 702) Airplanes.
Bombardier, Inc	CL-600-2D15 (Regional Jet Series 705) Airplanes.
Bombardier, Inc	CL-600-2D24 (Regional Jet Series 900) Airplanes.
Bombardier, Inc	DHC-8-100, DHC-8-200, DHC-8-300, and DHC-8-400 Airplanes.
Fokker Services B.V	F.27 Mark 050, 100, 200, 300, 400, 500, 600, and 700 Airplanes.
Fokker Services B.V	F.28 Mark 0070, 0100, 1000, 2000, 3000, and 4000 Airplanes.
McDonnell Douglas Corporation	DC-8-11, DC-8-12, DC-8-21, DC-8-31, DC-8-32, DC-8-33, DC-8-41, DC-8-42, DC-8-43, DC-8-51, DC-8-52, DC-8-53, DC-8-55, DC-8F-54, DC-8F-55, DC-8-61, DC-8-62, DC-8-63, DC-8-61F, DC-8-62F, DC-8-63F, DC-8-71, DC-8-72, DC-8-73, DC-8-71F, DC-8-72F, and DC-8-73F Airplanes.
McDonnell Douglas Corporation	DC-9-11, DC-9-12, DC-9-13, DC-9-14, DC-9-15, DC-9-15F, DC-9-21, DC-9-31, DC-9-32, DC-9-32 (VJ-9C), DC-9-32F, DC-9-33F, DC-9-34, DC-9-34F, DC-9-32F (C-9A, C-9B), DC-9-41, DC-9-51, DC-9-81 (MD-81), DC-9-82 (MD-82), DC-9-83 (MD-83), and DC-9-87 (MD-87) Airplanes.
McDonnell Douglas Corporation	DC-10-10, DC-10-10F, DC-10-15, DC-10-30, DC-10-30F (KC-10A and KDC-10), DC-10-40, and DC-10-40F Airplanes.
McDonnell Douglas Corporation	MD-11 and MD-11F Airplanes.

**Note 1:** This AD applies to Sigma Aero Seat passenger seat assemblies as installed on any airplane, regardless of whether the airplane has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance according to paragraph (g)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the

request should include specific proposed actions to address it.

**Subject**

(d) Air Transport Association (ATA) of America Code 25: Equipment/Furnishings.

**Reason**

(e) The mandatory continuing airworthiness information (MCAI) states: Cracks have been found on seats [with] backrest links P/N (part number) 90-000200-104-1 and 90-000200-104-2. These cracks can significantly affect the structural integrity of seat backrests.

Failure of the backrest links could result in injury to an occupant during emergency landing conditions. The required actions include a general visual inspection for cracking of the backrest links; replacement with new, improved links if cracking is found; and eventual replacement of all links with new, improved links.

**Actions and Compliance**

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

(1) At the later of the compliance times specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD, do a general visual inspection of the backrest links having P/Ns 90-000200-

104-1 and 90-000200-104-2, in accordance with Part One of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001:

(i) Before 6,000 flight hours on the backrest link since new.

(ii) Within 900 flight hours or 5 months after the effective date of this AD, whichever occurs later.

(2) If, during the inspection required by paragraph (f)(1) of this AD, cracking is found between the side of the backrest link and the lock-out pin hole but the cracking does not pass this lock-out pin hole (refer to Figure 2 of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001): Within 600 flight hours or 3 months after doing the inspection, whichever occurs first, replace both backrest links of the affected seat with new, improved backrest links having P/Ns 90-100200-104-1 and 90-100200-104-2, in accordance with Part Two of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001.

(3) If, during the inspection required by paragraph (f)(1) of this AD, cracking is found that passes beyond the lock-out pin hole (refer to Figure 2 of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001): Before further flight, replace both backrest links of the affected seat with new, improved backrest links having P/Ns 90-100200-104-1 and 90-100200-104-2, in accordance with Part Two of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001.

(4) If no cracking is found during the inspection required by paragraph (f)(1) of this AD: Do the replacement required by paragraph (f)(5) of this AD at the compliance time specified in paragraph (f)(5) of this AD.

(5) At the later of the compliance times specified in paragraphs (f)(5)(i) and (f)(5)(ii) of this AD, replace the links, P/Ns 90-000200-104-1 and 90-000200-104-2, with new improved links, P/Ns 90-100200-104-1 and 90-100200-104-2, in accordance with Part Two of *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001. Doing this replacement for an affected passenger seat assembly terminates the inspection requirements of paragraph (f)(1) of this AD for that passenger seat assembly.

(i) Before 12,000 flight hours on the backrest links, P/Ns 90-000200-104-1 and 90-000200-104-2, since new.

(ii) Within 900 flight hours or 5 months after the effective date of this AD, whichever occurs later.

#### FAA AD Differences

**Note 2:** This AD differs from the MCAI and/or service information as follows: The MCAI specifies doing repetitive inspections for cracking of links having over 12,000 flight hours since new until the replacement of the link is done. This AD does not include those repetitive inspections because we have reduced the compliance time for replacing those links. This AD requires replacing the link before 12,000 flight hours since new or within 900 flight hours or 5 months of the effective date of this AD, whichever occurs latest.

#### Other FAA AD Provisions

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

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Boston Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jeffrey Lee, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803; telephone (781) 238-7161; fax (781) 238-7170. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office.

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

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

#### Related Information

(h) Refer to MCAI French Airworthiness Directive 2001-613(AB), dated December 12, 2001; and *Sigma Aero Seat Service Bulletin 90-25-013*, Issue 3, dated December 19, 2001, including Annex 1, Issue 1, dated June 26, 2001; for related information.

Issued in Renton, Washington, on January 8, 2010.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010-697 Filed 1-15-10; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2010-0042; Directorate Identifier 2009-NM-010-AD]

RIN 2120-AA64

#### Airworthiness Directives; Saab AB, Saab Aerosystems Model SAAB 340A (SAAB/SF340A) and SAAB 340B Airplanes Modified in Accordance With Supplemental Type Certificate (STC) SA00244WI-D, ST00146WI-D, or SA984GL-D

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The FAA proposes to adopt a new airworthiness directive (AD) for certain Saab AB, Saab Aerosystems Model SAAB 340A (SAAB/SF340A) and SAAB 340B airplanes. This proposed AD would require inspecting the fuselage surface for corrosion and cracking behind the external adapter plate of the antennae installation, and repair if necessary. This proposed AD results from a report of a crack found behind the external adapter plate of the antennae during inspection. Similar cracking was found on two additional airplanes, and extensive corrosion was found on one airplane. We are proposing this AD to detect and correct corrosion and cracking behind the external adapter plate of the antennae of certain safe-life structure, which could result in reduced structural integrity and consequent rapid depressurization of the airplane.

**DATES:** We must receive comments on this proposed AD by March 5, 2010.

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

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

### Examining the AD Docket

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

#### FOR FURTHER INFORMATION CONTACT:

William Griffith, Aerospace Engineer, Airframe Branch, ACE-118W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946-4116; fax (316) 946-4107.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2010-0042; Directorate Identifier 2009-NM-010-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

##### Discussion

We received a report of a crack found behind the external adapter plate of the antennae during inspection of a Model SAAB 340A airplane, serial number 142. Similar cracking was found on two additional airplanes, and extensive corrosion was found on one airplane. These airplanes had Supplemental Type Certificate (STC) work done by a common installer. Investigation revealed that insufficient corrosion protection was applied during installation. No known data show that other airplanes with work done elsewhere in accordance with STC SA00244WI-D, ST00146WI-D, or SA984GL-D have had common corrosion issues. The STC data provided

show sufficient corrosion protection is specified in STCs SA00244WI-D, ST00146WI-D, and SA984GL-D for other airplanes, and the unsafe condition is limited to airplanes on which the identified STC work was done. Corrosion and cracking behind the external adapter plate of the antennae of certain safe-life structure if not detected and corrected, could result in reduced structural integrity and consequent rapid depressurization of the airplane.

The subject area on certain Model SAAB 340B airplanes is almost identical to that on the affected Model SAAB 340A airplanes. Therefore, those Model SAAB 340B airplanes may be subject to the unsafe condition revealed on the Model SAAB 340A airplanes.

#### FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in Sweden and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

We are proposing this AD, which would require inspecting the fuselage surface for corrosion or cracking behind the external adapter plate of the Supplemental Type Certificate antennae installation. This proposed AD also would require repair of any corrosion or cracking found. All actions, including any repairs, are required to be done in accordance with a method approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA. For airplanes on which no corrosion or cracking is found, the proposed AD would require ensuring that proper corrosion protection has been applied before reinstalling the adapter plate, in accordance with a method approved by the Manager, Wichita ACO.

This proposed AD does not provide credit for actions that may have already been done to address the identified unsafe condition since no FAA-approved method for accomplishing the required actions exists. However, if any operator already has removed the adapter plate and done a repair, that operator may request approval of an alternative method of compliance (AMOC) under the provisions of paragraph (j) of this proposed AD.

#### Costs of Compliance

This proposed AD would affect about 201 airplanes of U.S. registry. The proposed inspection would take about 4 work hours per airplane, at an average labor rate of \$80 per work hour. Based

on these figures, the estimated cost of the proposed AD for U.S. operators is \$64,320, or \$320 per airplane.

#### Authority for This Rulemaking

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

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

#### Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

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

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

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



**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

**Saab AB, Saab Aerosystems:** Docket No. FAA-2010-0042; Directorate Identifier 2009-NM-010-AD.

**Comments Due Date**

(a) The FAA must receive comments on this AD action by March 5, 2010.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to the Saab AB, Saab Aerosystems airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD, that have been modified in accordance with Supplemental Type Certificate (STC) SA00244WI-D, ST00146WI-D, or SA984GL-D.

(1) Model SAAB 340A (SAAB/SF340A) airplanes, serial numbers 004 through 159 inclusive.

(2) Model SAAB 340B airplanes, serial numbers 160 through 459 inclusive.

**Subject**

(d) Air Transport Association (ATA) of America Code 53: Fuselage.

**Unsafe Condition**

(e) This AD results from a report of a crack found behind the external adapter plate of the antennae during inspection. Similar cracking was found on two additional airplanes, and extensive corrosion was found on one airplane. The Federal Aviation Administration is issuing this AD to detect and correct corrosion and cracking behind the external adapter plate of the antennae of certain safe-life structure, which could result in reduced structural integrity and consequent rapid depressurization of the airplane.

**Compliance**

(f) You are responsible for having the actions required by this AD performed within the compliance times specified.

**Inspection/Corrective Actions**

(g) Within 600 flight cycles after the effective date of this AD: Remove the external adapter plate of the antennae installation and do a general visual inspection of the fuselage surface for corrosion and cracking behind the external adapter plate of the antennae installation. If any corrosion or cracking is found, repair before further flight. If no corrosion or cracking is found, before further flight, ensure that proper corrosion protection has been applied before reinstalling the adapter plate. Do all the actions required by this paragraph in

accordance with a method approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA.

**Note 1:** For the purposes of this AD, a general visual inspection is: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

**Reporting Requirement**

(h) At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD: Submit a report of the positive findings of the inspections required by paragraph (g) of this AD. Send the report to the Manager, Wichita ACO. The report must contain, at a minimum, the inspection results, a description of any discrepancies found, the airplane serial number, and the number of flight cycles and flight hours on the airplane since installation of the STC. Under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120-0056.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

**Special Flight Permit**

(i) Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), may be issued to operate the airplane to a location where the requirements of this AD can be accomplished, but concurrence by the Manager, Wichita ACO, FAA, is required prior to issuance of the special flight permit.

**Alternative Methods of Compliance (AMOCs)**

(j) The Manager, Wichita ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: William Griffith, Aerospace Engineer, Airframe Branch, ACE-118W, FAA, Wichita ACO, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946-4116; fax (316) 946-4107. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

**Related Information**

(k) None.

Issued in Renton, Washington, on January 7, 2010.

**Stephen P. Boyd,**

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

[FR Doc. 2010-698 Filed 1-15-10; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2010-0043; Directorate Identifier 2009-NM-128-AD]

RIN 2120-AA64

**Airworthiness Directives; McDonnell Douglas Corporation Model DC-10-10, DC-10-10F, and MD-10-10F Airplanes**

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain McDonnell Douglas Model DC-10-10, DC-10-10F, and MD-10-10F airplanes. This proposed AD would require a one-time high frequency eddy current inspection of fastener holes for cracks at the left and right side wing rear spar lower cap at station Xors=345, and other specified and corrective actions if necessary. This proposed AD results from a report of three instances of Model DC-10-10F airplanes having fuel leaks in the wing rear spar lower cap at station Xors=345. We are proposing this AD to prevent cracks in the spar cap, which if not corrected could lead to cracking of the lower wing skin, fuel leaks, and the inability of the structure to sustain limit load.

**DATES:** We must receive comments on this proposed AD by March 5, 2010.

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

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

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m.

and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800-0019, Long Beach, California 90846-0001; telephone 206-544-5000, extension 2; fax 206-766-5683; e-mail [dse.boecom@boeing.com](mailto:dse.boecom@boeing.com); Internet <https://www.myboeingfleet.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221 or 425-227-1152.

**Examining the AD Docket**

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

**FOR FURTHER INFORMATION CONTACT:** Carl Fountain, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712-4137; telephone (562) 627-5322; fax (562) 627-5210.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

We invite you to send any written relevant data, views, or arguments about

this proposed AD. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA-2010-0043; Directorate Identifier 2009-NM-128-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

**Discussion**

We have received a report of three instances of Model DC-10-10F airplanes having fuel leaks in the wing rear spar lower cap at station Xors=345. Investigation revealed the fuel leak was due to a crack in the lower cap. This crack extended into all three legs (aft, forward, and vertical) of the spar cap. Analysis of the cracked portion of the spar cap determined that the crack was due to fatigue and began at a fastener hole in the forward leg of the spar cap. This condition, if not corrected, could lead to cracking of the lower wing skin, fuel leaks, and the inability of the structure to sustain limit load.

**Relevant Service Information**

We have reviewed Boeing Alert Service Bulletin DC10-57A157, dated May 12, 2009. The service bulletin describes procedures for:

- Doing a high frequency eddy current inspection of fastener holes for

cracking at the left and right side wing rear spar lower cap.

- Cold working open holes and installing new second oversize fasteners in the left and right side wing rear spar lower cap if no cracking is found.
- Contacting Boeing for repair instructions and doing the repair if cracking is found.

**FAA's Determination and Requirements of This Proposed AD**

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Differences Between the Proposed AD and Service Bulletin."

**Differences Between the Proposed AD and Service Bulletin**

The service bulletin specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that we have authorized to make those findings.

**Costs of Compliance**

We estimate that this proposed AD would affect 68 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

TABLE—ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Cost per product	Number of U.S.-registered airplanes	Fleet cost
Inspection .....	2	\$80	\$160	68	\$10,880

**Authority for This Rulemaking**

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

We are issuing this rulemaking under the authority described in "Subtitle VII,

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

products identified in this rulemaking action.

**Regulatory Findings**

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the

distribution of power and responsibilities among the various levels of government.

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

1. Is not a "significant regulatory action" under Executive Order 12866.
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

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

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### The Proposed Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**McDonnell Douglas Corporation:** Docket No. FAA-2010-0043; Directorate Identifier 2009-NM-128-AD.

#### Comments Due Date

(a) We must receive comments by March 5, 2010.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to McDonnell Douglas Corporation Model DC-10-10, DC-10-10F, and MD-10-10F airplanes, certificated in any category, as specified in Boeing Alert Service Bulletin DC10-57A157, dated May 12, 2009.

#### Subject

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

#### Unsafe Condition

(e) This AD results from a report of three instances of Model DC-10-10F airplanes having fuel leaks in the wing rear spar lower cap at station Xors=345. The Federal Aviation Administration is issuing this AD to prevent cracking in the spar cap, which could lead to cracking of the lower wing skin, fuel leaks, and the inability of the structure to sustain limit load.

#### Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

#### Inspection

(g) Within 3,000 flight cycles after the effective date of this AD, do a one-time high frequency eddy current inspection for cracking of fastener holes at the left and right side wing rear spar lower cap at station Xors=345, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin DC10-57A157, dated May 12, 2009.

(1) If no cracking is found, before further flight, cold work open holes and install new second oversize fasteners and nut assemblies in the left and right side wing rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin DC10-57A157, dated May 12, 2009.

(2) If any cracking is found during any inspection required by this AD, before further flight, repair the left and right side wing rear spar lower cap using a method approved in accordance with the procedures specified in paragraph (h) of this AD.

#### Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Carl Fountain, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, California 90712-4137; telephone (562) 627-5322; fax (562) 627-5210.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on January 8, 2010.

**Stephen P. Boyd,**

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

[FR Doc. 2010-699 Filed 1-15-10; 8:45 am]

**BILLING CODE 4910-13-P**

#### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2009-0996]

RIN 1625-AA00

#### Safety Zones; Hydroplane Races Within the Captain of the Port Puget Sound Area of Responsibility

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish permanent safety zones for Hydroplane Races to take place on various dates on the waters of Dyes Inlet, Port Angeles and Lake Washington, WA. When these safety zones are activated, and thus subject to enforcement, this rule would limit the movement of non-participating vessels within the established race areas while hydroplane races are taking place. This proposed rule is needed to ensure the safety of the maritime public from inherent dangers associated with high-speed watercraft races on navigable waterways during these events.

**DATES:** Comments and related material must be received by the Coast Guard on or before March 22, 2010. Requests for public meetings must be received by the Coast Guard on or before 45 days after date of publication in the **Federal Register**.

**ADDRESSES:** You may submit comments identified by docket number USCG-2009-0996 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposed rule, call or e-mail ENS Ashley M.

Wanzer, Waterways Management, Sector Seattle, Coast Guard; telephone 206-217-6175, e-mail [SectorSeattleWWM@uscg.mil](mailto:SectorSeattleWWM@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

#### Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

#### Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2009-0996), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via [www.regulations.gov](http://www.regulations.gov), it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG-2009-0996" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may

change the rule based on your comments.

#### Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2009-0996" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

#### Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the *Federal Register* (73 FR 3316).

#### Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before 45 days after date of publication in the *Federal Register* using one of the four methods specified under ADDRESSES. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the *Federal Register*.

#### Background and Purpose

The Coast Guard is establishing three permanent safety zones on the waterways of Port Angeles, Dyes Inlet and Lake Washington, WA. These zones are necessary to ensure unencumbered access for rescuers in the event of an emergency and to ensure public safety from the numerous dangers associated with high speed watercraft races. Designating these three areas as hydroplane race areas expedites the process of activating the safety zones for these events to more effectively ensure the safety of the maritime public.

#### Discussion of Proposed Rule

This proposed rule will create three permanent safety zones on the waters of Dyes Inlet, Port Angeles and Lake

Washington, WA to protect the public from the inherent dangers associated with hydroplane races. The first safety zone is located at the northern section of Dyes inlet, west of Port Orchard, WA (all waters north of a line from point 47-37.36N 122-42.29W to 47-37.74N 122-40.64W (NAD 1983)); the second is located at Port Angeles, south of Ediz's Hook, Port Angeles, WA (All waters within the following points: 48-07.4N 123-25.57W; 48-07.43N 123-24.58W; 48-07.2N 123-25.52W; 48-07.25N 123-24.57W0 (NAD 1983)); and the third safety zone is located on Lake Washington, south of interstate 90 bridge and north of Andrew's Bay, WA (all waters east of the shoreline within the following points: 47°34.15' N, 122°16.40' W; 47°34.31' N, 122°15.96' W; 47°35.18' N, 122°16.31' W; 47°35.00' N, 122°16.71' W (NAD 1983)).

These safety zones are minimal in size and will be subject to enforcement only during hydroplane racing activities, historically 12 hours or less, with the purpose of most effectively providing safety for participants and to other waterway users. We expect races to occur multiple times throughout the year. Notification of the activation of the safety zone will be provided to the public via broadcast notice to mariners and an on-scene Patrol Commander will be present, allowing commercial vessels to transit the regulated area when safe to do so. Additionally, these safety zones are located in remote locations resulting in a minimal impact to other waterway users.

#### Regulatory Analyses

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

#### Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This rule is not a significant regulatory action because it will be enforced for short periods of time in small remote areas which are not considered high-density vessel traffic areas.

#### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this proposed rule would have

a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule will affect the following small entities: The owners or operators of vessels intending to transit or anchor within the safety zone while enforced on the waters of northern Dyes Inlet, Port Angeles and Lake Washington, Washington. This rule will not have a significant economic impact on a substantial number of small entities due to its short duration, small area and the ability of the on-scene Patrol Commander to allow commercial vessels to transit the regulated area when safe to do so. The only vessels likely to be impacted will be recreational boaters. Because the impact of this proposed rule is expected to be minimal, the Coast Guard certifies under 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

#### *Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact ENS Ashley M. Wanzer, Waterways Management, Sector Seattle, Coast Guard; telephone 206-217-6175, e-mail [SectorSeattleWWM@uscg.mil](mailto:SectorSeattleWWM@uscg.mil). The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

#### *Collection of Information*

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520.).

#### *Federalism*

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

#### *Unfunded Mandates Reform Act*

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

#### *Taking of Private Property*

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

#### *Civil Justice Reform*

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

#### *Protection of Children*

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

#### *Indian Tribal Governments*

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship

between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### *Energy Effects*

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

#### *Technical Standards*

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

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

#### *Environment*

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves establishing a safety zone to protect the public from the dangers associated with hydroplane racing.

Therefore, this rule is expected to be categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction, from further environmental documentation. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR Part 165 as follows:

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

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

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

2. Add § 165.xxxx to read as follows:

#### § 165.xxxx Safety Zones; Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility.

(a) *Location.* The following areas are safety zones for the purpose of reoccurring hydroplane races:

(1) The northern section of Dyes inlet, west of Port Orchard, WA, to include all waters of Dyes Inlet north of a line from point 47-37.36N 122-42.29W to 47-37.74N 122-40.64W (NAD 1983).

(2) Port Angeles, south of Ediz's Hook, Port Angeles, WA, to include all waters near Port Angeles within the following points: 48-07.4N 123-25.57W; 48-07.43N 123-24.58W; 48-07.2N 123-25.52W; 48-07.25N 123-24.57W (NAD 1983).

(3) Lake Washington, south of interstate 90 bridge and north of Andrew's Bay, WA, to include all waters of Lake Washington east of the shoreline within the following points: 47°34.15' N, 122°16.40' W; 47°34.31' N, 122°15.96' W; 47°35.18' N, 122°16.31' W; 47°35.00' N, 122°16.71' W (NAD 1983).

(b) *Notice of Enforcement or Suspension of Enforcement.* These safety zones will be activated and thus subject to enforcement, under the following conditions: The Coast Guard must receive and approve a marine event permit for each hydroplane event and then the Captain of the Port will cause notice of the enforcement of these safety zones to be made by all appropriate means to effect the widest publicity among the affected segments

of the public as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners and Local Notice to Mariners notifying the public of activation and suspension of enforcement of these safety zones. Additionally, an on-scene Patrol Commander will ensure enforcement of this safety zone by limiting the transit of non-participating vessel in the designated areas described above.

(c) *Definitions.* As used in this section, *Coast Guard Patrol Commander* means any designated commissioned, warrant, or petty officer of the Coast Guard. Additionally, any other Federal, state or local law enforcement agencies or private agencies hired by the sponsoring organization may be designated by the Coast Guard to fulfill the role of the *on-scene Patrol Commander*. The Patrol Commander is empowered to control the movement of vessels on the racecourse and in the adjoining waters described in paragraph (a) above when this regulation is in effect.

*Regulations.* (1) When these zones are enforced, non-participant vessels are prohibited from entering the regulated area unless authorized by the designated on-scene Patrol Commander. Spectator craft may remain in designated spectator areas but must follow the directions of the on-scene Patrol Commander. Spectator craft entering, exiting or moving within the spectator area must operate at speeds, which will create a minimum wake. (2) Emergency Signaling. A succession of sharp, short signals by whistle or horn from vessels patrolling the areas under the discretion of the Patrol Commander shall serve as a signal to stop. Vessels signaled shall stop and shall comply with the orders of the patrol vessel. Failure to do so may result in expulsion from the area. citation for failure to comply, or both.

Dated: December 17, 2009.

**L.R. Tumbarello,**

*Commander, U.S. Coast Guard, Captain of the Port, Puget Sound. Acting.*

[FR Doc. 2010-764 Filed 1-15-10; 8:45 am]

**BILLING CODE 9110-04-P**

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 54

[CC Docket No. 02-6; FCC 09-96]

#### Schools and Libraries Universal Service Support Mechanism

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, we propose revising the Federal Communications Commission's (Commission) rules regarding the schools and libraries universal service support mechanism, also known as the E-rate program, to comply with the requirements of the Protecting Children in the 21st Century Act. Among other things, the Protecting Children in the 21st Century Act, titled Promoting Online Safety in Schools, revised the Communications Act of 1934, as amended (the Act), by adding a new certification requirement for elementary and secondary schools that have computers with Internet access and receive discounts under the E-rate program. We also propose to revise related Commission rules to reflect existing statutory language more accurately.

**DATES:** Comments on the proposed rules are due on or before February 18, 2010 and reply comments are due on or before March 5, 2010. Written comments on the Paperwork Reduction Act proposed information collection requirements should be submitted on or before March 22, 2010. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** You may submit comments, identified by CC Docket No. 02-6, by any of the following methods:

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

- *Federal Communications Commission's Web site:* <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.

- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or phone: (202) 418-0530 or TTY: (202) 418-0432.

- In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act information collection requirements

contained herein should be submitted to the Federal Communications Commission via e-mail to [PRA@fcc.gov](mailto:PRA@fcc.gov) and to Nicholas A. Fraser, Office of Management and Budget, via e-mail to [Nicholas\\_A.\\_Fraser@omb.eop.gov](mailto:Nicholas_A._Fraser@omb.eop.gov) or via fax at 202-395-5167.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

Anita Cheng, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418-7400 or TTY: (202) 418-0484. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, send an e-mail to [PRA@fcc.gov](mailto:PRA@fcc.gov) or contact Judith B. Herman at 202-418-0214 or via email at [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rulemaking in CC Docket No. 02-6, FCC 09-96, adopted November 4, 2009, and released November 5, 2009. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (800) 378-3160 or (202) 863-2893, facsimile (202) 863-2898, or via the Internet at <http://www.bcpweb.com>. It is also available on the Commission's Web site at <http://www.fcc.gov>. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

• **Electronic Filers:** Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/> or the Federal eRulemaking Portal: <http://www.regulations.gov>.

• **Paper Filers:** Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number

appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• Effective December 28, 2009, all hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW-A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. **Please Note:** Through December 24, 2009, the Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. This filing location will be permanently closed after December 24, 2009. The filing hours at both locations are 8 a.m. to 7 p.m.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington DC 20554.

• In addition, one copy of each comment or reply comment must be sent to Charles Tyler, Telecommunications Access Policy Division, Wireline Competition Bureau, 445 12th Street, SW., Room 5-A452, Washington, DC 20554; e-mail: [Charles.Tyler@fcc.gov](mailto:Charles.Tyler@fcc.gov).

**People with Disabilities:** To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

**Initial Paperwork Reduction Act of 1995 Analysis:**

This document contains proposed information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995,

Public Law 104-13. Public and agency comments are due March 22, 2010.

Comments on the proposed information collection requirements should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4), we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

**OMB Control Number:** 3060-0853.

**Title:** FCC Form 479, Certification by Administrative Authority to Billed Entity of Compliance with Children's Internet Protection Act; FCC Form 486, Receipt of Service Confirmation Form, FCC Form 500, Funding Commitment (FRN) Change Request Form.

**Form Number(s):** FCC Forms 479, 486, 500.

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

**Respondents:** Business or other for-profit and not-for-profit institutions.

**Number of Respondents and Responses:** 75,000 respondents and 75,000 responses.

**Estimated Time per Response:** 1.07 hours (average time per response).

**Obligation to Respond:** Required to obtain or retain benefits.

**Frequency of Response:** Annual, on occasion, and third party disclosure requirement.

**Total Annual Burden:** 70,000 hours.

**Total Annual Cost:** N/A.

**Privacy Act Impact Assessment:** No impact.

**Nature of Extent of Confidentiality:** The Commission is not requesting that the respondents submit confidential information to the FCC. Respondents may, however, request confidential treatment for information they believe to be confidential under 47 CFR 0.459 of the Commission's rules.

**Needs and Uses:** The existing information collection requires schools and libraries to certify that they have in place certain Internet safety policies, pursuant to the Children's Internet Protection Act (CIPA), 47 U.S.C. 254(h) and (l), in order to receive E-rate

discounts for Internet access. This information collection is being revised to add a new certification that the E-rate applicant has updated its Internet safety policy to include plans for educating minors about appropriate online behavior, including interacting with other individuals on social networking websites and in chat rooms and cyberbullying awareness and response, as required by the Protecting Children in the 21st Century Act. This revision will not require any changes to the FCC Forms 479 or 486, which enable E-rate participants to certify that they are compliant with CIPA. This revision has no effect on the FCC Form 500, which is also part of this information collection. In addition, this information collection is being revised to add a rule provision requiring each Internet safety policy that is adopted pursuant to section 254(l) of the Act, as amended, to be made available to the Commission upon request by the Commission. Although this requirement is mandated by the statute, it is not currently in the Commission's rules.

### Synopsis of the Notice of Proposed Rulemaking

#### I. Introduction

1. In this notice of proposed rulemaking (NPRM), we propose revising the Federal Communications Commission's (Commission) rules regarding the schools and libraries universal service support mechanism, also known as the E-rate program, to comply with the requirements of the Protecting Children in the 21st Century Act. Among other things, section 215 of the Protecting Children in the 21st Century Act, titled Promoting Online Safety in Schools, revised section 254(h)(5)(B) of the Communications Act of 1934, as amended (the Act), by adding a new certification requirement for elementary and secondary schools that have computers with Internet access and receive discounts under the E-rate program. We also propose to revise related Commission rules to reflect existing statutory language more accurately.

#### II. Background

2. Under the E-rate program, eligible schools, libraries, and consortia that include eligible schools and libraries may apply for discounted eligible telecommunications, Internet access, and internal connections services. In accordance with the Children's Internet Protection Act (CIPA), to be eligible for E-rate discounts for Internet access and internal connection services, schools and libraries that have computers with

Internet access must certify that they have in place certain Internet safety policies and technology protection measures. As required by CIPA, § 54.520(c)(i) of the Commission's rules requires that the Internet safety policy must include a technology protection measure that protects against Internet access by both adults and minors to visual depictions that are (1) obscene, or (2) child pornography, or, with respect to use of the computers by minors, (3) harmful to minors. In addition, § 54.520(c)(i) requires the entity to certify that its policy of Internet safety includes monitoring the online activities of minors. Applicants make their CIPA certifications annually on the Confirmation of Receipt of Services Form (FCC Form 486).

3. Among other things, the Protecting Children in the 21st Century Act revised section 254(h)(5)(B) of the Act by adding a new certification for elementary and secondary schools that have computers with Internet access and receive discounts under the E-rate program. In addition to the existing CIPA certifications required of schools in section 254(h)(5) of the Act, the Protecting Children in the 21st Century Act requires the school, school board, local educational agency, or other authority with responsibility for administration of the school to certify that it "as part of its Internet safety policy is educating minors about appropriate online behavior, including interacting with other individuals on social networking Web sites and in chat rooms and cyberbullying awareness and response."

#### III. Discussion

##### A. Protecting Children in the 21st Century Act Rule Revisions

4. We seek comment on revising § 54.520(c)(i) of the Commission's rules to include the new certification requirement added by the Protecting Children in the 21st Century Act. We propose to revise § 54.520(c)(i) to add a certification provision that a school's Internet safety policy must include educating minors about appropriate online behavior, including interacting with other individuals on social networking websites and in chat rooms and cyberbullying awareness and response. We seek comment on this proposal.

5. In addition, we tentatively conclude that a recipient of E-rate funding for Internet access and internal connections should be required to certify, on its FCC Form 486 for funding year 2010, that it has updated its Internet safety policy to include plans

for educating minors about appropriate online behavior, including interacting with other individuals on social networking websites and in chat rooms and cyberbullying awareness and response, as required by the Protecting Children in the 21st Century Act. We note that the next opportunity for applicants to certify to the CIPA requirements, including this new certification, would be on the FCC Form 486 for funding year 2009, which would typically be filed after the start of the 2009 funding year (i.e., after July 1, 2009). Schools may, however, require additional time to amend their Internet safety policies and implement procedures to comply with the new requirements after the completion of this rulemaking proceeding. In addition, we note that Congress did not set a timeframe for implementation of the new certification. We seek comment on this tentative conclusion.

##### B. Other Proposed Rule Revisions

6. We also seek comment on revising certain rules to reflect more accurately existing statutory language regarding the CIPA certifications.

7. First, we propose to revise the rules so that the definitions of elementary and secondary schools are consistent throughout. At this time, rule §§ 54.500, 54.501, and 54.504 all contain differently worded definitions of elementary and secondary schools. We propose to define elementary and secondary schools in § 54.500 of the rules, and to revise §§ 54.501 and 54.504 to refer to § 54.500 definitions. We seek comment on this proposal.

8. Second, we propose to revise § 54.520(a)(1) to add "school board" to the definition of entities that are subject to CIPA certifications. Although section 254(h) of the Act includes the term "school board" as an entity to which the CIPA certifications apply, our rules do not include this term. We seek comment on this proposal.

9. Third, we propose to revise § 54.520(a)(4) to add the existing statutory definitions of the terms "minor," "obscene," "child pornography," "harmful to minors," "sexual act," "sexual contact," and "technology protection measure," consistent with the statute. § 54.520 of our rules does not currently include the definitions of these terms, but instead refers back to the statute. Including the statutory definitions of these terms in the definitions section of our rules could help clarify the CIPA requirements. We seek comment on this proposal.

10. Fourth, we propose to revise §§ 54.520(c)(1)(i) and 54.520(c)(2)(i)



consistent with sections 254(h)(5)(D), (h)(6)(D), (h)(5)(B)(ii), (C)(ii), and (h)(6)(B)(ii), (C)(ii) of the Act to require that the technology protection measures be in operation during any use of computers with Internet access, and that the technology protection measures may be disabled by an authorized person, during adult use, to enable access for bona fide research or other lawful purpose. The statute requires that schools and libraries certify that they are enforcing the operation of the technology protection measures during the use of computers by minors and adults. This enforcement requirement is not currently included in the Commission's rules. We seek comment on this proposal.

11. In addition, sections 254(h)(5)(D) and (h)(6)(D) of the Act permit a school or library administrator, supervisor, or other person authorized by the certifying authority to disable an entity's technology protection measure to allow bona fide research or other lawful use by an adult. We note that in the *CIPA Order*, although the Commission acknowledged this statutory provision, it declined to adopt any implementing rule provision, stating that

[w]e decline to promulgate rules mandating how entities should implement these provisions. Federally-imposed rules directing school and library staff when to disable technology protection measures would likely be overbroad and imprecise, potentially chilling speech, or otherwise confusing schools and libraries about the requirements of the statute. We leave such determinations to local communities, whom we believe to be most knowledgeable about the varying circumstances of schools or libraries within those communities.

The Commission stated that its decision was supported by commenter concerns about the difficulty of school or library staff in determining whether an adult user was engaging only in bona fide research or other lawful purposes.

12. We propose to revise the rules to codify this permission that a school or library administrator, supervisor, or other person authorized by the certifying authority may disable an entity's technology protection measure, during use by an adult, to allow bona fide research or other lawful use. We do not propose to adopt rules that mandate specific implementation methods, but merely mirror the statutory language. This will make clear that the statutory provision exists without imposing undue burdens on the entities to which it applies. We seek comment on whether it is sufficient to adopt this rule without specifying federal guidelines for determination of what constitutes bona fide research or other lawful use. We

seek comment on whether this statutory provision imposes an undue burden on E-rate beneficiaries, particularly on small entities, and if so, we seek comment on the least burdensome method of implementing this provision. For example, we note that the *CIPA Order* discussed leaving these determinations to local communities because they would be most knowledgeable about the varying circumstances of schools or libraries within those communities. We believe that our proposed rules are consistent with that position. We also seek comment on any other methods of implementing this statutory provision.

13. Fifth, we propose to revise §§ 54.520(c)(1)(iii)(B), (2)(iii)(B), and (3)(i)(B) to clarify that it is only in the first year of participation in the E-rate program that an entity may certify that it will complete all CIPA requirements by the next funding year and still receive funding for that year, as adopted in the *CIPA Order*. The text of the existing rules contains an option for an entity to certify that it will come into compliance with the CIPA requirements by the next funding year, but does not specify that this certification option is only applicable to entities that are applying for E-rate discounts for the first time. We seek comment on this proposal.

14. Sixth, we propose to add a rule provision to require local determination of what matter is inappropriate for minors. Among other things, the statute states that a determination regarding what matter is inappropriate for minors shall be made by the school board, local educational agency, library or other authority responsible for making the determination. Although this is mandated by the statute, it is not currently in the Commission's rules. We seek comment on this proposal. We also seek comment on whether this requirement will be burdensome, particularly for small entities. If so, we seek comment on how to reduce this statutorily mandated burden.

15. Seventh, we propose to add a rule provision requiring each Internet safety policy that is adopted pursuant to section 254(l) of the Act to be made available to the Commission upon request by the Commission. Although this requirement is mandated by the statute, it is not currently in the Commission's rules. We seek comment on this proposal. We also seek comment on the manner in which the Internet safety policy should be made available to the Commission and on the timing of such response. We also seek comment on the burdens that this requirement may impose on respondents,

particularly on small entities, and on how the burdens may be reduced.

16. Finally, we propose to add a rule provision requiring public notice and hearing to address any proposed Internet safety policy adopted pursuant to CIPA. Although this is mandated by the statute and was discussed in the *CIPA Order*, there is no provision addressing this issue in the existing rules. As discussed in the *CIPA Order*, this public notice and hearing requirement only applies to entities that have not already provided such notice and hearing relating to an Internet safety policy and technology protection measure. We seek comment on this proposal.

### Procedural Matters

#### *Initial Regulatory Flexibility Act Certification*

17. The Regulatory Flexibility Act (RFA), see 5 U.S.C. 603, requires that an agency prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." See 5 U.S.C. 605(b). The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." 5 U.S.C. 601(6). In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. 5 U.S.C. 601(3). A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). 15 U.S.C. 632.

13. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the notice of proposed rulemaking (NPRM). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM. The Commission will send a copy of this NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the NPRM (or summary thereof) will be published in the **Federal Register**.

## 1. Need for, and Objectives of, the Proposed Rules

19. In the NPRM, we seek comment on revising the Commission's rules to add a new certification for elementary and secondary schools that have computers with Internet access and receive discounts under the E-rate program, pursuant to the mandate of the Protecting Children in the 21st Century Act. Such action is necessary to comply with the Protecting Children in the 21st Century Act.

## 2. Legal Basis

20. The legal basis for the NPRM is contained in sections 1, 4(i), 201 through 205, 214, 254, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201-205, 214, 254, and 403, and § 1.411 of the Commission's rules, 47 CFR 1.411.

## 3. Description and Estimate of the Number of Small Entities to Which Rules May Apply

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

22. The Commission has determined that the group of small entities directly affected by the rules herein includes eligible schools and libraries. Further descriptions of these entities are provided below.

23. *Small Businesses.* Nationwide, there are a total of approximately 22.4 million small businesses according to SBA data.

24. *Small Organizations.* Nationwide, there are approximately 1.6 million small organizations.

25. *Small Governmental Jurisdictions.* The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States. We estimate that, of this total, 84,377 entities were "small

governmental jurisdictions." Thus, we estimate that most governmental jurisdictions are small.

26. As noted, "small entity" includes non-profit and small government entities. Under the schools and libraries universal service support mechanism, which provides support for elementary and secondary schools and libraries, an elementary school is generally "a non-profit institutional day or residential school that provides elementary education, as determined under state law." A secondary school is generally defined as "a non-profit institutional day or residential school that provides secondary education, as determined under state law," and not offering education beyond grade 12. For-profit schools and libraries, and schools and libraries with endowments in excess of \$50,000,000, are not eligible to receive discounts under the program, nor are libraries whose budgets are not completely separate from any schools. Certain other statutory definitions apply as well. The SBA has defined for-profit, elementary and secondary schools and libraries having \$6 million or less in annual receipts as small entities. In funding year 2007 approximately 105,500 schools and 10,950 libraries received funding under the schools and libraries universal service mechanism. Although we are unable to estimate with precision the number of these entities that would qualify as small entities under SBA's size standard, we estimate that fewer than 105,500 schools and 10,950 libraries might be affected annually by our action, under current operation of the program.

## 4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

27. Schools and libraries that have computers with Internet access must certify that they have in place certain Internet safety policies and technology protection measures in order to be eligible for E-rate discounts for Internet access and internal connection services. Pursuant to the mandate in the Protecting Children in the 21st Century Act, the NPRM proposes to revise § 54.520(c)(i) of the Commission's rules to add a provision that a school's Internet safety policy must include educating minors about appropriate online behavior, including interacting with other individuals on social networking websites and in chat rooms and cyberbullying awareness and response.

28. In addition, this NPRM revises certain rules to more accurately reflect the provisions of the Act with regard to certifications made pursuant to the

Children's Internet Protection Act (CIPA). Specifically, the rule revisions that may affect small entities require: (1) Schools and libraries to enforce the operation of technology protection measures during use of computers by minors and adults; (2) schools and libraries to disable technology protection measures to enable access for bona fide research or other lawful purpose; (3) local determination of what matter is inappropriate for minors; (4) schools and libraries to make available to the Commission, upon request by the Commission, any Internet safety policy that is adopted pursuant to section 254(l) of the Act; and (5) schools and libraries to provide public notice and hearing to address any proposed Internet safety policy that is adopted pursuant to CIPA.

## 5. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

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

30. With regard to the new certification requirements pursuant to the Protecting Children in the 21st Century Act, we do not believe that there will be significant economic impact on small entities. Currently, schools and libraries file the FCC Form 486 to certify their compliance with the requirements regarding Internet safety policies and technology protection measures. Because schools and libraries will continue to use the same FCC Form 486 to certify their compliance with these requirements, there will be no additional reporting requirements.

31. With regard to the remaining rule provisions, we believe that several of the rule revisions will have no economic impact on small entities because they merely clarify existing definitions and existing requirements. For example, the revisions regarding the definitions of elementary and secondary schools did not change the definitions, but merely clarified that the same definitions were utilized throughout the

rules, or codified existing statutory definitions.

32. Several other rule revisions will have little economic impact on small entities because schools and libraries have already implemented these measures. We acknowledge that the existing rules do not contain provisions requiring schools and libraries to enforce the operation of technology protection measures during use of computers by minors and adults or to provide public notice and hearing to address any proposed Internet safety policy that is adopted pursuant to CIPA. However, as a practical matter, current E-rate beneficiaries have already implemented these requirements, even though these statutory requirements are not specifically stated in the text of the Commission's rules. Schools and libraries would have been unable to make the proper CIPA certifications unless the technology protection measures have been enforced during computer use by minors and adults. In addition, the requirement to provide public notice and hearing was discussed extensively in the *CIPA Order* even though an implementing rule was not adopted.

33. The requirement that schools and libraries may disable technology protection measures to enable access for bona fide research or other lawful purpose may impose a burden on small entities. As stated in the NPRM, there are concerns about the difficulty of school or library staff determining whether an adult user was engaging only in bona fide research or other lawful purposes. Accordingly, the NPRM seeks comment on ways to implement this statutory mandate while keeping the burdens on entities at a minimum. The NPRM also seeks comment on ways to implement the rule revision requiring local determination of what matter is inappropriate for minors while minimizing burdens. Finally the NPRM proposes to require, pursuant to the statute, that schools and libraries make available to the Commission, upon request by the Commission, any Internet safety policy that is adopted pursuant to section 254(l) of the Act. Because this may have an impact on small economic entities, the NPRM proposes several methods of making the Internet safety policy available to the Commission, as well as seeking comment on ways to reduce this burden on respondents.

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

34. None.

#### Ex Parte Presentations

35. This proceeding shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules, 47 CFR 1.1200 through 1.1216. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. 47 CFR 1.1206(b)(2). Other requirements pertaining to oral and written presentations are set forth in § 1.1206(b) of the Commission's rules. 47 CFR 1.1206(b).

#### C. Comment Filing Procedures

36. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

37. *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/> or the Federal eRulemaking Portal: <http://www.regulations.gov>.

38. *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

39. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

40. Effective December 28, 2009, all hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW-A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. **Please Note:** Through December 24, 2009, the Commission's contractor will receive

hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. This filing location will be permanently closed after December 24, 2009. The filing hours at both locations are 8 a.m. to 7 p.m.

41. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

42. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW., Washington DC 20554.

43. In addition, one copy of each comment or reply comment must be sent to Charles Tyler, Telecommunications Access Policy Division, Wireline Competition Bureau, 445 12th Street, SW., Room 5-A452, Washington, DC 20554; e-mail: [Charles.Tyler@fcc.gov](mailto:Charles.Tyler@fcc.gov).

44. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

#### Ordering Clauses

45. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 4(i), 201-205, 214, 254, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201-205, 214, 254, and 403, and § 1.411 of the Commission's rules, 47 CFR 1.411, this notice of proposed rulemaking is adopted.

46. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this notice of proposed rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

#### List of Subjects in 47 CFR Part 54

Communications common carriers. Health facilities. Infants and children. Libraries, Reporting and recordkeeping requirements. Schools. Telecommunications, Telephone.

Federal Communications Commission.

Marlene H. Dortch,  
Secretary.

#### Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 54 to read as follows:

PART 54—UNIVERSAL SERVICE

1. The authority citation for part 54 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 201, 205, 214, and 254 unless otherwise noted.

2. Amend § 54.500 by revising paragraphs (c) and (k) to read as follows:

§ 54.500 Terms and definitions.

(c) Elementary school. An "elementary school" means an elementary school as defined in 20 U.S.C. 7801(18), a non-profit institutional day or residential school, including a public elementary charter school, that provides elementary education, as determined under state law.

(k) Secondary school. A "secondary school" means a secondary school as defined in 20 U.S.C. 7801(38), a non-profit institutional day or residential school that provides secondary education, as determined under state law. A secondary school does not offer education beyond grade 12.

3. Amend § 54.501 by revising paragraph (b)(1) to read as follows:

§ 54.501 Eligibility for services provided by telecommunications carriers.

(b) Schools. (1) Only schools meeting the statutory definition of "elementary school" or "secondary school" as defined in § 54.500 paragraphs (c) or (k), and not excluded under paragraphs (b)(2) or (b)(3) shall be eligible for discounts in telecommunications and other supported services under this part.

4. Amend § 54.504 by revising paragraph (b)(2)(i) and paragraph (c)(1)(i) to read as follows:

§ 54.504 Requests for services.

- (b) \* \* \*
(2) \* \* \*

(i) The schools meet the statutory definition of elementary or secondary schools in § 54.500 paragraphs (c) or (k) of this section, do not operate as for-profit businesses, and do not have endowments exceeding \$50 million.

- (c) \* \* \*
(1) \* \* \*

(i) The schools meet the statutory definition of elementary or secondary schools in § 54.500 paragraphs (c) or (k) of this section, do not operate as for-profit businesses, and do not have endowments exceeding \$50 million.

5. Amend § 54.520 by revising paragraphs (a)(1), (a)(4), (c)(1)(i), (c)(1)(iii)(B), (c)(2)(i), (c)(2)(iii)(B), (c)(3)(i)(B), and by adding paragraphs (c)(4), (c)(5), and (h) to read as follows:

§ 54.520 Children's Internet Protection Act certifications required from recipients of discounts under the federal universal service support mechanism for schools and libraries.

(a) \* \* \*
(1) School. For the purposes of the certification requirements of this rule, school means school, school board, school district, local education agency or other authority responsible for administration of a school.

- (4) Statutory definitions.
(i) The term "minor" means any individual who has not attained the age of 17 years.
(ii) The term "obscene" has the meaning given such term in 18 U.S.C. 1460.
(iii) The term "child pornography" has the meaning given such term in 18 U.S.C. 2256.
(iv) The term "harmful to minors" means any picture, image, graphic image file, or other visual depiction that—
(A) Taken as a whole and with respect to minors, appeals to a prurient interest in nudity, sex, or excretion;
(B) Depicts, describes, or represents, in a patently offensive way with respect to what is suitable for minors, an actual or simulated sexual act or sexual contact, actual or simulated normal or perverted sexual acts, or a lewd exhibition of the genitals; and
(C) Taken as a whole, lacks serious literary, artistic, political, or scientific value as to minors.
(v) The terms "sexual act" and "sexual contact" have the meanings given such terms in 18 U.S.C. 2246.
(vi) The term "technology protection measure" means a specific technology that blocks or filters Internet access to the material covered by a certification under paragraph (c)(1)(i) of this section.

(c) \* \* \*
(1) \* \* \*
(i) The Internet safety policy adopted and enforced pursuant to 47 U.S.C. 254(h) must include a technology protection measure that protects against Internet access by both adults and minors to visual depictions that are obscene, child pornography, or, with respect to use of the computers by minors, harmful to minors. The technology protection measure must be enforced during use of computers with

Internet access, although an administrator, supervisor, or other person authorized by the certifying authority under paragraph (c)(1) of this section may disable the technology protection measure concerned, during use by an adult, to enable access for bona fide research or other lawful purpose. This Internet safety policy must also include monitoring the online activities of minors and must educate minors about appropriate online behavior, including interacting with other individuals on social networking websites and in chat rooms and cyberbullying awareness and response.

(iii) \* \* \*
(B) Pursuant to the Children's Internet Protection Act, as codified at 47 U.S.C. 254(h) and (l), the recipient(s) of service represented in the Funding Request Number(s) on this Form 486, for whom this is the first year of participation in the federal universal service support mechanism for schools and libraries, is (are) undertaking such actions, including any necessary procurement procedures, to comply with the requirements of CIPA for the next funding year, but has (have) not completed all requirements of CIPA for this funding year.

(2) \* \* \*
(i) The Internet safety policy adopted and enforced pursuant to 47 U.S.C. 254(h) must include a technology protection measure that protects against Internet access by both adults and minors to visual depictions that are obscene, child pornography, or, with respect to use of the computers by minors, harmful to minors. The technology protection measure must be enforced during use of computers with Internet access, although an administrator, supervisor, or other person authorized by the certifying authority under paragraph (c)(1) of this section may disable the technology protection measure concerned, during use by an adult, to enable access for bona fide research or other lawful purpose.

(iii) \* \* \*
(B) Pursuant to the Children's Internet Protection Act, as codified at 47 U.S.C. 254(h) and (l), the recipient(s) of service represented in the Funding Request Number(s) on this Form 486, for whom this is the first year of participation in the federal universal service support mechanism for schools and libraries, is (are) undertaking such actions, including any necessary procurement procedures, to comply with the

requirements of CIPA for the next funding year, but has (have) not completed all requirements of CIPA for this funding year.

\* \* \* \* \*

(3) \* \* \*

(i) \* \* \*

(B) Pursuant to the Children's Internet Protection Act, as codified at 47 U.S.C. 254(h) and (l), the recipient(s) of service under my administrative authority and represented in the Funding Request Number(s) for which you have requested or received Funding Commitments, and for whom this is the first year of participation in the federal universal service support mechanism for schools and libraries, is (are) undertaking such actions, including any necessary procurement procedures, to comply with the requirements of CIPA

for the next funding year, but has (have) not completed all requirements of CIPA for this funding year.

\* \* \* \* \*

(4) *Local determination of content.* A determination regarding what matter is inappropriate for minors shall be made by the school board, local educational agency, library, or other authority responsible for making the determination. No agency or instrumentality of the United States Government may establish criteria for making such determination; review the determination made by the certifying school, school board, local educational agency, library, or other authority; or consider the criteria employed by the certifying school, school board, local educational agency, library, or other authority in the administration of the

schools and libraries universal service support mechanism.

(5) *Availability for review.* Each Internet safety policy adopted pursuant to 47 U.S.C. 254(l) shall be made available to the Commission, upon request for the Commission, by the school, school board, local educational agency, library, or other authority responsible for adopting such Internet safety policy for purposes of the review of such Internet safety policy by the Commission.

\* \* \* \* \*

(h) *Public notice; hearing.* A school or library shall provide reasonable public notice and hold at least one public hearing or meeting to address the proposed Internet safety policy.

[FR Doc. E9-30323 Filed 1-15-10; 8:45 am]

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# Notices

Federal Register

Vol. 75, No. 11

Tuesday, January 19, 2010

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## AFRICAN DEVELOPMENT FOUNDATION

### African Development Foundation, Board of Directors Meeting

**TIME:** Tuesday, January 26, 2010, 8:30 a.m. to 1 p.m.

**PLACE:** African Development Foundation, Conference Room, 1400 I Street, NW., Suite 1000, Washington, DC 20005.

**DATES:** Tuesday, January 26, 2010.

**STATUS:**

1. Open session, Tuesday, January 26, 2010, 8:30 a.m. to 12 a.m.; and
2. Closed session, Tuesday, January 26, 2010, 12 p.m. to 1 p.m.

Due to security requirements and limited seating, all individuals wishing to attend the open session of the meeting must notify Michele M. Rivard at (202) 673-3916 or [mrivard@usadf.gov](mailto:mrivard@usadf.gov) of your request to attend by 5 p.m. on Thursday, January 21, 2010.

**Lloyd O. Pierson,**  
*President & CEO, USADF.*

[FR Doc. 2010-787 Filed 1-15-10; 8:45 am]

**BILLING CODE 6117-01-P**

## DEPARTMENT OF AGRICULTURE

### Submission for OMB Review; Comment Request

January 12, 2010.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c)

ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### Farm Service Agency

**Title:** 7 CFR Part 772, Servicing Minor Program Loans.

**OMB Control Number:** 0560-0230.  
**Summary of Collection:** Section 331 and 335 of the Consolidated Farm and Rural Development Act, authorizes the Secretary of Agriculture to grant releases from personal liability where security property is transferred to approved applicants who, under agreement, assume the outstanding secured indebtedness. Section 335 provides servicing authority for real estate security; operation or lease of realty, disposition of surplus property; conveyance of complete interest of the United States; easements; and condemnations. The information is collected from Farm Service Agency (FSA) Minor Program borrowers who may be individual farmers or farming partnerships, associations, or corporations.

**Need and Use of the Information:** FSA will collect information related to a program benefit recipient or loan

borrower requesting action on security they own, which was purchased with FSA loan funds, improved with FSA loan funds or has otherwise been mortgaged to FSA to secure a Government loan. The information collected is primarily financial data, such as borrower asset values, current financial information and public use and employment data. Failure to collect this information will result in rejection of the borrower's request.

**Description of Respondents:** Farms; Individuals or households; Business or other-for-profit; Not-for-profit institutions; State, Local and Tribal Government.

**Number of Respondents:** 58.  
**Frequency of Responses:** Reporting: Annually.

**Total Burden Hours:** 37.

**Ruth Brown,**

*Departmental Information Collection Clearance Officer.*

[FR Doc. 2010-767 Filed 1-14-10; 8:45 am]

**BILLING CODE 3410-05-P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Green Mountain National Forest; Vermont; Deerfield Wind Project

**AGENCY:** Forest Service, USDA.

**ACTION:** Revision, notice of intent to prepare a supplemental draft environmental impact statement.

**SUMMARY:** The Forest Service is processing an application for a special use authorization from Deerfield Wind, LLC for the installation and operation of wind turbines on National Forest System (NFS) lands managed by the Green Mountain National Forest (GMNF). This notice notifies the public of the intent to complete and publish a supplemental draft environmental impact statement (SDEIS).

**DATES:** The SDEIS is expected in July 2010 and the final environmental impact statement (FEIS) and Record of Decision (ROD) is expected in December 2010.

**FOR FURTHER INFORMATION CONTACT:** Bob Bayer, Project Coordinator, Manchester Ranger District, USDA Forest Service, 2538 Depot Street, Manchester Center, VT 05255; 802-362-2307 ext. 218; e-mail: [rbayer@fs.fed.us](mailto:rbayer@fs.fed.us).

**SUPPLEMENTARY INFORMATION:** The original notice of intent to prepare the Deerfield Wind Project EIS was published in the **Federal Register** on July 15, 2005 (Vol. 70, No. 135, page 409750). A revised notice of intent was published in the **Federal Register** on September 27, 2007 (Vol. 72, No. 187, page 54893) to notice the public of changes to the project timeline, minor modifications to the proposed action, and asked for comments on those modifications. A draft environmental impact statement (DEIS) was released to the public in September 2008. A Notice of Availability (NOA) for the Deerfield Wind Project DEIS was published in the **Federal Register** on October 3, 2008 (Vol. 73, No. 193, page 57620) requesting comments on the DEIS through November 28, 2008.

Upon release of the SDEIS, the forest will publish a NOA in the **Federal Register** and take comments on the SDEIS. The comment period dates will be published in the NOA.

#### Responsible Official

At the present time, Jerri Marr, Acting Forest Supervisor, Green Mountain and Finger Lakes National Forests, 231 North Main Street, Rutland, VT 05701-2417, is the Responsible Official. The forest expects to fill the Forest Supervisor position on a permanent basis within the next two to three months. That person would become the Responsible Official for the project.

Dated: January 11, 2010.

Jerri Marr,

Forest Supervisor.

[FR Doc. 2010-652 Filed 1-15-10; 8:45 am]

BILLING CODE 3410-11-M

#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

[Docket No. APHIS-2008-0059]

##### ArborGen, LLC; Availability of an Environmental Assessment for Controlled Release of a Genetically Engineered Eucalyptus Hybrid

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** We are reopening the comment period for an environmental assessment for a proposed controlled field release of a genetically engineered clone of a *Eucalyptus* hybrid. This action will allow interested persons additional time to prepare and submit

comments on the revised environmental assessment.

**DATES:** We will consider all comments that we receive on or before February 18, 2010.

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0059>) to submit or view comments and to view supporting and related materials available electronically.

- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS-2008-0059, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2008-0059.

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

**Other Information:** Additional information about APHIS and its programs is available on the Internet at (<http://www.aphis.usda.gov>).

**FOR FURTHER INFORMATION CONTACT:** Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-7324. To obtain copies of the environmental assessment, contact Ms. Cynthia Eck at (301) 734-0667; email: ([cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov)).

**SUPPLEMENTARY INFORMATION:** On June 3, 2009, APHIS published a notice<sup>1</sup> in the **Federal Register** (74 FR 26648-26649, Docket No. APHIS-2008-0059) announcing the availability of an environmental assessment for public review and comment for a proposed controlled field release of a genetically engineered clone of a *Eucalyptus* hybrid.

Comments on the environmental assessment were required to be received on or before July 6, 2009. Commenters noted that one of the documents cited in the environmental assessment, a U.S.

<sup>1</sup> To view the notice, the environmental assessment, and the comments we have received, go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0059>).

Forest Service assessment of hydrological impacts from *Eucalyptus*, was not available for review and requested that the document be made available and the comment period for the environmental assessment extended. APHIS has amended the environmental assessment to include the Forest Service document and other relevant information, and is reopening the comment period on Docket No. APHIS-2008-0059 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between July 7, 2009 (the day after the close of the original comment period), and the date of this notice.

**Authority:** 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 6<sup>th</sup> day of January 2010.

Cindy Smith

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010-762 Filed 1-15-10; 2:16 pm]

BILLING CODE 3410-34-S

#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

[Docket No. APHIS-2006-0172]

##### Interstate Movement of Garbage from Hawaii; Availability of an Environmental Assessment

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

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

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment relative to a request to allow the interstate movement of garbage from Hawaii to a landfill in the State of Washington. The environmental assessment documents our review and analysis of the environmental impacts associated with, and alternatives to, the movement of palletized or containerized baled municipal solid waste to three existing ports on the Columbia River via barge and the transfer and transportation of the waste via truck or rail to the landfill. We are making the assessment available to the public for review and comment.

**DATES:** We will consider all comments that we receive on or before February 18, 2010.

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0172>) to submit or view comments and to view supporting and related materials available electronically.

- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS-2006-0172, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2006-0172.

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

**Other Information:** Additional information about APHIS and its programs is available on the Internet at (<http://www.aphis.usda.gov>).

**FOR FURTHER INFORMATION CONTACT:** Ms. Shannon Hamm, Associate Deputy Administrator, Policy and Program Development, APHIS, 4700 River Road Unit 20, Riverdale, MD 20737-1231; (301) 734-4957.

#### SUPPLEMENTARY INFORMATION:

##### Background

The importation and interstate movement of garbage is regulated by the Animal and Plant Health Inspection Service (APHIS) under 7 CFR 330.400 and 9 CFR 94.5 (referred to below as the regulations) in order to protect against the introduction into and dissemination within the United States of plant and animal pests and diseases.

In November 2009, APHIS received a revised petition from Hawaiian Waste Systems, LLC, to transport 150,000 tons of municipal solid waste (MSW) annually in plastic airtight bales that are either palletized or containerized in 20- and 40-foot shipping containers from the State of Hawaii to Roosevelt Regional Landfill in Washington State by any of three methods:

- Barge to Teevin Brother Terminal in Rainier, WA, followed by truck or rail transportation;

- Barge to the Port of Longview, WA, followed by truck or rail transportation; or

- Barge to the Port of Portland, OR, followed by truck or rail transportation.

APHIS had previously prepared a regional programmatic environmental assessment (REA) titled "Regional Movement of Plastic-baled Municipal Solid Waste from Hawaii to Washington, Oregon, and Idaho: Environmental Assessment" (February 2008).<sup>1</sup> The REA evaluated the environmental effects of transporting baled MSW by tug boat and barge across the Pacific Ocean and up the Columbia River. The REA included a general analysis of landfills that could accept MSW in the various States as well as an analysis of environmental effects of transportation via rail or truck from a port on the Columbia River to a MSW landfill. A finding of no significant impact for the February 2008 REA was issued by APHIS in June 2008.

The environmental assessment that we are making available through this notice, titled "Site Specific Environmental Assessment for Hawaiian Waste Management Systems, LLC to Transport Municipal Solid Waste from Hawaii to Roosevelt Regional Landfill" (December 2009), is tiered to the REA and analyzes the site-specific environmental effects of Hawaiian Waste Systems' revised petition.

We are making the environmental assessment available to the public for review and comment. We will consider all comments that we receive during the comment period (see **DATES** at the beginning of this notice). The environmental assessment may be viewed on the Internet on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the documents by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the document when requesting copies.

The environmental assessment has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

<sup>1</sup> To view the REA and finding of no significant impact, go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0070>).

Done in Washington, DC, this 13<sup>th</sup> day of January 2010.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010-944 Filed 1-15-10; 1:08 pm]

BILLING CODE 3410-34-S

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Plan Revision for Prescott National Forest, Yavapai and Coconino Counties, AZ

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of intent to revise Land and Resource Management Plan.

**SUMMARY:** As directed by the National Forest Management Act, the USDA Forest Service is revising the Prescott National Forest Land and Resource Management Plan (Forest Plan) and will also prepare an environmental impact statement for this revised plan. This notice briefly describes the nature of the decision to be made, the need for change and proposed action, and information concerning public participation. It also provides estimated dates for filing the environmental impact statement, the names and addresses of the responsible agency official, and the individuals who can provide additional information. Finally, this notice briefly describes the applicable planning rule and how work done on the plan revision under the 2008 planning rule will be used or modified for completing this plan revision.

The Prescott National Forest revised Forest Plan will supersede the land management plan previously approved by the Regional Forester on August 4, 1987, and amended 17 times from 1988 to 2008. Four of those amendments addressed project specific needs and the balance addressed programmatic needs. Programmatic needs for amendment included direction for habitat conservation for selected species, designation of a botanical area, treatment of noxious weeds, changes in utility corridor locations, clarification of grazing capacity, and adjustments to Prescott National Forest travel management policy. This amended Plan will remain in effect until the revision takes effect.

**DATES:** Comments concerning the need for change provided in this notice will be most useful in the development of the draft revised plan and draft environmental impact statement if received by February 15, 2010. The



agency expects to release a draft revised plan and draft environmental impact statement for formal comment near the end of calendar year 2010 and a final revised plan and final environmental impact statement near the end of calendar year 2011.

**ADDRESSES:** Send written comments to: Prescott National Forest, Attn: Forest Plan Revision Team, 344 South Cortez Street, Prescott, Arizona 86303. Comments may also be sent via e-mail by using the "Contact Us" page on the Prescott National Forest planning Web site: <http://www.fs.fed.us/r3/prescott/plan-revision/get-involved.shtml>.

**FOR FURTHER INFORMATION CONTACT:** Sally Hess-Samuels, Forest Planner, Prescott National Forest, 344 South Cortez Street, Prescott, Arizona 86303, [shesssamuelson@fs.fed.us](mailto:shesssamuelson@fs.fed.us), 928-443-8216. Information on this revision is also available at Prescott National Forest revision Web site: <http://www.fs.fed.us/r3/prescott/plan-revision/hindex.shtml>.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339 between 8 AM and 8 PM, Eastern Time Monday through Friday.

#### **SUPPLEMENTARY INFORMATION:**

#### **Name and Address of the Responsible Official**

The responsible official is Corbin Newman, Regional Forester, Southwestern Region, 333 Broadway SE, Albuquerque, NM 87102.

#### **Nature of the Decision To Be Made**

The Forest Plan provides guidance for all resource management activities on the Prescott National Forest. Approval of the revised Forest Plan will result in the following plan components to guide management for the next 10 to 15 years:

- Goals/desired conditions;
- Objectives;
- Forest-wide standards and guidelines;
- Management area desired conditions, standards, and guidelines;
- Suitability of lands for timber production, grazing, and recreation opportunities;
- Monitoring and evaluation requirements; and
- Recommendations may be made for special areas, such as Research Natural Areas, or areas that can only be designated by statute, such as Wilderness.

Goals/desired conditions provide a description of desired outcomes of forest management. Objectives provide projections of measurable outcomes intended to promote achievement of

Forest Plan goals/desired conditions. Forest-wide standards and guidelines provide management direction and guidance that is applicable across the Prescott National Forest. Management Area desired conditions, standards, and guidelines provide direction that applies to specific geographic areas within the Prescott National Forest. Identification of characteristics of lands where timber production, grazing, and recreation opportunities are suitable provides integration between particular uses and desired conditions and objectives for areas on the National Forest. Monitoring and evaluation indicates whether areas are trending toward goals/desired conditions so that needed adjustments can be made in the future. Special areas are places or areas within the National Forest System designated because of their unique or special characteristics. Some can be designated by the responsible official, such as a Botanical Area. Others, such as Wilderness or Wild and Scenic River designations, are recommended for designation by the responsible official, but Congressional act designates.

An environmental impact statement will be prepared that informs the Regional Forester so that he can decide which alternative set of plan components best meets the need to achieve quality land management under the sustainable multiple-use management concept and to meet the diverse needs of people, while protecting the resources of the Prescott National Forest, as required by the National Forest Management Act (NFMA) and the Multiple Use Sustained Yield Act.

The scope of this decision is limited to revisiting those portions of the current Forest Plan that need modification, correction, or creation of direction that is lacking. We expect to focus on areas identified as being most critically in need of change. Identification of the types of decisions that will not be made within the plan can be as important as knowing the decisions to be made. The authorization of project-level activities on the forests is not a decision made in the Forest Plan but occurs through subsequent project-specific decision-making. Designation of routes, trails, and areas for motorized vehicle travel has been documented in the 2009 Motorized Vehicle Use Map. Adjustments to the routes shown on the map are expected to be addressed in separate analyses and were not identified as a Need for Change in the Forest Plan. Some issues (e.g., hunting regulations), although important, are beyond the authority or control of the Prescott National Forest and will not be

considered. In addition, some issues, such as wild and scenic river suitability determinations, may not be undertaken at this time, but addressed later as a future Forest Plan amendment.

#### **Need for Change and Proposed Action**

The current Forest Plan is over 20 years old. Changes have taken place during that time based on changed economic, social, and ecological conditions; new policies and priorities; and new information based on monitoring and scientific research. Changes made during plan revision will be focused on three priority needs for change and two secondary needs for change. The three priority needs are (1) restore vegetation, structure, composition, and desired characteristics of fire to selected ecosystems, while responding to citizen concerns related to smoke emissions; (2) retain or improve watershed integrity to provide desired water quality, quantity and timing of delivery; and (3) provide sustainable and diverse recreation experiences that consider population demographic characteristics, reflect desires of local communities, avoid overcrowding and user conflicts, and minimize resource damage. Two other secondary needs were selected to be addressed with Forest Plan components and will likely be addressed as parts of the priority needs for change. They are: (a) Provide desired habitat for native fish species; and (b) enhance the value of open space provided by the Prescott National Forest by defining visual character within areas near or viewed by those in local communities. These needs are not adequately addressed in the current Forest Plan. Priority and secondary needs for change and means of addressing those needs during plan revision are described below:

1. Restore vegetation, structure, composition, and desired characteristics of fire to selected ecosystems, while responding to citizen concerns related to smoke emissions. In order to improve ecological health and sustainability within several plant communities, vegetation structure (arrangement of vegetation) and composition (types of vegetation species) need to be modified to more closely resemble the range of conditions that historically occurred.

The revised Forest Plan will define desired vegetative characteristics including: Desired species composition and vegetative transitions due to disturbances; structural characteristics such as spacing of shrub patches or tree groups and density of trees; and disturbance patterns such as frequency, severity, intensity, size and seasonality of fire. By trending toward defined

desired conditions, the following situations will begin to be addressed: (a) Risk of severe uncharacteristic wildfires that damage soils and impact human health and safety, (b) changes in ecosystems that could affect diversity of plant and animal species such as the spread of invasive plant species, (c) infrequent fire occurrences that do not emulate historic characteristics within some ecosystems. Objectives will focus attention on high priority areas for restoration activities such as thinning, planned burning, or treatment of invasive plant species. Guidelines will provide direction for use of restoration methods other than traditional thinning and planned burns in areas where possible impacts to species are not acceptable. In collaboration with citizens, Management Area direction will identify areas where fuel reduction activities other than burning will be emphasized, such as near structures or close to communities.

2. Retain or Improve watershed integrity to provide desired water quality, quantity, and timing of delivery. Watershed integrity is the completeness of watershed function in providing water quality, quantity and timing of delivery. It is influenced by soil function, biological function and geomorphology. Vegetative structure and composition, disturbance regimes and recreation activities all can affect watershed integrity.

The revised Forest Plan will describe desired characteristics of watersheds including: Soil and vegetation characteristics in uplands and in areas near streams, water bodies, and ground water dependent ecosystems; desired water quality characteristics and other characteristics of healthy watersheds. Standards and guidelines will be developed for sensitive areas to provide guidance for recreational activities, vegetation utilization, and vegetative ground cover within those areas. Addressing this need will move toward maintaining water quality and quantity for municipal watersheds and for aquatic and riparian species habitat, and will provide timing of delivery that is commensurate with healthy soil, biological function, and natural geomorphology.

3. Provide sustainable and diverse recreation experiences that consider population demographic characteristics, reflect desires of local communities, avoid overcrowding and user conflicts, and minimize resource damage. Providing sustainable recreation opportunities was the number one concern at public meetings held early in 2009. With increasing populations and numbers of visitors to the Prescott

National Forest, conflicts between types of activities, overcrowding, and over-use leading to resource impacts need to be addressed.

Numbers of recreationists on the Prescott National Forest have increased in recent years, both from increases in local population and from influx of visitors from the Phoenix metropolitan area. This has increased the potential for creating conflicts among all recreationists and leads to unmet recreational experience expectations. The increase in recreational use also interacts with ecosystems such as causing changes in habitat, wearing away vegetation, and spreading seeds of non-native plant species to new locations.

The revised Forest Plan will describe forest-wide desired conditions for recreation experiences and for interactions between recreational activities and ecosystems. Management area boundaries will be adjusted to reflect geographically contiguous areas so that strategies can be developed to better respond to desires of people who reside in or feel connected to specific areas within the Prescott National Forest. Management area guidance will include description of goals/desired conditions as well as standards and guidelines to mitigate or help control conflicts between people and the environment or among recreationists. Addressing this need will help visitors know where to find the experience they desire and will better address impacts of recreation use.

Two secondary needs for change were selected to be addressed with Forest Plan components.

(a) Provide desired habitat for native fish species. Native fish and other aquatic species are in decline within several watersheds. Native aquatic species are no longer found in five watersheds that overlap with the Prescott National Forest. The Prescott National Forest can provide habitat and watershed characteristics that will support native fish species. The Forest could also cooperate with the State of Arizona in addressing control of non-native species.

Desired conditions will be developed that describe desired aquatic habitat including stream flows, vegetation, and water quality at a Forest-wide scale. Standards and guidelines will be developed to help aquatic characteristics trend toward desired conditions.

(b) Enhance the value of open space provided by the Prescott National Forest by defining the visual character within areas near or viewed by those in local communities. The high rate of

population growth within Yavapai County combined with limited lands for development sensitizes residents to land development, land exchange, and land use issues. The Prescott National Forest has an opportunity via the Forest Plan to ensure that scenic values are taken into consideration as population density is expected to increase on other ownerships. Defining the value of Prescott National Forest open space will help to display the benefit these lands play in local communities, should land exchange be proposed.

A new inventory of scenic values has been completed and desired conditions, standards, and guidelines will be developed based on scenic values of landscapes. Other Revision Changes. Some components of the current Forest Plan are still adequate and timely; these will be carried forward into the revised Forest Plan.

Other components of the current Forest Plan will be modified or removed, for reasons including: they describe a purely administrative or procedural function; they duplicate direction that can be found in existing law, regulation, or Forest Service policy; they are based on outdated policies, science, or information; or they include out-of-date terminology. In addition, some standards and guidelines in the existing Forest Plan: May be unnecessarily prescriptive about how to accomplish a project, instead of focusing on the project outcome; do not support attaining desired conditions or accomplishing objectives; or are duplicative. Finally, portions of monitoring and evaluation guidance in the current Forest Plan focus on outputs rather than on progress toward attainment of goals/desired conditions.

#### Public Involvement

The Prescott National Forest has taken a collaborative approach in preparation for Forest Plan Revision. Rather than sponsoring several public meetings focused on plan revision, we engaged citizens in planning and ongoing stewardship of the forest. This included inviting citizens to share their desires for the future and invent new ways to support and sustain stewardship. Methods used include human geographic mapping, gaining understanding of informal community networks, reaching out to informal community leaders, and encouraging development of community visions. More standard methods that were used included public meetings in February of 2009 to discuss needs for change, use of the Prescott National Forest Web page to provide information and offer feedback forms, and face to face and written

communication with tribal entities. Information gathered from the public as well as science-based assessments were used to determine the need for change identified above.

We will continue efforts to have meaningful consultation and collaboration with tribal nations on a government-to-government basis. The Prescott National Forest also wants to continue collaborative efforts with members of the public as well as federal and state agencies, local governments and private organizations.

Continued public participation at multiple meetings sponsored by local groups or multi-interest organizations will take place throughout the winter and spring of 2010 to develop the proposed plan and alternatives. Public meetings are expected during the summer of 2010 to integrate and share the results of these efforts. Dates, times and locations of these meetings will be posted on the Prescott National Forest planning Web site as well as via community bulletin boards, e-mail announcements, and through community networks. The information gathered will be combined with other feedback to refine needs for change, if necessary, develop the proposed plan, and prepare the draft environmental impact statement. Once a draft environmental impact statement is published, formal comment periods will allow for comment on the proposed plan and the content of the EIS.

At this time, the Prescott National Forest is seeking input on its needs for change and proposals to address those needs. In particular, did we miss any important issues or concerns?

It is important that reviewers provide their comments at such times and in such a way that they are useful to the Agency's preparation of the revised plan and the EIS. Therefore, comments on the needs for change will be most valuable if received by February 15, 2010 and should clearly articulate the reviewers' concerns. The submission of timely and specific comments can affect a reviewer's ability to participate in subsequent administrative or judicial review. At this time, we anticipate using the 2000 planning rule pre-decisional objection process (36 CFR 219.32) for administrative review. Comments received in response to this solicitation, including the names and addresses of those who comment will be part of the public record. Comments submitted anonymously will be accepted and considered.

#### Applicable Planning Rule

Preparation of the revised plan was underway when the 2008 National

Forest System land management planning rule was enjoined on June 30, 2009, by the *United States District Court for the Northern District of California (Citizens for Better Forestry v. 12 United States Department of Agriculture*, 632 F. Supp. 2d 968 (N.D. Cal. June 30, 2009)). On December 18, 2009 the Department reinstated the previous planning rule, commonly known as the 2000 planning rule in the **Federal Register (Federal Register**, Volume 74, No. 242, Friday, December 18, 2009, pages 67059 thru 67075). The transition provisions of the reinstated rule (36 CFR 219.35 and appendices A and B) allow use of the provisions of the National Forest System land and resource management planning rule in effect prior to the effective date of the 2000 Rule (November 9, 2000), commonly called the 1982 Planning Rule, to amend or revise plans. The Prescott National Forest has elected to use the provisions of the 1982 Planning Rule, including the requirement to prepare an environmental impact statement, to complete its plan revision. In December of 2009, we prepared the Analysis of the Management Situation (AMS) that summarized social, economic, and ecological conditions and trends in and around the Prescott National Forest, identified initial needs for change, integrated needs for change, and along with public input, identified where the current Forest Plan provides inadequate or, in some cases unnecessary guidance for the present and future. The AMS was prepared using the provisions of the 1982 planning rule and is found on the Prescott National Forest planning Web site (See section called **FOR FURTHER INFORMATION** near the beginning of this notice for web link).

Although the 2008 planning rule is no longer in effect, information gathered prior to the court's injunction is useful for completing the plan revision using the provisions of the 1982 planning rule. The Prescott National Forest has concluded that the analyses begun or developed during the plan revision process to date are appropriate for continued use in the revision process. The ongoing inventory and evaluation of potential wilderness areas and the Draft Upper Verde River Eligibility Report Update for the National Wild and Scenic River System have been underway since 2008, are consistent with appropriate provisions of the 1982 planning rule, and will be brought forward into this plan revision process. Other reference reports that were used to prepare the Analysis of the Management Situation are listed below and will be brought forward in the plan

revision process. Prior to the injunction of the 2008 Planning Rule, we had taken the following steps in preparation for plan revision:

- Identified characteristics of communities near and within Prescott National Forest boundaries. Worked toward understanding the citizens within the community by encouraging each community to develop a vision for the landscape to which they were connected. Community visions can be found on the Prescott National Forest planning Web page (For Web link, see section labeled **FOR FURTHER INFORMATION** near the beginning of this notice).
  - Developed an Ecological Sustainability Report (2009) to provide information on the biological and physical environment of the Prescott National Forest and surrounding area. The diversity of ecosystems and species known to occur within the Prescott National Forest were profiled along with identification of existing threats and associated risks to long-term sustainability of those ecosystems and species. Ecological concerns identified helped to highlight specific elements of the current Forest Plan that may need to be changed. The Ecological Sustainability Report (ESR) will continue to be used as a reference in the planning process as appropriate to those items in conformance with the 2000 planning rule transition language and 1982 planning rule provisions. This is scientific information and is not affected by the change of planning rule. This information will be updated with any new available information (For Web link, see section labeled **FOR FURTHER INFORMATION** near the beginning of this notice).
  - Described the social and economic relationship between the Prescott National Forest and surrounding communities, in the document titled Prescott National Forest Economic and Social Sustainability Assessment (2008). It assists us in understanding the relationship between National Forest lands and surrounding communities and acts as an aid in identifying specific elements of the current Forest Plan that may need to be changed. The Economic and Social Sustainability Report was completed in 2008, is not affected by the change in planning rule, and will continue to be used as a reference in the planning process. This information will be updated with any new available information (For Web link, see section labeled **FOR FURTHER INFORMATION** near the beginning of this notice).
- Several assessments, such as those listed below, were also prepared before the 2008 planning rule was enjoined.

Each includes scientific information and is not affected by the change of planning rule. In each case information may be updated with any new available information. Both documents can be found at the following location: <http://www.fs.fed.us/r3/plan-revision/lassess/pres/index.shtml>.

- The Socioeconomic Assessment of the Prescott National Forest (2005) provides information based on existing secondary data, for example, county and state economic data, U.S. Census data, and a wide range of data from Forest Service databases.

- Attitudes, Beliefs and Values Toward National Forest System Lands: The Prescott National Forest (2006) documented a focus group study that provides information about attitudes, beliefs and values related to forest management and resources. As necessary or appropriate, the above listed material will be further adjusted as part of the planning process using the provisions of the 1982 planning rule.

(Authority: 16 U.S.C. 1600–1614; 36 CFR 219.35 (74 FR 67073–67074))

Dated January 8, 2010.

**Alan Quan,**

*Forest Supervisor.*

[FR Doc. 2010–642 Filed 1–15–10; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Notice of Proposed New Fee Sites; Federal Lands Recreation Enhancement Act, (Title VIII, Pub. L. 108–447)

**AGENCY:** Wallowa-Whitman National Forest, USDA Forest Service.

**ACTION:** Notice of proposed new fee sites.

**SUMMARY:** The Wallowa-Whitman National Forest is planning to charge fees at eight recreation sites. All sites have recently been reconstructed or amenities are being added to improve services and experiences. Fees are assessed based on the level of amenities and services provided, cost of operation and maintenance, market assessment, and public comment. The fees listed are only proposed and will be determined upon further analysis and public comments. Funds from fees would be used for the continued operation and maintenance of these recreation sites.

Moss Springs Guard Station will be available for overnight rental. A financial analysis is being completed to determine the rental fee but may range between \$60 and \$80 per night. Rental

cabins offer a unique experience and are a widely popular offering on National Forests. Moss Springs Guard Station was restored in the late 1990s to maintain its historic value and provide overnight use by the public. It was taken off the rental system over five years ago; however, renewed interest by the public for rental cabins has increased. Fees would continue to help protect the historic integrity of the Moss Springs Guard Station.

The following campgrounds are currently a fee free site: Two Color, Umapine, Boulder Park, North Fork Catherine Creek Group Site, Spring Creek and Oregon Trail Interpretive Park. These sites provide campsites, fire rings, picnic tables and toilets. New toilets were installed at most of these developed recreation sites within the last five years. The new fee will address sanitation and safety concerns, and improve deteriorating resource conditions and recreation experiences. A financial analysis is being completed to determine fee rates. The proposed fee to help maintain these sites would range between \$8 and \$15 a campsite and \$3 per one additional vehicle per campsite.

The Elkhorn Crest Trailhead would be re-established as a fee site since amenities such as garbage service have been added and interpretive signing is being developed for this site. Recreation Passes such as the Northwest Forest Pass would cover day use fees for this trailhead. Northwest Forest Passes are \$5 for a daily pass and \$30 for an annual pass.

**DATES:** The Agency must receive public comments before July 30, 2010. New fees would begin after July 30, 2010 and contingent upon completion of certain improvements. The cabin rental would be available once a final decision is made and is listed with the National Recreation Reservation Service.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Mail:* Wallowa-Whitman National Forest, ATTN: Recreation Fee Proposals, P.O. Box 907, Baker City, Oregon 97814.
- *Hand Delivery/Courier:* Wallowa-Whitman National Forest, ATTN: Recreation Fee Proposals, 1550 Dewey Avenue, Baker City, Oregon 97814.
- *E-Mail:* [dermovick@fs.fed.us](mailto:dermovick@fs.fed.us).
- *Fax:* 541–523–1315.

**FOR FURTHER INFORMATION CONTACT:** Dan Ermovick, Forest Recreation Manager, 541–523–1250. Information about proposed fee changes can also be found on the Wallowa-Whitman National Forest Web site: <http://www.fs.fed.us/r6/wallowa-whitman/recreation/index.html>

**SUPPLEMENTARY INFORMATION:** The Federal Recreation Lands Enhancement

Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established.

Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

People wanting to rent Moss Springs Guard Station would need to do so through the National Recreation Reservation Service, at <http://www.reserveusa.com> or by calling 1–877–444–6777 when it becomes available.

Dated: January 8, 2010.

**Steven A. Ellis,**

*Forest Supervisor.*

[FR Doc. 2010–889 Filed 1–15–10; 8:45 am]

BILLING CODE 3410–11–P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

*Agency:* U.S. Census Bureau.

*Title:* Generic Clearance for MAF & TIGER Updating Activities.

*OMB Control Number:* 0607–0809.

*Form Number(s):* Various.

*Type of Request:* Extension of an approved collection.

*Burden Hours:* 11,283.

*Number of Respondents:* 212,892.

*Average Hours per Response:* 3 minutes.

*Needs and Uses:* The Census Bureau requests approval from the Office of Management and Budget (OMB) for an extension of the generic clearance for a number of activities it plans to conduct to update its Master Address File (MAF) and maintain the linkage between the MAF and the Topologically Integrated Geographic Encoding and Referencing (TIGER) database of address ranges and associated geographic information. The Census Bureau plans to use the MAF for post-Census 2010 evaluations, various pre-2020 census tests, and as a sampling frame for the American Community Survey and our other demographic current surveys. In the past, the Census Bureau has built a new address list for each decennial census. The MAF built during Census 2000 will be updated thereafter, eliminating the need to

assemble a completely new address list for future censuses and surveys. The TIGER is a geographic system that maps the entire country in Census Blocks with applicable address ranges of living quarter location information. Linking MAF and TIGER allows us to assign each address to the appropriate Census Block, produce maps as needed and publish results at the appropriate level of geographic detail.

The generic clearance for the past three years has proved to be very beneficial to the Census Bureau. The generic clearance allowed us to utilize our limited resources on actual operational planning and development of procedures. The extension will be especially beneficial over the upcoming three years by enabling us to focus on the efforts to improve procedures for future Dress Rehearsals, and to continue updating the MAF.

We will follow the protocol of past generic clearances: 30 days before the scheduled start date of each census activity, we will provide OMB with a detailed background on the activity, estimates of respondent burden and samples of pertinent forms. After the close of each fiscal year, we will also file a year-end summary report with OMB, presenting the results of each activity conducted.

The following sections describe the categories of activities to be included under the clearance. The Census Bureau has conducted these activities (or similar ones) previously and the respondent burden remains relatively unchanged from one time to another.

#### **Demographic Area Address Listing (DAAL)**

The Demographic Area Address Listing (DAAL) program encompasses the geographic area updates for the Community Address Updating System (CAUS) and the area and group quarters frame listings for many ongoing demographic surveys (the Current Population Survey, the Consumer Expenditures Survey, *etc.*). The CAUS program is designed to address quality concerns relating to areas with high concentrations of noncity-style addresses, and to provide a rural counterpart to the update of city-style addresses the MAF receives from the U.S. Postal Services's Delivery Sequence File. The ongoing demographic surveys, as part of the 2000 Sample Redesign Program, used the MAF as one of several sources of addresses from which they selected their samples. In fiscal year 2010, the DAAL operation will also be used to assess a job aid used in the 2010 Address Canvassing operation to identify units in small multi-unit

structures. The DAAL program is a cooperative effort among many divisions at the Census Bureau; it includes automated listing software, systems, and procedures that will allow us to conduct listing operations in a dependent manner based on information contained in the MAF.

The DAAL operations will be conducted on an ongoing basis in potentially any county across the country. Field Representatives (FRs) will canvass selected Census 2000 tabulation blocks to improve the address list in areas where substantial address changes may have occurred that have not been added to the MAF through regular update operations, and/or in blocks in the area or group quarters frame sample for the demographic surveys. FRs will update existing address information, and, when necessary, contact individuals to collect accurate location and mailing address information. In general, contact will occur only when the FR is adding a unit to the address list, and/or the individual's address is not posted or visible to the FR. There is no pre-determined or scripted list of questions asked as part of this listing operation. If an address is not posted or visible to the FR, the FR will ask about the address of the structure, the mailing address, and, in some instances, the year the structure was built. If the occupants of these households are not at home, the FR may attempt to contact a neighbor to determine the best time to find the occupants at home and/or to obtain the correct address information. At group quarters, a facility manager is usually contacted to collect information concerning the facility.

DAAL is an ongoing operation. Listing assignments are distributed quarterly with the work conducted throughout the time period. We expect that DAAL listing operation will be conducted throughout the entire time period of the extension.

#### **American Housing Survey (AHS) Screening Operation**

The Census Bureau plans a screening operation to add housing units in independent living facilities to the American Housing Survey (AHS) sample. We define an independent living facility as a building with 5 or more housing units whose residents live independently and are generally self-sufficient but are able to get help with services like meals, transportation, and managing finances, as well as personal care such as bathing, eating, or dressing. The residents tend to be elderly but also include the disabled of all ages.

We plan on placing a flag on the MAF to identify the independent living units added to the AHS by this operation. AHS is the first current survey to attempt to identify independent living units. If the operation is successful, other current surveys will use the criteria developed to identify such units for inclusion in their samples and will also flag these units on the MAF. Having these units identified on the MAF increases its functionality. Independent living is one of the fastest growing types of housing. The Census Bureau needs to begin the process of identifying units in these facilities.

Depending on the sponsor's FY10 budget, there are an estimated 180 to 600 units in sample for the 2011 AHS-Metropolitan survey, we will screen from all 12 Regional Offices October 12-December 10, 2010. We would need to do this again in late 2012 for the 2013 AHS survey. The Regional Office Supervisors will telephone the facility contacts to confirm the status of the units. We will never contact the housing unit itself for this information. We expect the screening questions to take about 6 minutes once a contact person is located which equates to total respondent burden of 60 hours.

All information that identifies individuals will be held in strict confidence according to the provisions of Title 13, United States Code, Section 9. When contact is made, the Regional Office Supervisor will read the Confidentiality Notice that provides information on the confidential nature of Census Bureau data. This notice explains that any information given to the Census Bureau will be held in strict confidence. None of the questions asked during the screening are of a sensitive nature and there is no cost to facilities other than that of staff time to respond.

The list above is not exhaustive of all activities, which may be performed under this generic clearance. We will follow the approved procedure when submitting any additional activities not specifically listed here.

*Affected Public:* Individuals or households.

*Frequency:* On occasion.

*Respondent's Obligation:* Mandatory.

*Legal Authority:* The activities to be conducted under this clearance are authorized by Title 13 United States Code, Sections 141 and 193.

*OMB Desk Officer:* Brian Harris-Kojetin, (202) 395-7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6625, 14th and

Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at [dhynek@doc.gov](mailto:dhynek@doc.gov)).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202-395-7245) or e-mail ([bharrisk@omb.eop.gov](mailto:bharrisk@omb.eop.gov)).

Dated: January 12, 2010.

**Glenna Mickelson,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 2010-741 Filed 1-15-10; 8:45 am]

BILLING CODE 3510-07-P

## DEPARTMENT OF COMMERCE

### Minority Business Development Agency

[Docket No.: 0912231439-0019-020]

#### Amended Solicitation of Applications for the Minority Business Enterprise Center (MBEC) Program

**AGENCY:** Minority Business Development Agency, Commerce.  
**ACTION:** Notice.

**SUMMARY:** On December 30, 2009, the Minority Business Development Agency (MBDA) published a notice in the *Federal Register* (74 FR 69072) soliciting competitive grant applications under the Agency's Minority Business Enterprise Center (MBEC) program. The original notice solicited applications for operators of the New Orleans MBEC project, and identified New Orleans, LA as the physical location of the MBEC office and the New Orleans-Metairie-Kenner, LA Metropolitan Statistical Area (MSA) as the geographical service area for the project. In addition, the original solicitation provided for a pre-application conference to be held on January 15, 2010, and for an application closing date of February 1, 2010.

MBDA is publishing this notice to: correct certain errors in the original notice pertaining to the name, office location, and geographical service area of the project; change the date of the pre-application conference; and extend the closing date for submitting competitive grant applications to operate this project. Specifically, this notice renames the project from the New Orleans MBEC to the Louisiana MBEC, changes the physical location of the MBEC office from New Orleans, LA to the New Orleans-Metairie-Kenner MSA, and changes the geographical service area for this project from the New Orleans-Metairie-Kenner, LA MSA to the entire State of Louisiana. This notice

also changes the date of the pre-application conference from January 15, 2010 to January 26, 2010, and extends the closing date for the receipt of applications until February 15, 2010 at 5:00 p.m. Eastern Standard Time (EST). All other requirements for this competitive solicitation, including but not limited to application requirements, evaluation criterion, funding levels, and term of award, remain the same as those published in the original December 30, 2009 notice.

A link to the full text of the Amended Announcement of Federal Funding Opportunity (FFO) for this solicitation may be accessed at: <http://www.Grants.gov>, <http://www.mbda.gov>, or by contacting Rita Gonzales, Program Manager, MBDA Office of Business Development, 1401 Constitution Avenue, NW., Room 5075, Washington, DC 20230; telephone: 202-482-1940. The Amended FFO contains a full and complete description of the application and programmatic requirements for this solicitation. In order to receive proper consideration, applicants must comply with the requirements contained in the Amended FFO. Applications received by MBDA as of the date of this notice will be returned without prejudice to the applicant, so as to provide the applicant with an opportunity to revise the application consistent with the changes identified in this notice and in the Amended FFO.

The application requirements for this solicitation invoke collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, SF-LLL, and CD-346 has been approved by OMB under the respective control numbers 4040-0004, 4040-0006, 4040-0007, 0348-0046, and 0605-0001. Notwithstanding any other provisions of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the PRA unless that collection of information displays a currently valid OMB Control Number.

This notice has been determined to be not significant for purposes of E.O. 12866. In addition, prior notice and an opportunity for public comment are not required by the Administrative Procedure Act for rules concerning public property, loans, grants, benefits, or contracts (5 U.S.C. 533(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 533 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory

flexibility analysis is not required and has not been prepared.

Dated: January 13, 2010.

**David A. Hinson,**

*National Director, Minority Business Development Agency.*

[FR Doc. 2010-831 Filed 1-15-10; 8:45 am]

BILLING CODE 3510-21-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### Availability of Seats for the Gulf of the Farallones National Marine Sanctuary Advisory Council

**AGENCY:** Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

**ACTION:** Notice and request for applications.

**SUMMARY:** The ONMS is seeking applicants for the following vacant seats on the Gulf of the Farallones National Marine Sanctuary Advisory Council (council): Conservation Primary (1 seat) and Alternate (2 seats); Education Primary and Alternate; Community-at-Large San Francisco/San Mateo Primary and Alternate; Community-at-Large Marin/Sonoma Primary; Research Primary and Alternate; Maritime Activities Commercial Primary and Alternate; and Maritime Activities Recreation Primary and Alternate. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve 2-3 year terms, pursuant to the council's Charter.

**DATES:** Applications are due by March 1, 2010.

**ADDRESSES:** Application kits may be obtained from <http://www.farallones.noaa.gov/manage/sac.html>, or Kelley Higgason, 991 Marine Dr., The Presidio, San Francisco, CA 94129, [kelly.higgason@noaa.gov](mailto:kelly.higgason@noaa.gov). Completed applications should be mailed to the above address or emailed to [kelly.higgason@noaa.gov](mailto:kelly.higgason@noaa.gov).

**FOR FURTHER INFORMATION CONTACT:** Kelley Higgason, 991 Marine Dr., The Presidio, San Francisco, CA 94129, 415-

561-6622 ext. 202,  
kelley.higgason@noaa.gov.

**SUPPLEMENTARY INFORMATION:** The Sanctuary Advisory Council provides the Sanctuary Superintendent with advice on the management of the Sanctuary. Members provide advice to the Superintendent on issues affecting resource protection, the Sanctuary's primary purpose. The Council, through its members, serves as liaisons to the community regarding Sanctuary issues and acts as a conduit, relaying the community's interests, concerns, and management needs to the Sanctuary. The Sanctuary Advisory Council members represent public interest groups, local industry, commercial and recreational user groups, academia, conservation groups, government agencies, and the general public. Members serve either two- or three-year terms in order to stagger Council membership and allow continuity.

**Authority:** 16 U.S.C. Sections 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

**Daniel J. Basta,**

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010-680 Filed 1-15-10; 8:45 am]

BILLING CODE 3510-NK-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XT76

#### False Killer Whale Take Reduction Team Meeting

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

**ACTION:** Notice of establishment of a False Killer Whale Take Reduction Team and meeting; request for comment.

**SUMMARY:** NMFS is establishing a Take Reduction Team (TRT) and convening a TRT meeting to address the incidental mortality and serious injury of the Hawaii Pelagic, Hawaii Insular, and Palmyra Atoll stocks of false killer whales (*Pseudorca crassidens*) in the Hawaii-based deep-set and shallow-set longline fisheries. The TRT will develop a Take Reduction Plan (TRP) as required in the Marine Mammal Protection Act (MMPA). NMFS will charge the TRT with developing a plan to reduce incidental mortality and serious injury

of these stocks in the Hawaii-based longline fisheries to a level less than the Potential Biological Removal (PBR) level for each stock within 6 months of implementation of the plan and to a level approaching a zero mortality and serious injury rate within 5 years of implementation of the plan.

**DATES:** The meeting will be held on February 17, 2010, from 1 p.m. to 5 p.m., on February 18, 2010, from 8:30 a.m. to 5 p.m., and from February 19, 2010, from 8 a.m. to 1 p.m. Comments on the inclusion within the scope of the TRT of non-strategic marine mammal stocks interacting with the Category I Hawaii-based deep-set longline fishery must be received by February 18, 2010.

**ADDRESSES:** The False Killer Whale TRT meeting will be held at the Sheraton Waikiki, 2255 Kalakaua Avenue, Honolulu, HI; Phone: (808) 922 4422, Fax: (808) 931 8883.

You may submit comments, information, or data, identified by the Regulation Identifier Number [RIN 0648-XT76], by any one of the following methods: (1) Electronic Submissions: Submit all electronic information via the Federal eRulemaking Portal at <http://www.regulations.gov>; (2) Mail: Assistant Regional Administrator, Protected Resources Division, National Marine Fisheries Service, Pacific Islands Regional Office, 1601 Kapiolani Boulevard Suite 1110, Honolulu, HI 96814.

Instructions: All comments received are a part of the public record and may be posted to <http://www.regulations.gov> without change. All personal identifying information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Nancy Young, NMFS, Pacific Islands Region, (808) 944-2282, [nancy.young@noaa.gov](mailto:nancy.young@noaa.gov); or Kristy Long, NMFS, Office of Protected Resources, (301) 713-2322, [kristy.long@noaa.gov](mailto:kristy.long@noaa.gov).

**SUPPLEMENTARY INFORMATION:** Section 118(f)(1) of the Marine Mammal Protection Act (MMPA) requires NMFS to develop and implement take reduction plans designed to assist in the recovery or prevent the depletion of each strategic stock that interacts with

Category I and II fisheries. It also provides NMFS discretion to develop and implement a take reduction plan for any other marine mammal stocks that interact with a Category I fishery, which the agency determines, after notice and opportunity for public comment, has a high level of mortality and serious injury across a number of such marine mammal stocks.

The MMPA defines a strategic stock as a marine mammal stock: (1) for which the level of direct human-caused mortality exceeds the Potential Biological Removal (PBR) level; (2) which is declining and is likely to be listed under the Endangered Species Act (ESA) in the foreseeable future; or (3) which is listed as threatened or endangered under the ESA or as a depleted species under the MMPA (16 U.S.C. 1362(2)). PBR is the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population. Category I or II fisheries are fisheries that, respectively, have frequent or occasional incidental mortality and serious injury of marine mammals.

As required under section 118 (f)(7) of the MMPA, the TRT shall develop a draft TRP by consensus, and shall submit this draft TRP to NMFS not later than 6 months after the date of the establishment of the TRT. The Secretary of Commerce (Secretary) shall then consider the TRP, and no later than 60 days after the submission of the draft TRP, NMFS shall publish in the **Federal Register** the TRP and any implementing regulations proposed by the team for a public comment period not to exceed 90 days. Within 60 days of the close of the comment period, NMFS shall issue a final TRP and any implementing regulations.

#### Marine Mammal Stocks Included Within the TRT Scope

Three false killer whale stocks identified in the U.S. Pacific Marine Mammal Stock Assessment Reports (SAR) (Carretta *et al.*, 2009a) are included within the scope of the TRT:

(1) *False killer whale, Hawaii Pelagic stock.* The Hawaii Pelagic stock includes false killer whales inhabiting waters outside of the February-September longline exclusion zone around the main Hawaiian Islands. The stock has been designated as strategic because the average annual mortality and serious injury (M&SI) of false killer whales incidental to the Category I Hawaii-based deep-set longline fishery (7.4 animals per year) exceeds the

stock's PBR level (2.5 animals per year) (Carretta *et al.*, 2009b).

(2) *False killer whale, Hawaii Insular stock.* The Hawaii Insular stock includes false killer whales inhabiting waters within the February-September longline exclusion zone around the main Hawaiian Islands. The level of M&SI of this stock is not above the stock's PBR level (0.8 animals per year), and the stock is not strategic (Carretta *et al.*, 2009b). The Final 2008 SAR and Draft 2009 SAR for the Insular stock indicate no documented serious injuries or mortalities of animals incidental to Hawaii's longline fisheries. However, the Insular stock may be subject to interactions with longline fisheries: from October to January, a small subset of longline fishing effort takes place within the current stock range of the Hawaii Insular stock. Baird and Gorgone (2005) documented a high rate of dorsal fin disfigurements, which were consistent with injuries from unidentified fishing line. At the present time, it is unknown whether these injuries might have been caused by longline gear or other hook-and-line gear used around the main Hawaiian Islands.

There is overlap in the geographic ranges of the Hawaii Pelagic and Hawaii Insular stocks, and some serious injuries and mortalities that were attributed to the Pelagic stock may in fact have been from the Insular stock. Several of the observed false killer whale takes have been in sets that straddled the current stock boundary (i.e., the set start- and set end-locations were on either side of the boundary). The boundaries between the stocks will likely be revised for the Draft 2010 SAR, and takes may be reassigned from the Pelagic stock to the Insular stock. As a result, the Insular stock may also be listed as strategic in the Draft 2010 SAR. Additionally, a status review has been initiated to determine if listing of the insular population of Hawaiian false killer whales under the ESA is warranted (75 FR 316, January 5, 2010). Based on the overlap between the Insular and Pelagic stocks within the range of the Hawaii-based longline fisheries, the potential for the Insular population to be listed under the ESA in the foreseeable future, and evidence that the Insular stock is declining (Reeves *et al.*, 2009), the Hawaii Insular stock of false killer whales is included within the scope of the TRT. NMFS solicits public comments on whether to include the non-strategic Insular stock within the scope of the TRT.

(3) *False killer whale, Palmyra Atoll stock.* The Palmyra Atoll stock includes false killer whales found within the U.S.

Exclusive Economic Zone (EEZ) of Palmyra Atoll. Human-caused M&SI levels (0.3 animals per year) do not exceed this stock's PBR (6.4 animals per year), and this stock is not strategic (Carretta *et al.*, 2009b). However, NMFS is including this stock in the scope of the TRT because there are documented interactions between the Category I deep-set longline fishery and this stock. NMFS estimated the take rate of false killer whales in longline fisheries as over 4-times higher within EEZ waters of Palmyra Atoll (3.3 per 1000 sets) compared to the Hawaiian Islands EEZ (0.7 per 1000 sets) and waters outside U.S. EEZs (0.8 per 1000 sets) (Forney and Kobayashi, 2007).

In addition, data indicate that false killer whale depredation of catch and/or bait is increasing in the Hawaii-based longline fisheries. False killer whales have been observed while vessels are in transit, indicating that they may be following fishing boats. This behavior is likely to increase interactions, and in fact, for the first time, there have been multiple takes documented per set and per trip during 2008 and 2009 (NMFS Observer Program). Based on this information, NMFS is concerned that the Palmyra Atoll stock may also have an increasing potential to interact with the longline fisheries in the near future. NMFS is including the Palmyra Atoll stock of false killer whales in the scope of the TRT based on the documented high take rates of false killer whales by Hawaii-based longline fisheries operating within the Palmyra Atoll EEZ as described above, as well as the potential for increased interactions in the future. NMFS solicits public comments on including the non-strategic Palmyra Atoll stock within the scope of the TRT.

#### Marine Mammal Stocks Not Included Within the TRT Scope

NMFS considered additional marine mammal stocks, but determined not to include the following within the scope of the TRT:

(1) *False killer whale, American Samoa stock.* This stock is newly defined for the 2010 Draft SARs, and includes false killer whales found within the EEZ of American Samoa. No abundance estimate or PBR level is currently available for this stock. Therefore, the level of M&SI occurring incidental to commercial fisheries, particularly the American Samoa longline fishery, cannot be assessed relative to PBR. However, NMFS analysis suggests that the estimated rate of fisheries-related M&SI within the American Samoa EEZ (7.8 animals per year) exceeds the range of likely PBRs

(0.4-7.5) (NMFS unpublished data). Additional research on the abundance of false killer whales in American Samoa is needed to resolve the stock's status. Because NMFS lacks population structure and abundance data, as well as relatively low observer coverage in the American Samoa longline fishery (as noted below), this stock will not be included in the scope of the TRT.

(2) *Other marine mammal stocks in the Pacific Islands Region.* All but one of the other marine mammal stocks in the Pacific Islands Region that interact with the fisheries under the scope of the TRT (see below) are already at or below the insignificance threshold, which has been defined in MMPA implementing regulations as 10% of PBR (50 CFR 229.2), and will not be included in the scope of the TRT.

The humpback whale (*Megaptera novaeangliae*) is listed as "endangered" under the ESA, and designated as "depleted" under the MMPA. As a result, the Central North Pacific (CNP) stock of humpback whale is classified as a strategic stock (Allen and Angliss, 2009). Total estimated M&SI of this stock is below the PBR of 20.4, but above 10% of PBR. The Draft 2009 SAR indicates no M&SI of this stock from Hawaii-based longline fisheries (Allen and Angliss 2009), but one serious injury was reported in the Hawaii-based shallow-set longline fishery during 2006, with 100% observer coverage (Forney 2009). NMFS previously conducted an analysis considering multiple quantitative and qualitative factors to identify its priorities for establishing TRTs. The CNP stock of humpback whales was considered a low priority, and only for its interactions with commercial fisheries in the Alaska Region. The stock's recovery does not appear to have been affected by interactions with commercial fisheries, as results from the 2004-2006 Structure of Populations, Levels of Abundance, and Status of Humpbacks (SPLASH) project indicate stock abundance has increased by 5.5-6.0% per year (Allen and Angliss 2009). The humpback whale will not be included in the scope of the present TRT.

#### Commercial Fisheries Included Within the TRT Scope

The TRT will address the following two fisheries:

(1) *Hawaii-based deep-set longline fishery.* The Category I Hawaii-based deep-set longline fishery operates both within and outside of the Hawaii EEZ (defined on the MMPA List of Fisheries (LOF) as the "HI deep-set (tuna target) longline/set line" and "Western Pacific Pelagic (Deep-set component)")



fisheries). There have been numerous M&SI of false killer whales documented in this fishery, including an estimated 7.4 animals per year from the strategic Hawaii Pelagic stock of false killer whales, 0.3 animals per year from the non-strategic Palmyra Atoll stock, and 5.4 animals per year in international waters, where no U.S. stocks are currently defined under the MMPA (Carretta *et al.*, 2009b; Forney and Kobayashi, 2007). At minimum, this fishery meets the MMPA requirement for the development of a TRP because of the level of M&SI of false killer whales belonging to the strategic Hawaii Pelagic stock.

(2) *Hawaii-based shallow-set longline fishery.* The Category II Hawaii-based shallow-set longline fishery operates both within and outside of the Hawaii EEZ (defined on the MMPA LOF as the "HI shallow-set (swordfish target) longline/set line" and "Western Pacific Pelagic (Shallow-set component" fisheries). No documented interactions with false killer whales have been reported in the Final 2008 SAR or Draft 2009 SAR (Carretta *et al.* 2009a, 2009b). However, there was an observed interaction with a false killer whale from the Hawaii Pelagic stock in 2008 that was determined to be a non-serious injury, and another observed interaction that resulted in a serious injury of either a false killer whale or a short-finned pilot whale, outside of U.S. EEZs (Forney 2009). Another false killer whale interaction was documented in 2009 just outside of the longline exclusion boundary (and thus likely from the strategic Pelagic stock), but the determination regarding the severity of the injury (i.e., serious versus not serious) has not yet been made. Due to the concern over the rapid increase in the number of false killer whale takes that are occurring in the deep-set longline fishery, and the shallow-set fishery's recent interactions with false killer whales (potentially with a strategic stock), this fishery will be included in the scope of the TRT.

#### Commercial Fisheries Not Included Within the TRT Scope

The following fisheries were considered, but are not included in the scope of the TRT:

(1) *American Samoa longline fishery.* This Category II fishery differs from the Hawaii-based longline fisheries in terms of gear and fishing practices, target species, and geographical area of operation. Observer coverage has been less than 10% since a mandatory observer program began in 2006. As stated above, there is very little information on the level of interactions

with false killer whales. Two false killer whales were observed killed or seriously injured by the fishery in 2008 (Oleson 2009), but it is unknown whether this level is unsustainable because an abundance estimate and calculation of PBR for the newly-defined American Samoa stock of false killer whales are not available. Because NMFS lacks information about the impact this fishery is having on the poorly understood American Samoa stock of false killer whales, and because the differences between this fishery and the two Hawaii-based longline fisheries would likely detract from the focus of the TRT, this fishery is not being included within the scope of the TRT.

(2) *Hawaii shortline fishery.* This fishery was added to the 2010 LOF as a Category II fishery, classified by analogy (50 CFR 229.2, definition of "Category II fishery") to the two Hawaii-based longline fisheries, based on the similarities between the gear used, areas fished, and target species in the three fisheries, and anecdotal reports of interactions with marine mammals off the north side of the island of Maui. These reports have not been confirmed, and thus the species involved and extent of the interactions are unknown. The Western Pacific Fishery Management Council (Council) is considering management of the fishery. Information gathered by Council staff indicates that the shortline fishery is very small, with few participants and low levels of landings. There is also a small amount of data available and no observer coverage. Data confidentiality would likely be an issue, making an understanding of the fishery and its potential impacts on false killer whale stocks difficult. This fishery will not be considered part of the scope of the TRT. However, if the shortline fishery is documented to interact with a strategic stock in the future, NMFS will consider bringing it under the scope of the TRT at a later time.

#### List of Invited Participants

MMPA section 118 (f)(6)(C) requires that members of TRTs have expertise regarding the conservation or biology of the marine mammal species that the TRP will address, or the fishing practices that result in the incidental mortality or serious injury of such species. The MMPA further specifies that TRTs shall, to the maximum extent practicable, consist of an equitable balance among representatives of resource user and non-user interests.

NMFS has asked the following individuals to serve as members of the TRT, which is tasked with developing recommendations to reduce mortalities

and serious injuries of three false killer whale stocks incidental to Hawaii-based longline fisheries: William Aila, Hui Malama I Kohola; Robin Baird, Cascadia Research Collective; Hannah Bernard, Hawaii Wildlife Fund; Steven Beverly, Secretariat of the Pacific Community; Brendan Cummings, Center for Biological Diversity; Paul Dalzell, Western Pacific Fishery Management Council; Roger Dang, Pacific Fishing & Supply, Inc.; Clint Funderburg, Fishing Vessels Rachel and Golden Sable; John Hall, Fishing Vessel Zephyr; Kristy Long, NMFS Office of Protected Resources; Kristine Lynch, Marine Mammal Commission; Paul Nachtigall, Hawaii Institute of Marine Biology; David Nichols, State of Hawaii; Victoria O'Connell, Coastal Marine Research; Jerry Ray, Fishing Vessel Katy Mary; Andrew Read, Duke University; Lance Smith, NMFS Pacific Islands Regional Office; Ryan Steen, Stoel Rives LLP; and Sharon Young, The Humane Society of the United States.

Other individuals from NMFS and state and Federal agencies may be present as observers or for their scientific expertise. Members of TRTs serve without compensation, but may be reimbursed by NMFS, upon request, for allowable travel costs and expenses incurred in performing their duties as members of the team. The TRT will hold its first meeting from February 17–19, 2010 in Honolulu, Hawaii (see **DATES** and **ADDRESSES**).

NMFS fully intends to conduct the TRT process in a way that provides for national consistency yet accommodates the unique regional characteristics of the fishery and marine mammal stocks involved. Take Reduction Teams are not subject to the Federal Advisory Committee Act (5 App. U.S.C.).

Meetings are open to the public.

#### Public Comments Solicited

Comments are solicited on the inclusion within the scope of the TRT of the non-strategic Hawaii Insular and Palmyra Atoll stocks of false killer whales.

#### References

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- Carretta J.V., K.A. Forney, M.S. Lowry, J. Barlow, J. Baker, D. Johnston,

B. Hanson, and M.M. Muto. 2009a U.S. Pacific marine mammal stock assessments: 2008. NOAA Technical Memorandum NMFS-SWFSC-434. 340p.

Carretta, J.V., K.A. Forney, M.S. Lowry, J. Barlow, J. Baker, D. Johnston, B. Hanson, R.L. Brownell Jr., J. Robbins, D.K. Mattila, K. Ralls, M.M. Muto, D. Lynch, and L. Carswell. 2009b. Draft U.S. Pacific Marine Mammal Stock Assessments: 2009. Available from SWFSC, 8604 La Jolla Shores Drive, La Jolla, CA 92037.

Forney, K.A. 2009. Serious injury determinations for cetaceans caught in Hawaii longline fisheries during 1994–2008. Draft document, October 19, 2009. PSRG-2009-16.

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Oleson, E.M. 2009. Characteristics of the American Samoa Longline Fishery and Estimates of Cetacean Take, 2006–2008. PSRG-2009-14.

Reeves, R.R., S. Leatherwood, and R.W. Baird. 2009. Evidence of a Possible Decline since 1989 in False Killer Wales (*Pseudorca crassidens*) around the Main Hawaiian Islands. *Pacific Science* 63: 253–261.

Dated: January 13, 2010.

**James H. Lecky,**

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

[FR Doc. 2010-335 Filed 1-15-10; 8:45 am]

BILLING CODE 3510-22-S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XS98

#### Atlantic Highly Migratory Species; Advisory Panel

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

**ACTION:** Notice.

**SUMMARY:** NMFS solicits nominations for the Advisory Panel (AP) for Atlantic Highly Migratory Species (HMS) Southeast Data, Assessment, and Review (SEDAR) Workshops (this AP is also called the “SEDAR Pool”). The SEDAR Pool is comprised of a group from which individuals will be selected to review and/or provide the data and analyses and advise NMFS regarding the scientific information, including but not

limited to data, analyses, and models, used in stock assessments for sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. Nominations are being sought for a three-year appointment. Individuals with definable interests in the recreational and commercial fishing and related industries, environmental community, academia, and non-governmental organizations will be considered for membership on the SEDAR Pool.

**DATES:** Nominations must be received on or before February 18, 2010.

**ADDRESSES:** You may submit nominations and request the SEDAR Pool Statement of Organization, Practices, and Procedures by any of the following methods:

- Email: [SEDAR.pool@noaa.gov](mailto:SEDAR.pool@noaa.gov).
- Mail: Karyl Brewster-Geisz, Highly Migratory Species Management Division, NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Include on the envelope the following identifier: “SEDAR Pool Nomination.”
- Fax: 301-713-1917.

Additional information on SEDAR and the SEDAR guidelines can be found at <http://www.sefsc.noaa.gov/sedar/>.

**FOR FURTHER INFORMATION CONTACT:** Karyl Brewster-Geisz, (301) 713-2347, ext. 111.

#### SUPPLEMENTARY INFORMATION:

##### Introduction

Section 302(g)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.*, states that each Council shall establish such advisory panels as are necessary or appropriate to assist it in carrying out its functions under the Act. For the purposes of this section, NMFS considers the above provisions to be applicable to the HMS Management Division. As such, NMFS is establishing the SEDAR Pool under this section. The SEDAR Pool will be a group from which individuals will be selected to review and/or provide the data and analyses and advise NMFS regarding the scientific information, including but not limited to data, analyses, and models, used in stock assessments for sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. While the SEDAR Pool is being created specifically for Atlantic sharks, it may be expanded to include other HMS, as needed. Under section 302(i)(1), the Federal Advisory Committee Act (FACA) shall not apply to advisory panels established under section 302(g).

The primary purpose of the individuals in the SEDAR Pool is to review and/or provide, at SEDAR

workshops, the scientific information, including but not limited to data, analyses, and models, used in stock assessments that are used to advise NMFS, as a delegate to the Secretary of Commerce (Secretary), about the conservation and management of the Atlantic HMS, specifically but not limited to, Atlantic sharks. Individuals in the SEDAR Pool may be selected to participate in the various data, assessment, and review workshops during the SEDAR process of any HMS stock assessment. Individuals that participated in a data and/or assessment workshop for a particular stock assessment may also be asked to attend and/or provide information during the review workshop to ensure that any questions the reviewers may have can be answered quickly and accurately. To ensure that the peer review is unbiased, individuals who participate in a data and/or assessment workshop for a particular stock assessment will not be asked to participate in the review workshop.

Members of the SEDAR Pool may serve as members of other APs concurrent with or following their service on the SEDAR Pool, except that members of the SEDAR Pool that were invited to participate in the data and/or assessment workshops for any particular species during a specific stock assessment may not participate in the relevant review workshop for that stock assessment.

#### Procedures and Guidelines

##### A. Participants

The SEDAR Pool will be comprised of representatives of: commercial and recreational fisheries for Atlantic HMS, the environmental community active in the conservation and management of Atlantic HMS, and the academic community that have relevant research either with sharks or shark-like species and/or stock assessment methodologies for any marine fish species. Members of the SEDAR Pool must have demonstrated experience in the fisheries, related industries, research, teaching, writing, conservation, or management of marine organisms. The distribution of representation among the interested parties is not defined and the number of members in the SEDAR Pool is not limited.

Additional members of the SEDAR Pool may also include representatives from each of the five Atlantic Regional Fishery Management Councils, each of the 18 constituent states, both the U.S. Virgin Islands and Puerto Rico, and each of the constituent interstate commissions: the Atlantic States Marine

Fisheries Commission and the Gulf States Marine Fisheries Commission.

If NMFS requires additional members to ensure a diverse pool of individuals to draw from for data or assessment workshops, NMFS may request individuals to be members of the SEDAR Pool outside of the annual nomination period.

Panel members serve at the discretion of the Secretary. Not all members will attend each SEDAR workshop. Rather, NMFS will invite certain members to participate at specific stock assessment workshops dependent on their ability to participate, discuss, and recommend scientific decisions regarding the species being assessed. If an invited SEDAR Pool member is unable to attend the workshop, the member may send a designee who may represent them and participate in the activities of the workshop. In order to ensure the designee meets the requirements of participating in the data and/or assessment workshop, the designee must receive written approval of the Director of the Office of Sustainable Fisheries at least six weeks in advance of the beginning of the relevant data and/or assessment workshop. Written notification must include the name, address, telephone, e-mail, and position of the individual designated. A designee may not name another designee.

NMFS is not obligated to fulfill any requests (e.g., requests for an assessment of a certain species) that may be made by the SEDAR Pool or its individual members. Members of the SEDAR Pool who are invited to attend stock assessment workshops may be reimbursed for their travel-related expenses to attend such workshops.

#### B. Nomination Procedures for Appointments to the SEDAR Pool

Member tenure will be for three years. Nominations are sought for terms beginning February 2010 and expiring January 2013. Nomination packages should include:

1. The name, address, phone number, and e-mail of the applicant or nominee;
2. A description of his/her interest in Atlantic shark stock assessments or the Atlantic shark fishery;
3. A statement of background and/or qualifications; and
4. A written commitment that the applicant or nominee shall participate actively and in good faith in the tasks of the SEDAR Pool, as requested.

#### C. Meeting Schedule

Individual members of the SEDAR Pool meet to participate in stock assessments at the call of the Office of Sustainable Fisheries, NMFS. Stock

assessment timing, frequency, and relevant species will vary depending on the need determined by NMFS and SEDAR staff. Meetings and meeting logistics will be determined according to the SEDAR Guidelines. All meetings are open for observation by the public.

Dated: January 12, 2010.

**Emily Menashes,**

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

[FR Doc. 2010-836 Filed 1-15-10; 8:45 am]

**BILLING CODE 3510-22-S**

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Information Collection; Submission for OMB Review, Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (hereinafter the "Corporation"), has submitted a public information collection request (ICR) entitled the President's Volunteer Service Awards, parts A, B, C, D and E to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, David Premo at (202) 606-6717. Individuals who use a telecommunications device for the deaf (TTY-TDD) may call (202) 606-3472 between 8:30 a.m. and 5 p.m. Eastern Time, Monday through Friday.

**ADDRESSES:** Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in this **Federal Register**:  
 (1) *By fax to:* (202) 395-6974. Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; and  
 (2) *Electronically by e-mail to:* smar@omb.eop.gov.

#### **SUPPLEMENTARY INFORMATION:**

*The OMB is particularly interested in comments which:*

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including

whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

#### **Comments**

A 60-day public comment Notice was published in the **Federal Register** on October 14, 2009. This comment period ended December 13, 2009. No public comments were received from this Notice.

*Description:* The Corporation is seeking approval of the renewal of the President's Volunteer Service Awards application. The President's Volunteer Service Awards were created by Executive Order on January 30, 2003. The awards are administered by the Corporation for National and Community Service. Under the Executive Order, the Corporation was directed to (among other things) design and recommend programs to recognize individuals, schools, and organizations that excel in their efforts to support volunteer service and civic participation, especially with respect to students in primary schools, secondary schools, and institutions of higher learning. The President's Volunteer Service Awards meet this requirement. In order to recognize individuals, schools and organizations, the program must collect information about the individuals and organizations and their activities to verify that they have earned the award.

The information collected will be used by the Program primarily to identify recipients of the President's Volunteer Service Awards and the Call to Service Awards (4000 hours or more.) Individuals or organizations can be nominated by an organization or third party. The nominations will be reviewed by the administering agency for compliance and awards will be made on that basis. Information also will be used to assure the integrity of the Program (so that, for example, an individual or organization does not receive an award twice for the same project), for reporting on the

accomplishments of the Program, for the public awareness campaign (such as press releases and Web site information on winning projects), and to further the purposes of the Executive Order (such as fostering partnerships and coordination of projects and to promote civic engagement).

*Type of Review:* Renewal.

*Agency:* Corporation for National and Community Service.

*Title:* President's Volunteer Service Awards, parts A, B, C, D and E

*OMB Number:* 3045-0086.

*Agency Number:* None.

*Affected Public:* All citizens of the United States.

*Total Respondents:* 200,000.

*Frequency:* On occasion.

*Average Time per Response:* 20 minutes.

*Estimated Total Burden Hours:* 66,666 hours.

*Total Burden Cost (capital/startup):* None.

*Total Burden Cost (operating/maintenance):* None.

*Dated:* January 11, 2010.

**Rhonda Taylor,**

*Acting Director of Corporate Relations.*

[FR Doc. 2010-788 Filed 1-15-10; 8:45 am]

BILLING CODE 6050-SS-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Department of Defense Historical Advisory Committee Charter

**AGENCY:** Department of Defense (DoD).

**ACTION:** Federal advisory committee charter.

**SUMMARY:** Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.65, the Department of Defense gives notice that it intends to renew the charter for the Department of Defense Historical Advisory Committee (hereafter referred to as the Committee).

**FOR FURTHER INFORMATION CONTACT:** Jim Freeman, DoD Committee Management Office, 703-601-6128.

**SUPPLEMENTARY INFORMATION:** The Committee, pursuant to 41 CFR 102-3.50(d), is a discretionary Federal advisory committee established to provide the Secretary of Defense and the Secretaries of the Military Departments independent advice and recommendations on matters regarding the professional standards, historical methodology, program priorities, liaison

with professional groups and institutions, and adequacy of resources of the various historical programs and associated activities of the Department of Defense.

The Secretary of Defense and or the Secretaries of the Military Departments or their designated representatives may act upon the Committee's advice and recommendations.

The Committee shall be composed of not more than six members, who are the Historians for the Office of the Secretary of Defense, the Office of the Chairman of the Joint Chiefs of Staff, and the Military Services. Committee members appointed by the Secretary of Defense, who are not full-time or permanent part-time federal employees, shall be appointed on an annual basis as experts and consultants under the authority of 5 U.S.C. 3109 and serve as special government employees. In addition, they shall serve without compensation except for travel and per diem for official Committee-related travel.

The Historian for the Office of the Secretary of Defense shall serve as the Committee's Chairperson.

The Committee shall meet at the call of the Committee's Designated Federal Officer, in consultation with the Chairperson. The estimated number of Committee meetings is one per year.

The Designated Federal Officer, pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with DoD policies and procedures. In addition, the Designated Federal Officer is required to attend all Committee and subcommittee meetings. In the absence of the Designated Federal Officer the Alternate Designated Federal Officer shall attend the meeting.

With DoD approval, the Committee is authorized to establish subcommittees, as necessary and consistent with its mission. These subcommittees or working groups shall operate under the provisions of the Federal Advisory Committee Act of 1972, the Government in the Sunshine Act of 1976, and other appropriate Federal regulations.

Such subcommittees or workgroups shall not work independently of the chartered Committee, and shall report all their recommendations and advice to the Committee for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered Committee nor can they report directly to the Department of Defense or any Federal officers or employees who are not Committee members.

Pursuant to 41 CFR 102-3.105(j) and 102-3.140, the public or interested organizations may submit written

statements to the Department of Defense Historical Advisory Committee membership about the Committee's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Department of Defense Historical Advisory Committee.

All written statements shall be submitted to the Designated Federal Officer for the Department of Defense Historical Advisory Committee, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Designated Federal Officer can be obtained from the GSA's FACA Database—<https://www.fido.gov/facadatabase/public.asp>.

The Designated Federal Officer, pursuant to 41 CFR 102-3.150, will announce planned meetings of the Department of Defense Historical Advisory Committee. The Designated Federal Officer, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

*Dated:* January 13, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2010-839 Filed 1-15-10; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Negotiation of a Reciprocal Defense Procurement Memorandum of Understanding With the Czech Republic

**AGENCY:** Department of Defense (DoD).

**ACTION:** Request for public comments.

**SUMMARY:** DoD is contemplating a Reciprocal Defense Procurement Memorandum of Understanding with the Czech Republic. DoD is requesting industry feedback regarding its experience in public defense procurements conducted by or on behalf of the Czech Republic Ministry of Defense or Armed Forces.

**DATES:** Comments must be received by February 18, 2010.

**ADDRESSES:** Submit comments to the Director, Defense Procurement and Acquisition Policy, 3060 Defense Pentagon, Room 3B855, Attn: Ms. Susan Hildner, Washington, DC 20301-3060; or by e-mail to [emily.clarke@osd.mil](mailto:emily.clarke@osd.mil).

**FOR FURTHER INFORMATION CONTACT:** Ms. Emily Clarke, OUSD(AT&L), Director, Defense Procurement and Acquisition Policy, Contract Policy and

International Contracting; Room 5E621, 3060 Defense Pentagon, Washington, DC 20301-3060; telephone (703) 697-9351.

**SUPPLEMENTARY INFORMATION:** The Reciprocal Defense Procurement Memorandums of Understanding (RDP MOUs) that DoD has with 21 "qualifying" countries are signed at the level of the Secretary of Defense and his counterpart. The purpose of RDP MOUs is to promote rationalization, standardization, and interoperability of conventional defense equipment with allies and friendly governments. These MOUs provide a framework for ongoing communication regarding market access and procurement matters that affect effective defense cooperation.

RDP MOUs generally include language by which the parties agree that their defense procurements will be conducted in accordance with certain implementing procedures. *These procedures relate to—*

- Publication of notices of proposed purchases;
- The content and availability of solicitations for proposed purchases;
- Notification to each unsuccessful offeror;
- Feedback, upon request, to unsuccessful offerors concerning the reasons they were not allowed to participate in a procurement or were not awarded a contract; and
- Providing for the hearing and review of complaints arising in connection with any phase of the procurement process to ensure that, to the extent possible, complaints are equitably and expeditiously resolved.

Based on the MOU, each country affords the other certain benefits on a reciprocal basis consistent with national laws and regulations. The benefits that the United States accords to the products of qualifying countries include—

- Offers of qualifying country end products are evaluated without applying the price differentials otherwise required by the Buy American Act and the Balance of Payments Program;
- The chemical warfare protection clothing restrictions in 10 U.S.C. 2533a and the specialty metals restriction in 10 U.S.C. 2533b do not apply to products manufactured in a qualifying country; and
- Customs, taxes, and duties are waived for qualifying country end products and components.

If DoD signs an RDP MOU with the Czech Republic, the Czech Republic would be listed as one of the "qualifying countries" in the definition of "qualifying country" at DFARS 225.003 and offers of products of the Czech

Republic or that contain components from the Czech Republic would be afforded the benefits available to all qualifying countries. This also means that U.S. products would be exempt from any analogous "Buy Czech Republic" and "Buy European Union" laws or policies applicable to procurements by the Czech Republic Ministry of Defense or Armed Forces.

While DoD is evaluating the Czech Republic's laws and regulations in this area, DoD would benefit from U.S. industry's experience in participating in the Czech Republic's public defense procurements. DoD is, therefore, asking U.S. firms that have participated or attempted to participate in procurements by or on behalf of the Czech Republic's Ministry of Defense or Armed Forces to let us know if the procurements were conducted in accordance with published procedures with transparency, integrity, fairness, and due process, and if not, the nature of the problems encountered.

DoD is also interested in comments relating to the degree of reciprocity that exists between the U.S. and the Czech Republic when it comes to the openness of defense procurements to offers of products from the other country.

**Amy G. Williams,**  
*Editor, Defense Acquisition Regulations System.*

[FR Doc. 2010-901 Filed 1-15-10; 8:45 am]

**BILLING CODE 5001-08-P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Hanford

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Thursday, February 4, 2010—9 a.m.—5 p.m.

Friday, February 5, 2010—8:30 a.m.—4 p.m.

**ADDRESSES:** Red Lion Hotel, 1101 North Columbia Center Boulevard, Kennewick, WA 99336.

**FOR FURTHER INFORMATION CONTACT:** Paula Call, Federal Coordinator, Department of Energy Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, A7-75, Richland, WA

99352; Phone: (509) 376-2048; or E-mail: [Paula\\_K\\_Call@rl.gov](mailto:Paula_K_Call@rl.gov).

#### SUPPLEMENTARY INFORMATION:

**Purpose of the Board:** The purpose of the Board is to make recommendations to DOE-EM and site management in the areas of environmental restoration, waste management, and related activities.

#### Tentative Agenda:

- Agency Updates, including progress on the American Recovery and Reinvestment Act (Department of Energy Office of River Protection [ORP] and Richland Operations Office; Washington State Department of Ecology; U.S. Environmental Protection Agency [EPA])

- Committee Updates, including: Tank Waste Committee; River and Plateau Committee; Health, Safety and Environmental Protection Committee; Public Involvement Committee; and Budgets and Contracts Committee
- Long-term Stewardship Presentation (Jay Pendegrass, Environmental Law Institute, and Mike Bellot, EPA)

- ORP System Plan Revision 4
- Mission Support Alliance Contract Overview

- Draft Tank Closure and Waste Management Environmental Impact Statement

- Process for Review of Agency Response to Board Advice
- Potential Board Advice/Letters
- Board Business

**Public Participation:** The meeting is open to the public. The EM SSAB, Hanford, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paula Call at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Paula Call at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

**Minutes:** Minutes will be available by writing or calling Paula Call's office at

the address or phone number listed above. Minutes will also be available at the following Web site: <http://www.hanford.gov/?page=413&parent=397>.

Issued at Washington, DC on January 8, 2010.

**Rachel Samuel,**  
Deputy Committee Management Officer.

[FR Doc. 2010-568 Filed 1-15-10; 8:45 am]

BILLING CODE 6450-01-P

## DEPARTMENT OF ENERGY

### Office of Energy Efficiency and Renewable Energy

#### Hydrogen and Fuel Cell Technical Advisory Committee (HTAC)

**AGENCY:** Department of Energy, Office of Energy Efficiency and Renewable Energy.

**ACTION:** Notice of Open Meeting.

**SUMMARY:** The Hydrogen and Fuel Cell Technical Advisory Committee (HTAC) was established under section 807 of the Energy Policy Act of 2005 (EPACT), Public Law No. 109-58; 119 Stat. 849. The Federal Advisory Committee Act, Public Law No. 92-463, 86 Stat. 770, requires that agencies publish notice of an advisory committee meeting in the *Federal Register*. To attend the meeting and/or to make oral statements during the public comment period, please e-mail [HTAC@nrel.gov](mailto:HTAC@nrel.gov) at least 5 business days before the meeting. Please indicate if you will be attending the meeting, whether you want to make an oral statement on February 10, 2010, and what organization you represent.

**DATES:** Wednesday, February 10, 2010, 8:30 a.m.–5:30 p.m. Thursday, February 11, 2010, 8:30 a.m.–3 p.m.

**ADDRESSES:** Radisson Reagan National, 2020 Jefferson Davis Highway, Arlington, VA.

**FOR FURTHER INFORMATION CONTACT:** [HTAC@nrel.gov](mailto:HTAC@nrel.gov).

#### SUPPLEMENTARY INFORMATION:

*Purpose of the Meeting:* To provide advice, information, and recommendations to the Secretary on the program authorized by title VIII of EPACT.

*Tentative Agenda:* (Subject to change; updates will be posted on <http://hydrogen.energy.gov> and copies of the final agenda will be available the date of the meeting).

- DOE Program Update and Budget Process Overview
- National Academy of Science Study Overview

- University of California (UC) Davis Electric Drive Vehicle Study Overview
- National Renewable Energy Laboratory (NREL) Study Overview: Analysis of Hydrogen Storage vs. Batteries for Large Scale Storage of Electricity
- 2009 HTAC Report Development
- Discussion on Recommendations
- Open Discussion

**Public Participation:** In keeping with procedures, members of the public are welcome to observe the business of the meeting of HTAC and to make oral statements during the specified period for public comment. The public comment period will take place between 8:30 a.m. through 9 a.m. on February 10, 2010. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, e-mail [HTAC@nrel.gov](mailto:HTAC@nrel.gov) at least 5 business days before the meeting. Please indicate if you will be attending the meeting, whether you want to make an oral statement, and what organization you represent (if appropriate). Members of the public will be heard in the order in which they sign up for the public comment period. Oral comments should be limited to two minutes in length. Reasonable provision will be made to include the scheduled oral statements on the agenda. The chair of the committee will make every effort to hear the views of all interested parties and to facilitate the orderly conduct of business. If you would like to file a written statement with the committee, you may do so either by submitting a hard copy at the meeting or by submitting an electronic copy to [HTAC@nrel.gov](mailto:HTAC@nrel.gov).

*Minutes:* The minutes of the meeting will be available for public review at <http://hydrogen.energy.gov>.

Issued at Washington, DC on January 12, 2010.

**Rachel Samuel,**  
Deputy Committee Management Officer.

[FR Doc. 2010-864 Filed 1-15-10; 8:45 am]

BILLING CODE 6450-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9104-4]

### Clean Water Act Section 303(d): Call for Data for the Illinois River Watershed in Oklahoma and Arkansas

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

**ACTION:** Request for data.

**SUMMARY:** EPA Region 6 is developing a watershed model for the Illinois River

watershed in Oklahoma and Arkansas to address nutrient water quality impairments. The results of this watershed model may be used to develop one or more total maximum daily loads (TMDLs) for the Illinois River Watershed. EPA requests that the public provide any water quality related data and information that may be relevant to the development of the Illinois River Watershed model and TMDL by March 3, 2010. In addition, EPA requests that all data submissions include the quality assurance and quality control documentation. All data submissions should be provided in an electronic format, if possible. EPA will review all data and information submitted and will consider them in the development of the model and TMDL, as appropriate.

**DATES:** Data and Information must be submitted in writing to EPA on or before March 3, 2010. If you anticipate that you will be providing data and information, but find it difficult to do so within the period of time allowed, you should advise the contact listed below as soon as possible.

**ADDRESSES:** You may submit data and information to EPA Region 6 by e-mail or U.S. post mail. To submit your data and information by e-mail, send them to [Smith.Diane@epa.gov](mailto:Smith.Diane@epa.gov). To submit your data and information by U.S. mail, mark them to the attention of Diane Smith, Environmental Protection Specialist, Water Quality Division, (6WQ), U.S. Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

**FOR FURTHER INFORMATION CONTACT:** Diane Smith, Environmental Protection Specialist, Water Quality Protection Division, U.S. EPA Region 6, 1445 Ross Avenue, Dallas, TX 75202-2733, (214) 665-2145.

**SUPPLEMENTARY INFORMATION:** The Illinois River is a tributary of the Arkansas River, approximately 100 mi (160 km) long, between the States of Arkansas and Oklahoma. The Illinois River rises in the Ozark Mountains in the northwest corner of Arkansas (Washington County) and flows west into northeast Oklahoma. The Oklahoma portion of the Illinois River is currently designated as a scenic river. In addition, several segments of the Illinois River are on the State of Oklahoma's 303(d) list (impaired waters list) for total phosphorus, while the main-stem Illinois River in Arkansas is not listed for total phosphorus. However, several tributaries (e.g., Osage Creek, Muddy Fork, and Spring Creek) to the Illinois River in Arkansas are currently on the Arkansas 303(d) list for total

phosphorus. The purpose of this project is to develop a scientifically robust watershed model to determine the reductions in phosphorus loads that are needed to meet water quality standards in both States. This watershed model will serve as a tool to effectively identify nutrient reductions needed to ensure that water quality standards for phosphorus are protected in both States; and, to devise varying allocation and load reductions scenarios needed to guide appropriate point and non-point source controls.

Specifically, EPA is soliciting technical information on measurements of nutrients and related constituents in surface waters, and all associated information needed to support development of the Illinois River Watershed model and one or more planned TMDLs. Examples of data requested include:

1. *Monitoring data* of nutrients, sediment, flow, water temperature, dissolved oxygen and organics (oxygen demand) for any locations within the Illinois River watershed, including the main-stem, its tributaries and other water-bodies.

2. *Watershed land use/land cover characteristics*, including topography, hydrography, drainage patterns, soils, cropping patterns, and other potential nutrient sources. GIS (geographic information system) coverage is preferred for this type of spatial data.

3. *Precipitation and meteorological data*, including evaporation, air temperature, wind movement, solar radiation, dew-point temperature, and cloud cover. Daily data for the 1980–2010 time periods is needed. Precipitation data at shorter time intervals, (e.g., hourly or 15-minute) is needed for some locations to provide adequate coverage and definition of rainfall patterns across the watershed.

4. *Hydrography and geomorphological data* for channels and major water-bodies, including channel lengths and slopes, cross-sections and geometry, bed composition (sediment particle sizes, nutrients), stage/storage/surface area information, etc. Prior flood insurance and associated modeling studies would be useful.

5. *Other nutrient source information and/or water quality assessments specifically addressing wastewater discharges, agricultural water diversions and/or agricultural return flows, water supply intake structures, and information regarding the distribution, population and locations of feedlots, pastures, cattle and poultry houses.*

6. *Prior investigations and modeling studies that analyze monitoring data, describe agronomic and poultry*

practices, estimate nonpoint source loading rates for nutrients by source category, assess water quality impacts and/or biotic endpoints for any sites within the watershed.

Dated: January 11, 2010.

**Troy C. Hill,**

*Acting Director, Water Quality Protection Division, EPA Region 6.*

[FR Doc. 2010–829 Filed 1–15–10; 8:45 am]

**BILLING CODE 6560–50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2010–0013; FRL–9104–5]

### Board of Scientific Counselors, Executive Committee Meeting—February 2010

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

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency, Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Executive Committee.

**DATES:** The meeting will be held on Thursday, February 4, 2010, from 9 a.m. to 5 p.m., and will continue on Friday, February 5, 2010, from 8:30 a.m. until 12 noon. All times noted are Eastern Standard Time. The meeting may adjourn early if all business is finished. Requests for the draft agenda or for making oral presentations at the meeting will be accepted up to one business day before the meeting.

**ADDRESSES:** The meeting will be held at the Marriott at Metro Center hotel, 775 12th Street, NW., Washington, DC 20005. Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2010–0013, by one of the following methods:

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

- *E-mail:* Send comments by electronic mail (e-mail) to: [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov), Attention Docket ID No. EPA–HQ–ORD–2010–0013.

- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2010–0013.

- *Mail:* Send comments by mail to: Board of Scientific Counselors, Executive Committee Meeting—February 2010 Docket, Mailcode: 2822T, 1301 Constitution Avenue, NW., Washington, DC 20004, Attention

Docket ID No. EPA–HQ–ORD–2010–0013.

- *Hand Delivery or Courier.* Deliver comments to: EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2010–0013.

Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–ORD–2010–0013. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/dockets>.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at

the Board of Scientific Counselors, Executive Committee Meeting—February 2010 Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

**FOR FURTHER INFORMATION CONTACT:** The Designated Federal Officer via mail at: Greg Susanke, Mail Code 8104-R, Office of Science Policy, Office of Research and Development, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via phone/voice mail at: (202) 564-9945; via fax at: (202) 565-2911; or via e-mail at: [susanke.greg@epa.gov](mailto:susanke.greg@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**General Information**

Any member of the public interested in receiving a draft BOSC agenda or making a presentation at the meeting may contact Greg Susanke, the Designated Federal Officer, via any of the contact methods listed in the **FOR FURTHER INFORMATION CONTACT** section above. In general, each individual making an oral presentation will be limited to a total of three minutes.

Proposed agenda items for the meeting include, but are not limited to: Executive Committee review of the BOSC Computational Toxicology Letter report; update on BOSC program review

subcommittees (Drinking Water, Global Change); an ORD briefing on revisions to the program review process; a briefing from the BOSC Decision Analysis Workgroup and discussion of draft workgroup product; an ORD update; and future issues and plans. The meeting is open to the public.

**Information on Services for Individuals with Disabilities:** For information on access or services for individuals with disabilities, please contact Greg Susanke (202) 564-9945 or [susanke.greg@epa.gov](mailto:susanke.greg@epa.gov). To request accommodation of a disability, please contact Greg Susanke, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: January 5, 2010.

**Fred Hauchman,**

*Director, Office of Science Policy.*

[FR Doc. 2010-827 Filed 1-15-10; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

[EPA-HQ-OECA-2009-0986; FRL-9098-3]

**Public Comment on Candidate National Enforcement and Compliance Assurance Priorities for Fiscal Years 2011-2013**

*Correction*

In notice document E9-31042 beginning on page 146 in the issue of

Monday, January 4, 2010 make the following corrections:

On page 147, in the first column, under the "DATES:" section, in the second line, "January 19, 2009" should read "January 19, 2010".

[FR Doc. C1-2009-31042 Filed 1-15-10; 8:45 am]

**BILLING CODE 1505-01-D**

**FEDERAL COMMUNICATIONS COMMISSION**

**Sunshine Act Meeting; Open Commission Meeting; Wednesday, January 20, 2010**

Date: January 13, 2010.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, January 20, 2010, which is scheduled to commence at 10:30 a.m. in Room TW-C305, at 445 12th Street, SW., Washington,

The meeting will also include a report on the status of the National Broadband plan.

ITEM NO.	BUREAU	SUBJECT
1	MEDIA .....	TITLE: Review of the Commission's Program Access Rules and Examination of Programming Tying Arrangements (MB Docket No. 07-198) SUMMARY: The Commission will consider a Report and Order to further promote competition in the video distribution market through rules addressing terrestrially delivered, cable-affiliated programming.
2	WIRELESS TELE-COMMUNICATIONS .....	TITLE: Amendment of Parts 15, 74 and 90 of the Commission's Rules Regarding Low Power Auxiliary Stations, Including Wireless Microphones (WT Docket No. 08-166) SUMMARY: The Commission will consider an Order and Further Notice of Proposed Rulemaking to complete an important component of the DTV transition by prohibiting the further distribution and sale of devices that operate in the 700 MHz frequency and setting a date by which existing devices must clear the band to enable the rollout of public safety services and accelerate the deployment of next generation wireless networks.



ITEM NO.	BUREAU	SUBJECT
3	CONSUMER GOVERNMENTAL AFFAIRS .....	TITLE: Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991 (CG Docket No. 02-278) SUMMARY: The Commission will consider a Notice of Proposed Rulemaking that would harmonize the Commission's rules regarding prerecorded telemarketing calls with the Federal Trade Commission's recently amended Telemarketing Sales Rule.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e-mail to: [fcc504@fcc.gov](mailto:fcc504@fcc.gov) <<mailto:fcc504@fcc.gov>> or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418-0500; TTY 1-888-835-5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live web page at [www.fcc.gov/live](http://www.fcc.gov/live) <<http://www.fcc.gov/live>>.

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993-3100 or go to [www.capitolconnection.gmu.edu](http://www.capitolconnection.gmu.edu) <<http://www.capitolconnection.gmu.edu>>.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor. Best Copy and Printing, Inc. (202) 488-5300; Fax (202) 488-5563; TTY (202) 488-5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by e-mail at [FCC@BCPIWEB.com](mailto:FCC@BCPIWEB.com).

Federal Communications Commission.

**Marlene H. Dortch.**

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2010-949 Filed 1-14-10; 4:15 pm]

BILLING CODE 6712-01-S

## FEDERAL RESERVE SYSTEM

### Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

#### SUMMARY:

#### Background

Notice is hereby given of the final approval of proposed information collections by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

#### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Michelle Store—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829).

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

*Final approval under OMB delegated authority of the extension for three years, with revision, of the following report:*

*Report title:* The Government Securities Dealers Reports: Weekly Report of Dealer Positions (FR 2004A), Weekly Report of Cumulative Dealer Transactions (FR 2004B), Weekly Report of Dealer Financing and Fails (FR

2004C), Weekly Report of Specific Issues (FR 2004SI), Daily Report of Specific Issues (FR 2004SD), Daily Report of Specific Issues ad hoc (FR 2004SD), and Daily Report of Dealer Activity in Treasury Financing (FR 2004WI).

*Agency form number:* FR 2004.

*OMB control number:* 7100-0003.

*Frequency:* Weekly, daily.

*Reporters:* Dealers in the U.S. government securities market.

*Estimated annual reporting hours:* FR 2004A, 1,404 hours; FR 2004B, 1,872 hours; FR 2004C, 1,170 hours; FR 2004SI, 1,872 hours; FR 2004SD, 900 hours; FR 2004SD ad hoc, 936 hours; FR 2004WI, 2,880 hours.

*Estimated average hours per response:* FR 2004A, 1.5 hours; FR 2004B, 2.0 hours; FR 2004C, 1.25 hours; FR 2004SI, 2.0 hours; FR 2004SD, 2.0 hours; FR 2004SD ad hoc, 2.0 hours; FR 2004WI, 1.0 hour.

*Number of respondents:* 18.

*General description of report:* This information collection is authorized by sections 2A, 12A, and 14 of the Federal Reserve Act (12 U.S.C. 225a, 263, and 353-359) and is required to obtain or retain a benefit. Individual respondent data are regarded as confidential under the Freedom of Information Act (5 U.S.C. 552(b)(4) and (b)(8)).

*Abstract:* The FR 2004A collects weekly data on dealers' outright positions in Treasury and other marketable debt securities. The FR 2004B collects cumulative weekly data on the volume of transactions made by dealers in the same instruments for which positions are reported on the FR 2004A. The FR 2004C collects weekly data on the amounts of dealer financing and fails. The FR 2004SI collects weekly data on position, transaction, financing, and fails for the most recently issued on-the-run Treasury securities (the most recently issued Treasury securities for each maturity class). When unusual trading practices occur for a specific security, this information can be collected on a daily basis on the FR 2004SD for either on-the-run Treasury securities or off-the-run Treasury securities. The FR 2004WI collects daily

data on positions in to-be-issued Treasury coupon securities, mainly the trading on a when-issued delivery basis.

**Current Actions:** On November 2, 2009, the Federal Reserve published a notice in the **Federal Register** (74 FR 56633) requesting public comment for 60 days on the extension, with revision, of the FR 2004. The comment period for this notice expired on January 4, 2010. The Federal Reserve did not receive any comments. The revisions will be implemented as proposed.

**Final approval under OMB delegated authority of the implementation of the following survey:**

**Report title:** Central Bank Survey of Foreign Exchange and Derivatives Market Activity.

**Agency form number:** FR 3036.

**OMB control number:** 7100-0285.

**Frequency:** One-time.

**Reporters:** Financial institutions that serve as intermediaries in the wholesale foreign exchange and derivatives market and dealers.

**Estimated annual reporting hours:** 2,165 hours.

**Estimated average hours per response:** Turnover survey, 55 hours; outstandings survey, 60 hours.

**Number of respondents:** Turnover survey, 35; outstandings survey, 4.

**General description of report:** This information collection is voluntary (12 U.S.C. 225a and 263) and is given confidential treatment (5 U.S.C. 552(b)(4)).

**Abstract:** The FR 3036 is the U.S. part of a global data collection that is conducted by central banks once every three years. More than 50 central banks plan to conduct the survey in 2010. The Bank for International Settlements compiles national data from each central bank to produce global market statistics.

The Federal Reserve System and other government agencies use the survey to monitor activity in the foreign exchange and derivatives markets. Respondents use the published data to gauge their market share.

**Current Actions:** On November 2, 2009, the Federal Reserve published a notice in the **Federal Register** (74 FR 56633) requesting public comment for 60 days on the implementation of the FR 3036. The comment period for this notice expired on January 4, 2010. The Federal Reserve did not receive any comments. The survey will be implemented as proposed.

Board of Governors of the Federal Reserve System, January 12, 2010.

**Jennifer J. Johnson,**  
Secretary of the Board.

[FR Doc. 2010-751 Filed 1-15-10; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Biodefense Science Board: Notification of Public Teleconference

**AGENCY:** Department of Health and Human Services, Office of the Secretary.  
**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Biodefense Science Board (NBSB) will hold a teleconference meeting. The meeting is open to the public. Pre-registration is NOT required, however, individuals who wish to participate in the public comment session should e-mail [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV) to RSVP.

**DATES:** The meeting will be held on February 10, 2010 from 2 p.m. to 4 p.m. ET.

**ADDRESSES:** The meeting will occur by teleconference. To attend, call 1-866-395-4129, pass-code "ASPR." Please call 15 minutes prior to the beginning of the conference call to facilitate attendance.

**FOR FURTHER INFORMATION:** E-mail: [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV)

**SUPPLEMENTARY INFORMATION:** Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

The Board will discuss and consider recommendations from the National Biodefense Science Board's Medical Countermeasure Markets and Sustainability Working Group report titled "Inventory of Issues Constraining or Enabling Industry Involvement in Medical Countermeasure Efforts."

Members of the public are invited to attend by teleconference via a toll-free call-in phone number. The teleconference will be operator assisted to allow the public the opportunity to provide comments to the Board. Public participation will be limited to time and space available. Public comments will

be limited to no more than 3 minutes per speaker. To be placed on the public comment list, notify the operator when you join the teleconference.

Public comments received by close of business one week prior to each teleconference will be distributed to the NBSB in advance. Submit comments via e-mail to [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV), with "NBSB Public Comment" as the subject line.

A draft agenda and any additional materials/agendas will be posted on the NBSB Web site (<http://www.hhs.gov/aspr/omsph/nbsb/>) prior to the meeting.

Dated: January 11, 2010.

**Nicole Lurie,**

Assistant Secretary for Preparedness and Response.

[FR Doc. 2010-778 Filed 1-15-10; 8:45 am]

**BILLING CODE 4150-37-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Advisory Committees; Filing of Closed Meeting Reports

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2009.

**ADDRESSES:** Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860.

**FOR FURTHER INFORMATION CONTACT:** Teresa L. Hays, Committee Management Officer, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

**SUPPLEMENTARY INFORMATION:** Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app. 1) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2008, through September 30, 2009: *Center for Biologics Evaluation and Research;*

Blood Products Advisory Committee,

Vaccines and Related Biological Products Advisory Committee, Center for Drug Evaluation and Research:

Anesthetic and Life Support Drugs Advisory Committee, Antiviral Drugs Advisory Committee, Endocrinologic and Metabolic Drugs Advisory Committee, Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of report for Circulatory System Devices Panel).

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and
2. The Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: January 13, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-807 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0488]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs; Adverse Event Reports on Forms FDA 1932, 1932a, and 2301**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of

Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0284. Also include the FDA docket number found in brackets in the heading of this document

**FOR FURTHER INFORMATION CONTACT:**

Denver Presley, Jr. Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Records and Reports Concerning Experience With Approved New Animal Drugs; Adverse Event Reports on Forms FDA 1932, 1932a, and 2301 (OMB Control Number 0910-0284)—Extension**

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(l) and § 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see § 514.80(b)).

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may not be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

Under § 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, "Transmittal of Periodic Reports and Promotional Material for New Animal Drugs" (see § 514.80(d)). Form FDA 1932a, "Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report" allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

The electronic versions of Forms FDA 1932 and 1932a have been incorporated into the agency-wide information collection (MedWatch<sup>Plus</sup> Portal and Rational Questionnaire) that was announced for public comment in the **Federal Register** on October 23, 2008 (73 FR 63153). MedWatch<sup>Plus</sup> Portal and Rational Questionnaire is part of a new electronic system for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. In the **Federal Register** of May 20, 2009 (74 FR 23721), FDA announced the submission for OMB review and clearance of the electronic data collection using MedWatch<sup>Plus</sup> Portal and Rational Questionnaire.

Burden hours for the electronic versions of these forms were included as part of the MedWatch<sup>Plus</sup> Portal and Rational Questionnaire information collection approved under OMB control number 0910-0645. It is estimated that, during the first 3 years that the MedWatch<sup>Plus</sup> Portal is in use, half of the reports will be submitted in paper format and half will be submitted electronically. In order to avoid double counting, an estimated 50 percent of total annual responses for FDA Form 1932 (404) and FDA Form 1932a (81.5) are counted here as part of OMB Control No. 0910-0284 for the paper versions of Forms FDA 1932 and 1932a, and an estimated 50 percent of the total annual responses (404) and (81.5) for Form FDA 1932 and FDA Form 1932a respectively, are counted as part of OMB Control No. 0910-0645 for the electronic reporting of these adverse reports using the MedWatch<sup>Plus</sup> Portal.

In the **Federal Register** of October 15, 2009 (74 FR 52967), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

In a separate 30-day notice, FDA requested public comment on data elements associated with revisions to Forms FDA 1932 and 1932a (both paper and electronic) under revised OMB Control No. 0910-0645 (November 20, 2009, 74 FR 60265). The agency plans to give companies time to accommodate the revisions since the proposed revisions may require changes to validated databases. The agency plans to provide a transition period for respondents until September 30, 2010, during which the current FDA Form 1932 (version dated 01/2007—approved under this OMB Control No. 0910-0284) will be accepted as well as the revised FDA Form 1932 approved under revised OMB Control No. 0910-0645. After the transition period, Form FDA 2301 will

continue to be counted as part of OMB Control No. 0910-0284.

The reporting and recordkeeping burden estimates, including the total number of annual responses, are based

on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The annual frequency of responses was calculated

as the total annual responses divided by the number of respondents.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section or Section of the Act	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3)	1932 <sup>2</sup>	404	44.26	17,881	1	17,881
Voluntary reporting FDA Form 1932a for the public	1932a <sup>2</sup>	81.5	1	81.5	1 <sup>3</sup>	81.5
514.80(b)(4)	2301	84	17.0	1,428	16	22,848
514.80(b)(5)(i)	2301	84	0.31	26	2	52
514.80(b)(5)(ii)	2301	84	33.92	2,849	2	5,698
514.80(b)(5)(iii)	2301	646	0.08	51.68	2	103
Total hours						46,663.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Burden hours were determined as explained previously.

<sup>3</sup> The hours per response for paper versions of Forms FDA 1932 and 1932a are assumed to be 1 hour. The hours per response for the electronic version of Form FDA 1932 is assumed to be 1 hour, while the electronic version of Form FDA 1932a is assumed to take .6 hours to complete the form and gather the required information as part of the MedWatch<sup>Plus</sup> Portal information collection (see 74 FR 23721 at 23727).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
514.80(e) <sup>2</sup>	646	7.20	4,651	14	65,116.8

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Section 514.80(e) covers all recordkeeping hours for all adverse event reporting.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-782 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0483]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet—Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0511. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Medical Device User Fee Cover Sheet—Form FDA 3601—OMB Control Number 0910-0511—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the "Medical Device User Fee Cover Sheet," is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees

submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications. The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal year (FY) 2008. CDRH received approximately

5,095 annual responses that included the following submissions: 16 premarket approval applications (PMAs) (PDP, PMR, and BLA),<sup>1</sup> 3,625 premarket notifications, 8 modular premarket applications, 9 panel track supplements, 201 real-time supplements, 173 180-day supplements, 633 30-day notices, 93 513(g) requests, and 337 annual fees for periodic reporting.

CBER received approximately 97 annual responses that included the following submissions: 2 PMAs, 1 BLA efficacy supplement, 50 premarket notifications, 3 180-day supplements, 2

real-time supplements, 20 30-day notices, 3 513(g) requests, and 16 annual fees for periodic reporting. The number of received annual responses in FY 2008 included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Medical Device Manufacturers .....	3601	5,192	1	5,192	18/60	1,558

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of October 15, 2009 (74 FR 52965), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: January 12, 2010.\*

**David Dorsey**,  
Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-790 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0465]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0546. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Food Additive Petitions (OMB Control Number 0910-0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use.

Section 409(b) of the act specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but seek to explain the requirements and provide a standard format for submission of petitions, that when implemented, will speed up the time for processing. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573, 582, and 584 of the act. The labeling regulations are considered by FDA to be cross referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

In the **Federal Register** of October 6, 2009 (74 FR 51287), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

<sup>1</sup> PDP means product development protocol, PMR means postmarketing requirements, and BLA means biologics license applications.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6 amendment of petition	2	2	4	1300	5,200
Total Hours					18,200

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

**571.1(c) moderate category:** For food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of one petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

**571.1(c) complex category:** For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

**571.6:** For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

Thus, the estimated total annual burden for this information collection is 18,200 hours.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-783 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0487]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0582. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—(OMB Control Number 0910-0582)—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations

addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1; 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level one guidance document issued under the Good Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total

recordkeeping burden of 2,800 hours (700 x 4 = 2,800). FDA estimates that the cost of developing standard operating procedures for each recordkeeper is \$300 (6 hours of work at \$50/hour (h)). This results in a total cost to industry of \$210,000 (\$300 x 700 recordkeepers). FDA estimates that operating costs for collecting this information is \$300 per

recordkeeper (6 hours of work at \$50/h). This results in a total operational and maintenance cost to industry of \$210,000 (\$300 x 700 recordkeepers). The total cost of this recordkeeping, capital plus operational and maintenance cost is estimated to be \$420,000.

In the **Federal Register** of October 20, 2009 (74 FR 53749), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Section of the Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
520(g)	700	1	700	4	2,800

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. Due to a clerical error, the capital costs and operating and maintenance costs that appeared in a notice issued in the **FEDERAL REGISTER** of October 20, 2009 (74 FR 53749 at 53750) were incorrect. The costs were actually salary costs; Table 1 of this document contains the correct cost burden.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-791 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0480]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions Reports and Records

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0078. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices, and allow investigators the maximum freedom

possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety or welfare of human subjects, are subject to the full requirements of the IDE regulation. Non-significant risk device investigations, ones that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements. The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available. Section 812.10 of the act, permits the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety. Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations.

Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in the original IDE application is evaluated by the Center for Devices and Radiological Health to

determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE. Upon approval of an IDE application by FDA, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation which affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Section 812.150 requires a sponsor to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress. Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this

information to determine if wider distribution of the device is in the interests of the public health. Section 812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device and to ensure the integrity of the controlled clinical trials. Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study, records of receipt, use or disposition of devices, records of each subject's case history and exposure to the device, informed consent documentation, study protocol and documentation of any deviation from the protocol. Sponsors are required to

maintain records including correspondence and reports concerning the study, records of shipment and disposition, signed investigator agreements, adverse device effects information and for a non-significant risk device study, an explanation of the non-significant risk determination, records of device name and intended use, study objectives, investigator information, investigational review board information, and statement on the extent that good manufacturing practices will be followed.

In the *Federal Register* of October 23, 2009 (74 FR 54824), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
812.10	1	1	1	1	1
812.20, 812.25, and 812.27	465	0.5	233	80	18,640
812.35 and 812.150 (reports for significant risk studies)	465	7.8	3,627	6	21,762
812.150 (reports for non-significant risk studies)	465	0.017	8	6	48
812.36(c)	1	1	1	120	120
812.36(f)	1	2	2	20	40
Total					40,611

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. Due to a reevaluation of the burden, the burden hours and annual responses which appeared in a notice issued in the *FEDERAL REGISTER* of October 23, 2009 (74 FR 54824) have been adjusted.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
812.140 Original	465	0.5	233	10	2,330
812.140 Supplemental	465	7	3,255	1	3,255
812.140 Non-significant	465	1	465	6	2,790
Total					8,375

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. The estimate of the burden is based on the number of IDEs received in the last 3 years.



Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-793 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0474]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0510. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—(OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph "g" to

section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program. FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria."

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

In the **Federal Register** of October 22, 2009 (74 FR 54570), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section of the Act	Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
704(g)	Request for Accreditation	3	1	3	80	240
Total Hours						240

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-796 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0475]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0114. Also

include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C.

334(g)), to detain during established inspections, devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in a March 9, 1979, **Federal Register** (44 FR 13234) on administrative detention procedures, which includes among other things, certain reporting requirements and recordkeeping requirements under § 800.55(g) and (k), (21 CFR 800.55(g) and (k)). Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permits FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an

unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the May 18, 1979, **Federal Register** (44 FR 29221) contained certain reporting requirements under 21 CFR 895.21(d) and 895.22(a). Section 895.21(d) states that if the Commissioner of Food and Drugs (the Commissioner), decides to initiate a proceeding to make a device, "a banned device," a notice of proposed rulemaking will be published in the **Federal Register** and this document will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling, change of labeling, change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a

manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of three firms whose devices had been detained.

In the **Federal Register** of October 16, 2009 (74 FR 53257), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Totals					441

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Totals					461

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-795 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0484]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of

Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0584. Also include the FDA docket number found in brackets in the heading of the document.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—(OMB Control Number 0910-0584)—Extension**

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with 21 U.S.C. 360c(a)(1)(B), because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls

many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and "other appropriate actions as the Secretary deems necessary" (21 U.S.C. 360c(a)(1)(B)). This information-collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses. FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification will be codified in 21 CFR 866.3332, a regulation that will describe the new classification for reagents for detection of specific novel influenza A viruses and set forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation will refer to the special controls guidance document entitled "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses," which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease

prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 10 hours. This results in a total data collection burden of 200 hours (10 x 20 = 200). FDA estimates that cost of developing standard operating procedures for each data collection is \$500 (10 hours of work at \$50/hour). This results in a total cost to industry of \$5,000 (\$500 x 10 respondents). The guidance also refers to previously approved information collections found in FDA regulations. The information collections in 21 CFR part 820 have been approved under OMB control number 0910-0073.

In the *Federal Register* of October 13, 2009 (74 FR 52493), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it was not PRA related.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
513(g)	10	2	20	15	300

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Due to a clerical error, capital costs and operating and maintenance costs that appeared in a notice published in the **Federal Register** of October 20, 2009 (74 FR 53749) were incorrect. There are actually no capital and maintenance costs; additionally, the hours per response which were reported as 10 are actually 15. Table 1 of this document contains the correct hour burden.

Dated: January 12, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-794 Filed 1-15-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0486]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 18, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0508. Also include the FDA docket number found in brackets in the heading of the document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### **Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification—OMB Control Number 0910-0508—Extension**

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2009 (74 FR 38444), announcing fees for fiscal year (FY) 2010. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a "small business." This means there are two levels of fees, a standard fee, and a reduced or waived small business fee (FDA Form 3602—For Domestic Small Business Applicants For FY 2010). You can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than \$100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours, and the total must be no more than \$100 million. If your gross receipts or sales are no more than \$30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application (product development protocol, biologics licensing application, or Premarket Report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the "small business" criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a "small business" within the meaning of MDUFMA (FDA Form 3602A—For Foreign Small Business Applicants). The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid. Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory

threshold, currently, \$100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a "National Taxing Authority Certification," must: Be in English; be from the national taxing authority of the country in which the business is headquartered; provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; provide the dates during which the reported receipts or sales were collected; and bear the official seal of the national taxing authority. Both FDA Forms 3602 and 3602A are available in the guidance document, "Guidance for Industry, FDA and Foreign Governments: FY 2010 MDUFMA Small Business Qualification and Certification," available on the Internet at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf>.

This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2010.

The FDA Form 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit FDA Form 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602A, FDA believes each business will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification, because there is a different tax verification process by each country's National Taxing Authority. The information collection for FDA Form 3602 is currently approved under OMB control

number 0910-0508. The information collection for FDA Form 3602A is currently approved under OMB control number 0910-0613. With this request for approval, FDA is requesting to consolidate OMB approvals 0910-0508

and 0910-0613 into one information collection using the OMB control number 0910-0508.

In the **Federal Register** of October 23, 2009 (74 FR 54826), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000
3602A Sections I and II	340	1	340	1	340
3602A Section III	33	7	231	1	231
Totals					3,571

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

[FR Doc. 2010-792 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Endocrinologic and Metabolic Drugs Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on February 24, 2010, from 8 a.m. to 5 p.m.

**Location:** Hilton Washington DC/Silver Spring, The Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

**Contact Person:** Paul Tran, RPh., Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: paul.tran@fda.hhs.gov, or FDA

Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss the safety and efficacy of new drug application (NDA) 22-505, for EGRIFTA (tesamorelin acetate) sterile lyophilized powder for injection, by Theratechnologies, Inc. EGRIFTA is an analogue (a chemical compound that resembles another compound in structure) of growth hormone releasing hormone (GHRH). The proposed indication (use) for EGRIFTA in this application is to induce and maintain a reduction of excess visceral abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy (a condition in which abnormal deposits of fat are seen partly as a result of using certain drugs to treat HIV disease).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/>

[default.htm](#). Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 9, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 10, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisory>

*Committees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 12, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-785 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0001]

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Vaccines and Related Biological Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 22, 2010, from 8:30 a.m. to approximately 1:30 p.m.

*Location:* Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD.

*Contact Person:* Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss and make recommendations on the

selection of strains to be included in the influenza virus vaccine for the 2010 - 2011 influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 19, 2010. Oral presentations from the public will be scheduled between approximately 11:20 a.m. and 12:20 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 11, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 12, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 12, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-789 Filed 1-15-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel: SBIR Phase 1 Integrated Prediction Systems.

*Date:* February 9, 2010.

*Time:* 10 a.m. to 12 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* NIEHS, 530 Keystone Building, 530 Davis Drive, Durham, NC 27709 (Telephone Conference Call).

*Contact Person:* RoseAnne M. McGee, Associate Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel: SBIR Phase 1 qNPA Metabolism HTS Assay.

*Date:* February 9, 2010.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* NIEHS, 530 Keystone Building, 530 Davis Drive, Durham, NC 27709 (Telephone Conference Call).

*Contact Person:* RoseAnne M. McGee, Associate Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences,

P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

**Name of Committee:** National Institute of Environmental Health Sciences Special Emphasis Panel; SBIR Phase 1 Novel HTS for Gap Junctional Communication.

**Date:** February 10, 2010.

**Time:** 10 a.m. to 11:30 a.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** NIEHS, 530 Keystone Building, 530 Davis Drive, DURHa.m., NC 27709 (Telephone Conference Call).

**Contact Person:** RoseAnne M. McGee, Associate Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

**Name of Committee:** National Institute of Environmental Health Sciences Special Emphasis Panel; SBIR Phase 1 Zebrafish Cardiotoxicity Assay.

**Date:** February 11, 2010.

**Time:** 10 a.m. to 12 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** NIEHS, 530 Keystone Building, 530 Davis Drive, DURHa.m., NC 27709 (Telephone Conference Call).

**Contact Person:** RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

**Name of Committee:** National Institute of Environmental Health Sciences Special Emphasis Panel; SBIR Phase 1 Transgenic C Elegans.

**Date:** February 11, 2010.

**Time:** 1 p.m. to 3 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** NIEHS, 530 Keystone Building, 530 Davis Drive, DURHa.m., NC 27709 (Telephone Conference Call).

**Contact Person:** RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

**Name of Committee:** National Institute of Environmental Health Sciences Special Emphasis Panel; SBIR Phase 1 Multiplex Array for Mold Biomarkers.

**Date:** February 11, 2010.

**Time:** 3:30 p.m. to 5 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** NIEHS, 530 Keystone Building, 530 Davis Drive, DURHa.m., NC 27709 (Telephone Conference Call).

**Contact Person:** RoseAnne M. McGee, Associate Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat.

Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mcgee1@niehs.nih.gov](mailto:mcgee1@niehs.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

**Dated:** January 12, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-862 Filed 1-15-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** Musculoskeletal, Oral And Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

**Date:** February 10-11, 2010.

**Time:** 8 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Sheraton Belfina Santa Monica Hotel, 530 Pico Boulevard, Santa Monica, CA 90405.

**Contact Person:** Jean D. Sipe, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892. 301/435-1743, [sipej@csr.nih.gov](mailto:sipej@csr.nih.gov).

**Name of Committee:** Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

**Date:** February 10-11, 2010.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, [knechtm@csr.nih.gov](mailto:knechtm@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Member Conflict: NAME and IRAP.

**Date:** February 10, 2010.

**Time:** 12 p.m. to 2 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

**Contact Person:** Elisabeth Koss, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1721, [kosse@csr.nih.gov](mailto:kosse@csr.nih.gov).

**Name of Committee:** Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

**Date:** February 11, 2010.

**Time:** 7 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Mission Bay, 1441 Quivira Road, San Diego, CA 92109.

**Contact Person:** Paek-Gyu Lee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5203, MSC 7812, Bethesda, MD 20892, (301) 435-0902, [leepg@csr.nih.gov](mailto:leepg@csr.nih.gov).

**Name of Committee:** Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurotransmitters, Receptors, and Calcium Signaling Study Section.

**Date:** February 11-12, 2010.

**Time:** 8:30 a.m. to 5:30 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hotel Monaco, 700 F Street, NW., Washington, DC 20004.

**Contact Person:** Peter B. Guthrie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [guthriep@csr.nih.gov](mailto:guthriep@csr.nih.gov).

**Name of Committee:** Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

**Date:** February 11-12, 2010.

**Time:** 9 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** The River Inn, 924 25th Street, NW., Washington, DC 20037.

**Contact Person:** David J. Remondini, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301-435-1038, [remondid@csr.nih.gov](mailto:remondid@csr.nih.gov).

*Nome of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflicts: Arthritis, Connective Tissue and Skin Study Section.

*Date:* February 11, 2010.

*Time:* 10 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

*Contact Person:* Jean D. Sipe, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892, 301/435-1743, [sipej@csr.nih.gov](mailto:sipej@csr.nih.gov).

*Nome of Committee:* Center for Scientific Review Special Emphasis Panel; Development Methods of In Vivo Imaging and Bioengineering Research.

*Date:* February 11-12, 2010.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

*Contact Person:* Behrouz Shabestari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7854, Bethesda, MD 20892, (301) 435-2409, [shobestb@csr.nih.gov](mailto:shobestb@csr.nih.gov).

*Nome of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

*Date:* February 12, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

*Contact Person:* Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, [pelhomj@csr.nih.gov](mailto:pelhomj@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

*Dated:* January 11, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-861 Filed 1-15-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Intercellular Interactions Study Section, February 11, 2010, 8 a.m. to February 12, 2010, 5

p.m., Sheraton Fisherman's Wharf Hotel, 2500 Mason Street, San Francisco, CA 94133 which was published in the **Federal Register** on January 11, 2010, 75 FR 1397-1399.

The meeting will be one day only February 11, 2010. The meeting time and location remain the same. The meeting is closed to the public.

*Dated:* January 11, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-860 Filed 1-15-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular Neuropharmacology and Signaling Study Section, February 4, 2010, 8 a.m. to February 5, 2010, 5 p.m., Hotel Monaco, 700 F Street, NW., Washington, DC 20001 which was published in the **Federal Register** on January 11, 2010, 75 FR 1397-1399.

The meeting will be one day only February 4, 2010, from 8 a.m. to 7 p.m. The meeting location remains the same. The meeting is closed to the public.

*Dated:* January 11, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-857 Filed 1-15-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Nome of Committee:* National Cancer Institute Special Emphasis Panel; T32.

*Date:* January 26, 2010.

*Time:* 5 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

*Contact Person:* Robert Bird, PhD, Chief, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8113, Bethesda, MD 20892-8328, 301-496-7978, [birdr@mail.nih.gov](mailto:birdr@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

*Nome of Committee:* National Cancer Institute Special Emphasis Panel; NCI Clinical Studies P01.

*Date:* February 1-3, 2010.

*Time:* 3 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Majed M. Hamawy, MBA, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8135, Bethesda, MD 20852, 301-594-5659, [mh101v@nih.gov](mailto:mh101v@nih.gov).

*Nome of Committee:* National Cancer Institute Special Emphasis Panel; Cellular and Tissue Oncology.

*Date:* February 9-11, 2010.

*Time:* 5 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Shakeel Ahmad, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8139, Bethesda, MD 20892-8328, (301) 594-0114, [ohmoads@mail.nih.gov](mailto:ohmoads@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

*Dated:* January 11, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-856 Filed 1-15-10; 8:45 am]

**BILLING CODE 4140-01-P**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2010-N-0020]

**Use of Tobacco Marketing Descriptors to Convey Modified Risk; Request for Comments**
**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to provide an opportunity for interested parties to share information, research, and ideas on tobacco product marketing descriptors that may be considered similar to the prohibited terms "light," "mild," and "low." This information will be used to further FDA's efforts to reduce misleading and deceptive advertising practices.

**DATES:** Submit electronic or written comments by February 18, 2010.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kathleen K. Quinn, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 240-276-1717, [Kathleen.Quinn@fda.hhs.gov](mailto:Kathleen.Quinn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**
**I. Background**

Tobacco products are responsible for more than 440,000 deaths each year. The Centers for Disease Control and Prevention report that 70 percent of the 46 million adults who currently smoke in the United States want to quit. Since the introduction to the American market in the 1960s of cigarettes marketed as "light," "low," or "mild," millions of smokers have turned to these products in the false belief that they pose fewer health hazards and may facilitate quitting. While scientific evidence has demonstrated that light cigarettes do not reduce the health risks associated with smoking, sales of light cigarettes have continued to climb, accounting for 92.7 percent of cigarettes sold in the United States in 2006. Curbing the significant adverse consequences of tobacco use is one of the most important public health goals of our time. One step toward the realization of that goal is to prevent misleading labeling claims and to

regulate "modified risk" tobacco products.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 911(b) to the Federal Food, Drug, and Cosmetic Act (the act), banning the manufacture of any tobacco product "the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors;" as of June 22, 2010.

We are requesting comments that will inform the agency's development of guidance on the meaning of the term "similar descriptors." A copy of the Tobacco Control Act is available at <http://www.fda.gov/tobacco>.

**II. Request for Comments and Information**

Product packaging plays a critical role in fostering brand loyalty and communicating messages to consumers about the risks and benefits of product use. FDA is aware that messages of reduced harm can be conveyed through a variety of visual cues. We are therefore requesting comment on ways in which descriptors that may be considered similar to "light," "mild" and "low" used on tobacco product packaging could impact consumer perceptions of risk. Such descriptors may include:

- Adjectives like "silver," "fine," or "smooth,"
- Colors like white, silver or pastels;
- Printed numbers associated with risk level;
- Letters (e.g., "L") or other symbols that connote "light,"
- Depiction of filters or other images that imply purification or healthfulness;
- Words used in brand names that have associations with potency, risk, or healthfulness; and
- Use of terms such as "natural" and "no additives."

The agency will consider information submitted to the docket in developing guidance on the meaning of the term "similar descriptors" as it pertains to the label, labeling, or advertising of modified risk tobacco products.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic

comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified by the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 12, 2010.

**David Dorsey,**
*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-784 Filed 1-15-10; 8:45 am]

**BILLING CODE 4160-01-S**
**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. DHS-2009-0162]

**RIN 1601-ZA08**
**Identification of Foreign Countries Whose Nationals Are Eligible To Participate in the H-2A and H-2B Visa Programs**
**AGENCY:** Office of the Secretary, DHS.

**ACTION:** Notice.

**SUMMARY:** Under Department of Homeland Security (DHS) regulations, U.S. Citizenship and Immigration Services (USCIS) may only approve petitions for H-2A and H-2B nonimmigrant status for nationals of countries that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated by notice published in the *Federal Register*. That notice must be renewed each year. This notice announces that the Secretary of Homeland Security, in consultation with the Secretary of State, is identifying 39 countries whose nationals are eligible to participate in the H-2A and H-2B programs for the coming year.

**DATES:** *Effective Date:* This notice is effective January 18, 2010, and shall be without effect at the end of one year after January 18, 2010.

**FOR FURTHER INFORMATION CONTACT:** Alex Hartman, DHS Office of Policy, Department of Homeland Security, Washington, DC 20528 (202) 282-9820.

**SUPPLEMENTARY INFORMATION:**

*Background:* Pursuant to 8 CFR 214.2(h)(5)(i)(F)(1)(i) and 8 CFR 214.2(h)(6)(i)(E)(1), USCIS may only approve H-2A and H-2B petitions for nationals of countries that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated as participating countries. Such designation must be

published as a notice in the **Federal Register** and expires after one year.

In designating countries to include on the list, DHS, with the concurrence of the Secretary of State, will take into account factors including, but not limited to: (1) The country's cooperation with respect to issuance of travel documents for citizens, subjects, nationals and residents of that country who are subject to a final order of removal; (2) the number of final and unexecuted orders of removal against citizens, subjects, nationals and residents of that country; (3) the number of orders of removal executed against citizens, subjects, nationals and residents of that country; and (4) such other factors as may serve the U.S. interest. See 8 CFR 214.2(h)(5)(i)(F)(1)(i) and 8 CFR 214.2(h)(6)(i)(E)(1).

In December 2008, DHS published in the **Federal Register** two notices, "Identification of Foreign Countries Whose Nationals Are Eligible to Participate in the H-2A Visa Program," and "Identification of Foreign Countries Whose Nationals Are Eligible to Participate in the H-2B Visa Program," designating 28 countries whose nationals are eligible to participate in the H-2A and H-2B programs. See 73 FR 77,043 (Dec. 18, 2008); 73 FR 77,729 (Dec. 19, 2008). The initial designations were composed of countries that are important for the operation of the H-2A and H-2B programs and are cooperative in the repatriation of their citizens, subjects, nationals or residents who are subject to a final order of removal from the United States. The notices cease to have effect at the end of one year after January 17 and January 18, 2009 respectively. See 8 CFR 214.2(h)(5)(i)(F)(2) and 8 CFR 214.2(h)(6)(i)(E)(3).

Following consultations with the Department of State, the Secretary of Homeland Security finds, with the concurrence of the Secretary of State, that the 28 countries designated in the December 18 and 19, 2008 notices continue to meet the standards identified in those notices for eligible countries and therefore should remain designated as countries whose nationals are eligible to participate in the H-2A and H-2B programs.

Furthermore, the Secretary of Homeland Security, with the concurrence of the Secretary of State, finds that it is now appropriate to add 11 additional countries to the list of countries whose nationals are eligible to participate in the H-2A and H-2B programs. This determination is made taking into account the four factors identified above. The Secretary of Homeland Security considered other

pertinent factors: including, but not limited to, evidence of past usage of the H-2A and H-2B programs by nationals of the countries to be added, as well as evidence relating to the economic impact on particular U.S. industries or regions resulting from the addition or continued non-inclusion of specific countries. In consideration of all of the above, this notice designates for the first time Croatia, Ecuador, Ethiopia, Ireland, Lithuania, The Netherlands, Nicaragua, Norway, Serbia, Slovakia, and Uruguay as countries whose nationals are eligible to participate in the H-2A and H-2B programs.

#### Designation of Countries Whose Nationals Are Eligible To Participate in the H-2A and H-2B Visa Programs

Pursuant to the authority provided to the Secretary of Homeland Security under sections 241, 214(a)(1), and 215(a)(1) of the Immigration and Nationality Act (INA) (8 U.S.C. 1231, 1184(a)(1), and 1185(a)(1)), I have designated, with the concurrence of the Secretary of State, that nationals from the following countries are eligible to participate in the H-2A and H-2B visa programs:

Argentina, Australia, Belize, Brazil, Bulgaria, Canada, Chile, Costa Rica, Croatia, Dominican Republic, Ecuador, El Salvador, Ethiopia, Guatemala, Honduras, Indonesia, Ireland, Israel, Jamaica, Japan, Lithuania, Mexico, Moldova, The Netherlands, Nicaragua, New Zealand, Norway, Peru, Philippines, Poland, Romania, Serbia, Slovakia, South Africa, South Korea, Turkey, Ukraine, United Kingdom, Uruguay.

This notice does not affect the status of aliens who currently hold H-2A or H-2B nonimmigrant status.

Nothing in this notice limits the authority of the Secretary of Homeland Security or his or her designee or any other federal agency to invoke against any foreign country or its nationals any other remedy, penalty or enforcement action available by law.

Janet Napolitano,  
Secretary.

[FR Doc. 2010-960 Filed 1-15-10; 8:45 am]

BILLING CODE 9110-9M-P

#### DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2009-0160]

#### Homeland Security Advisory Council

AGENCY: The Office of Policy, DHS.

**ACTION:** Committee management; Notice of partially closed federal advisory committee meeting.

**SUMMARY:** The Homeland Security Advisory Council (HSAC) will meet on February 3, 2010, in New York, New York. The meeting will be partially closed to the public.

**DATE:** The HSAC will meet February 3, 2010, from 9 a.m. to 3 p.m. and the meeting is open to the general public from 10:30 a.m. to 12 p.m. EST. The meeting is closed from 9 a.m. to 10:30 a.m. and then again from 12 p.m. to 3 p.m.

**ADDRESSES:** The open portion of the meeting will be held at the Grand Hyatt New York, 109 East 42nd Street at Grand Central Terminal, in the Empire Ballroom in New York, New York. Requests to have written material distributed to each member of the committee prior to the meeting must reach the below contact person by January 25, 2010. Comments must be identified by **Federal Register** Notice DHS-2009-0160 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* [HSAC@dhs.gov](mailto:HSAC@dhs.gov). Fax: 202-282-9207.
- *Mail:* Homeland Security Advisory Council, 1100 Hampton Park Boulevard, Mailstop 0850, Capitol Heights, MD 20745.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and DHS-2009-0160. Comments received will be posted without alteration at <http://www.regulations.gov>, including provided personal information.

*Docket:* For docket access to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Homeland Security Advisory Council, (202) 447-3135, [HSAC@dhs.gov](mailto:HSAC@dhs.gov).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2. The HSAC provides independent advice to the Secretary of the Department of Homeland Security to aid in the creation and implementation of critical and actionable policies and capabilities across the spectrum of homeland security operations. The HSAC periodically reports to the Secretary, as requested, on such matters. The HSAC serves as the Secretary's primary advisory body with the goal of providing strategic, timely and actionable advice.

The HSAC will meet publicly to swear in new Council members, receive observations and remarks from DHS senior leadership, and review and deliberate recommendations from the Homeland Security Advisory Council's Sustainability and Efficiency Task Force and receive a report from the Quadrennial Review Advisory Council on its support of the Quadrennial Homeland Security Review program.

Closed portions of the meeting will include updates on operational challenges, intelligence briefings, and pre-decisional policies. The briefings will include information on sensitive homeland security procedures and the capabilities of the Department of Homeland Security components. The meeting will also include informational briefings of the Department's sensitive processes including law enforcement and transportation security procedures. HSAC members will receive classified and sensitive intelligence briefings during the closed session.

**Basis for Closure:** In accordance with Section 10(d) of the Federal Advisory Committee Act, it has been determined that this HSAC meeting concerns matters that would likely "disclose investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records \* \* \* [and] the production of such records or information would \* \* \* disclose investigative techniques and procedures", 5 U.S.C. 552b(c)(7)(E), and would likely "significantly frustrate implementation of a proposed agency action" within the meaning of 5 U.S.C. 552b(c)(9)(B). Discussion of ongoing investigations with Department of Homeland Security enforcement Components and outside law enforcement partners fall within the meaning of 5 U.S.C. 552b(7)(E) insofar as they will "disclose investigative techniques and procedures." Additionally, release of information presented during the briefings and the nature of the discussion would lead to premature disclosure of information on Department of Homeland Security actions that would be "likely to significantly frustrate implementation of a proposed agency action." Therefore, the portion of the HSAC's meeting from 9 a.m. to 10:30 p.m. EST and then from 1 p.m. to 3 p.m. EST is closed to the public.

**Public Attendance:** Members of the public must pre-register to attend the public session and seating is available on a first-come, first-served basis per the above procedures. For security reasons, we request that any member of the public wishing to attend the public session provide his or her full legal

name, date of birth, e-mail, and phone number to the HSAC no later than 5:00 p.m. EST on January 25, 2010. Please submit requests to attend via e-mail at [HSAC@dhs.gov](mailto:HSAC@dhs.gov) or via phone at (202) 447-3135. Photo identification may be required for entry into the public session. Registration begins at 9:00 a.m. Those attending the public session of the meeting must be present and seated by 9:30 a.m.

**Identification of Services for Individuals with Disabilities:** For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the HSAC as soon as possible.

Dated: January 14, 2010.

**Rebecca L. Sharp,**  
Executive Director, Homeland Security  
Advisory Council.

[FR Doc. 2010-942 Filed 1-15-10; 8:45 am]

BILLING CODE 9010-9M-P

## DEPARTMENT OF HOMELAND SECURITY

### United States Immigration and Customs Enforcement

#### Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request

**ACTION:** 60-Day notice of information collection for review; Form G-79A, Information relating to beneficiary of private bill; OMB Control No. 1653-0026.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until March 22, 2010.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20536; (202) 732-6337.

Comments are encouraged and will be accepted for sixty days until March 22, 2010. Written comments and suggestions from the public and affected

agencies concerning the proposed collection of information should address one or more of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information Collection

- (1) *Type of Information Collection:* Extension of currently approved information collection.
  - (2) *Title of the Form/Collection:* Information Relating to Beneficiary of Private Bill.
  - (3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form G-79A, U.S. Immigration and Customs Enforcement.
  - (4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households. The information is needed to report on Private Bills to Congress when requested.
  - (5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at 1 hour (60 minutes) per response.
  - (6) *An estimate of the total public burden (in hours) associated with the collection:* 100 annual burden hours.
- Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be requested via e-mail to: [forms.ice@dhs.gov](mailto:forms.ice@dhs.gov) with "Form G-79A" in the subject line.

Dated: January 6, 2010.

**Joseph M. Gerhart,**  
Chief, Records Management Branch, U.S.  
Immigration and Customs Enforcement,  
Department of Homeland Security.

[FR Doc. 2010-804 Filed 1-15-10; 8:45 am]

BILLING CODE 9111-28-P

**DEPARTMENT OF HOMELAND SECURITY**
**United States Immigration and Customs Enforcement**
**Agency Information Collection Activities: New Information Collection; Comment Request**

**ACTION:** 30-Day notice of information collection for review; 287(g) Candidate questionnaire; OMB Control No. 1653-NEW.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The Information Collection was previously published in the **Federal Register** on November 5, 2009 Vol. 74 No. 213 57326, allowing for a 60 day public comment period. USICE received no comments on this Information Collection from the public during this 60 day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days until February 18, 2010.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who

are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**Overview of This Information Collection**

(1) *Type of Information Collection:* New Information Collection.

(2) *Title of the Form/Collection:* 287(g) Candidate Questionnaire.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, local or tribal governments. This questionnaire is used for the purposes of determining whether or not a state or local law enforcement officer will be granted Federal immigration enforcement authority under the 287(g) program. This information is used by program managers and trainers in the 287(g) program to make a positive or negative decision for a potential candidate to be admitted into the program.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 300 responses at 25 minutes (0.416 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 124.8 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information regarding this Information Collection should be requested via e-mail to: [forms.ice@dhs.gov](mailto:forms.ice@dhs.gov) with "287(g) Program Candidate Questionnaire" in the subject line.

Dated: January 6, 2010.

**Joseph M. Gerhart,**

*Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.*

[FR Doc. 2010-805 Filed 1-15-10; 8:45 am]

**BILLING CODE 9111-28-P**

**DEPARTMENT OF HOMELAND SECURITY**
**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1870-DR; Docket ID FEMA-2008-0018]

**Alabama; Major Disaster and Related Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Alabama (FEMA-1870-DR), dated December 31, 2009, and related determinations.

**DATES:** *Effective Date:* December 31, 2009.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated December 31, 2009, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Alabama resulting from severe storms and flooding during the period of December 12-18, 2009, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Alabama.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael Bolch, of FEMA is appointed to act as the Federal

Coordinating Officer for this major disaster.

The following areas of the State of Alabama have been designated as adversely affected by this major disaster:

Barbour, Butler, Clarke, Coffee, Conecuh, Covington, Crenshaw, Dale, Escambia, Geneva, Henry, and Pike Counties for Public Assistance.

All counties within the State of Alabama are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-865 Filed 1-15-10; 8:45 am]

BILLING CODE 9111-23-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1869-DR; Docket ID FEMA-2008-0018]

#### New York; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of New York (FEMA-1869-DR), dated December 31, 2009, and related determinations.

**DATES:** *Effective Date:* December 31, 2009.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472. (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated December 31, 2009, the President issued a major disaster declaration under the authority of the Robert T. Stafford

Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of New York resulting from severe storms and flooding associated with Tropical Depression Ida and a nor'easter during the period of November 12-14, 2009, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of New York.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of New York have been designated as adversely affected by this major disaster:

Nassau and Suffolk Counties for Public Assistance.

All counties within the State of New York are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-868 Filed 1-15-10; 8:45 am]

BILLING CODE 9111-23-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1862-DR; Docket ID FEMA-2008-0018]

#### Virginia; Amendment No. 1 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA-1862-DR), dated December 9, 2009, and related determinations.

**DATES:** *Effective Date:* November 16, 2009.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this disaster is closed effective November 16, 2009.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-854 Filed 1-15-10; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1870-DR; Docket ID FEMA-2008-0018]

**Alabama; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Alabama (FEMA-1870-DR), dated December 31, 2009, and related determinations.

**DATES:** *Effective Date:* January 8, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Alabama is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of December 31, 2009.

Chilton and Russell Counties for Public Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2010-853 Filed 1-15-10; 8:45 am]

**BILLING CODE 9111-23-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1867-DR; Docket ID FEMA-2008-0018]

**New Jersey; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of New Jersey (FEMA-1867-DR), dated December 22, 2009, and related determinations.

**DATES:** *Effective Date:* December 23, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Stephen M. De Blasio Sr., of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of William L. Vogel as Federal Coordinating Officer for this disaster.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2010-851 Filed 1-15-10; 8:45 am]

**BILLING CODE 9111-23-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1861-DR; Docket ID FEMA-2008-0018]

**Arkansas; Amendment No. 3 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Arkansas (FEMA-1861-DR), dated December 3, 2009, and related determinations.

**DATES:** *Effective Date:* January 1, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Kevin L. Hannes, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of W. Michael Moore as Federal Coordinating Officer for this disaster.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2010-871 Filed 1-15-10; 8:45 am]

**BILLING CODE 9111-23-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-1863-DR; Docket ID FEMA-2008-0018]

**Louisiana; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA-1863-DR), dated December 10, 2009, and related determinations.

**DATES:** *Effective Date:* December 31, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of December 10, 2009.

Catahoula and Franklin Parishes for Public Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2010-872 Filed 1-15-10; 8:45 am]

**BILLING CODE** 9111-23-P

**DEPARTMENT OF THE INTERIOR****Office of the Secretary****Blackstone River Valley National Heritage Corridor Commission: Notice of Meeting**

Notice is hereby given in accordance with Section 552b of Title 5, United States Code, that a meeting of the John H. Chafee Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, February 25, 2010.

The Commission was established pursuant to Public Law 99-647. The purpose of the Commission is to assist federal, state and local authorities in the development and implementation of an integrated resource management plan for those lands and waters within the Corridor.

The meeting will convene on February 25, 2010 at 9 a.m. at the Woonsocket City Hall located at 169 Main Street, Woonsocket, RI for the following reasons:

1. Approval of Minutes
2. Chairman's Report
3. Executive Director's Report
4. Financial Budget
5. Public Input

It is anticipated that about thirty people will be able to attend the session in addition to the Commission members.

Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made prior to the meeting to: Jan H. Reitsma, Executive Director, John H. Chafee Blackstone River Valley National Heritage Corridor Commission, One Depot Square, Woonsocket, RI 02895, Tel.: (401) 762-0250.

Further information concerning this meeting may be obtained from Jan H. Reitsma, Executive Director of the Commission at the aforementioned address.

**Jan H. Reitsma,**  
*Executive Director, BRVNHCC.*

**Notice of Full Commission Meeting for the John H. Chafee Blackstone River Valley National Heritage Corridor Commission**

Notice is hereby given, in accordance with section 552b of Title 5, United States Code, that the meeting of the Full Commission of the John H. Chafee Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, February 25, 2010 at 9 a.m. at the Woonsocket City Hall located at 169 Main Street, Woonsocket, RI. The purpose of the Commission is to

assist federal, state and local authorities in the development and implementation of an integrated Resource Management Plan for those lands and waters within the Corridor in Rhode Island and Massachusetts.

[FR Doc. 2010-813 Filed 1-15-10; 8:45 am]

**BILLING CODE** 4310-RK-P

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****Notice of Proposed Information Collection for 1029-0051**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement.

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

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for 30 CFR part 840—State Regulatory Authority: Inspection and Enforcement, has been forwarded to the Office of Management and Budget (OMB) for review and approval. This information collection request describes the nature of the information collection and its expected burden and cost.

**DATES:** OMB has up to 60 days to approve or disapprove the information collection requests but may respond after 30 days. Therefore, public comments should be submitted to OMB by February 18, 2010, in order to be assured of consideration.

**ADDRESSES:** Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via e-mail at [OIRA\\_Docket@omb.eop.gov](mailto:OIRA_Docket@omb.eop.gov), or by facsimile to (202) 395-5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202—SIB, Washington, DC 20240, or electronically to [jtrelease@osmre.gov](mailto:jtrelease@osmre.gov). Please reference 1029-0051 in your correspondence.

**FOR FURTHER INFORMATION CONTACT:** To receive a copy of the information collection request, contact John Trelease at (202) 208-2783. You may also contact Mr. Trelease at [jtrelease@osmre.gov](mailto:jtrelease@osmre.gov).

**SUPPLEMENTARY INFORMATION:** OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13), require that interested members of the

public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted the request to OMB to renew its approval for the collection of information found at 30 CFR part 840. OSM is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029-0051, and may be found in OSM's regulations at 30 CFR 840.10. Individuals are required to respond to obtain a benefit.

As required under 5 CFR 1320.8(d), a Federal Register notice soliciting comments on this collection was published on September 23, 2009 (74 FR 48587). No comments were received.

This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

**Title:** 30 CFR part 840—State Regulatory Authority: Inspection and Enforcement.

**OMB Control Number:** 1029-0051.

**Abstract:** This provision requires the regulatory authority to conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports for public review. This information is necessary to meet the requirements of the Surface Mining Control and Reclamation Act of 1977 and its public participation provisions. Public review assures that the State is meeting the requirements for the Act and approved State regulatory program.

**Bureau Form Number:** None.

**Frequency of Collection:** Once, monthly, quarterly, and annually.

**Description of Respondents:** State Regulatory Authorities.

**Total Annual Responses:** 80,280.

**Total Annual Burden Hours:** 575,472.

**Total Non-wage Costs:** \$1,440.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the places listed in ADDRESSES. Please refer to control number 1029-0051 in all correspondence.

Before including your address, phone number, e-mail address, or other

personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 12, 2010.

**John R. Craynon,**

*Division of Regulatory Support.*

[FR Doc. 2010-676 Filed 1-15-10; 8:45 am]

BILLING CODE 4310-05-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLIDI03000.L12200000.AL0000]

#### Notice of Availability of Travel Map, Challis Field Office, Idaho

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of availability.

**SUMMARY:** The Bureau of Land Management (BLM) announces the availability of a travel management map depicting designated roads, vehicle ways and trails on public lands managed by the BLM Challis Field Office, Idaho. The map describes seasonal closure areas and trails and the daytime use restriction at the Challis Bridge Recreation Site in Idaho.

**SUPPLEMENTARY INFORMATION:** The BLM Challis Field Office manages nearly 800,000 acres of public lands, principally in Custer County, Idaho. The Challis Field Office completed its Resource Management Plan (RMP) in 1999. This RMP recommended that the Field Office complete a Travel Management Plan to administer all aspects of motorized and non-motorized travel in the field office. The Challis Travel Management Plan was approved in June of 2008.

**ADDRESSES:** Copies of the map are available to the public by contacting the BLM Challis Field Office, 1151 Blue Mountain Road, Challis, Idaho 83226; by telephone at (208) 879-6200; or on the following Web site: <http://www.blm.gov/id/st/en/fo/challis.html>.

**FOR FURTHER INFORMATION CONTACT:** Please contact David Rosenkrance, Field Manager, at the Challis Field Office at the address and phone number listed above.

Dated: January 19, 2010.

**David Rosenkrance,**

*Challis Field Manager.*

[FR Doc. 2010-739 Filed 1-15-10; 8:45 am]

BILLING CODE 4310-GG-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLOPRP0600 L51010000.ERO000 LVRWH09H0600; HAG 10-0091]

#### Notice of Intent To Prepare an Environmental Impact Statement for the Proposed West Butte Wind Power Right-of-Way, Crook and Deschutes Counties, OR

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of intent.

**SUMMARY:** In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Deschutes Field Office, Prineville, Oregon, intends to prepare an Environmental Impact Statement (EIS) for the proposed West Butte Wind Power Right-of-Way (ROW) in Crook and Deschutes Counties, Oregon, and by this notice is announcing the beginning of the scoping process to solicit public comments and identify issues.

**DATES:** This notice initiates the public scoping process for the EIS. Comments on issues may be submitted in writing until February 3, 2010. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local media, newspapers, and the BLM Web site at: <http://www.blm.gov/or/districts/prineville>. In order to be considered in the Draft EIS, all comments must be received prior to the close of the scoping period or 15 days after the last public meeting, whichever is later. We will provide additional opportunities for public participation upon publication of the Draft EIS.

**ADDRESSES:** You may submit comments related to the West Butte Wind Power ROW by any of the following methods:

- **Web site:** [http://www.or.blm.gov/or/districts/prineville/plans/wbw\\_power\\_row/request](http://www.or.blm.gov/or/districts/prineville/plans/wbw_power_row/request).
- **E-mail:** [ssoro@or.blm.gov](mailto:ssoro@or.blm.gov).
- **Fax:** (541) 416-6798.
- **Mail:** West Butte Wind Power Right-of-Way Lead, BLM Prineville District Office, 3050 N.E. 3rd Street, Prineville, Oregon 97754.



Documents pertinent to this proposal may be examined at the Prineville District Office.

**FOR FURTHER INFORMATION CONTACT:** For further information and to have your name added to our mailing list, contact the West Butte Wind Power Right-of-Way Project Lead, telephone (541) 416-6885; address 3050 N.E. 3rd Street, Prineville, Oregon 97754; e-mail [ssoro@or.blm.gov](mailto:ssoro@or.blm.gov).

**SUPPLEMENTARY INFORMATION:** The applicant, West Butte Wind Power, LLC, has requested a ROW authorization to construct 3.9 miles of road and an adjacent power transmission line on public land. The ROW request is associated with a proposed wind farm development on adjacent private lands which would include up to 52 wind turbines and ancillary facilities. The project is 25 miles southeast of Bend, Oregon, located on the north side of U.S. Highway 20. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives, and guide the process for developing the EIS. The BLM has identified the following preliminary issues: Vegetation, wildlife and wildlife habitat, visual resources, cultural and tribal resources, noise, socioeconomic impacts, and public safety impacts.

The BLM will use and coordinate the NEPA commenting process to satisfy the public involvement process for Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American tribal consultations will be conducted and tribal concerns, including impacts on Indian trust assets, will be given due consideration. Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BLM's decision on this project, are invited to participate in the scoping process. Federal, State, local agencies, or Tribes, if eligible, may request, or be requested by the BLM, to participate as a cooperating agency.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Authority:** 40 CFR 1501.7.

December 31, 2009.  
**Deborah Henderson-Norton,**  
*Prineville District Manager.*  
 [FR Doc. 2010-838 Filed 1-15-10; 8:45 am]  
**BILLING CODE 4310-33-P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before December 26, 2009. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202-371-6447. Written or faxed comments should be submitted by February 3, 2010.

**J. Paul Loether,**  
*Chief, National Register of Historic Places/  
 National Historic Landmarks Program.*

### ARKANSAS

#### Jefferson County

Antioch Missionary Baptist Church  
 Cemetery, 500 N. McKinney Rd., Sherrill,  
 09001299.

### CALIFORNIA

#### San Francisco County

One Lombard Street, 1 Lombard St., San  
 Francisco, 09001300.

### GEORGIA

#### Douglas County

Beulah Grove Lodge No. 372, Free and  
 Accepted York Masons—Pleasant Grove  
 School, 2525 Old Lower River Rd.,  
 Douglasville, 09001301.

### IOWA

#### Cedar County

Red Oak Grove Presbyterian Church and  
 Cemetery, 751 King Ave., Tipton,  
 09001302.

#### Plymouth County

Sacred Heart Hospital, 110 6th Ave. NE,  
 LeMars, 09001303.

#### Washington County

Miller, Alex and Ola (Viola) (Babcock),  
 House, 429 S. Marion Ave., Washington,  
 09001304.

### KENTUCKY

#### Boyle County

Terrace Court Historic District, Terrace Ct.,  
 N. and S. sides, W. of Old Wilderness Rd.,  
 Danville, 09001305.

#### Campbell County

Newport Courthouse Square Historic District,  
 York St., Court Pl., Fourth St., Newport,  
 09001306.

#### Green County

Mud Brick House in Greensburg, 429  
 Campbellsville Rd., Greensburg, 09001307

#### Henry County

Callaway-Goodridge-Robertson Farm, 6041  
 KY 1861, Smithfield, 09001308.

#### Kenton County

Fourth District Elementary School, 1508-  
 1510 Scott St., Covington, 09001309.  
 Gaines, Col. Abner, House (Boundary  
 Increase), Address Restricted, Walton,  
 09001310.

#### Mason County

Helena United Methodist Church, 6479  
 Helena Rd., Helena, 09001311.

#### Simpson County

Franklin Grade and High School, 513 W.  
 Madison St., Franklin, 09001312.

#### Warren County

Milliken Building, 1039 College St., Bowling  
 Green, 09001313.

### WISCONSIN

#### Brown County

Main Avenue Historic District, 301-377 (odd  
 only) Main Ave., De Pere, 09001314.

#### Forest County

Minertown—Oneva, State Trunk Hwy. 32,  
 Carter, 09001315.

[FR Doc. 2010-841 Filed 1-15-10; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Consent Decree Pursuant to Comprehensive Environmental Response, Compensation and Liability Act

Notice is hereby given that on January 8, 2010, a proposed Consent Decree in *United States v. Davenport Realty Trust, et al.*, Civil Action No. 1:07-cv-00010-PB, was lodged with the United States District Court for the District of New Hampshire.

The proposed Consent Decree will settle the United States' claims on behalf of the U.S. Environmental Protection Agency ("EPA") brought against defendant Davenport Realty Trust ("Davenport" or "Settling Defendant") pursuant to Sections 106 and 107 of the Comprehensive Environmental Response,

Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9606 and 9607, with respect to the Beede Waste Oil Superfund Site in Plaistow, New Hampshire. Pursuant to the Consent Decree, Davenport—a *de minimis* party at the Site—will pay \$120,000.00 toward financing the work at the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to [pubcomment-ees.enrd@usdoj.gov](mailto:pubcomment-ees.enrd@usdoj.gov) or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Davenport Realty Trust, et al.*, Civil Action No. 1:07-cv-00010-PB, D.J. Ref. 90-11-3-07039/9. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. § 6973(d).

The proposed Consent Decree may be examined at the Office of the United States Attorney, District of New Hampshire, 53 Pleasant Street, Concord, New Hampshire 03301, and at the United States Environmental Protection Agency, Region I, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109-3912. During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice Web site, [http://www.usdoj.gov/enrd/Consent\\_Decrees.html](http://www.usdoj.gov/enrd/Consent_Decrees.html). A copy of the proposed Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood ([tonia.fleetwood@usdoj.gov](mailto:tonia.fleetwood@usdoj.gov)), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. If requesting a copy by mail from the Consent Decree Library, please enclose a check in the amount of \$5.50 (\$0.25 per page reproduction cost) payable to the United States Treasury or, if requesting by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

**Maureen Katz,**

*Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2010-761 Filed 1-15-10; 8:45 am]

BILLING CODE 4410-15-P

**DEPARTMENT OF JUSTICE**

**Notice of Lodging Proposed Consent Decree**

Pursuant to Section 122(d)(2) of CERCLA, 42 U.S.C. 9622(d)(2), notice is hereby given that on January 8, 2010, a proposed Consent Decree in *U.S. v. The City and County of Denver*, Civil Action No. 1:97-cv-1611, was lodged with the United States District Court for the District of Colorado.

The proposed Consent Decree concerns a complaint filed by the United States against the City and County of Denver, Colorado, in which the United States sought a declaratory judgment that a "disposal fee" established by ordinance by the City and County of Denver ("Denver") was void and unenforceable against the United States and other persons performing remedial actions at operable units of the Denver Radium Superfund Site ("Site") and a permanent injunction prohibiting Denver from enforcing the disposal fee against those entities. Denver counterclaimed against the United States pursuant to Section 107 of CERCLA, 42 U.S.C. 9607, seeking its claimed response costs relating to the Site.

Under the proposed Consent Decree, the United States will pay Denver the sum of \$550,000 in settlement of Denver's counterclaims against the United States. In addition, among other provisions of the proposed Consent Decree, Denver releases the United States, its contractors, and potentially responsible parties acting under the direction of the United States, from any obligation to pay fees pursuant to Denver's ordinance; Denver agrees to implement certain institutional controls regarding the Site; and that under certain conditions, Denver is granted a covenant not to sue for future CERCLA liability at sites to which it sends wastes removed from the Site.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Daniel Pinkston, Environmental Defense Section, Environment and Natural Resources Section, U.S. Department of Justice, 1961 Stout Street, 8th Floor, Denver, Colorado 80294, [daniel.pinkston@usdoj.gov](mailto:daniel.pinkston@usdoj.gov), and refer to *U.S. v. The City and County of Denver*, DJ # 90-11-6-18417.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Colorado, Alfred A. Arraj United States Courthouse, Room A105, 901 19th

Street, Denver, CO 80294-3589. In addition, the proposed Consent Decree may be viewed at [http://www.usdoj.gov/enrd/Consent\\_Decrees.html](http://www.usdoj.gov/enrd/Consent_Decrees.html).

**Maureen M. Katz,**

*Assistant Section Chief, Environment & Natural Resources Division.*

[FR Doc. 2010-727 Filed 1-15-10; 8:45 am]

BILLING CODE P

**DEPARTMENT OF JUSTICE**

**Office of Justice Programs**

[OMB Number 1121-0306]

**Agency Information Collection Activities: Proposed Collection; Comments Requested**

**ACTION:** 60-Day notice of information collection under review: Reinstatement, with change, of a previously approved collection for which approval has expired, State Court Processing Statistics 2009.

The Department of Justice, Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until March 22, 2010. This process is conducted in accordance with 5 CFR 1320.10.

If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Thomas H. Cohen, (202) 514-8344, Bureau of Justice Statistics, Office of Justice Programs, Department of Justice, 810 Seventh Street, NW., Washington, DC 20531 or [Thomas.H.Cohen@usdoj.gov](mailto:Thomas.H.Cohen@usdoj.gov).

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used:—Enhance the quality, utility, and clarity of the information to be collected; and—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information

(1) *Type of information collection:* Reinstatement, with change, of a previously approved collection for which OMB approval has expired, State Court Processing Statistics, 2009.

(2) *The title of the form/collection:* State Court Processing Statistics, 2009.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form labels are SCPS—2009, SATCS—2009, Bureau of Justice Statistics, Office of Justice Programs, U.S. Department of Justice.

(4) *Affected Public Who Will be Asked or Required to Respond, as well as a Brief Abstract:* State Trial Courts and Pretrial Agencies. *Abstract:* The State Court Processing Statistics (SCPS) project covers felony case processing in a sample of the nation's 75 most populous counties on a recurring basis. In the SCPS data collection program, felony defendants are tracked for up to 1 year with data collected on a variety of felony case processing characteristics. These include the types of arrest charges filed against felony defendants, conditions of pretrial release, and pretrial misconduct which includes the court appearance record, violations of release conditions, and re-arrests committed while on pretrial release. The adjudication outcomes encompassing the dismissal, diversion, guilty plea, and trial conviction rates for felony defendants are also recorded. For those defendants convicted, sentencing data are collected. The SCPS 2009 project also involves collecting aggregate information on the electronic data storage and transfer capacities of courts located in a sample of the nation's 900 most populous counties.

(5) *An Estimate of the Total Number of Respondents and the Amount of Time Estimated for an Average Respondent to Respond:* It is estimated that information will be collected on a total of 15,000 felony defendants from 40 responding counties. The estimated burden hours will be contingent upon

the counties electronic storage and transfer capabilities. Data collection will occur in a more timely and expeditious manner among counties with the capacities to electronically transfer all their case processing, pretrial, and criminal history information to the data collection agent. It is estimated that about 10 of the 40 counties have the capacity to transfer entire files of SCPS cases and that it should take these counties about 15 hours per county to produce programs capable of transferring the SCPS data to the data collection agent. For the remaining 30 counties that lack the capacity to engage in electronic transfers, data collection will involve manually coding the SCPS survey forms for an online or paper based submission. Prior SCPS data collection endeavors show an estimated one hour to manually code each SCPS case for online or paper based submission. In addition to collecting case processing information, courts located in 200 jurisdictions will be asked to complete a spreadsheet surveying their overall levels of case and pretrial automation. Pretests of the instrument found that the average time to complete the spreadsheet was about 2 hours per trial court.

(6) *An Estimate of the Total Public Burden (in hours) Associated with the Collection:* The estimated public burden associated for the SCPS data collection is 11,800 hours. In the 30 counties in which SCPS cases are manually coded for paper or online based submission, an estimated 11,250 data collection forms (375 forms per county) will be coded and it should take an estimated one hour to code each data collection form. Hence, the estimated public burden associated with the manual based collection of SCPS data forms should be about 11,250 hours. In the 10 counties in which SCPS cases can be transferred through computerized case management systems, it should take an estimated 150 hours (15 hours per county) to generate the programs capable of transferring information for these SCPS cases. Lastly, about 400 hours will be required to complete the spreadsheets surveying the overall levels of case and pretrial automation for courts located in 200 counties (200 counties multiplied by 2 hours per spreadsheet). Therefore, the total burden time for the SCPS 2009 project should be about 11,800 hours (11,250 hours for manual based data collection + 150 hours for computerized transfer of automated SCPS data + 400 hours for the survey of court automation capacities).

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, United States

Department of Justice, Justice Management Division, Policy and Planning Staff, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 12, 2010.

Ms. Lynn Bryant,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2010-768 Filed 1-15-10; 8:45 am]

BILLING CODE 4410-18-P

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—International Electronics Manufacturing Initiative

Notice is hereby given that, on December 15, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), International Electronics Manufacturing Initiative ("iNEMI") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Elec & Eltek, Kowloon, HONG KONG—CHINA; Guangdong Shengyi Sci. Tech Co., Guangdong, PEOPLE'S REPUBLIC OF CHINA; Ibsiden, Toshiba-cho, JAPAN; Pacific Insulating Material Co., Ltd., Shenzhen, PEOPLE'S REPUBLIC OF CHINA; Lenovo, Quarry Bay, HONG KONG—CHINA; and Quanta Computer Inc., Tao Yuan Shien, TAIWAN, have been added as parties to this venture.

Also, Agile Software Corporation, San Jose, CA; NanoDynamics, Inc., Buffalo, NY; Ciba, Tarrytown, NY; 3M, St. Paul, MN; Ministère du Développement économique, de l'Innovation et de l'Exportation (Gouvernement du Québec) Montreal, Quebec, CANADA; Motorola, Inc., Schaumburg, IL; Jabil Circuit, St. Petersburg, FL; and ERSA North America, Plymouth, WI have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and iNEMI intends to file additional written notifications disclosing all changes in membership.

On June 6, 1996, iNEMI filed its original notification pursuant to Section 6(a) of the Act. The Department of

Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 28, 1996 (61 FR 33774).

The last notification was filed with the Department on November 4, 2008. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on December 12, 2008 (73 FR 75772).

**Patricia A. Brink,**  
*Deputy Director of Operations, Antitrust Division.*

[FR Doc. 2010-641 Filed 1-15-10; 8:45 am]

BILLING CODE 4410-11-M

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—Institute of Electrical and Electronics Engineers

Notice is hereby given that, on December 28, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the Institute of Electrical and Electronics Engineers ("IEEE") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, 22 new standards have been initiated and seven existing standards are being revised. More detail regarding these changes can be found at <http://standards.ieee.org/standardswire/sba/09-11-09.html>.

On September 17, 2004, IEEE filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 3, 2004 (69 FR 64105).

The last notification was filed with the Department on July 6, 2009. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2009 (74 FR 38473).

**Patricia A. Brink,**  
*Deputy Director of Operations, Antitrust Division.*

[FR Doc. 2010-639 Filed 1-15-10; 8:45 am]

BILLING CODE 4410-11-M

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—DVD Copy Control Association

Notice is hereby given that, on December 3, 2009, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), DVD Copy Control Association ("DVD CCA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Quatius Limited, Kowloon, HONG KONG-CHINA has been added as a party to this venture. Also, Futarque A/S, Aalborg, DENMARK; Hyo Seong Techno Corporation, Seoul, REPUBLIC OF KOREA; OPT Corporation, Nagano-ken, JAPAN; and Shinano Kenshi Co., Ltd., Nagano-ken, JAPAN have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DVD CCA intends to file additional written notifications disclosing all changes in membership.

On April 11, 2001, DVD CCA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2001 (66 FR 40727)

The last notification was filed with the Department on September 4, 2009. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 27, 2009 (74 FR 55258)

**Patricia A. Brink,**  
*Deputy Director of Operations, Antitrust Division.*

[FR Doc. 2010-640 Filed 1-15-10; 8:45 am]

BILLING CODE 4410-11-M

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

[Docket No. OSHA-2010-0004]

#### OSHA Listens; Occupational Safety and Health Administration Stakeholder Meeting

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) is announcing a public meeting to solicit comments and suggestions from stakeholders on key issues facing the agency.

**DATES:** The public meeting will be held on February 10, 2010, from 9 a.m. to 5 p.m. Persons interested in attending the meeting must register by February 3, 2010. In addition, comments relating to the "Scope of Meeting" section of this document must be submitted in written or electronic form by March 30, 2010.

**ADDRESSES:** The public meeting will be held at the Frances Perkins Building Auditorium, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Submit written comments to the OSHA Docket Office, Docket No. OSHA-2010-0004, Technical Data Center, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2350. Submit electronic comments by e-mail to: [stakeholder.meeting@dol.gov](mailto:stakeholder.meeting@dol.gov). All comments should be identified with Docket No. OSHA-2010-0004.

**Registration To Attend and/or To Participate in the Meeting:** If you wish to attend the public meeting and/or make an oral presentation at the meeting, you must register by e-mail to: [stakeholder.meeting@dol.gov](mailto:stakeholder.meeting@dol.gov) by close of business on February 3, 2010. When registering, you must provide the following information: (1) Your name, title, company or organization (if applicable), address, phone number and e-mail address, and (2) if you wish to make a short presentation, the specific topic or issue to be addressed. Actual times provided for presentation will depend on the number of requests. There is no fee to register for the public meeting. Registration on the day of the public meeting will be permitted on a space-available basis beginning at 8:30 a.m.

We will do our best to accommodate all persons who wish to make a presentation at the meeting. OSHA

encourages persons and groups having similar interests to consolidate their information for presentation through a single representative. After reviewing the requests to present, we will contact each participant prior to the meeting with the amount of time available and the approximate time that the participant's presentation is scheduled to begin. Presenters must then send the final electronic copies of their presentations in Microsoft Word or Adobe Portable Document Format (PDF) to: [stakeholder.meeting@dol.gov](mailto:stakeholder.meeting@dol.gov) by February 8, 2010.

**FOR FURTHER INFORMATION CONTACT:** For further information please contact Cori Hutcheson, Office of the Assistant Secretary, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: 202-693-2507; fax: 202-693-1659; e-mail: [stakeholder.meeting@dol.gov](mailto:stakeholder.meeting@dol.gov). Individuals with disabilities wishing to attend the meeting should contact Veneta Chatmon at (202) 693-1912, by February 3, 2010, to obtain appropriate accommodations.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Occupational Safety and Health Administration is committed to ensuring safe workplaces for workers, and that the agency's efforts are effective, efficient and reflect the real world experiences of the workplace.

Public engagement in the work of Government is a priority for the Obama Administration and is important to enhance the work of OSHA. On January 21, 2009, President Obama issued a Memorandum to the heads of executive departments and agencies regarding openness in government.<sup>1</sup> In the Memorandum, the Administration noted that government should be participatory: "Public engagement enhances the Government's effectiveness and improves the quality of its decisions. Knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge."

Executive agencies were instructed to offer Americans increased opportunities to participate in policymaking and to provide their Government with the benefits of their collective expertise and information. The Memorandum further instructed Executive agencies to solicit public input on how we can increase

and improve opportunities for public participation in Government.

On December 8, 2009, the Office of Management and Budget (OMB) issued an Open Government Directive,<sup>2</sup> directing the heads of Executive departments and agencies to take specific actions to implement the principles of transparency, participation and collaboration set forth in the President's Memorandum. Regarding the principle of participation, OMB Director, Peter R. Orszag, directed agencies to "promote opportunities for the public to participate throughout the decision-making process".

In keeping with the Presidential Memorandum and the OMB Directive, OSHA is holding a public meeting and establishing a public docket to seek input from interested parties. OSHA LISTENS, the public meeting to solicit input from interested stakeholders, will be held on February 10, 2010.

**II. Scope of Meeting**

OSHA is interested in obtaining information from the public on key issues facing the agency. In particular, the agency invites input on the following:

1. What can the agency do to enhance and encourage the efforts of employers, workers and unions to identify and address workplace hazards?
2. What are the most important emerging or unaddressed health and safety issues in the workplace, and what can OSHA do to address these?
3. How can the agency improve its efforts to engage stakeholders in programs and initiatives?
4. What specific actions can the agency take to enhance the voice of workers in the workplace, particularly workers who are hard to reach, do not have ready access to information about hazards or their rights, or are afraid to exercise their rights?
5. Are there additional measures to improve the effectiveness of the agency's current compliance assistance efforts and the on site consultation program, to ensure that small businesses have the information needed to provide safe workplaces?
6. Given the length and difficulty of the current OSHA rulemaking process, and given the need for new standards that will protect workers from unaddressed, inadequately addressed and emerging hazards, are there policies and procedures that will decrease the

time to issue final standards so that OSHA may implement needed protections in a timely manner?

7. As we continue to progress through a new information age vastly different from the environment in which OSHA was created, what new mechanisms or tools can the agency use to more effectively reach high risk employees and employers with training, education and outreach? What is OSHA doing now that may no longer be necessary?

8. Are there indicators, other than worksite injuries and illness logs, that OSHA can use to enhance resource targeting?

9. In the late 1980s, OSHA and its stakeholders worked together to update the Permissible Exposure Limits (PELs) (exposure limits for hazardous substances; most adopted in 1971), but the effort was unsuccessful. Should updating the PELs be a priority for the agency? Are there suggestions for ways to update the PELs, or other ways to control workplace chemical exposures?

**III. Request for Comments**

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. To permit time for interested persons to submit data, information, or views on the issues in the "Scope of Meeting" section of this notice, submit comments by March 30, 2010. When commenting on multiple issues, identify each comment using the number of the issue as provided in the "Scope of Meeting" section of this notice. Please include Docket No. OSHA-2010-0004. Comments received may be seen in the U.S. Department of Labor, OSHA Docket Office, (see **ADDRESSES**), between 8:15 a.m. and 4:45 p.m., Monday through Friday. OSHA is also exploring additional electronic means for the public to provide comments and feedback on this topic.

**IV. Transcripts**

Transcripts of the meeting will be available for review approximately 30 days after the meeting at: <http://www.osha.gov> and at U.S. Department of Labor, OSHA Docket Office (see **ADDRESSES**).

Signed in Washington, DC, on January 13, 2010.

**David Michaels,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2010-814 Filed 1-15-10; 8:45 am]

**BILLING CODE 4510-26-P**

<sup>1</sup> Presidential Documents, Memorandum for the Heads of Executive Departments and Agencies on Transparency and Open Government (January 21, 2009) (74 FR 4685, January 26, 2009), available at: [http://www.whitehouse.gov/the\\_press\\_office/TransparencyandOpenGovernment/](http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/).

<sup>2</sup> Presidential Document, Memorandum for the Heads of Executive Departments and Agencies, entitled Open Government Directive (December 8, 2009), may be found at: [http://www.whitehouse.gov/omb/assets/memoranda\\_2010/m10-06.pdf](http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-06.pdf).

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[Notice (10-001)]

**NASA Advisory Council; Science Committee; Planetary Science Subcommittee; Meeting****AGENCY:** National Aeronautics and Space Administration.**ACTION:** Notice of meeting.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

**DATES:** Wednesday, February 3, 2010, 11 a.m. to 1 p.m. Eastern Standard Time.

**ADDRESSES:** This meeting will take place telephonically and by WebEx. Any interested person may call the USA toll free conference call number (866) 844-9416, pass code PSS, to participate in this meeting by telephone. International callers may contact Ms. Marian Norris for country-specific conference call numbers. The WebEx link is <https://nasa.webex.com/>, meeting number 993131217, and password PSSM33ting.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4452, fax (202) 358-4118, or [mnorris@nasa.gov](mailto:mnorris@nasa.gov).

**SUPPLEMENTARY INFORMATION:** The agenda for the meeting includes the following topics:

- President's 2011 budget
- Mars Science Laboratory Update

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: January 11, 2010.

**P. Diane Rausch,**  
*Advisory Committee Management Officer,  
National Aeronautics and Space  
Administration.*

[FR Doc. 2010-779 Filed 1-15-10; 8:45 am]

**BILLING CODE 7510-13-P****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[Notice (10-004)]

**NASA Advisory Council; Science Committee; Heliophysics Subcommittee; Meeting****AGENCY:** National Aeronautics and Space Administration.**ACTION:** Notice of meeting.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) announces a meeting of the Heliophysics Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

**DATES:** Wednesday, February 17, 2010, 9 a.m. to 5 p.m.; Thursday, February 18, 2010, 8:30 a.m. to 5 p.m.; and Friday, February 19, 2009, 8:30 a.m. to 1 p.m., EST.

**ADDRESSES:** NASA Headquarters, 300 E Street, SW., Room 3H46, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4452, fax (202) 358-4118, or [mnorris@nasa.gov](mailto:mnorris@nasa.gov).

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

- Heliophysics Division Overview and Program Status
- Senior Review Guidelines
- Heliophysics Technology Development Approaches
- Research and Analysis Programs Status
- Implementation of Roadmap Recommendations

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: full name; gender; date/

place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at [mnorris@nasa.gov](mailto:mnorris@nasa.gov) or by telephone at (202) 358-4452.

Dated: January 12, 2010.

**P. Diane Rausch,**  
*Advisory Committee Management Officer,  
National Aeronautics and Space  
Administration.*

[FR Doc. 2010-786 Filed 1-15-10; 8:45 am]

**BILLING CODE 7510-13-P****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[Notice (10-003)]

**NASA Advisory Council; Science Committee; Meeting****AGENCY:** National Aeronautics and Space Administration.**ACTION:** Notice of meeting.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) announces a meeting of the Science Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

**DATES:** Tuesday, February 16, 8 a.m. to 5 p.m., and Wednesday, February 17, 2010, 8 a.m. to 5 p.m. Eastern Standard Time.

**ADDRESSES:** NASA Headquarters, 300 E Street, SW., Room 3H46 (Tuesday, February 16, 2010) and Room 8R40 (Wednesday, February 17, 2010), Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4452, fax (202) 358-4118, or [mnorris@nasa.gov](mailto:mnorris@nasa.gov).

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

- Science Mission Directorate Overview and Program Status:
- Discussion of 2010 Science Plan
- Discussion of Subcommittees

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at [mnorris@nasa.gov](mailto:mnorris@nasa.gov) or by telephone at (202) 358-4452.

Dated: January 11, 2010.

**P. Diane Rausch,**

*Advisory Committee Management Officer,  
National Aeronautics and Space  
Administration.*

[FR Doc. 2010-781 Filed 1-15-10; 8:45 am]

BILLING CODE 7510-13-P

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (10-002)]

### NASA Advisory Council; Science Committee; Astrophysics Subcommittee; Meeting

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

**DATES:** Tuesday, February 2, 8:45 a.m. to 5 p.m., and Wednesday, February 3, 2010, 8:30 a.m. to 3 p.m. Eastern Standard Time.

**ADDRESSES:** NASA Headquarters, 300 E Street, SW., Room 8R40, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358-4452, fax (202) 358-4118, or [mnorris@nasa.gov](mailto:mnorris@nasa.gov).

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

—Astrophysics Division Update  
—Updates on Select Astrophysics Missions

—Discussion of 2010 Science Plan  
—Discussion of Analysis Groups

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 7 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at [mnorris@nasa.gov](mailto:mnorris@nasa.gov) or by telephone at (202) 358-4452.

Dated: January 11, 2010.

**P. Diane Rausch,**

*Advisory Committee Management Officer,  
National Aeronautics and Space  
Administration.*

[FR Doc. 2010-780 Filed 1-15-10; 8:45 am]

BILLING CODE 7510-13-P

## NATIONAL SCIENCE FOUNDATION

### National Science Board; Sunshine Act Meetings; Notice

The National Science Board's Subcommittee on Facilities, Committee on Strategy and Budget, pursuant to NSF regulations (45 CFR Part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science

Board business and other matters specified, as follows:

**DATE AND TIME:** Wednesday, January 20, 2010 at 12 p.m.

**SUBJECT MATTER:** Discussion of NSF Facilities Portfolio Review Materials.

**STATUS:** Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Please refer to the National Science Board Web site (<http://www.nsf.gov/nsb>) for information or schedule updates, or contact: Elizabeth Strickland, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-7000.

**Ann Ferrante,**

*Technical Writer/Editor.*

[FR Doc. 2010-950 Filed 1-14-10; 4:15 pm]

BILLING CODE 7555-01-P

## NATIONAL TRANSPORTATION SAFETY BOARD

### Sunshine Act Meeting

**TIME AND DATE:** 9:30 a.m., Tuesday, February 2, 2010.

**PLACE:** NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

**STATUS:** The one item is open to the public.

### Matter To Be Considered

8090A Crash on Approach to Airport. Colgan Air, Inc., Operating as Continental Connection Flight 3407, Bombardier DHC-8-400, N200WQ, Clarence Center, New York, February 12, 2009.

**NEWS MEDIA CONTACT:** Telephone: (202) 314-6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314-6305 by Friday, January 29, 2010.

The public may view the meeting via a live or archived webcast by accessing a link under "News & Events" on the NTSB home page at <http://www.nts.gov>.

**FOR MORE INFORMATION CONTACT:** Candi Bing, (202) 314-6403.

Dated: January 14, 2010.

**Candi R. Bing,**

*Alternate Federal Register Liaison Officer.*

[FR Doc. 2010-959 Filed 1-14-10; 4:15 pm]

BILLING CODE 7533-01-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2010-0013]

### Withdrawal of Regulatory Guide 1.148

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Withdrawal of Regulatory Guide 1.148, "Functional Specification for Active Valve Assemblies in Systems Important to Safety in Nuclear Power Plants."

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Herrity, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-251-7447 or e-mail [Thomas.Herrity@nrc.gov](mailto:Thomas.Herrity@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 1.148, "Functional Specification for Active Valve Assemblies in Systems Important to Safety in Nuclear Power Plants." RG 1.148 was published in March 1981. It endorsed the guidance provided by the American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) standard N278.1-1975 and addressed the functional specification for active valve assemblies (e.g., Motor Operated Valve (MOV) actuators). ASME/ANSI Standard N278.1-1975 has been superseded by ASME QME-1, which defines requirements and provides guidelines for qualifying active mechanical equipment used in nuclear power plants.

The NRC is withdrawing RG 1.148 because the guidance it provides is outdated, and is essentially replaced by the recently issued Revision 3 of RG 1.100, "Seismic Qualification of Electric and Mechanical Equipment for Nuclear Power Plants," which endorses ASME QME-1.

#### II. Further Information

The withdrawal of RG 1.148 does not alter any prior or existing licensing commitments based on its use. The guidance provided in this regulatory guide is neither necessary nor current. Regulatory guides may be withdrawn when their guidance is superseded by congressional action or no longer provides useful information.

Regulatory guides are available for inspection or downloading through the NRC's public Web site under "Regulatory Guides" in the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc->

*collections*. Regulatory guides are also available for inspection at the NRC's Public Document Room (PDR), Room O-1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738. The PDR's mailing address is US NRC PDR, Washington, DC 20555-0001. You can reach the PDR staff by telephone at 301-415-4737 or 800-397-4209, by fax at 301-415-3548, and by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 11th day of January, 2010.

For the Nuclear Regulatory Commission.

**Andrea D. Valentin,**

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2010-816 Filed 1-15-10; 8:45 am]

BILLING CODE 7590-01-P

## RAILROAD RETIREMENT BOARD

### Agency Forms Submitted for OMB Review, Request for Comments

**Summary:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) is forwarding two (2) Information Collection Requests (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB). Our ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collections of information to determine (1) the practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if RRB and OIRA receive them within 30 days of publication date.

#### 1. Title and Purpose of Information Collection

*Vocational Report; 3220-0141*

Section 2 of the Railroad Retirement Act (RRA) provides for payment of disability annuities to qualified employees and widow(ers). The establishment of permanent disability

for work in the applicants "regular occupation" or for work in any regular employment is prescribed in 20 CFR 220.12 and 220.13 respectively.

The RRB utilizes Form G-251, *Vocational Report*, to obtain an applicant's work history. This information is used by the RRB to determine the effect of a disability on an applicant's ability to work. Form G-251 is designed for use with the RRB's disability benefit application forms and is provided to all applicants for employee disability annuities and to those applicants for a widow(er)'s disability annuity who indicate that they have been employed at some time.

Completion is required to obtain or retain a benefit. One response is requested of each respondent. The completion time for Form G-251 is estimated at between 30 and 40 minutes per response.

*Previous Requests for Comments:* The RRB has already published the initial 60-day notice (74 FR 56244 on October 30, 2009) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

*Title:* Vocational Report.

*Form(s) submitted:* G-251.

*OMB Control Number:* 3220-0141.

*Expiration date of current OMB clearance:* 1/31/2010.

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

*Affected Public:* Individuals or households.

*Estimated annual number of respondents:* 6,000.

*Total annual responses:* 6,000.

*Total annual reporting hours:* 3,045.

*Abstract:* Section 2 of the Railroad Retirement Act provides for the payment of disability annuities to qualified employees and widower(s). In order to determine the effect of a disability on an applicant's ability to work, the RRB needs the applicants work history. The collection obtains the information needed to determine their ability to work.

*Changes Proposed:* The RRB proposes minor non-burden, impacting changes to Form G-251.

#### 2. Title and Purpose of Information Collection

*Job Information Report; 3220-0193*

In July of 1997, the Railroad Retirement Board (RRB) adopted standards for the adjudication of occupational disabilities under the Railroad Retirement Act (RRA). As part of these standards, the RRB requests job information to determine an applicant's



eligibility for an occupational disability. The job information received from the railroad employer and railroad employee is compared, reconciled (if needed), and then used in the occupational disability determination process. The process of obtaining information from railroad employers used to determine an applicant's eligibility for an occupational disability is outlined in 20 CFR 220.13(b)(2)(e).

To determine an occupational disability, the RRB determines if an employee is precluded from performing the full range of duties of his or her regular railroad occupation. This is accomplished by comparing the restrictions on impairment(s) causes against an employee's ability to perform his/her normal duties. To collect information needed to determine the effect of a disability on an applicant's ability to work, the RRB needs the applicant's work history. The RRB currently utilizes Form G-251, *Vocational Report* (OMB 3220-0141), to obtain this information from the employee applicant.

**Note:** Form G-251 is provided to all applicants for employee disability annuities and to those applicants for a widow(er)'s disability annuity who indicate that they have been employed at some time.

In accordance with the standards, the RRB also requests pertinent job information from employers. The employer is given thirty days from the date of the notice to respond. The responses are not required, but are voluntary. If the job information is received timely, it is compared to the job information provided by the employee. Any material differences are resolved by an RRB disability examiner. Once resolved, the information is compared to the restrictions caused by the medical impairment. If the restrictions prohibit the performance of the regular railroad occupation, the claimant is found occupationally disabled.

The RRB uses two forms to secure job information data from the railroad employer. RRB Form G-251a, *Employer Job Information* (job description), is released to an employer when an application for an occupational disability is filed by an employee whose regular railroad occupation is one of the more common types of railroad jobs (locomotive engineer, conductor, switchman, etc.) It is accompanied by a \*generic job description\* for that particular railroad job. The generic job descriptions describe how these select occupations are generally performed in the railroad industry. However, not all occupations are performed the same

way from railroad to railroad. Thus, the employer is given an opportunity to comment on whether the job description matches the employee's actual duties. If the employer concludes that the generic job description accurately describes the work performed by the applicant, no further action will be necessary. If the employer determines that the tasks are different, it may provide the RRB with a description of the actual job tasks. The employer has thirty days from the date the form is released to reply.

Form G-251b, *Employer Job Information* (general), is released to an employer when an application for an RRB occupational disability is filed by an employee whose regular railroad occupation does not have a generic job description. It notifies the employer that the employee has filed for a disability annuity and that, if the employer wishes, it may provide the RRB with job duty information. The type of information the RRB is seeking is outlined on the form. The employer has thirty days from the date the form is released to reply.

The completion time for Form G-251a and G-251b is estimated at 20 minutes. Completion is voluntary. The RRB estimates that approximately 125 G-251a's and 305 G-251b's are completed annually. The RRB proposes no changes to Forms G-251a and G-251b.

**Previous Requests for Comments:** The RRB has already published the initial 60-day notice (74 FR 18408 on November 9, 2009) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

#### Information Collection Request (ICR)

**Title:** Job Information Report.

**Form(s) submitted:** G-251a, *Employer Job Information* (position description); G-251b, *Employer Job Information* (general)

**OMB Control Number:** 3220-0193.

**Expiration date of current OMB clearance:** 1/31/2010.

**Type of request:** Extension without change of a currently approved collection.

**Affected public:** Business or other-for-profit.

**The proposed estimated annual burden for this collection is unchanged as follows:**

Estimated annual number of respondents: 430.

Total annual responses: 430.

Total annual reporting hours: 144.

**Abstract:** The collection obtains information used by the Railroad Retirement Board (RRB) to assist in determining whether a railroad employee is disabled from his or her regular occupation. It provides, under

certain conditions, railroad employers with the opportunity to provide information to the RRB regarding the employee applicant's job duties.

**Changes Proposed:** The RRB proposes no changes to the forms in the information collection.

**Additional Information or Comments:** Copies of the form and supporting documents can be obtained from Charles Mierzwa, the agency clearance officer at (312-751-3363) or [Charles.Mierzwa@rrb.gov](mailto:Charles.Mierzwa@rrb.gov).

Comments regarding the information collection should be addressed to Patricia A. Henaghan, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611-2092 or [Patricia.Henaghan@rrb.gov](mailto:Patricia.Henaghan@rrb.gov) and to the OMB Desk Officer for the RRB, at the Office of Management and Budget, Room 10230, New Executive Office Building, Washington, DC 20503.

Charles Mierzwa,  
Clearance Officer.

[FR Doc. 2010-848 Filed 1-15-10; 8:45 am]

BILLING CODE 7905-01-P

## SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11962 and #11963]

### Virginia Disaster Number VA-00027

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 1.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Virginia (FEMA-1862-DR), dated 12/09/2009.

**Incident:** Severe Storms and Flooding Associated with Tropical Depression Ida and a Nor'easter.

**Incident Period:** 11/11/2009 through 11/16/2009.

**Effective Date:** 01/07/2010.

**Physical Loan Application Deadline Date:** 02/08/2010.

**Economic Injury (EIDL) Loan Application Deadline Date:** 09/09/2010.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of

Virginia, dated 12/09/2009, is hereby amended to establish the incident period for this disaster as beginning 11/11/2009 and continuing through 11/16/2009.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2010-849 Filed 1-15-10; 8:45 am]

**BILLING CODE 8025-01-P**

## SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12008 and #12009]

**Alabama Disaster Number AL-00028**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 1.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Alabama (FEMA-1870-DR), dated 12/31/2009.

Incident: Severe Storms and Flooding.  
Incident Period: 12/12/2009 through 12/18/2009.

**DATES:** *Effective Date:* 01/08/2010.

*Physical Loan Application Deadline Date:* 03/01/2010.

*Economic Injury (EIDL) Loan Application Deadline Date:* 10/01/2010.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Alabama, dated 12/31/2009, is hereby amended to include the following areas as adversely affected by the disaster.

*Primary Counties:* Russell, Chilton.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2010-850 Filed 1-15-10; 8:45 am]

**BILLING CODE 8025-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

### Order of Suspension of Trading; East Delta Resources Corp.

January 13, 2010.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of East Delta Resources Corp. ("East Delta") because it has not filed any periodic reports since the period ended September 30, 2008.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of East Delta.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of East Delta is suspended for the period from 9:30 a.m. EST on January 13, 2010, through 11:59 p.m. EST on January 27, 2010.

By the Commission.

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2010-833 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61330; File No. SR-NYSEArca-2009-106]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving Proposed Rule Change Relating to the Listing Fee and Annual Fee Applicable to Derivative Securities Products

January 12, 2010.

On November 24, 2009, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposal to amend its Schedule of Fees and Charges for Exchange Services ("Fee Schedule") to revise the listing and annual fees applicable to Derivative Securities Products ("DSPs") listed on NYSE Arca, LLC ("NYSE Arca Marketplace"), the equities facility of NYSE Arca Equities. The proposed rule change was published for comment in the *Federal Register* on December 10, 2009.<sup>3</sup> The Commission received no

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 61104 (December 3, 2009), 74 FR 65568.

comments regarding the proposal. This order approves the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 of the Act.<sup>4</sup> Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(4) of the Act,<sup>5</sup> which requires that the rules of the exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Commission also finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,<sup>6</sup> which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

NYSE Arca proposes to revise its listing fee and annual fee applicable to DSPs listed on the NYSE Arca Marketplace.<sup>7</sup> Specifically, NYSE Arca proposes to increase the listing fee for each issue of DSPs from current \$5,000 to \$7,500, except Managed Fund Shares listed under NYSE Arca Equities Rule 8.600 and Managed Trust Securities listed under NYSE Arca Equities Rule 8.700. For Managed Fund Shares and Managed Trust Securities, the Exchange proposes to increase the listing fee from current \$5,000 to \$10,000.

The Exchange also proposes to amend the annual fee applicable to DSPs. Except Managed Fund Shares and Managed Trust Securities, the Exchange proposes to increase the annual fee for DSPs from current \$2,000 to \$5,000 for each issue with fewer than 25 million shares outstanding; from current \$4,000 to \$7,500 for each issue with 25 million

<sup>4</sup> 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>5</sup> 15 U.S.C. 78f(b)(4).

<sup>6</sup> 15 U.S.C. 78f(b)(5).

<sup>7</sup> As specified in footnote 3 to the Fee Schedule, for the purposes of the Fee Schedule, the term "Derivative Securities Products" includes securities described in NYSE Arca Equities Rules 5.2(j)(3) (Investment Company Units); 8.100 (Portfolio Depository Receipts); 8.200 (Trust Issued Receipts); 8.201 (Commodity-Based Trust Shares); 8.202 (Currency Trust Shares); 8.203 (Commodity Index Trust Shares); 8.204 (Commodity Futures Trust Shares); 8.300 (Partnership Units); 8.500 (Trust Units); 8.600 (Managed Fund Shares); and 8.700 (Managed Trust Securities).

to 49,999,999 shares outstanding; and from current \$8,000 to \$10,000 for each such issue with 50 million to 99,999,999 shares outstanding. For DSP issues that have 100 million shares or more outstanding, except Managed Fund Shares and Managed Trust Securities, the annual fee would remain unchanged.

For Managed Fund Shares and Managed Trust Securities, the Exchange proposes to impose an annual fee for each such issue as follows:

SHARES OUTSTANDING  
[Each issue]

SHARES OUTSTANDING [Each issue]	Annual Fee
Less than 25 million .....	\$7,500
25 million up to 49,999,999 .....	10,000
50 million up to 99,999,999 .....	12,500
100 million up to 249,999,999 ..	20,000
250 million up to 499,999,999 ..	30,000
500 million and over .....	40,000

The Exchange represents that, as the industry evolves with innovative product lines for investors, the proposed increases in the listing fee and the annual fee support the increased costs incurred by the Exchange for the rule making process, listing administration process, issuer services, and consultative legal services provided to issuers. Additionally, the Exchange states that a higher listing fee and annual fee for Managed Fund Shares and Managed Trust Securities reflect the greater resources the Exchange generally expends to provide services in connection with the listing and administration of these securities. The Commission finds that the proposed rule change is designed to equitably allocate reasonable dues, fees, and other charges among issuers of DSPs, and is consistent with the requirements of the Act.<sup>8</sup>

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,<sup>9</sup> that the proposed rule change (SR-NYSEArca-2009-106), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>10</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-801 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>8</sup> 15 U.S.C. 78f.

<sup>9</sup> 15 U.S.C. 78s(b)(2).

<sup>10</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61319; File No. SR-FINRA-2009-093]

### Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Repeal NASD Rule 2450 (Installment or Partial Sales), NASD Interpretive Material 2830-2 ("IM-2830-2") (Maintaining the Public Offering Price) and Incorporated NYSE Rule 413 (Uniform Forms) as Part of the Process of Developing a Consolidated FINRA Rulebook

January 8, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 23, 2009, Financial Industry Regulatory Authority, Inc. ("FINRA") (f/k/a National Association of Securities Dealers, Inc. ("NASD")) filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to repeal NASD Rule 2450 (Installment or Partial Sales), NASD Interpretive Material 2830-2 ("IM-2830-2") (Maintaining the Public Offering Price), and Incorporated NYSE Rule 413 (Uniform Forms), as part of the process of developing a consolidated FINRA rulebook.

The text of the proposed rule change is available on FINRA's Web site at <http://www.finra.org>, at the principal office of FINRA and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B,

and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

As part of the process of developing a new consolidated rulebook ("Consolidated FINRA Rulebook"),<sup>3</sup> FINRA is proposing to repeal NASD Rule 2450 (Installment or Partial Sales), NASD IM-2830-2 (Maintaining the Public Offering Price), and Incorporated NYSE Rule 413 (Uniform Forms) to eliminate duplicative and unnecessary rules and remove outdated provisions from the Consolidated FINRA Rulebook.

##### NASD Rule 2450 (Installment or Partial Sales)

NASD Rule 2450 prohibits any arrangement whereby the customer of a member submits partial or installment payments for the purchase of a security with the following exceptions: (1) If a member is acting as agent or broker in such transaction, then the member must immediately make an actual purchase of the security for the account of the customer, and immediately take possession or control of the security and maintain possession or control of the security as long as the member is under the obligation to deliver the security to the customer; (2) if a member is acting as principal in such transaction, the member must, at the time of the transaction, own such security and maintain possession or control of the security as long as the member is under the obligation to deliver the security to the customer; and (3) where the provisions of Regulation T,<sup>4</sup> if applicable to the member, are satisfied.

The rule also prohibits the member, whether acting as principal or agent, in connection with any installment or partial sales transaction, from making any agreement with the customer whereby the member would be allowed to pledge or hypothecate any security involved in such transaction for any

<sup>3</sup> The current FINRA rulebook consists of (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE ("Incorporated NYSE Rules") (together, the NASD Rules and Incorporated NYSE Rules are referred to as the "Transitional Rulebook"). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE ("Dual Members"). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, see *Information Notice*, March 12, 2008 (Rulebook Consolidation Process).

<sup>4</sup> Federal Reserve Board, Regulation T (Credit by Brokers and Dealers), 12 CFR 220 *et seq.*

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

amount in excess of the indebtedness of the customer to such member.

Section 220.8 of Regulation T permits the purchase of a security in the cash account predicated on either (1) there being sufficient funds in the account; or (2) the member accepting in good faith the customer's agreement that full cash payment will be made.<sup>5</sup> The rule further stipulates that payment must be made within a specified payment period.<sup>6</sup> Regulation T also allows the purchase of a security in a margin account, whereby a customer must deposit an initial requirement, based upon the amount of the transaction, within the specified payment period.

FINRA proposes to repeal NASD Rule 2450 in light of the explicit provisions in Regulation T requiring the deposit of sufficient funds within the specified payment period. FINRA also believes the hypothecation prohibition in NASD Rule 2450 would no longer be relevant because it is predicated on a partial or installment payment under the rule.

NASD IM-2830-2 (Maintaining the Public Offering Price)

Section 22(d) of the Investment Company Act generally prohibits a registered investment company, its principal underwriter, or a dealer from selling the fund's shares at a price other than the current public offering price described in the prospectus. As a general matter, this means that a broker-dealer must sell shares of a mutual fund to investors at the fund's current net asset value, plus any applicable sales load. Section 22(d) excepts from this prohibition sales to the fund itself, the fund's principal underwriter or another dealer.

In the 1950s, FINRA adopted an interpretation of Section 22(d) and NASD Rule 2420,<sup>7</sup> now codified as NASD IM-2830-2, that requires members to sell mutual funds at the public offering price not only to investors, but also to any non-member broker or dealer. NASD IM-2830-2 provides examples of transactions that would violate this prohibition. At the time NASD IM-2830-2 was adopted,

<sup>5</sup> See Regulation T 220.8(a)(1).

<sup>6</sup> According to Section 220.2 of Regulation T, payment period "means the number of business days in the standard securities settlement cycle in the United States, as defined in paragraph (a) of SEC Rule 15c6-1 (17 CFR 240.15c6-1(a)), plus two business days."

<sup>7</sup> NASD Rule 2420 imposes various restrictions on dealings with non-member brokers and dealers, including prohibiting a member from dealing with any non-member broker or dealer except at the same prices, for the same commissions or fees, and on the same terms and conditions as the member firm offers to the general public. NASD Rule 2420 will be addressed as part of a separate phase of the rulebook consolidation process.

some broker-dealers doing business with the public were not NASD members. Accordingly, it was possible for member firms to sell shares of mutual funds to non-member broker-dealers at a price below the current public offering price because of the exception in Section 22(d) for sales to other dealers. However, these kinds of transactions were inconsistent with the requirement under NASD Rule 2420 that transactions with non-member firms be on the same terms as transactions with the public.

Since the adoption of NASD IM-2830-2, the laws governing broker-dealers have changed, and today virtually all broker-dealers doing business with the public are FINRA members. In addition, NASD IM-2830-2 largely duplicates the requirement in Section 22(d) to sell mutual fund shares to investors at the current public offering price. As a result, FINRA believes NASD IM-2830-2 no longer serves any useful purpose, and proposes not to incorporate its content into the Consolidated FINRA Rulebook.

Incorporated NYSE Rule 413

Incorporated NYSE Rule 413 requires members to adopt such uniform forms as the NYSE may prescribe to facilitate the orderly flow of transactions within the financial community. This provision was adopted in 1973 to apply to forms generally, including membership forms.

The FINRA By-Laws contain several provisions by which FINRA may prescribe processes for members' activities, including the use of uniform forms.<sup>8</sup> Accordingly, FINRA proposes to repeal Incorporated NYSE Rule 413 in light of these provisions.

FINRA will announce the implementation date of the proposed rule change in a Regulatory Notice to be published no later than 90 days following Commission approval. The implementation date will be no later

<sup>8</sup> See, e.g., the following provisions of the FINRA By-Laws: Article IV, Section 1 (providing that FINRA may prescribe the process for application for FINRA membership); Article IV, Section 8 (providing that FINRA may prescribe the process for members to advise FINRA regarding branch offices, including the opening, closing, relocation, change in designated supervisor, or change in designated activities of any branch office); Article V, Section 2 (providing that FINRA may prescribe the process for application for registration by registered representatives and associated persons); and Article V, Section 3 (providing that FINRA may prescribe the process for members' notification of termination of registered persons). In addition, FINRA has issued for comment proposed FINRA Rule 4540 governing information and data reporting and filing requirements. See *Regulatory Notice 09-02* (January 2009). (FINRA Requests Comment on Proposed Consolidated FINRA Rule Governing Information and Data Reporting and Filing Requirements).

than 180 days following Commission approval.

## 2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,<sup>9</sup> which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change will further these requirements by eliminating duplicative and unnecessary rules and advancing the development of a more efficient and effective Consolidated FINRA Rulebook.

### B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

<sup>9</sup> 15 U.S.C. 78o-3(b)(6).

• Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-FINRA-2009-093 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-FINRA-2009-093. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission,<sup>10</sup> all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-FINRA-2009-093 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-798 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61338; File No. SR-FINRA-2009-084]

### Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change To Adopt FINRA Rule 5330 (Adjustment of Orders) in the Consolidated FINRA Rulebook

January 12, 2010.

On November 24, 2009, the Financial Industry Regulatory Authority, Inc. ("FINRA") (f/k/a National Association of Securities Dealers, Inc. ("NASD")) filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to adopt NASD Rule 3220 (Adjustment of Open Orders) as a FINRA rule in the consolidated FINRA rulebook with several changes and to renumber NASD Rule 3220 as FINRA Rule 5330 in the consolidated FINRA rulebook. The proposed rule change was published for comment in the **Federal Register** on December 8, 2009.<sup>3</sup> The Commission received no comments on the proposal. This order approves the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.<sup>4</sup> In particular, the Commission finds that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,<sup>5</sup> which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The Commission believes that the proposed rule change is appropriate to continue to set forth how members are to adjust the terms of open orders when such orders involve a security that is subject to a dividend, payment, or distribution. The Commission notes that members will be prohibited from executing or permitting the execution of

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 61083 (December 1, 2009), 74 FR 64774.

<sup>4</sup> In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. See 15 U.S.C. 78c(f).

<sup>5</sup> 15 U.S.C. 78o-3(b)(6).

such open orders without first reconfirming the order with the customer when the value of a distribution cannot be determined. The Commission also notes that members will now be required to cancel all orders (both buy and sell), rather than just open orders, if a security is the subject of a reverse split. Members also will be required to notify a customer with a pending order that is not otherwise required to be adjusted under the rule when his or her order is the subject of a reverse split. The Commission believes that the proposed rule change will conform FINRA Rule 5330 with current trading practices, including the conversion from fractional to decimal trading increments. The Commission further believes that the proposed rule change will bring uniformity and harmonization to the treatment of open orders by conforming FINRA Rule 5330 with comparable rules of other self-regulatory organizations.<sup>6</sup>

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,<sup>7</sup> that the proposed rule change (SR-FINRA-2009-084) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>8</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-819 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61333; File No. SR-NYSE-2009-117]

### Self-Regulatory Organizations; New York Stock Exchange LLC; Order Approving Proposed Rule Change Amending Its Listing Fees for Structured Products

January 12, 2010.

#### I. Introduction

On November 19, 2009, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change

<sup>6</sup> See, e.g., Nasdaq Rule 4761 and NYSE-ARCA Rule 7.39.

<sup>7</sup> 15 U.S.C. 78s(b)(2)

<sup>8</sup> 17 CFR 200.30-3(a)(12)

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>10</sup> The text of the proposed rule change is available on the Commission's Web site at <http://www.sec.gov/>.

<sup>11</sup> 17 CFR 200.30-3(a)(12).

amending its maximum fee for structured products. The proposed rule change was published in the **Federal Register** on December 8, 2009.<sup>3</sup> The Commission received no comments on the proposal. This order approves the proposed rule change.

## II. Description of the Proposal

The Exchange proposes to apply a maximum listing fee in any calendar year (including initial and annual listing fees) of \$500,000 in connection with the listing under Section 902.05 of the Listed Company Manual (the "Manual") of any individual issuance of securities, with retroactive application to any securities listed on or after the date of November 19, 2009. Currently, Section 902.05 sets forth listing fees applicable to securities traded on the equity floor of the Exchange and listed under Section 703.18, the equity criteria set out in Section 703.19, and Section 703.21. Additionally, Section 902.05 provides that issuers of "retail debt securities" are subject to an annual maximum aggregate listing fee of \$500,000 for all retail debt securities issued in a calendar year. Further, under Section 902.02 of the Manual, companies are subject to the maximum of \$500,000 per issuer for initial and annual fees payable on listed equity securities. Under Sections 902.02 and 902.05, the total maximum fee of \$500,000 billable to an issuer in a calendar year under the fee cap in Section 902.02 includes all annual fees billed to an issuer for listed retail debt securities. However, securities listed under Section 902.05, other than retail debt securities, are not subject to the maximum fees set forth in Section 902.02 or any maximum fee established in Section 902.05.

The Exchange proposes to establish a maximum fee in any calendar year (including both initial and annual listing fees) per issuance listed under Section 902.05 of \$500,000. In the Notice, the Exchange stated that by applying a maximum fee, the Exchange would rectify an anomaly under the Exchange's fee structure, whereby issuers of securities listed under Section 902.05 (other than retail debt securities), could pay fees in excess of \$500,000, while the fees for all other categories of securities would be capped. The Exchange further represented in its filing that it did not believe that any revenue it would forego as a result of the proposed fee cap would negatively

affect its ability to fund its regulatory program.

## III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds that the proposal is consistent with Sections 6(b)(4) and (b)(5) of the Act,<sup>4</sup> which require, among other things, that the rules of an exchange (i) provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities, and (ii) are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As noted above, the NYSE fee cap for structured products listed under Section 902.05 of the Manual applies to any individual issuance of securities. This is in contrast to the \$500,000 maximum total fee billed to an issuer for generally all listed equity issuances in a calendar year.<sup>5</sup> According to the Exchange, it is appropriate to have a separate fee cap for each individual issuance of structured products, as many companies list multiple new classes of structured products within a calendar year, requiring the repeated utilization of the Exchange's operational and regulatory resources to a degree that is not normally the case with respect to equity securities subject to the cap under Section 902.02. Particularly, the Exchange states that no company will pay a higher initial or annual listing fees in connection with the listing of structured products as a result of the proposed amendment and some companies will pay less if their fees in relation to an individual structured product would exceed \$500,000 in the absence of the proposed cap.

Finally, the Exchange believes that the application of the maximum listing fee, as proposed, should be retroactively applied to any securities listed on or after November 19, 2009, as it will enable companies to benefit from the proposed fee cap without having to delay their listing until after Commission approval solely for the purpose of benefitting from the fee reduction.

Based on the above, the Commission believes that the Exchange's proposed rule change provides for the equitable allocation of reasonable dues, fees, and other charges among issuers, in that it

applies uniformly to all companies listing structured products. The Commission also believes that the proposal does not unfairly discriminate between issuers as all companies will be subject to the same fee schedule. While the Commission recognizes that the fee cap proposal for structured products is applied per issuance, unlike the aggregated fee cap for all equity securities in Section 902.02, the Exchange has provided a reasonable justification for that difference and therefore, we find that it meets the requirements under Sections 6(b)(4) and 6(b)(5) of the Act. The Commission notes that the proposal caps the maximum amount payable by issuers for the listing of structured products. The Commission further notes that the Exchange has represented that despite any reduction, the Exchange will continue to have sufficient revenue to continue to adequately fund its regulatory activities. Finally, the Commission believes that the proposed maximum listing fees for structured products is appropriate and, as proposed by the Exchange, can be applied retroactively to any securities listed on or after November 19, 2009, because no company will be subject to increased fees as a result of the proposal and as noted above, some companies may pay less than currently required under the existing fees. Further, it will allow companies that have listed new classes of securities after the date of filing of this proposed rule change to benefit from any applicable reduction in listing fees. The Commission also notes that the change, including the retroactive effect, was published for notice and comment in the **Federal Register** and we did not receive any comments.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with the Act.<sup>6</sup>

## IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>7</sup> that the proposed rule change (SR-NYSE-2009-117) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>8</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-821 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>6</sup> 15 U.S.C. 78f(b)(4). In approving the proposed rule change, the Commission has considered the proposed rule's impact in efficiency, competition and capital formation. See 15 U.S.C. 78c(f).

<sup>7</sup> 15 U.S.C. 78s(b)(2).

<sup>8</sup> 17 CFR 200.30-3(a)(12).

<sup>3</sup> See Securities Exchange Act Release No. 61091 (December 1, 2009), 74 FR 64797 (hereinafter referred to as "Notice").

<sup>4</sup> 15 U.S.C. 78f(b)(4) and (b)(5).

<sup>5</sup> See Section 902.02 of the Manual.

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61329; File No. SR-CBOE-2009-101]

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Professional Fees

January 11, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 24, 2009, Chicago Board Options Exchange, Incorporated ("CBOE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE is proposing to amend its Fees Schedule as it relates to fees for certain orders. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.org/legal>), at the Exchange's Office of the Secretary and at the Commission.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

On December 17, 2009, the Securities and Exchange Commission approved a proposed rule change by the CBOE to

establish a Professional<sup>3</sup> designation.<sup>4</sup> This designation provides that certain non-broker-dealer customers will participate in CBOE's allocation process on equal terms with broker-dealer orders. In the aforementioned filing, the Exchange represented that it intends to establish, via a separate rule filing, transaction fees applicable to Professionals. In accordance with that representation, the Exchange now proposes to amend its fees schedule to establish the transaction fees that would be applicable to Professional orders. These fees will be commencing on January 4, 2010.

The Exchange proposes to charge Professional orders in the same manner that it charges Voluntary Professional orders. Specifically, Professional orders will be charged a \$0.20 per contract transaction fee in all equity options and options on indexes, exchange-traded funds and holding company depository receipts (except those listed below). The Exchange proposes a \$0.40 per contract transaction fee in DXL, OEX, XEO, and DVS options and all volatility index options, and a \$0.85 per contract transaction fee in credit default and credit default basket options. The Exchange proposes to amend footnote 14 (index option surcharge fee) to clarify that the Surcharge Fee would apply to Professionals.

The Exchange notes that the Options Regulatory Fee contained in section 12 will apply to Professionals as it currently does to Voluntary Professionals (no changes to the text are needed to reflect this).<sup>5</sup> In addition, the Exchange notes that, as with Voluntary Professionals, Professional orders will not be subject to the order handling system order cancellation fee contained in section 14 (no changes to the text are needed to reflect this).

Lastly, the Exchange is proposing one other change to its fees schedule that will be applicable to both Voluntary Professional orders and Professional orders. Specifically, the Exchange is proposing to amend section 20 (non-customer linkage fees) to provide that the non-customer linkage fees will be

assessed on Voluntary Professional orders and Professional orders.<sup>6</sup>

###### 2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,<sup>7</sup> in general, and furthers the objectives of Section 6(b)(4)<sup>8</sup> of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE members and other persons using its facilities. The proposed fee changes would enable the Exchange to implement the Professional designation.

###### B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

###### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change establishes or changes a due, fee, or other charge imposed by the Exchange, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>9</sup> and Rule 19b-4(f)(2)<sup>10</sup> thereunder. At any time within 60 days of the filing of the proposed rule change the Commission may summarily abrogate such proposed rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors,

<sup>6</sup> Under the non-customer linkage fee, for any non-customer order routed to other exchanges, CBOE assesses the following costs to the member that submitted the non-customer order to CBOE: (i) Charge a \$0.05 per contract routing fee, (ii) pass through all actual charges assessed by the away exchange(s) (these are calculated on an order-by-order basis since different away exchanges charge different amounts), and (iii) charge CBOE's customary execution fees applicable to the order. The routing fee helps offset costs incurred by the Exchange in connection with using an unaffiliated broker-dealer to access other exchanges. Passing through charges assessed by other exchanges for "linkage" executions and charging for related CBOE executions are appropriate because non-customer order flow can route directly to those exchanges if desired and the Exchange chooses not to absorb those costs at this time.

<sup>7</sup> 15 U.S.C. 78f(b).

<sup>8</sup> 15 U.S.C. 78f(b)(4).

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 19b-4(f)(2).

<sup>3</sup> See CBOE Rule 1.1(ggg).

<sup>4</sup> See Securities Exchange Act Release No. 61198 (December 17, 2009) (SR-CBOE-2009-078).

<sup>5</sup> The Options Regulatory Fee is assessed by CBOE to each member for all options transactions executed or cleared by the member that are cleared by The Options Clearing Corporation ("OCC") in the customer range, excluding Linkage orders, regardless of the exchange on which the transaction occurs. Professional orders, which will use order origin code "W," are cleared in the customer range at OCC.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

or otherwise in furtherance of the purposes of the Act.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2009-101 on the subject line.

##### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2009-101. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission,<sup>11</sup> all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-

<sup>11</sup> The text of the proposed rule change is available on CBOE's Web site at <http://www.cboe.org/legal>, on the Commission's Web site at <http://www.sec.gov>, at CBOE, and at the Commission's Public Reference Room.

2009-101 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>12</sup>

Florence E. Harmon,  
Deputy Secretary.

[FR Doc. 2010-823 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61326; File No. SR-Phlx-2009-113]

### Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing of Proposed Rule Change by NASDAQ OMX PHLX, Inc. Relating to Index Option Position Limits

January 11, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 29, 2009, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange, pursuant to Section 19(b)(1) of the Act<sup>3</sup> and Rule 19b-4 thereunder,<sup>4</sup> proposes to increase the position limits<sup>5</sup> for certain narrow-based (industry) index option contracts.<sup>6</sup> Phlx also proposes to amend Rule 1001A to delete obsolete references to index options which no longer trade on the Exchange, and to delete the word "Phlx" from the term "Phlx/KBW Bank Index".

The text of the proposed rule change is set forth below. Proposed new language is in italics and deleted language is bracketed.

<sup>12</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(1).

<sup>4</sup> 17 CFR 240.19b-4.

<sup>5</sup> Position limits generally impose a ceiling on the number of option contracts in each class on the same side of the market (*i.e.*, aggregating long calls and short puts or long puts and short calls) that can be held or written by an investor or group of investors acting in concert.

<sup>6</sup> Also known as Sector Index Options.

Rule 1001A.

#### Position Limits

(a) Except as otherwise indicated, the position limit for a broad-based (market) index option shall be 25,000 contracts on the same side of the market. All other broad-based (market) index options contracts shall be subject to a contract limitation fixed by the Exchange, which shall not be larger than the limits provided in this section (a), except certain positions must be aggregated in accordance with paragraph (d) or (e) below:

(i) Respecting the Value Line Composite Index; VLE, and the U.S. Top 100 Index, TPX, 75,000 contracts total, of which no more than 45,000 contracts can be in the nearest expiration month.

(ii) Respecting the National Over-the-Counter Index, XOC, 75,000 contracts total.

(iii) Respecting the Nasdaq Composite Index, (1) 50,000 contracts total for full-size options, with 30,000 contracts in the nearest expiration month, and (2) 500,000 contracts total for mini size options, with 300,000 contracts total in the nearest expiration month.]

(i[v]) Respecting the Full Value Russell 2000® Options and the Reduced Value Russell 2000® Options, there shall be no position limits.

(ii[v]) Respecting the Full Value Nasdaq 100 Options and the Reduced Value Nasdaq 100 Options, there shall be no position limits.

(b)(i) In determining compliance with Rule 1001, option contracts on a narrow-based (industry) index shall, subject to the procedures specified in subparagraph (iii) of this rule, be subject to the following position limits:

—18,000 contracts (*or 54,000 contracts for options on the PHLX Oil Service Sector, PHLX Semiconductor Sector, PHLX Utility Sector, PHLX Gold/Silver Sector, PHLX Housing Sector, SIG Energy MLP Index, SIG Oil Exploration & Production Index and the NASDAQ China Index*) if the Exchange determines, at the time of a review conducted pursuant to subparagraph (ii) of this paragraph (b), that any single underlying stock accounted, on average, for 30% or more of the index value during the 30-day period immediately preceding the review; or

—24,000 contracts (*or 72,000 contracts for options on the PHLX Oil Service Sector, PHLX Semiconductor Sector, PHLX Utility Sector, PHLX Gold/Silver Sector, PHLX Housing Sector, SIG Energy MLP Index, SIG Oil Exploration & Production Index and the NASDAQ China Index*) if the Exchange determines, at the time of a review conducted pursuant to subparagraph (ii) of this paragraph (b), that any single underlying stock accounted, on average, for 20% or more of the index value or that any five underlying stocks together accounted, on average, for more than 50% of the index value, but that



no single stock in the group accounted, on average, for 30% or more of the index value, during the 30-day period immediately preceding the review; or  
 —31,500 contracts (or 94,500 contracts for options on the PHLX Oil Service Sector, PHLX Semiconductor Sector, PHLX Utility Sector, PHLX Gold/Silver Sector, PHLX Housing Sector, SIG Energy MLP Index, SIG Oil Exploration & Production Index and the NASDAQ China Index) if the Exchange determines that the conditions specified above which would require the establishment of a lower limit have not occurred, or  
 —44,000 contracts total with respect to the [Phlx]/KBW Bank Index.

(ii)–(iii)—No Change.

(c) Reporting Requirements for Options on Market Indexes.—Each member or member organization that maintains a position on the same side of the market [in excess of 60,000 contracts for its own account or for the account of a customer in the Value Line Composite Index, VLE, and the U.S. Top 100 Index, TPX or the National Over-the-Counter Index, XOC, or] in excess of 100,000 contracts for its own account or for the account of a customer in the Full Value Russell 2000® Options, RUT; or in excess of 100,000 contracts for its own account or for the account of a customer in the Full Value Nasdaq 100 Options, NDX must file a report with the Exchange that includes, but is not limited to, data related to the option position, whether such position is hedged and if applicable, a description of the hedge and information concerning collateral used to carry the position. Registered Options Traders are exempt from this reporting requirement. For positions exceeding the position limit in paragraph (a), Commentary .01 contains the requirements for qualifying for the Index Hedge Exemption under this Rule.

(d)–(e)—No Change.

Commentary—No Change.

\* \* \* \* \*

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The purpose of the proposed rule change is to increase index option

position limits in Phlx Rule 1001A applicable to options on the PHLX Oil Service Sector, PHLX Semiconductor Sector, PHLX Utility Sector, PHLX Gold/Silver Sector, PHLX Housing Sector, SIG Energy MLP Index, SIG Oil Exploration & Production Index and the NASDAQ China Index) (collectively, the "Specified Index Options") in order to attract additional trading interest and promote depth and liquidity in those options.<sup>7</sup>

Exchange exercise limits in Phlx Rule 1002A, Exercise Limits, which rule is not proposed to be amended, are established by reference to position limits. The proposed increase in position limits would therefore effectively also increase exercise limits.<sup>8</sup>

The Exchange believes that the current position limits constrain certain investors from trading the Specified Index Options, the markets for which have become well established and liquid. Pursuant to Rule 1001A, the three tiered levels of position limits are 18,000, 24,000, and 31,500 contracts. These position limits, which are similar among all the options exchanges respecting narrow-based index options, are based generally on the degree of concentration of a component stock of the index.<sup>9</sup> In some cases the existing position limits for the Specified Index Options force these same investors out of transparent listed markets and into opaque over-the-counter ("OTC") transactions. The Exchange proposes to increase these limits to 54,000, 72,000, and 94,500 contracts, respectively, for the Specified Index Options.

The Exchange recognizes that the purpose of position limits is to prevent manipulation and protect against

disruption of the markets for both the option as well as the underlying security. The Exchange has considered the effects of increased position limits for the Specified Index Options on the marketplace, and believes that manipulation and disruption concerns are addressed by a combination of existing surveillances and the implementation of tiered position limits.

Increasing position limits for the Specified Index Options should increase market transparency to the benefit of the investing public by attracting more existing over the counter transactions in these securities to listed, centrally cleared markets. The Exchange dedicates substantial resources to monitoring the markets for evidence of manipulation or disruption caused by investors with positions at or near current position or exercise limits. The proposed increased position limits would not diminish the surveillance function in this regard. The Exchange believes an increase in position limits for the Specified Index Options at this time would reduce risk for manipulation and also benefit the investing public.

The proposed higher position limits for the Specified Index Options would serve to better accommodate the hedging needs of Exchange market makers and specialists, who are restricted by current position limit levels. Exchange members and customers have indicated that the current position limits hamper their ability to execute investment strategies in respect of narrow-based indexes and have requested increased position limits. The market's need for these higher position limits is particularly critical for institutional hedging and other high volume trading objectives, and in view of the large portfolios common to institutional trading and the tendency to use larger-sized transactions to execute complex cross-market strategies. Floor members have also expressed the negative effect of the current low position limits on index options trading in an exchange environment. The Exchange believes, based on such member and customer requests, that the current position limit levels for the Specified Index Options continue to discourage market participation by large investors as well as institutions that compete to facilitate the trading interests of some of the largest investors. Accordingly, this proposal aims to also accommodate the liquidity and hedging needs of large investors and their facilitators.

Investors that are not able to take large positions in the Specified Index Options

<sup>7</sup> The SIG indexes noted herein are trademarks of SIG Indices, LLLP.

<sup>8</sup> Phlx Rule 1002A, states, in relevant part: "\* \* \* exercise limits for index options contracts shall be equivalent to the position limits described in Rule 1001A."

<sup>9</sup> Specifically, Phlx Rule 1001A(b)(i) currently provides the following position limits for narrow-based index options: (1) 18,000 contracts if the Exchange determines that any single underlying stock accounted, on average, for 30% or more of the index value during the 30-day period immediately preceding the semi-annual review of narrow-based index option position limits; (2) 24,000 contracts if the Exchange determines, at the time of a semi-annual review, that any single underlying stock accounted, on average, for 20% or more of the index value or that any five underlying stocks together accounted, on average, for more than 50% of the index value, but that no single stock in the group accounted, on average, for 30% or more of the index value, during the 30-day period immediately preceding the review; or (3) 31,500 contracts if the Exchange determines that the conditions specified above which would require the establishment of a lower limit have not occurred. Additionally, the rule provides that position limits with respect to options on the KBW Bank Index are 44,000 contracts.

due to the restrictive index option position limits of Rule 1001A may resort in the alternative to executing that strategy in the OTC markets, where index option position limit rules do not constrain their ability to structure the desired strategy, and where regulators are limited in their ability to monitor and surveil market activity altogether. In today's evolving regulatory climate, the Exchange believes that the Commission should encourage migration of trading from opaque and largely unregulated OTC markets onto exchanges which are able to provide regulators with greater transparency and control. Additionally, by raising position limits, the Exchange should be able to increase investor participation in its markets for Specified Index Options, thereby reducing even further any potential for manipulation of index option settlement prices.

The Exchange understands based on conversations with Commission staff that the Commission's understanding of appropriate position limit levels is based upon an economic analysis of that issue conducted under the auspices of the Commission over five years ago (the "SEC Study").<sup>10</sup> The Exchange understands that the goal of the SEC Study's analysis was to determine a methodology for setting optimal position limits for index option contracts in order to minimize the potential for manipulation of the index options' settlement prices. The Exchange also understands that SEC staff have recently reviewed the SEC's study's analysis to reflect changes in market and regulatory environment and have analyzed the Specified Index Options in light of its review.

Markets to buy and sell the individual index component stocks are now much more efficient, liquid, competitive and automated in nature making it highly unlikely that any one person or institution, either acting alone or in concert, could successfully influence the price of an underlying component stock to the extent that would be necessary to measurably affect the settlement price of one of the Specified Index Options. Since 2002, average daily volume has nearly tripled.<sup>11</sup> Furthermore, liquidity measures of the

<sup>10</sup> Exchange staff had previously discussed with Commission staff the issue of the position limits counseled by the SEC Study in the context of an earlier proposed rule change filed by the Exchange to raise the Sector Index option contracts' position limits. That filing was ultimately withdrawn by the Exchange at Commission staff's request. See SR-Phlx-2008-56.

<sup>11</sup> In 2002 United States equities markets averaged 77 billion shares traded per month. So far in 2009 United States equities markets are averaging 225 billion shares traded per month—nearly three times the trading volume of the 2002 markets.

price impact of a trade show an improvement of tenfold or more relative to 2002 values. Finally, the stocks which are the individual index components of the Specified Index Options trade actively on a number of national market centers as well as OTC, and all major market centers have become highly automated and fully linked in response to Regulation NMS.

Finally, the Exchange is proposing to amend Rule 1001A to delete obsolete references to options on the Value Line Composite Index, the U.S. Top 100 Index and the National Over-the-Counter Index, as these index options are no longer traded on the Exchange, and is removing the word "Phlx" from the term Phlx/KBW Bank Index, as the index is now known simply as the "KBW Bank Index".

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act<sup>12</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act<sup>13</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by establishing increased position limits for the Specified Index Options which should allow more efficient use of those options by market participants.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory

<sup>12</sup> 15 U.S.C. 78f(b).

<sup>13</sup> 15 U.S.C. 78f(b)(5).

organization consents, the Commission will:

(a) by order approve such proposed rule change, or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-Phlx-2009-113 on the subject line.

### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2009-113. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2009-113 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>14</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-800 Filed 1-15-10; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61337; File No. SR-Phlx-2009-104]

### Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the Fee Schedule

January 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 22, 2009, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. Phlx filed the proposal pursuant to Section 19(b)(3)(A)<sup>3</sup> of the Act and Rule 19b-4(f)(2)<sup>4</sup> thereunder. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to: (i) Decrease options transaction charges for ROTs to \$.21 per contract; (ii) assess a \$.05 per contract fee for equity options that are directed to specialists, Streaming Quote Traders ("SQTs")<sup>5</sup> and Remote Streaming Quote Traders ("RSQTs")<sup>6</sup> by a member or member

organization and are executed electronically in lieu of the existing specialist and Registered Options Trader (on-floor) ("ROTs") equity options transaction fees; (iii) eliminate the monthly 4.5 million contracts (the "Volume Threshold") for ROTs and specialists; (iv) create a \$900,000 monthly cap on equity options transactions executed by ROTs or specialists ("Monthly Cap"); (v) increase the Firm equity option transaction charge from \$.24 to \$.25 and increase the Firm Related Equity Option Cap from \$75,000 to \$85,000; (vi) increase Index Options transaction charges from \$.24 to \$.30; (vii) eliminate the SQT and RSQT permit credits; (viii) eliminate the current permit fee structure and instead implement a \$1,000 permit fee, regardless of classification; (ix) eliminate the Other Permit Holders fee category; (x) increase the Trading Floor Personnel Registration Fee from \$50 to \$100; (xi) increase the current Order Entry Port from \$250 to \$500 and only charge per mnemonic instead of per mnemonic per port; (xii) amend the SQF Port Fee to assess a \$500 per month per SQF port in lieu of the current structure of \$250 for the first five ports and \$1000 for additional port thereafter and also rename the SQF Port Fee as the "Active SQF Port Fee"; (xiii) eliminate the \$0.02 per contract SQF Port Fee; (xiv) eliminate references to Pilot FCOs; and (xv) eliminate and amend corresponding endnotes related to amendments indicated herein and make other clarifying amendments.

While changes to the Exchange's fee schedule pursuant to this proposal are effective upon filing, the Exchange has designated this proposal to be operative for trades settling on or after January 1, 2010.

The text of the proposed rule change is available on the Exchange's Web site at <http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

Generally, the purpose of the proposed rule change is to update the Exchange's fee schedules by adopting new fees, amending existing fees and deleting fees and text that are no longer deemed necessary.

#### Equity Options, Sector Index Options Fees and U.S. Dollar-Settled Foreign Currency Option Fees

The Exchange proposes to amend the current options transaction charge of \$.22 for ROTs and decrease that fee to \$.21 per contract side, similar to the rate charged to specialists. The Exchange also proposes to assess [sic] specialists, SQTs and RSQTs ("Directed Participants" or "Directed Specialists, RSQTs, or SQTs")<sup>7</sup> an equity options transaction fee of \$.05 per contract fee in equity options that are directed to the Directed Participants by a member or member organization ("Order Flow Provider" or "OFP")<sup>8</sup>, and executed electronically on the Exchange's electronic trading platform for options, the Phlx XL II system. The Exchange currently assesses this fee on Standard and Poor's Depository Receipts/SPDRs ("SPY")<sup>9</sup> equity options that are directed to specialists, SQTs and RSQTs by a member or member organization and are executed electronically in lieu of the existing specialist and ROT equity options transaction fees.<sup>10</sup> The Exchange proposes expanding this to all equity options transactions sent to these Directed Participants. The \$.05 per contract rate would be assessed to the Direct Participants, in lieu of the equity options transactions fees of \$.21 per contract side. Customers who are on the contra-side of a trade involving Directed

<sup>7</sup> See Exchange Rule 1080(l). " \* \* \* The term 'Directed Specialist, RSQT, or SQT' means a specialist, RSQT, or SQT that receives a Directed Order." A Directed Participant has a higher quoting requirement as compared with a specialist, SQT or RSQT who is not acting as a Directed Participant. See Exchange Rule 1014.

<sup>8</sup> See Exchange Rule 1080(l). " \* \* \* The term 'Order Flow Provider' ('OFP') means any member or member organization that submits, as agent, customer orders to the Exchange."

<sup>9</sup> SPY options are based on the SPDR exchange-traded fund ("ETF"), which is designed to track the performance of the S&P 500 Index.

<sup>10</sup> See Securities Exchange Act Release No. 60587 (August 28, 2009), 74 FR 46920 (September 8, 2009) (SR-Phlx-2009-73).

<sup>14</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(2).

<sup>5</sup> An SQT is an Exchange Registered Options Trader ("ROT") who has received permission from the Exchange to generate and submit option quotations electronically through an electronic interface with AUTOM via an Exchange approved proprietary electronic quoting device in eligible options to which such SQT is assigned. See Exchange Rule 1014(b)(ii)(A).

<sup>6</sup> An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically through AUTOM in eligible options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. See Exchange Rule 1014(b)(ii)(B).

Orders are not be [sic] subject to a fee and will remain free of charge.

The Exchange currently provides a discount for ROTs (on-floor) and specialists that exceed 4.5 million contracts in a given month (the "Volume Threshold") by assessing \$0.01 per contract on contract volume above the Volume Threshold instead of the applicable options transaction charges. The Exchange proposes to eliminate the Volume Threshold and instead establish a monthly cap for ROTs and specialists of \$900,000. The Exchange believes that by eliminating the current 4.5 million contracts Volume Threshold and instead proposing a Monthly Cap, a greater number of members will benefit from the Monthly Cap.

The Exchange also proposes to increase the Firm equity options transaction charge from \$.24 to \$.25 and increase the Firm Related Equity Option Cap from \$75,000 to \$85,000. Additionally, the Exchange proposes to increase the Sector Index Options Fees for ROTs, specialists and Firm from \$.24 to \$.30. The Exchange believes that these increases will be offset by other fee amendments that are proposed herein.

In connection with these above-referenced proposals the Exchange proposes to delete endnotes A, B, D and 1 and amend endnote 5 in connection with the proposed amendments specified herein. Endnotes A, B, D and 1 are no longer necessary in light of the proposed amendments herein. Endnote 5 is being amended to correspond with the proposed amendments. The Exchange proposes to delete endnote 5 from the Sector Index Options Fees, specifically the Firm Proprietary Fee, as that reference was inadvertently not removed at the time the Exchange filed a proposed rule change eliminating the options transaction charge associated with the sector index options in the \$75,000 Firm-Related Equity Option and Index Option Cap calculation.<sup>11</sup> Also, the Exchange proposes to delete endnote 5 from the U.S. Dollar-Settled Foreign Currency Options Fees, specifically, the Firm Proprietary Fee, as that reference was inadvertently not removed at the time the Exchange filed a proposed rule change redefining the firm proprietary order to exclude U.S. Dollar-Settled Foreign Currency Option Fees from the Firm-Related Cap.<sup>12</sup>

<sup>11</sup> See Securities Exchange Act Release No. 59545 (March 9, 2009), 74 FR 11158 (March 16, 2009) (SR-Phlx-2009-20).

<sup>12</sup> See Securities Exchange Act Release No. 59393 (February 11, 2009), 74 FR 7721 (February 19, 2009) (SR-Phlx-2009-12).

#### Permit Fees and Credits

The Exchange proposes to eliminate the permit credit associated with SQT and RSQT fees. Currently, a member organization is eligible to receive a monthly credit against the SQT fee for the number of actual permits issued to the member organization that are utilized by the SQT. Similarly, the RSQT member organizations' fees are subject to credits based on the number of permits applicable to such member organization, subject to the maximum allowable permit credit applicable to each RQST category. The Exchange is proposing to eliminate these credits. In connection with eliminating these credits the Exchange proposes to amend endnote 35 and eliminate endnote 40 to reflect the elimination of the credits. This proposal to eliminate the credit is consistent with the Exchange's proposal to eliminate the current permit fee structure wherein permit holders are categorized differently and assessed differently based on type of permit holder and number of permits held and instead propose one permit fee of \$1,000 for all permit holders. The Exchange would therefore propose removing all other categories and the tiered structure associated with the number of permits held and instead assess only one fee per permit holder. The Exchange believes that while some members may be assessed a higher fee, for example an Order Flow Provider will now be assessed \$1,000 as opposed to \$500, and others will be assessed a lower fee, Floor Brokers, Specialists, ROTs, Off-Floor Traders or Market Makers will be assessed \$1,000 instead of \$1,200 for the first permit and \$1,000 thereafter, overall members will be assessed equally for a permit and no distinction will be made by category or number of permits. The Exchange believes that this fee structure is more equitable and therefore the credit associated with SQT and RSQTs is no longer required. The Exchange believes that this proposal to institute a single permit fee is simpler and treats are [sic] members alike, regardless of classification.

Additionally, the Exchange proposes to eliminate the "Other Permit Holder" category. The Other Permit Holder category was adopted for billing purposes to address the limited situation where permit holders did not fall under one of the existing permit fee categories. Status as an Other Permit Holder requires that a permit holder or the member organization for which they solely qualify has no transaction activity for the applicable monthly billing period. Should a permit holder actively transact business during a particular

month, the highest applicable monthly permit fee will apply to such permit holder and the member organization for that monthly period. The "other" status only applies to permit holders who solely qualify their member organization, or in other words there is just one permit holder in that member organization. If there is more than one permit holder in a member organization and that permit holder does not fit within any of the existing permit fee categories, then this "other" category does not apply. Such permit holder or the member organization they solely qualify for must apply for such "other" status in writing to the Membership Department.<sup>13</sup>

The Exchange believes that this classification is no longer necessary and all members should be required to pay the same permit fee regardless of classification.<sup>14</sup> Likewise the Exchange proposes to eliminate endnote 45(b), which endnote references the Other Permit Holder Fee.

#### Other Access Service, Cancellation, Membership, Regulatory and Other Fees

The Exchange proposes to increase the Trading Floor Personnel Registration Fee from \$50 to \$100. This fee is imposed on member/participant organizations for individuals who are employed by such member/participant organizations and who work on the Exchange's trading floor, such as clerks, interns, stock execution clerks that handle equity orders that are part of an options contingency order and other associated persons, but who are not registered as members or participants. The Exchange is increasing this fee to keep pace with rising regulatory costs associated with its obligations to conduct oversight on on-floor trading activities. In connection with this proposal the Exchange proposes to amend endnote 55 to conform the language of the endnote to this proposed fee increase.

The Exchange proposes to amend its port fees. Currently, the Exchange assesses a monthly fee of \$250.00 for the Order Entry Port Fee.<sup>15</sup> The \$250 monthly Order Entry Port Fee is assessed per member organization order

<sup>13</sup> See Securities Exchange Act Release No. 59641 (March 27, 2009), 74 FR 15024 (April 2, 2009) (SR-Phlx-2009-26).

<sup>14</sup> There are currently no members who are assessed the Other Permit Holder Fee.

<sup>15</sup> The Order Entry Port Fee is a connectivity fee assessed on members in connection with routing orders to the Exchange via an external order entry port. Members access the Exchange's network through order entry ports. A member organization may have more than one order entry port.

entry mnemonic<sup>16</sup>. The Exchange assesses the \$250 monthly Order Flow Port Fee on members regardless of whether the order entry mnemonic is active<sup>17</sup> during the billing month. The fee is assessed regardless of usage, and solely on the number of order entry ports assigned to each member organization. The Exchange proposes to increase the fee from \$250 to \$500 per month per mnemonic. Also, the Exchange proposed to modify the manner in which members are assessed the Order Entry Port Fee to assess the fee per mnemonic instead of per mnemonic and per the number of order entry ports. The Exchange proposes to amend the Fee Schedule to note that the fee is assessed per mnemonic.

Additionally, the Exchange proposes to amend the SQF Port Fee to change the name to the "Active SQF Port Fee" and also amend the fee structure to eliminate the current tiered structure and instead propose a monthly fee of \$500 per port. "SQF" stands for specialized quote feed and is a proprietary quoting system that allows specialists, streaming quote traders and remote streaming quote traders to connect and send quotes into Phlx XL II, bypassing the Exchange's Auto-Quote System.<sup>18</sup> The SQF Port Fee is assessed in connection with sending quotes to the Exchange. Currently, the SQF Port Fee is assessed as follows: for the first 5 active SQF ports, a member organization would be charged \$250 per port per month and, for each additional active SQF port (over the first 5 active SQF ports), the member organization would be charged \$1,000 per port per month. Additionally, the same member organization would be credited \$0.02 per side for every option contract executed on the Exchange in that same month (excluding executions resulting from dividend, merger and short stock interest strategies) up to the amount of the SQF Port Fees when the member organization or one of its employees is designated as a specialist, SQT or RSQT and the transaction is billed according to the specialist or ROT transaction and/or comparison rates.<sup>19</sup> The SQF

Port Fee and corresponding credit are applied per member organization.<sup>20</sup>

In connection with this proposal a corresponding amendment is proposed to endnote 65 to clarify the endnote. The Exchange believes that by billing the Order Entry Port Fee per mnemonic instead of per mnemonic per port, member assessments will be reduced. The proposal to amend the SQF Port Fee is meant to simplify the fee structure. The Exchange believes that these increases in fees are necessary to keep pace with escalating technology costs.

#### Other Amendments

The Exchange proposes to eliminate endnote E which relates to a Pilot Program which is set to expire December 31, 2009 ("Pilot"). The Pilot is applicable to specialists and ROTs trading certain U.S. dollar-settled foreign currency options ("FCOs"), specifically the Mexican peso, Swedish krona, South African rand or the New Zealand dollar ("Pilot FCOs"). The Pilot Program allows the Exchange to waive the applicable specialist and ROT option transaction fees for specialists and ROTs trading Pilot FCOs.<sup>21</sup> The Exchange pays a \$1,700 monthly stipend ("Monthly Stipend") per currency to each member organization acting as a specialist.<sup>22</sup> As the Pilot is set to expire, the Exchange proposes to eliminate endnote E which makes reference to the Pilot.

While changes to the Exchange's fee schedule pursuant to this proposal are effective upon filing, the Exchange has designated this proposal to be operative for trades settling on or after January 1, 2010.

#### 2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act<sup>23</sup> in general, and furthers the objectives of Section 6(b)(4) of the Act<sup>24</sup> in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members. Specifically, the Exchange believes that this proposal is equitable because it would apply evenly to specialists and ROTs transacting equity options contracts sent to the Exchange for execution, in that any specialist, SQT or

RSQT may act as a Directed Participant and receive the \$.05 per contract fee. The Exchange believes that by eliminating the Volume Threshold and instead proposing a Monthly Cap of \$900,000 that members will benefit from such a cap and this would decrease fee assessments to member organizations and incentivize them to transact more business on the Exchange. This also applies to the decrease from \$22 [sic] to \$21 [sic] for ROTs in options transaction charges. The Exchange is also increasing certain fees including the Firm Fee, the Sector Index Options Fees and the Trading Floor Personnel Registration Fee and also increasing the Firm Related Equity Option Cap. The Exchange believes that other fee changes, which benefit members, will offset, to a certain degree, these proposed increases. Specifically, the Trading Floor Personnel Registration Fee is tied to increase costs of regulating floor members. The proposed amendments to the permit fees will simplify the permit fee structure and assess one fee on all permit holders. The elimination of the Other Permit category should not impact members as this category is no longer applicable. Also, the proposed permit fee is equitable in that all members will be required to pay the same permit fee under the new structure. The elimination of the permit fee credit is encompassed in the overall proposal to amend the fee structure related to permit fees. The Exchange believes that the permit fee credit is no longer necessary under this new permit fee proposal. The proposed amendments to the Port Fees should allow the Exchange to keep pace with increasing technology costs. Finally, other amendments are conforming and clarifying amendments to reflect the proposed amendments discussed herein with respect to the explanatory endnotes.

#### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

#### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

<sup>16</sup> Order entry mnemonics are codes that identify member organization order entry ports.

<sup>17</sup> An order entry mnemonic is considered active if a member organization sends at least one order to the Exchange using that order entry mnemonic during the applicable billing month. See Securities Exchange Act Release No. 58728 (October 3, 2008), 73 FR 59695 (October 9, 2008) (SR-Phlx-2008-70).

<sup>18</sup> See Exchange Rule 1080, Commentary .01(b).

<sup>19</sup> The Exchange is proposing to eliminate the SQT and RSQT credits as proposed herein.

<sup>20</sup> SQTs and RSQTs are assessed fees pursuant to the ROT rates as SQTs and RSQTs are deemed to be ROTs. See Exchange Rule 1014(b)(ii)(A) and (B).

<sup>21</sup> FCOs are currently traded on the Exchange under the name Phlx World Currency Options® ("WCOs").

<sup>22</sup> See Securities Exchange Act Release No. 60392 (July 28, 2009), 74 FR 38477 (August 3, 2009) (SR-Phlx-2009-57).

<sup>23</sup> 15 U.S.C. 78f(b).

<sup>24</sup> 15 U.S.C. 78f(b)(4).

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act<sup>25</sup> and paragraph (f)(2) of Rule 19b-4<sup>26</sup> thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-Phlx-2009-104 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.
- All submissions should refer to File Number SR-Phlx-2009-104. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission,<sup>27</sup> all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in

<sup>25</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

<sup>26</sup> 17 CFR 240.19b-4(f)(2).

<sup>27</sup> The text of the proposed rule change is available on the Commission's Web site at [www.sec.gov](http://www.sec.gov).

the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2009-104 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>28</sup>

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010-824 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61336; File No. SR-CBOE-2009-092]

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change To Amend Rule 8.91—Limitations on Dealings of DPMs and Affiliated Persons of DPMs

January 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 23, 2009, Chicago Board Options Exchange, Incorporated ("CBOE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and is approving the proposed rule change on an accelerated basis.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend Rule 8.91—*Limitations on Dealings of DPMs and Affiliated Persons of DPMs*. The text of the proposed rule change is

available on the Exchange's Web site (<http://www.cboe.org/Legal>), at the Office of the Secretary, CBOE and at the Commission.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

CBOE proposes to amend Rule 8.91—*Limitation on Dealings of DPMs and Affiliated Persons of DPMs* and Rule 8.93—*e-DPM Obligations*. Specifically, CBOE proposes to delete all of existing Rule 8.91, including the *Guidelines for Exemptive Relief Under Rule 8.91(e) for Members Affiliated with DPMs* ("Guidelines for Exemptive Relief"), and replace those provisions with the specific requirement applicable to e-DPMs set forth in Rule 8.93(x) relating to the adoption of information barriers and compliance with Rule 4.18. CBOE also proposes to adopt in both Rule 8.91 and Rule 8.93 a limited exception for integrated market making in broad-based, highly capitalized and liquid ETFs and trust issued receipts ("TIRs").

CBOE Rule 8.91 and the Guidelines for Exemptive Relief under Rule 8.91 were adopted in 1999, although the provisions contained therein were initially promulgated in 1987.<sup>3</sup> Since that time, there have been very few changes to Rule 8.91 and the Guidelines for Exemptive Relief. Recently, members have requested that CBOE evaluate Rule 8.91 and the Guidelines for Exemptive Relief to determine whether any changes would be appropriate given that the rule has been in effect in its current form for many years and the functions and responsibilities of DPMs have changed over time. For example, in 2005 CBOE amended its rules to eliminate the DPM's responsibility to act as agent in the options in which it

<sup>28</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 43004 (6/30/00), 65 FR 43060 (7/12/00), approving SR-CBOE-98-54.

is assigned.<sup>4</sup> As a result, DPMs essentially act as market-makers in their assigned classes, with higher quoting obligations than market-makers and additional responsibilities for which they receive a participation entitlement. Also, the prior restriction on Market-Makers affiliated with a DPM holding an appointment and submitting electronic quotations in an affiliated DPM's class has been eliminated (provided CBOE uses an algorithm in the class that does not allocate trades, in whole or in part, in an equal percentage based on the number of market participants quoting at the best bid or offer).<sup>5</sup> DPMs also can request to operate away from CBOE's trading floor as an Off-Floor DPM, similar to an e-DPM.<sup>6</sup>

In 2004, CBOE established a new category of market-making participant called e-DPMs, who are member organizations appointed to operate on CBOE as competing DPMs/specialists in a broad number of option classes.<sup>7</sup> e-DPMs have specific obligations set forth in Rule 8.93, and are otherwise not subject to the provisions in Rule 8.91 and the Guidelines for Exemptive Relief. Rather, under Rule 8.93(x), e-DPMs are required to "maintain information barriers that are reasonably designed to prevent the misuse of material, non-public information with any affiliates that may conduct a brokerage business in option classes allocated to the e-DPM or act as specialist or Market-Maker in any security underlying options allocated to the e-DPM, and otherwise comply with the requirements of Rule 4.18 regarding the misuse of material non-public information."

Rule 4.18 requires all members (other than lessor members who are not registered as broker-dealers) to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of material, nonpublic information by such member or persons associated with such member. For purposes of Rule 4.18, conduct constituting the misuse of material non-public information includes, but is not limited to: (i) Trading in any securities issued by a

corporation, partnership, TIR or ETF or similar entities, or in any related securities or related options or other derivative securities, while in possession of material, nonpublic information concerning that corporation, partnership, TIR or ETF or similar entities; (ii) trading in any underlying security or related options or other derivative securities, while in possession of material, nonpublic information concerning imminent transactions in the above; and (iii) disclosing to another person or entity any material, non-public information involving a corporation, partnership, TIR or ETF or similar entities or an imminent transaction in an underlying security or related securities for the purpose of facilitating the possible misuse of such material, non-public information. Rule 4.18 also requires members to establish, maintain and enforce specific policies and procedures for compliance with Rule 4.18.

Given that the functions and obligations of DPMs and e-DPMs are substantially similar, CBOE believes that it would be appropriate for DPMs and e-DPMs to be subject to the same requirements relating to the maintenance of information barriers with any affiliates that may conduct a brokerage business<sup>8</sup> in option classes allocated to the DPM or act as a specialist or market-maker in any security underlying options allocated to the DPM. CBOE also notes that DPMs do not have any advantages regarding relevant trading information provided by the Exchange vis-à-vis other members in their appointed classes. Accordingly, CBOE proposes to delete the existing provisions in Rule 8.91 and the Guidelines for Exemptive Relief, and replace them with the provisions in Rule 8.93(x) relating to the maintenance of information barriers and compliance with Rule 4.18. Rule 8.91(a), as amended, provides that a DPM shall provide its information barriers to the Exchange and obtain prior written approval, which is consistent with the current provisions of Rule 8.91(e).<sup>9</sup>

In addition to the above, CBOE proposes to adopt an exception to the requirement that a DPM or e-DPM in an option overlying a broad-based and highly capitalized ETF or TIR is required to maintain information

barriers with any affiliate that acts as a specialist or market-maker in the underlying broad-based ETF or TIR. CBOE notes that this exception currently exists for CBSX DPMs and CBOE DPMs (see Rule 54.7), and believes it is consistent with what the SEC has previously approved.<sup>10</sup>

## 2. Statutory Basis

The Exchange believes the rule proposal is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>11</sup> Specifically, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5) Act<sup>12</sup> requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest. Deleting existing Rule 8.91 and replacing those provisions with the specific requirement applicable to e-DPMs set forth in Rule 8.93(x) should clarify the regulatory obligations of DPMs while retaining an appropriate regulatory requirement relating to the adoption of information barriers and compliance with CBOE Rule 4.18.

### B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

## III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

<sup>10</sup> See Securities Exchange Act Release No. 55392 (3/2/07), 72 FR 10572 (3/8/07), approving SR-CBOE-2006-112; Securities Exchange Act Release No. 54422 (9/11/06), 71 FR 54537 (9/15/06), approving SR-CBOE-2004-21; Securities Exchange Act Release No. 47200 (1/15/03), 68 FR 3907 (1/27/03), approving SR-CBOE-2002-63.

<sup>11</sup> 15 U.S.C. 78f(b).

<sup>12</sup> 15 U.S.C. 78f(b)(5).

<sup>4</sup> See Securities Exchange Act Release No. 52798 (11/18/05), 70 FR 71344 (11/28/05), approving SR-CBOE-2005-46.

<sup>5</sup> See Securities Exchange Act Release No. 59539 (3/9/09), 74 FR 11143 (3/16/09), granting immediate effectiveness to SR-CBOE-2009-015; Securities Exchange Act Release No. 57742 (4/30/08), 73 FR 25067 (5/6/08), granting immediate effectiveness to SR-CBOE-2008-50.

<sup>6</sup> See Securities Exchange Act Release No. 57568 (3/26/08), 73 FR 18016 (4/2/08), granting immediate effectiveness to SR-CBOE-2008-032.

<sup>7</sup> See Securities Exchange Act Release No. 50003 (7/12/04), 69 FR 43028 (7/19/04), approving SR-CBOE-2004-24.

<sup>8</sup> The reference to "brokerage business" includes conducting an investment banking business or a public securities business.

<sup>9</sup> If a DPM's "Chinese Wall" procedures were previously approved by the Exchange pursuant to Rule 8.91(e), the procedures do not need to be re-approved by the Exchange as a result of this rule change unless the procedures are subsequently modified.

**Electronic Comments**

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2009-092 on the subject line.

**Paper Comments**

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2009-092. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR-CBOE-2009-092 and should be submitted on or before February 9, 2010.

**IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change**

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>13</sup> The

<sup>13</sup> In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Commission believes that the proposal is consistent with Section 6(b)(5)<sup>14</sup> in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange is proposing to eliminate the requirement that DPMs maintain certain specifically-prescribed information barriers as described in CBOE Rule 8.91. In its place, the Exchange proposes to amend CBOE Rule 8.91. Amended CBOE Rule 8.91 will continue to require information barriers, but will permit a Designated Primary Market Maker to develop and apply its own policies and procedures to, among other things, prevent the misuse of material nonpublic information. CBOE Rule 8.91 addresses concerns arising from the potential for the sharing of material non-public information between a DPM's market making activities and other business activities of the DPM or its affiliates. For instance, one such concern is that the DPM or affiliate engaging in other business activities might use non-public information that was acquired by the DPM through its role as a market maker, such as trading based on information on the DPM's book. Another concern is that the DPM might use material non-public information received from the entity engaging in other business activities, such as trading based on a change in the firm's buy or sell recommendation.<sup>15</sup>

While amended CBOE Rule 8.91 will no longer prescribe the specific information barriers a DPM must establish, the rule will require that such information barriers be reasonably designed to prevent the misuse of material non-public information by the member or persons associated with the member. Amended CBOE Rule 8.91 also will explicitly reference current CBOE Rule 4.18, which among other things, provides that the misuse of material non-public information includes trading in a security or related option or other derivative security while in possession of material non-public information concerning imminent transactions in the security, related option, or other

<sup>14</sup> 15 U.S.C. 78f(b)(5).

<sup>15</sup> See Securities Exchange Act Release No. 58328 (August 7, 2008), 73 FR 48260 (August 18, 2008) (SR-NYSE-2008-45) (articulating concerns in the context of approving changes to NYSE Rule 98).

derivative securities.<sup>16</sup> In addition, the proposed rule change requires that the member provide a copy of its information barrier policies and procedures to the Exchange for prior written approval. The Commission believes that, with adequate oversight by the Exchange of its members and prior review and approval of a DPM's information barrier, the amendment of CBOE Rule 8.91 should not materially increase the potential for the misuse of nonpublic information.

Pursuant to this proposal rule change, members may utilize the flexible, principles-based approach to modify their information barriers as appropriate to reflect changes to their business model, business activities, or to the securities market itself. A member should be proactive in assuring that its information barriers reflect the current state of its business and continue to be reasonably designed to achieve compliance with applicable federal securities law and regulations, and with applicable Exchange rules.

The Commission believes that the regulatory approach in this proposed rule change is similar to the regulatory approach of NYSE Arca, Inc. In particular, the CBOE approach, like the NYSE Arca approach, does not require market makers to maintain certain specifically-prescribed information barriers.<sup>17</sup> Unlike NYSE Arca's approach, however, CBOE's rules continue to require all DPMs to maintain information barriers.<sup>18</sup> The basis for this difference is that NYSE Arca's market makers and Lead Market Makers do not have any advantages regarding relevant trading information provided by NYSE Arca, either at, or prior to, the point of execution vis-à-vis other market participants. CBOE, on the other hand, represented only that its DPMs do not have any advantages regarding relevant trading information provided by the Exchange vis-à-vis other members in their appointed classes.<sup>19</sup>

CBOE also proposes to exempt DPMs and e-DPMs in an option overlying a broad-based ETF or TIR from the requirement to maintain barriers between it and any affiliates that act as a specialist or market-maker in the

<sup>16</sup> See CBOE Rule 4.18, Interpretations and Policies .01.

<sup>17</sup> See Securities Exchange Act Release No. 60604 (September 1, 2009), 74 FR 46272 (September 8, 2009) (SR-NYSEArca-2009-78).

<sup>18</sup> *Id.*

<sup>19</sup> CBOE members have access to auctions that other market participants do not, including, for example, the Automated Improvement Mechanism ("AIM") (CBOE Rule 6.74A), and the Solicitation Auction Mechanism (CBOE Rule 6.74B).



underlying broad-based ETF or TIR, provided that the capitalization and liquidity requirements for the component securities of the broad-based ETF or TIR set forth in CBOE Rule 54.7, Interpretation and Policy .03 are satisfied. The Commission believes that this exemption to the information barrier requirements is consistent with the Act. The Commission notes that this exemption is currently available to CBSX DPMs.<sup>20</sup> In addition, CBOE Rule 54.7, Interpretation and Policy .03 contains capitalization and liquidity requirements for the component securities of the broad-based ETFs and TIRs, which, together with the proposed exemption, are consistent with what the Commission has previously approved.<sup>21</sup> As the Commission noted previously, these capitalization and liquidity requirements for the component securities should reduce the likelihood that any market participant has an unfair informational advantage about the ETF, TIR, or its related options, or its component securities, or that a market participant would be able to manipulate the prices of the ETFs, TIRs, or their related options.<sup>22</sup>

The Commission also finds good cause, pursuant to Section 19(b)(2) of the Act,<sup>23</sup> for approving the proposed rule change prior to the 30th day after the date of publication of notice in the *Federal Register*. Although this proposed rule change does not require that DPMs maintain certain specifically-prescribed information barriers, it does require that DPMs establish and maintain information barriers that are reasonably designed to achieve compliance with applicable securities law and regulations, and with applicable Exchange rules. In addition, the rule requires that such barriers be pre-approved by the Exchange. The revised rule thus does not represent a significant change from the current rule, and is at least as stringent as the approach currently employed by NYSE Arca and Nasdaq.<sup>24</sup> The Commission

believes that, with Exchange approval and oversight, elimination of prescriptive information barrier requirements should not reduce the effectiveness of the CBOE rules which would now permit a DPM to develop and apply its own policies and procedures to, among other things, prevent the misuse of material nonpublic information.

#### V. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>25</sup> that the proposed rule change (SR-CBOE-2009-092) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>26</sup>

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010-822 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61331; File No. SR-CBOE-2010-002]

#### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit Concurrent Listing of \$3.50 and \$4 Strikes for Classes in the \$0.50 Strike and \$1 Strike Programs

January 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on January 7, 2010, the Chicago Board Options Exchange, Incorporated ("Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder.<sup>4</sup> The Commission is publishing this notice to

(adopting Nasdaq IM-2110-2; IM-2110-3; IM-2110-4, and Rule 3010); see also *supra* note 17.

<sup>25</sup> 15 U.S.C. 78s(b)(2).

<sup>26</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A)(iii).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to amend Interpretation and Policy .01 to Rule 5.5, *Series of Options Open for Trading*, to permit the concurrent listing of \$3.50 and \$4 strikes for classes that participate in both the \$0.50 Strike and \$1 Strike Programs. The text of the rule proposal is available on the Exchange's Web site (<http://www.cboe.org/legal>), at the Exchange's Office of the Secretary and at the Commission.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange recently implemented a rule change that permits strike price intervals of \$0.50 for options on stocks trading at or below \$3.00 ("\$0.50 Strike Program").<sup>5</sup> As part of the filing to establish the \$0.50 Strike Program, the Exchange contemplated that a class may be selected to participate in both the \$0.50 Strike Program and the \$1 Strike Program. Under the \$1 Strike Program, new series with \$1 intervals are not permitted to be listed within \$0.50 of an existing \$2.50 strike price in the same series, except that strike prices of \$2 and \$3 are permitted to be listed within \$0.50 of a \$2.50 strike price for classes also selected to participate in the \$0.50 Strike Program.<sup>6</sup> Under CBOE's existing rule, for classes selected to participate in both the \$0.50 Strike Program and the \$1 Strike Program, the Exchange may either: (a) List a \$3.50 strike but not list

<sup>5</sup> See Exchange Act Release No. 60695 (September 18, 2009), 74 FR 49055 (September 24, 2009) (SR-CBOE-2009-069). See also Interpretation and Policy .01(b) to Rule 5.5.

<sup>6</sup> See Interpretation and Policy .01(a)(2) to Rule 5.5.

<sup>20</sup> See CBOE Rule 54.7(d).

<sup>21</sup> See Securities Exchange Act Release No. 54422 (September 11, 2006), 71 FR 54537 (September 15, 2006) (SR-CBOE-2004-21) (approving CBOE Rule 54.7); Securities Exchange Act Release No. 46213 (July 16, 2002), 67 FR 48232 (July 23, 2002) (SR-Amex-2002-21) (permitting side-by-side trading and integrated market making in broad-based ETFs and TIRs without information or physical barriers or other restrictions).

<sup>22</sup> See Securities Exchange Act Release No. 46213 (July 16, 2002), 67 FR 48232 (July 23, 2002) (SR-Amex-2002-21) (permitting side-by-side trading and integrated market making in broad-based ETFs and TIRs without information or physical barriers or other restrictions).

<sup>23</sup> 15 U.S.C. 78s(b)(2).

<sup>24</sup> See Securities Exchange Act Release No. 53128 (Jan. 13, 2006), 71 FR 3550 (January 23, 2006)

a \$4 strike; or (b) list a \$4 strike but not list a \$3.50 strike. For example, under the Exchange's current rules, if a \$3.50 strike for an option class in both the \$0.50 and \$1 Strike Programs was listed, the next highest permissible strike price would be \$5.00. Alternatively, if a \$4 strike was listed, the next lowest permissible strike price would be \$3.00. The intent of the \$0.50 Strike Program was to expand the ability of investors to hedge risks associated with stocks trading at or under \$3 and to provide finer intervals of \$0.50, beginning at \$1 up to \$3.50. As a result, the Exchange believes that the current filing is consistent with the purpose of the \$0.50 Strike Program and will permit the Exchange to fill in any existing gaps resulting from having to choose whether to list a \$3.50 or \$4 strike for options classes in both the \$0.50 and \$1 Strike Programs.

Therefore, the Exchange is submitting the current filing to permit the listing of concurrent \$3.50 and \$4 strikes for classes that are selected to participate in both the \$0.50 Strike Program and the \$1 Strike Program. To effect this change, the Exchange is proposing to amend Interpretation and Policy .01(a)(2) to Rule 5.5 by adding \$4 to the strike prices of \$2 and \$3 currently permitted if a class participates in both the \$0.50 Strike Program and the \$1 Strike Program.

The Exchange is also proposing to amend the current rule text to delete references to "\$2.50 strike prices" (and the example utilizing \$2.50 strike prices) and to replace those references with broader language, e.g., "existing strike prices."

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act<sup>7</sup> and the rules and regulations thereunder and, in particular, the requirements of Section 6(b) of the Act.<sup>8</sup> Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>9</sup> requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest by permitting the Exchange to list more granular strikes on options overlying lower priced securities, which the Exchange believes

will provide investors with greater flexibility by allowing them to establish positions that are better tailored to meet their investment objectives.

## B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

## C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>10</sup> and Rule 19b-4(f)(6) thereunder.<sup>11</sup>

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

## Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2010-002 on the subject line.

## Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2010-002. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-2010-002 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>12</sup>

**Florence E. Harmon,**  
Deputy Secretary.

[FR Doc. 2010-820 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>7</sup> 15 U.S.C. 78s(b)(1).

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(5).

<sup>10</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>11</sup> 17 CFR 240.19b-4(f)(6).

<sup>12</sup> 17 CFR 200.30-3(a)(12).

**SECURITIES AND EXCHANGE  
COMMISSION**

[Release No. 34-61334; File No. SR-ISE-2009-115]

**Self-Regulatory Organizations;  
International Securities Exchange,  
LLC; Notice of Filing and Immediate  
Effectiveness of Proposed Rule  
Change Relating to a Market Maker  
Incentive Plan for Foreign Currency  
Options**

January 12, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 31, 2009, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's  
Statement of the Terms of Substance of  
the Proposed Rule Change**

The ISE is proposing to extend an incentive plan for market makers in three foreign currency options ("FX Options"). The text of the proposed rule change is available on the Exchange's Web site (<http://www.ise.com>), on the Commission's Web site at <http://www.sec.gov>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's  
Statement of the Purpose of, and  
Statutory Basis for, the Proposed Rule  
Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

**A. Self-Regulatory Organization's  
Statement of the Purpose of, and  
Statutory Basis for, the Proposed Rule  
Change**
**1. Purpose**

On August 3, 2009, the Exchange began trading options on the New Zealand dollar ("NZD"), the Mexican peso ("PZO") and the Swedish krona ("SKA")<sup>3</sup> and adopted an incentive plan applicable to market makers in NZD, PZO and SKA.<sup>4</sup> The Exchange subsequently extended the date by which market makers may join the incentive plan.<sup>5</sup> The purpose of this proposed rule change is to again extend the date by which market makers may join the incentive plan.

In order to promote trading in these FX Options, the Exchange has an incentive plan pursuant to which the Exchange waives the transaction fees for the Early Adopter<sup>6</sup> FXPMM<sup>7</sup> and all Early Adopter FXCMMs<sup>8</sup> that make a market in NZD, PZO and SKA for as long as the incentive plan is in effect. Further, pursuant to a revenue sharing agreement entered into between an Early Adopter Market Maker and ISE, the Exchange pays the Early Adopter FXPMM forty percent (40%) of the transaction fees collected on any customer trade in NZD, PZO and SKA and pays up to ten (10) Early Adopter FXCMMs that participate in the incentive plan twenty percent (20%) of the transaction fees collected for trades between a customer and that FXCMM. Market makers that do not participate in the incentive plan are charged regular transaction fees for trades in these products. In order to participate in the incentive plan, market makers are required to enter into the incentive plan no later than December 31, 2009. The Exchange now proposes to extend the

<sup>3</sup> The Commission previously approved the trading of options on NZD, PZO and SKA. See Exchange Act Release No. 34-55575 [sic] (April 3, 2007), 72 FR 17963 (April 10, 2007) (Order approving the listing and trading of FX Options).

<sup>4</sup> See Exchange Act Release No. 34-60536 [sic] (August 19, 2009), 74 FR 43204 (August 26, 2009) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fee Changes and an Incentive Plan for Three Foreign Currency Options).

<sup>5</sup> See Exchange Act Release No. 34-60810 [sic] (October 9, 2009), 74 FR 53527 (October 19, 2009) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to a Market Maker Incentive Plan for Foreign Currency Options).

<sup>6</sup> Participants in the incentive plan are known on the Exchange's Schedule of Fees as Early Adopter Market Makers.

<sup>7</sup> A FXPMM is a primary market maker selected by the Exchange that trades and quotes in FX Options only. See ISE Rule 2213.

<sup>8</sup> A FXCMM is a competitive market maker selected by the Exchange that trades and quotes in FX Options only. See ISE Rule 2213.

date by which market makers may enter into the incentive plan to March 31, 2010.

**2. Statutory Basis**

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,<sup>9</sup> in general, and furthers the objectives of Section 6(b)(4),<sup>10</sup> in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities. The Exchange believes the proposed rule change will permit additional market makers to join the incentive plan which in turn will generate additional order flow to the Exchange by creating incentives to trade these FX Options as well as defray operational costs for Early Adopter Market Makers.

**B. Self-Regulatory Organization's  
Statement on Burden on Competition**

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

**C. Self-Regulatory Organization's  
Statement on Comments on the  
Proposed Rule Change Received From  
Members, Participants or Others**

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

**III. Date of Effectiveness of the  
Proposed Rule Change and Timing for  
Commission Action**

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act<sup>11</sup> and Rule 19b-4(f)(2)<sup>12</sup> thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

<sup>9</sup> 15 U.S.C. 78f(b).

<sup>10</sup> 15 U.S.C. 78f(b)(4).

<sup>11</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>12</sup> 17 CFR 19b-4(f)(2).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

*Electronic Comments*

• Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

• Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File No. SR-ISE-2009-115 on the subject line.

*Paper Comments*

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File No. SR-ISE-2009-115. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of ISE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-ISE-2009-115 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

**Florence E. Harmon,**

*Deputy Secretary.*

[FR Doc. 2010-818 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

<sup>13</sup> 17 CFR 200.30-3(a)(12).

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-51322; File No. SR-CHX-2010-01]

**Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Implement a Tiered Fee Schedule**

January 11, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on January 4, 2010, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. CHX filed the proposal pursuant to Section 19(b)(3)(A) of the Act<sup>3</sup> and Rule 19b-4(f)(2) thereunder,<sup>4</sup> which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The CHX proposes to amend its Schedule of Participant Fees and Assessments (the "Fee Schedule"), effective January 4, 2010, to implement a tiered rate of fees when removing or providing liquidity on the Exchange. The text of the proposed rule change is available on the Exchange's Web site at [http://www.chx.com/rules/proposed\\_rules.htm](http://www.chx.com/rules/proposed_rules.htm), on the Commission's Web site at <http://www.sec.gov>, at CHX, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(2).

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

**1. Purpose**

Through this filing, the Exchange would amend its Fee Schedule, effective January 4, 2010, to provide for a tiered schedule of fees and rebates for Participants for trade executions of single-sided orders in securities priced over \$1 in the event that certain volume thresholds are achieved. The volume thresholds are based on the Participant's Average Daily Volume ("ADV"), which is determined, with respect to a given Participant, by the number of shares such Participant has executed as a liquidity provider in any and all trading sessions on average per trading day (excluding partial trading days) across all tapes on the trading facilities of the CHX (excluding all cross transactions) for the calendar month in which the executions occurred.

According to this proposal, a Participant entering a single-sided (i.e., not a cross order type) order in Tape A and C securities would be charged a fee of \$0.003/share when removing liquidity from the Matching System if its monthly ADV (as defined above) is 500,000 shares or less. Such Participants would also receive a rebate of \$0.0026/share when they provided liquidity to the Matching System. Participants which had a monthly ADV of greater than 500,000 up to and including 5,000,000 shares would be charged a fee of \$0.0029 when removing liquidity. Participants falling into this category would also receive a rebate of \$0.0028/share when providing liquidity to the Matching System. Finally, Participants which had a monthly ADV of greater than 5,000,000 shares would pay a fee of \$0.0028 when removing liquidity from the Matching System and a rebate of \$0.003 when they provided liquidity.

For Tape B securities, a Participant entering a single-sided (i.e., not a cross order type) order would be charged a fee of \$0.003/share when removing liquidity from the Matching System if its monthly ADV is 500,000 shares or less. Such Participants would also receive a rebate of \$0.0028/share when they provided liquidity to the Matching System. Participants which had a monthly ADV of greater than 500,000 up to and including 5,000,000 shares would be charged a fee of \$0.0029 when removing liquidity. Participants falling into this category would also receive a rebate of \$0.003/share when providing liquidity to the Matching System. Finally, Participants which had a monthly ADV greater than 5,000,000

shares would pay a fee of \$0.0028 when removing liquidity from the Matching System and a rebate of \$0.0032 when they provided liquidity.

Under this program, Participants which, on a net basis, provide Tape A and C securities would pay fees at lower volume levels but, as their monthly ADV increases, this rate structure will ultimately invert. Through this mechanism, the Exchange seeks to maximize revenue at lower volume levels while incenting all Participants to provide greater liquidity to the Matching System. Furthermore, the Exchange believes that the increased rebate will help attract additional orders to be displayed and executed on our trading facilities. The Exchange notes that a number of other exchanges have tiered fee schedules which offer different rates depending on the monthly ADV of liquidity-providing executions on their facilities, and our proposed fee structure will help us remain competitive with these entities.<sup>5</sup> The Exchange believes that the implementation of a tiered fee schedule may incent firms to display their orders on our trading facility and increase the volume of securities traded here.

## 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act<sup>6</sup> in general, and furthers the objectives of Section 6(b)(4) of the Act<sup>7</sup> in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members. Among other things, the change to the fee schedule would provide incentives to Participants to increase the amount of liquidity provided on our trading facilities, which may contribute to an increase in trading volume on the Exchange and in the income derived therefrom.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act<sup>8</sup> and Rule 19b-4(f)(2) thereunder.<sup>9</sup> At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/sro/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-CHX-2010-01 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CHX-2010-01. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro/shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-CHX-2010-01 and should be submitted on or before February 9, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>10</sup>

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010-799 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61317; File No. SR-ISE-2009-103]

### Self-Regulatory Organizations; International Securities Exchange, LLC; Order Approving a Proposed Rule Change Relating to Market Data Fees

January 8, 2010.

#### I. Introduction

On November 25, 2009, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to amend its Schedule of Fees. Notice of the proposed rule change was published for comment in the **Federal Register** on December 1, 2009.<sup>3</sup> The Commission received no comments on the proposal. This order approves the proposed rule change.

#### II. Description of Proposal

The Exchange proposes to amend its Schedule of Fees to (1) increase the annual subscription rate for the ISE Open/Close Trade Profile, (2) adopt subscription fees for the sale of three

<sup>5</sup> See, e.g., Nasdaq Stock Market ("Nasdaq") Rule 7018; National Stock Exchange ("NSX") Fee Schedule; NYSE Arca Fee Schedule; International Securities Exchange ("ISE") Fee Schedule (equity mid-point match orders).

<sup>6</sup> 15 U.S.C. 78f(b).

<sup>7</sup> 15 U.S.C. 78f(b)(4).

<sup>8</sup> 15 U.S.C. 78s(b)(3)(A)(ii).

<sup>9</sup> 17 CFR 240.19b-4(f)(2).

<sup>10</sup> 17 CFR 200.30-3(a)(12).

<sup>11</sup> 15 U.S.C. 78s(b)(1).

<sup>12</sup> 17 CFR 240.19b-4.

<sup>13</sup> See Securities Exchange Act Release No. 61086 (December 8, 2009), 74 FR 64783 ("Notice").

new market data offerings, all of which are based on the ISE Open/Close Trade Profile, and (3) increase the annual subscription and ad-hoc request rates for ISE's Historical Options Tick Data.

#### 1. ISE Open/Close Trade Profile

ISE currently sells a market data offering comprised of the entire opening and closing trade data of ISE listed options of both customers and firms ("ISE Open/Close Trade Profile").<sup>4</sup> The data is compiled and formatted by ISE as an end of day file. This market data offering is currently available to both members and non-members on an annual subscription basis.<sup>5</sup> ISE represents that it has added additional fields to this offering over the last two years and therefore, the costs of gathering and storing the data underlying the ISE Open/Close Trade Profile have increased. As a result, ISE now proposes to increase the subscription rate for both members and non-members to \$750 per month, effective January 4, 2010.

#### 2. New Open/Close Market Data Products

The Exchange proposes to expand its suite of ISE Open/Close Trade Profile market data offerings with three new products.

##### a. ISE Open/Close Trade Profile Intraday

The ISE Open/Close Trade Profile Intraday offering uses the same process as that used for the ISE Open/Close Trade Profile. The ISE Open/Close Trade Profile Intraday has the same trade-related fields contained in the ISE Open/Close Trade Profile. The ISE Open/Close Trade Profile Intraday file contains data that is updated at 10-minute intervals throughout the trading day. ISE proposes to charge both members and non-members \$2,000 per month on an annual subscription basis.

##### b. Historical ISE Open/Close Trade Profile Intraday

The Historical ISE Open/Close Trade Profile Intraday offering is a compilation of the ISE Open/Close Trade Profile Intraday files. ISE proposes to sell Historical ISE Open/Close Trade Profile Intraday on an ad-hoc basis. An ad-hoc request can be for any number of months, quarters or years for which the data is available. Members and non-members will be able to purchase this data by paying a one-time fee of \$1,000

per month, \$2,000 per quarter or \$8,000 per year.<sup>6</sup>

##### c. ISE Open/Close Trade Profile and ISE Open/Close Trade Profile Intraday

As noted above, the Exchange already sells the ISE Open/Close Trade Profile end of day data. To incentivize current subscribers of ISE Open/Close Trade Profile to also subscribe to the ISE Open/Close Trade Profile Intraday offering, the Exchange proposes to offer a discounted subscription rate. Subscribers to both the ISE Open/Close Trade Profile and the ISE Open/Close Trade Profile Intraday will pay an annual subscription rate of \$2,500 per month.

All of the ISE Open/Close Trade Profile market data offerings, including the new products proposed by the Exchange, are compiled and formatted by ISE and sold as a zipped file.

##### 3. Historical Options Tick Data

ISE currently creates market data that consists of options quotes and orders that are generated by its members and all trades that are executed on the Exchange. ISE also produces a Best Bid/Offer, or BBO, with the aggregate size from all outstanding quotes and orders at the top price level, or the "top of the book." This data is formatted according to Options Price Reporting Authority ("OPRA") specification and sent to OPRA for redistribution. OPRA processes ISE data along with the same data sets from the other six options exchanges and creates a National BBO, or "NBBO," from all seven options exchanges.

ISE also captures the OPRA tick data<sup>7</sup> and makes it available as an "end of day" file<sup>8</sup> or as a "historical" file<sup>9</sup> for ISE members and non-ISE members alike. ISE has data available from June 2005 through the present month. ISE currently charges all subscribers of

Historical Options Tick Data \$1,500 per month per firm on an annual subscription basis. For ad-hoc requests, ISE charges \$85 per day, with a minimum order size of \$1,000 plus a processing fee to pay for hard drives and shipping. ISE also currently charges a processing fee of \$499 per order for up to 400 Giga Bytes (GB). An order that exceeds 400 GB is currently charged an additional \$399 for up to another 400 GB.<sup>10</sup>

The Exchange now proposes to increase the annual subscription rate to \$2,000 per month per firm. For ad-hoc requests, the Exchange proposes to increase the rate to \$120 per day. The minimum order size of \$1,000 will remain unchanged as will the processing fees of \$499 and \$399. As the size of the data has increased since the Exchange first introduced this product, the Exchange is also increasing the size allowance for ad-hoc requests from 400 Giga Bytes to 1.5 Terabytes (TB). Pursuant to this proposed rule change, for ad-hoc requests, the Exchange will charge a processing fee of \$499 per order for up to 1.5 TB. An order that exceeds 1.5 TB will be charged an additional \$399 for up to another 1.5 TB. These fee changes will be made effective by the Exchange on January 4, 2010.

The Exchange's market research indicates that OPRA tick data is primarily used by market participants in the financial services industry for back-testing trading models, post-trade analysis, compliance purposes and analyzing time and sales information. This market data offering provides both ISE members and non-members with a choice to subscribe to a service that provides a daily file on an on-going basis (end of day file), or simply request data on an ad-hoc basis for a pre-determined date range (historical file).

### III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>11</sup> In particular, the

<sup>6</sup> For example, a subscriber that wants to purchase data for August 2009 would pay \$1,000; a subscriber that wants to purchase data for July, August and September of 2009 would pay \$2,000; a subscriber that wants to purchase data for all twelve months of 2009 would pay \$8,000.

<sup>7</sup> The Exchange collects this data throughout each trading day and at the end of each trading day, the Exchange compresses the data and uploads it onto a server. Once the data is loaded onto the server, it is then made available to subscribers.

<sup>8</sup> An end of day file refers to OPRA tick data for a trading day that is distributed prior to the opening of the next trading day. An end of day file is made available to subscribers as soon as practicable at the end of each trading day on an on-going basis pursuant to an annual subscription or through an ad-hoc request.

<sup>9</sup> An end of day file that is distributed after the start of the next trading day is called a historical file. A historical file is available to customers for a pre-determined date range by ad-hoc requests only.

<sup>4</sup> See Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (approving SR-ISE-2007-70).

<sup>5</sup> The current subscription rate for both members and non-members is \$600 per month.

<sup>10</sup> See Securities Exchange Act Release Nos. 53212 (February 2, 2006), 71 FR 6803 (February 9, 2006) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Establishing Fees for Historical Options Tick Market Data) (SR-ISE-2006-07); and 53390 (February 28, 2006), 71 FR 11457 (March 7, 2006) (Order Granting Accelerated Approval of a Proposed Rule Change Establishing Fees for Historical Options Tick Market Data for Non-Members) (SR-ISE-2006-08).

<sup>11</sup> In approving this proposed rule change, the Commission has considered the proposed rule's

Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(4) of the Act,<sup>12</sup> which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facilities. The Commission also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,<sup>13</sup> which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Commission further believes that the proposed rule change is consistent with Section 6(b)(8) of the Act<sup>14</sup> in that it does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Because ISE's instant proposal relates to the distribution of non-core data, the Commission will apply the market-based approach set forth in the Commission's approval of a NYSE Arca market data proposal.<sup>15</sup> The Commission believes that ISE was subject to significant competitive forces in setting the terms of its proposal, including the level of fees.<sup>16</sup> Specifically, the Exchange has a compelling need to attract order flow to maintain its share of trading volume, imposing pressure on the Exchange to act reasonably in establishing fees for these data offerings.<sup>17</sup> Further, ISE is

impacted on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>12</sup> 15 U.S.C. 78f(b)(4).

<sup>13</sup> 15 U.S.C. 78f(b)(5).

<sup>14</sup> 15 U.S.C. 78f(b)(8).

<sup>15</sup> See Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR-NYSEArca-2006-21).

<sup>16</sup> The Commission has previously made a finding that the options industry is subject to significant competitive forces. See Securities Exchange Act Release No. 59949 (May 20, 2009), 74 FR 25593 (May 28, 2009) (SR-ISE-2009-97) (order approving ISE's proposal to establish fees for a real-time depth of market data offering).

<sup>17</sup> ISE states that it has a compelling need to attract order flow from market participants in order to maintain its share of trading volume. ISE further states that this compelling need to attract order flow imposes significant pressure on ISE to act reasonably in setting the fees for its market data

constrained in pricing these data offerings because of the availability of alternatives to purchasing ISE's market data products.<sup>18</sup> Finally, the Commission does not believe that a substantial countervailing basis exists to support a finding that the proposed fees fail to meet the requirements of the Act or the rules thereunder. The Commission did not receive any comments on the terms of the proposal. Further, the fees charged will be the same for all market participants, and therefore do not unreasonably discriminate among market participants. In addition, ISE represents that it has enhanced its Open/Close Trade Profile and Historical Options Ticket Data offerings, and that the increase "is nominal in light of the increased costs borne by the Exchange for the enhancements."<sup>19</sup>

#### IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR-ISE-2009-103), be and hereby is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>20</sup>

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010-704 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

offerings, particularly given that the market participants that will pay such fees often will be the same market participants from whom ISE must attract order flow. These market participants include broker-dealers that control the handling of a large volume of customer and proprietary order flow. ISE states that, given the portability of order flow from one exchange to another, any exchange that sought to charge unreasonably high market data fees would risk alienating many of the same customers on whose orders it depends for competitive survival. See Notice, *supra* note 3, at 64785.

<sup>18</sup> For example, the Exchange represents that all of the information available in the Historical Options Tick Data product is available from the core data feed offered by the Options Price Reporting Authority. Further, the Exchange represents that CBOE is a potential competitor because it also sells an Open/Close market data product. See Notice, *supra* note 3, at 64785.

<sup>19</sup> See Notice, *supra* note 3, at 64784.

<sup>20</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-61314; File No. SR-NASDAQ-2009-112]

### Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend NASDAQ Rules 1140 and 3080 to Reflect Changes to a Corresponding FINRA Rule

January 7, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on December 30, 2009, The NASDAQ Stock Market LLC (the "Exchange" or "NASDAQ") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b-4(f)(6) under the Act,<sup>3</sup> which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change to amend NASDAQ Rules 1140 and 3080 to reflect recent changes to a corresponding rule of the Financial Industry Regulatory Authority ("FINRA"). The Exchange will implement the proposed rule change thirty days after the date of the filing. The text of the proposed rule change is available at <http://nasdaqomx.cchwallstreet.com>, at the Exchange's principal office, on the Commission's Web site at <http://www.sec.gov>, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 17 CFR 240.19b-4(f)(6).

places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

*1. Purpose*

Many of NASDAQ's rules are based on rules of FINRA (formerly the National Association of Securities Dealers ("NASD")). Beginning in 2008, FINRA embarked on an extended process of moving rules formerly designated as "NASD Rules" into a consolidated FINRA rulebook. In most cases, FINRA has renumbered these rules, and in some cases has substantively amended them. Accordingly, NASDAQ also has initiated a process of modifying its rulebook to ensure that NASDAQ rules corresponding to FINRA/NASD rules continue to mirror them as closely as practicable. In some cases, it is not possible for the rule numbers of NASDAQ rules to mirror corresponding FINRA rules, because existing or planned NASDAQ rules make use of those numbers. However, wherever possible, NASDAQ plans to update its rules to reflect changes to corresponding FINRA rules.

This filing addresses NASDAQ Rules 1140 and 3080 which follow or incorporate by reference former NASD Rules 1140 and 3080. In SR-FINRA-2009-019,<sup>4</sup> FINRA modified, renumbered, and transitioned these NASD rules into the FINRA Consolidated Rule Manual. This proposal makes conforming changes to the NASDAQ rules but does not re-number them.

Rule 1140 requires each Nasdaq member to file its Forms U4, U5, BR, BDW, and BD amendments (referred to collectively as "Uniform Forms") via electronic process or such other process as Nasdaq may prescribe to the Web CRD, the centralized database for registration and qualification information for firms and their associated persons. Rule 1140 also requires that the member retain and provide upon regulatory request every original, signed initial and transfer Form U4 that form the basis of the member's electronically filed Forms U4 and every record of the member's electronically filed initial and amended Forms U5.

<sup>4</sup> See Securities Exchange Act Release No. 60348 (July 20, 2009), 74 FR 37077 (July 27, 2009) (SR-FINRA-2009-019).

In SR-FINRA-2009-019, FINRA proposed and the Commission approved the following changes to Rule 1140:

- Codified that every initial and transfer electronic Form U4 must be based on an original, manually signed Form U4 provided to the member by the person on whose behalf the Form U4 is being filed.

- Modified the signature requirement with respect to amendments to disclosure information in the Form U4. The new FINRA rule would permit a firm to file amendments to the Form U4 disclosure information without obtaining the registered person's manual signature if the firm uses reasonable efforts to (1) provide the registered person with a copy of the amended disclosure information prior to filing and (2) obtain the registered person's written acknowledgment (which may be electronic) prior to filing that the information has been received and reviewed. The proposed rule change also requires a member, as part of its recordkeeping requirements, to retain the written acknowledgment in accordance with SEA Rule 17a-4(e)(1) and make it available promptly upon regulatory request.

- Clarified that a member must submit disclosure information to which it has knowledge in those cases where the member is not able to obtain an associated person's manual signature or written acknowledgment of the amendment. Proposed supplementary material sets forth examples of reasons why a member may not be able to obtain the associated person's manual signature or written acknowledgment.

- Incorporated Web CRD's current practice of permitting Form U4 administrative information to be amended without obtaining the associated person's signature (manual or otherwise). Proposed supplementary material explains that such administrative information includes items such as the addition of state or self regulatory organization registrations, exam scheduling, and updates to residential, business, and personal history.

- Proposed supplementary material expressly permitted the registered principal(s) or corporate officer(s) who is responsible for supervising a firm's electronic filings to delegate to another associated person (who need not be registered) the electronic filing of the member's forms via Web CRD. The delegatee may also acknowledge, electronically, that he is making the filing on behalf of the member and the member's associated person. The proposed supplementary material makes clear, however, that the principal(s) or

corporate officer(s) may not delegate any of his or her supervision, review and approval responsibilities and must take reasonable and appropriate action to ensure that all delegated electronic filing functions are properly executed and supervised.

- Continued to permit firms to enter into third-party agreements for the electronic filing of the required forms. The supplementary material makes clear that the firm remains responsible for complying with the requirements of the rule.

- Made other technical changes, such as making clarifying rule cross-references, replacing the reference to fingerprint "cards" with fingerprint "information," and noting the applicable retention periods for the forms under SEA Rule 17a-4.

NASDAQ proposes to adopt these approved changes in Nasdaq Rule 1140. NASDAQ does not propose to re-number Rule 1140 to 1010 as did FINRA.

Nasdaq Rule 3080 (Disclosure to Associated Persons When Signing Form U-4) requires members to provide each associated person, whenever the associated person is asked to sign a new or amended Form U4, with certain written disclosures regarding the nature and process of arbitration proceedings. The associated person agrees to be bound by this process upon signing a Form U4. The disclosures required by NASD Rule 3080 may be given by the same member firm to the same associated person on more than one occasion during that person's employment, if the associated person has reason to re-sign the Form U4. NASD Rule 3080 does not address any private arbitration agreements that the associated person might enter into with the member firm. The disclosure language in NASD Rule 3080 explains that the Form U4 contains a pre-dispute arbitration clause, indicates in which Item of the Form U4 the clause is located and advises the associated person to read the pre-dispute arbitration clause. Rule 3080 was modeled on the disclosure given to customers when signing pre-dispute arbitration agreements with member firms, as contained in NASD Rule 3110(f).

NASDAQ Rule 3080 currently incorporates by reference NASD Rule 3080. In SR-FINRA-2009-019, FINRA transferred NASD Rule 3080 to the FINRA Consolidated Rule Manual and re-numbered it as FINRA Rule 2263. *FINRA's proposed rule change made the following changes:*

- Amended the current title "Disclosure to Associated Person When



Signing Form U4" to clarify that the rule relates to arbitration disclosures. Accordingly, the new proposed title is "Arbitration Disclosure to Associated Persons Signing or Acknowledging Form U4."

- Clarified that a member must provide the required arbitration disclosures whenever a member asks an associated person, pursuant to proposed FINRA Rule 1010 (as described above), to manually sign an initial or amended Form U4, or to otherwise provide written (which may be electronic) acknowledgement of an amendment to the Form.

- Updated the rule language to reflect recent amendments to FINRA's Code of Arbitration Procedure requiring arbitrators to provide an explained decision to the parties in eligible cases if there is a joint request by all parties at least 20 days before the first scheduled hearing date.

NASDAQ is proposing to continue to incorporate FINRA Rule 2263 in NASDAQ Rule 3080. This will result in NASDAQ adopting the changes described above.

## 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,<sup>5</sup> in general, and with Sections 6(b)(5) of the Act,<sup>6</sup> in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed changes will conform NASDAQ Rules 1140 and 3080 to recent changes made to corresponding FINRA rules, to promote application of consistent regulatory standards.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

*Because the foregoing proposed rule change does not:* (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>7</sup> and Rule 19b-4(f)(6) thereunder.<sup>8</sup>

Normally, a proposed rule change filed under 19b-4(f)(6) may not become operative prior to 30 days after the date of filing. However, Rule 19b-4(f)(6)(iii)<sup>9</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. Nasdaq has requested that the Commission waive the 30-day operative delay. In its filing, Nasdaq noted that the proposal would amend NASDAQ Rules 1140 and 3080 to reflect recent changes to a corresponding rule of FINRA.

The Commission believes that waiver of the 30-day operative period is consistent with the protection of investors and the public interest. The proposed rule change would allow greater consistency between NASDAQ and FINRA rules, which should benefit NASDAQ and FINRA members, regulators, and the investing public. In addition, the Commission notes that the changes proposed in this filing are in all material respects the same as changes proposed in FINRA's filing, which was published for comment, and for which no comment letters were received.<sup>10</sup> Accordingly, the Commission

<sup>7</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>8</sup> 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires that a self-regulatory organization submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that Nasdaq satisfied the five-day pre-filing notice requirement.

<sup>9</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>10</sup> See Securities Exchange Act Release No. 61151 (December 10, 2009)(SR-NASDAQ-2009-109).

designates the proposal to be effective upon filing with the Commission.<sup>11</sup>

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NASDAQ-2009-112 on the subject line.

#### Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2009-112. This file number should be included on the subject line if e-mail is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2009-112, and should be submitted on or before February 9, 2010.

<sup>11</sup> For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>5</sup> 15 U.S.C. 78f.

<sup>6</sup> 15 U.S.C. 78f(b)(5).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>12</sup>

Florence E. Harmon,

*Deputy Secretary.*

[FR Doc. 2010-797 Filed 1-15-10; 8:45 am]

BILLING CODE 8011-01-P

## DEPARTMENT OF STATE

[Public Notice 6875]

**Designations of Foreign Terrorist Organizations; In the Matter of the Designation of: al-Qa'ida in the Arabian Peninsula (AQAP), Also Known as al-Qa'ida Organization in the Arabian Peninsula (AQAP), Also Known as al-Qa'ida in Yemen (AQY), Also Known as al-Qa'ida in the South Arabian Peninsula, as a Foreign Terrorist Organization Pursuant to Section 219 of the Immigration and Nationality Act, as Amended.**

Based upon a review of the Administrative Record assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that there is a sufficient factual basis to find that the relevant circumstances described in section 219 of the Immigration and Nationality Act, as amended (hereinafter "INA") (8 U.S.C. 1189), exist with respect to al-Qa'ida in the Arabian Peninsula (AQAP), also known as al-Qa'ida of Jihad Organization in the Arabian Peninsula, also known as Tanzim Qa'idat al-Jihad fi Jazirat al-Arab, also known as al-Qa'ida Organization in the Arabian Peninsula (AQAP), also known as al-Qa'ida in Yemen (AQY), also known as al-Qa'ida in the South Arabian Peninsula.

Therefore, I hereby designate the aforementioned organization and its aliases as a foreign terrorist organization pursuant to section 219 of the INA.

This determination shall be published in the **Federal Register**.

December 14, 2009.

**Hillary Rodham Clinton,**

*Secretary of State, Department of State.*

[FR Doc. 2010-880 Filed 1-15-10; 8:45 am]

BILLING CODE 4710-10-P

<sup>12</sup> 17 CFR 200.30-3(a)(12).

## DEPARTMENT OF STATE

[Public Notice 6873]

**In the Matter of the Designation of Nasir al-Wahishi, Also Known as Abu Basir, Also Known as Abu Basir Nasir al-Wahishi, Also Known as Naser Abdel Karim al-Wahishi, Also Known as Nasir Abd al-Karim al-Wuhayshi, Also Known as Abu Basir Nasir al-Wuhayshi, Also Known as Nasser Abdul-karim Abdullah al-Wouhichi, Also Known as Abu Baseer al-Wehaishi, Also Known as Abu Basir Nasser al-Wuhishi as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended**

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Nasir al-Wahishi, and also known as Abu Basir, also known as Abu Basir Nasir al-Wahishi, also known as Naser Abdel Karim al-Wahishi, also known as Nasir Abd al-Karim al-Wuhayshi, also known as Abu Basir Nasir al-Wuhayshi, also known as Nasser Abdul-karim Abdullah al-Wouhichi, also known as Abu Baseer al-Wehaishi, also known as Abu Basir Nasser al-Wuhishi committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that "prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously," I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 14, 2009.

**Hillary Rodham Clinton,**

*Secretary of State, Department of State.*

[FR Doc. 2010-875 Filed 1-15-10; 8:45 am]

BILLING CODE 4710-10-P

## DEPARTMENT OF STATE

[Public Notice 6874]

**In the Matter of the Designation of al-Qa'ida in the Arabian Peninsula (AQAP), Also Known as al-Qa'ida of Jihad Organization in the Arabian Peninsula, Also Known as Tanzim Qa'idat al-Jihad fi Jazirat al-Arab, Also Known as al-Qa'ida Organization in the Arabian Peninsula (AQAP), Also Known as al-Qa'ida in Yemen (AQY), Also Known as al-Qa'ida in the South Arabian Peninsula as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended**

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the organization known as al-Qa'ida in the Arabian Peninsula (AQAP), and also known as al-Qa'ida of Jihad Organization in the Arabian Peninsula, also known as Tanzim Qa'idat al-Jihad fi Jazirat al-Arab, also known as al-Qa'ida Organization in the Arabian Peninsula (AQAP), also known as al-Qa'ida in Yemen (AQY), also known as al-Qa'ida in the South Arabian Peninsula committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that "prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously," I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 14, 2009.

**Hillary Rodham Clinton,**

*Secretary of State, Department of State.*

[FR Doc. 2010-946 Filed 1-15-10; 8:45 am]

BILLING CODE 4710-10-P

## DEPARTMENT OF STATE

[Public Notice 6872]

**In the Matter of the Designation of Said Ali al-Shihri, Also Known as Abu-Sayyaf, Also Known as Abu-Sufyan al-Azidi, Also Known as Abu-Sayyaf al-Shihri, Also Known as Abu Sufian Kadhhaab Matrook, Also Known as Sa'id Ali Jabir al-Khathim al-Shihri, Also Known as Salad, Also Known as Abu Salah Abu Sufyan, Also Known as Salah al-Din, Also Known as Abu Osama, Also Known as Abu Sulaiman, Also Known as Nur al-Din Afghani Azibk, Also Known as Alakhaddm (variant: Akhdam), as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended**

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Said Ali al-Shihri, and also known as Abu-Sayyaf, also known as Abu-Sufyan al-Azidi, also known as Abu-Sayyaf al-Shihri, also known as Abu Sufian Kadhhaab Matrook, Also known as Sa'id Ali Jabir al-Khathim al-Shihri, also known as Salad, also known as Abu Salah Abu Sufyan, also known as Salah al-Din, also known as Abu Osama, also known as Abu Sulaiman, also known as Nur al-Din Afghani Azibk, also known as Alakhaddm (variant: Akhdam) committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that "prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously," I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 14, 2009.

Hillary Rodham Clinton,

Secretary of State, Department of State.

[FR Doc. 2010-884 Filed 1-15-10; 8:45 am]

BILLING CODE 4710-10-P

## DEPARTMENT OF TRANSPORTATION

## Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2006-25756]

## Commercial Driver's License Standards: Application for Exemption; Volvo Trucks North America (Volvo)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA announces that Volvo Trucks North America (Volvo) has applied for an exemption from the Federal requirement for a driver of commercial motor vehicles (CMVs) to hold a commercial driver's license (CDL). Volvo requests that the exemption cover two Swedish field test engineers who will test-drive CMVs for Volvo within the United States. These two Volvo employees both hold a valid Swedish CDL. Volvo states the exemption is needed to support a Volvo field test to meet future clean air standards, to test-drive Volvo prototype vehicles to verify results in "real world" environments, and to deliver the vehicles if necessary in the United States. Volvo believes the knowledge and skills tests and training program that Swedish drivers undergo to obtain a Swedish CDL ensures the exemption would provide a level of safety that is equivalent to, or greater than, the level of safety obtained by complying with the U.S. requirements for a CDL.

**DATES:** Comments must be received on or before February 18, 2010.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System Number FMCSA-2006-25756 by any of the following methods:

- *Web site:* [www.regulations.gov](http://www.regulations.gov).

Follow the instructions for submitting comments on the Federal electronic docket site.

- *Fax:* 1-202-493-2251.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

- *Hand Delivery:* Ground Floor, Room W12-140, DOT Building, 1200 New Jersey Avenue, SE., Washington, DC.

between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

**Instructions:** All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the Public Participation heading below. Note that all comments received will be posted without change to [www.regulations.gov](http://www.regulations.gov), including any personal information provided. Please see the Privacy Act heading below.

**Docket:** For access to the docket to read background documents or comments received, go to [www.regulations.gov](http://www.regulations.gov) at any time or to the ground floor, Room W12-140, DOT Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

**Privacy Act:** Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476) or you may visit [www.regulations.gov](http://www.regulations.gov).

**Public Participation:** The [www.regulations.gov](http://www.regulations.gov) Web site is generally available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the "help" section of the [www.regulations.gov](http://www.regulations.gov) Web site and also at the DOT's <http://docketsinfo.dot.gov> Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert Schultz, FMCSA Driver and Carrier Operations Division; Office of Bus and Truck Standards and Operations; Telephone: 202-366-4325. E-mail: [MCPSD@dot.gov](mailto:MCPSD@dot.gov).

## SUPPLEMENTARY INFORMATION:

## Background

Section 4007 of the Transportation Equity Act for the 21st Century (Pub. L. 105-178, 112 Stat. 107, June 9, 1998) amended 49 U.S.C. 31315 and 31136(e) to provide authority to grant exemptions from motor carrier safety regulations. Under its regulations, FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide

the public an opportunity to inspect the information relevant to the application, including the conducting of any safety analyses. The Agency must also provide an opportunity for public comment on the application.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for denying or, in the alternative, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

#### Request for Exemption

Volvo has applied for an exemption from the commercial driver's license (CDL) rules, specifically 49 CFR 383.23 that prescribes licensing requirements for drivers operating commercial motor vehicles (CMVs) in interstate or intrastate commerce. Volvo requests the exemption because its driver-employees are citizens and residents of Sweden, and therefore cannot apply for a CDL in any of the United States. A copy of the application is in Docket No. FMCSA-2006-25756.

The exemption would allow two drivers to operate CMVs in interstate commerce as part of a team of drivers who will support a Volvo field test to meet future air quality standards. The drivers will test-drive Volvo prototype vehicles at its test site and in the vicinity around Phoenix, Arizona, verify results in "real world" environments, and, if necessary, deliver the vehicles in the U.S. The drivers are: Magnus Ericsson and Conny Harlin, and Volvo requests that the exemption cover a two-year period beginning February 1, 2010.

These drivers each hold a valid Swedish CDL, and as explained by Volvo in previous exemption requests, drivers applying for a Swedish-issued CDL must undergo a training program and pass knowledge and skills tests. Volvo also stated in prior exemption requests that the knowledge and skills tests and training program that Swedish drivers undergo to obtain a Swedish CDL ensure the exemption provides a level of safety that is equivalent to, or greater than, the level of safety obtained

by complying with the U.S. requirement for a CDL.

FMCSA has previously determined the process for obtaining a Swedish-issued CDL is comparable to, or as effective as the Federal requirements of Part 383, and adequately assesses the driver's ability to operate CMVs in the U.S. In the past 2 years, FMCSA has published several notices of similar Volvo requests. An FMCSA notice of final disposition of a similar request from Volvo was published on January 5, 2009, granting this exemption to Volvo for a Swedish CDL driver permitting operation of CMVs in the U.S. (74 FR 333).

#### Request for Comments

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on Volvo's application for an exemption from the CDL requirements of 49 CFR 383.23. The Agency will consider all comments received by close of business on February 18, 2010. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: January 8, 2010.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. 2010-832 Filed 1-15-10; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Notice of Intent To Prepare an Environmental Assessment and Request for Public Scoping Comments for the Air Tour Management Plan Program at Death Valley National Park

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

**ACTION:** Notice of intent to prepare an Environmental Assessment and to request Public Scoping comments.

**SUMMARY:** The FAA, with NPS as a cooperating agency, has initiated development of an Air Tour Management Plan (ATMP) for Death Valley National Park (DEVA), pursuant to the National Parks Air Tour Management Act of 2000 (Public Law 106-181) and its implementing regulations (14 CFR Part 136, Subpart B, National Parks Air Tour Management). The objective of the ATMIP is to

develop acceptable and effective measures to mitigate or prevent the significant adverse impacts, if any, of commercial air tour operations upon the natural resources, cultural resources, and visitor experiences of a national park unit and any tribal lands within or abutting the park. It should be noted that the ATMP has no authorization over other non-air-tour operations such as military and general aviation operations. In compliance with the National Environmental Policy Act of 1969 (NEPA) and FAA Order 1050.1E, an Environmental Assessment is being prepared.

The ATMP will be prepared using an Aviation Rulemaking Committee (ARC) process, as authorized under 49 U.S.C. 106. The purpose of using the ARC process is to provide early advice, information, and recommendations from interested stakeholders to the FAA and NPS, regarding environmental and other issues to consider in the development of an ATMP. The DEVA ARC is composed of various representatives including air tour operators, federal, local and regional agencies, environmental organizations, local businesses, and the Timbisha Shoshone tribe. It is chaired by the Superintendent of Death Valley National Park.

In June 2009, the ARC held a two-day kickoff meeting at DEVA; minutes may be found at: [http://www.faa.gov/about/office\\_org/headquarters\\_offices/arc/programs/air\\_tourmanagement\\_plan/park\\_specific\\_plans/Death\\_Valley.cfm](http://www.faa.gov/about/office_org/headquarters_offices/arc/programs/air_tourmanagement_plan/park_specific_plans/Death_Valley.cfm).

The purpose of the kickoff meeting was for stakeholders to have the opportunity to provide advice, information, and recommendations to the FAA and NPS regarding environmental and other issues to consider in the development of an ATMP. Materials presented at the meeting included information on: Park resources; the acoustical environment at DEVA; military operations over DEVA and the surrounding areas; current and historical air tour operations; and a map of current air tour flight paths. Comments were received from members of the ARC regarding sensitive park resources, tribal concerns, changes in tourism patterns, and air tour operations. After a generalized map of current air tour flight paths was presented, ARC members made suggestions regarding options for an air tour flight track that would consolidate flight paths and modify elevations and flight locations. ARC members' recommendations attempted to address the concerns raised at the meeting. Refer to the Public Scoping Document (mentioned below) to see how these

suggestions are incorporated into an air tour route.

Based on input received at the meeting, the FAA and NPS have decided to proceed with ATMP development at DEVA via the ARC process. The FAA is now inviting the public, agencies, and other interested parties to provide comments, suggestions, and input on the scope of issues and the identification of significant issues regarding commercial air tours and their potential impacts on natural, cultural, and historical resources. Input is also welcome on other areas to be addressed in the environmental process, such as past, present, and future actions (which, when considered with ATMP alternatives, may result in potentially significant cumulative impacts), and potential ATMP alternatives.

**DATES:** By this notice, the FAA is requesting comments on the scope of the environmental assessment for the ATMP at Death Valley National Park. Comments must be submitted by February 18, 2010.

**FOR FURTHER INFORMATION CONTACT:** Keith Lusk—Mailing address: P.O. Box 92007, Los Angeles, California 90009-2007. Telephone: (310) 725-3808. Street address: 15000 Aviation Boulevard, Lawndale, California 90261. E-mail: [Keith.Lusk@faa.gov](mailto:Keith.Lusk@faa.gov). Written comments on the scope of the Environmental Assessment should be submitted electronically via the electronic public comment form on the NPS Planning, Environment and Public Comment System at: <http://parkplanning.nps.gov/projectHome.cfm?parkId=297&projectId=27781>, or sent to the mailing address or e-mail address above.

**SUPPLEMENTARY INFORMATION:** A Public Scoping Document that describes the project in greater detail is available at:

- The NPS Planning, Environment and Public Comment System at: <http://parkplanning.nps.gov/projectHome.cfm?parkId=297&projectId=27781>
- [http://www.faa.gov/about/office\\_org/headquarters\\_offices/arc/programs/air\\_tourmanagement\\_plan/park\\_specific\\_plans/Death\\_Valley.cfm](http://www.faa.gov/about/office_org/headquarters_offices/arc/programs/air_tourmanagement_plan/park_specific_plans/Death_Valley.cfm)
- The following locations within Death Valley National Park: Furnace Creek Visitor Center & Museum, Stovepipe Wells Ranger Station, Scotty's Castle
- Shoshone Museum, Shoshone, CA
- Eastern Sierra Interagency Center, Highway 395 and Highway 136, Lone Pine, CA
- Beatty Library District, 400 North 4th Street, Beatty, NV
- Inyo County Free Library: 168 North Edwards Street, Independence, CA;

210 Academy Street and 110 North Main Street in Bishop, CA

- Pahrump Community Library: 701 East Street, Pahrump, NV
- Amargosa Valley Library: 829 East Farm Road, Amargosa Valley, NV

**Notice Regarding FOIA:** Individuals may request that their name and/or address be withheld from public disclosure. If you wish to do this, you must state this prominently at the beginning of your comment. Commentators using the Web site can make such a request by checking the box "keep my contact information private." Such requests will be honored to the extent allowable by law, but you should be aware that pursuant to the Freedom of Information Act, your name and address may be disclosed. We will make all submissions from organizations, businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses available for public inspection in their entirety.

Issued in Hawthorne, CA, on January 7, 2010.

**Barry Brayer,**

*Manager, Special Programs Staff, Western-Pacific Region.*

[FR Doc. 2010-685 Filed 1-15-10; 8:45 am]

**BILLING CODE M**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2006-26367]

#### Motor Carrier Safety Advisory Committee Public Meeting

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of Motor Carrier Safety Advisory Committee Meeting.

**SUMMARY:** FMCSA announces that its Motor Carrier Safety Advisory Committee (MCSAC) will hold a committee meeting on February 1-2, 2010 to complete its work of providing information, concepts and ideas to the Agency relating to the hours-of-service (HOS) requirements for drivers of property-carrying vehicles.

**DATES:** The meeting will be held on February 1-2, 2010, from 8:30 a.m. to 4:30 p.m. Eastern Standard Time.

**Location:** This meeting is open to the public via conference call. Any interested person may call 1-800-593-0737, passcode 1997315, to listen to the entire meeting.

**Matters To Be Considered:** The MCSAC will complete its work on Task

10-01, provide information, concepts and ideas to FMCSA relating to the HOS requirements for drivers of property-carrying vehicles.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jack Kostelnik, Acting Chief, Strategic Planning and Program Evaluation Division, Office of Policy Plans and Regulation, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, (202) 366-5721, [mcsac@dot.gov](mailto:mcsac@dot.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### MCSAC

Section 4144 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59, 119 Stat. 1144, August 10, 2005) required the Secretary of Transportation to establish a Motor Carrier Safety Advisory Committee. The committee provides advice and recommendations to the FMCSA Administrator on motor carrier safety programs and regulations, and operates in accordance with the Federal Advisory Committee Act (5 U.S.C. App 2).

##### Hours-of-Service Task

On October 26, 2009, Public Citizen, *et al.*, (the Petitioners) and FMCSA entered into a settlement agreement pursuant to which the parties agreed to seek to have the petition for judicial review of the November 19, 2008, Final Rule on hours of service of drivers held in abeyance pending the publication of a Notice of Proposed Rulemaking (NPRM). The settlement agreement states that FMCSA will submit the draft NPRM to the Office of Management and Budget (OMB) within nine months of the date of the settlement, and will publish a Final Rule within 21 months of the date of the settlement agreement. The settlement agreement does not include any guidance, direction(s) or restrictions on the scope and content of the forthcoming NPRM or make any commitments on the outcome of the notice-and-comment rulemaking process. The current rule will remain in effect during the rulemaking proceedings.

The MCSAC began work on Task 10-01 at its December 7-9, 2009, meeting. Information from that meeting has been posted to the Committee's Web site, <http://mcsac.fmcsa.dot.gov>.

The MCSAC task is one of several steps that FMCSA is taking as it revisits the HOS requirements for drivers of property-carrying vehicles. Other steps will include holding public listening

sessions across the country beginning on January 19, 2009 and the opportunity for public comment on the forthcoming NPRM.

## II. Meeting Participation

The February 1–2 MCSAC meeting is open to the public via teleconference so that all interested parties, including safety advocacy groups, State safety agencies, motor carriers, motor carrier associations, owner-operators, drivers, and labor unions may listen to the discussion.

For information on services for individuals with disabilities or to request special assistance, please e-mail your request to [mcsac@dot.gov](mailto:mcsac@dot.gov) by Wednesday, January 27, 2010.

Please note that because of time limitations, oral comments will not be accepted via the teleconference line. However, members of the public are invited to participate in one of the public listening sessions announced on January 5, 2010 (75 FR 285), and elsewhere in today's **Federal Register**, and to provide oral and/or written comments, information, concepts and ideas the Agency should consider in developing the forthcoming HOS NPRM during one of those public listening sessions.

Interested parties may also submit written comments on this topic to Federal Docket Management System (FDMC) Docket Number FMCSA–2006–26367 using any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Fax:** 202–493–2251.
- **Mail:** Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Room WI2–140, Washington, DC 20590.
- **Hand Delivery:** U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Room WI2–140, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Issued on: January 13, 2010.

**Larry W. Minor,**

*Associate Administrator for Policy and Program Development.*

[FR Doc. 2010–828 Filed 1–15–10; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Thirteenth Plenary Meeting, RTCA Special Committee 205/EUROCAE WG 71: Software Considerations in Aeronautical Systems

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

**ACTION:** Notice of RTCA Special Committee 205/EUROCAE WG 71: Software Considerations in Aeronautical Systems meeting.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 205/EUROCAE WG 71: Software Considerations in Aeronautical Systems.

**DATES:** The meeting will be held February 8–12, 2010.

**ADDRESS:** The meeting will be held at MainSail Hotel and Conference Center, 5108 Eisenhower Boulevard, Tampa, Florida 33634, Phone: (813) 243–2600.

**FOR FURTHER INFORMATION CONTACT:** RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site <http://www.rtca.org>.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 205: EUROCAE WG 71: Software Considerations in Aeronautical Systems meeting. The agenda will include:

#### Day 1—Monday, February 8, 2010

- 08:15 a.m.—Registration
- 08:30 a.m.—Chair's Introductory Remarks
- 08:45 a.m.—Facilities Review
- 08:50 a.m.—Recognition of the FAA Federal and EASA Representatives
- 09:00 a.m.—Review of Meeting Agenda and Agreement of Previous Minutes
- 09:15 a.m.—Host Presentation
- 09:30 a.m.—Reports of Sub-Group Activity
- 10:00 a.m.—Other Committee/Other Documents Interfacing Personnel Reports (CAST, Unmanned Aircraft Systems, Security, WG–63/SAE S–18)
- 10:30 a.m.—Break
- 10:45 a.m.—Sub-Group Break Out Sessions
- 10:45 a.m.—New Member Introduction Session—All new committee members are invited to attend an introduction session to explain the operation of the committee, the various sub-groups and the topics they are dealing with and the Web site.

- 11:45 a.m.—Lunch
- 13:00 p.m.—Sub-Group Break Out Sessions
- 13:00 p.m.—CAST Meeting
- 14:30 p.m.—Break
- 14:45 p.m.—Plenary Session: Text Acceptance (for papers posted, commented on and reworked prior to Plenary)
- 18:00 p.m.—Close of Day

#### Day 2—Tuesday, February 9, 2010

- 08:00 a.m.—Executive Committee and SG Chairs/Secretaries Meeting
- 08:30 a.m.—Sub-Group Break Out Sessions
- 10:00 a.m.—Break
- 10:30 a.m.—Sub-Group Break Out Sessions
- 12:30 p.m.—IP submittals due for Wednesday Plenary
- 12:45 p.m.—Lunch
- 14:00 p.m.—Sub-Group Break Out Sessions
- 14:45 p.m.—Break
- 15:00 p.m.—Mandatory Paper Reading Session
- 17:00 p.m.—Close
- 17:00 p.m.—Executive Committee and SG Chairs/Secretaries Meeting

#### Day 3—Wednesday, February 19, 2010

- 08:30 a.m.—IP Comment Reply & Sub-Group Break Out Sessions (focused on finalizing any changes to papers being presented later in the morning)
- 10:00 a.m.—Break
- 10:30 a.m.—IP Comment Reply & Sub-Group Break Out Sessions (cont.)
- 12:00 p.m.—Lunch
- 13:15 p.m.—Sub-Group Break Out Sessions
- 13:15 p.m.—CAST Meeting
- 14:45 p.m.—Break
- 15:00 p.m.—Plenary Text Acceptance (for papers posted, commented on and reworked prior to Plenary)

**Note:** If required for text acceptance, the end time for this session may extend up to 19:30 p.m.

- 18:00 p.m.—Close
- Evening—Social Event

#### Day 4—Thursday, February 11, 2010

- 08:30 a.m.—Sub-Group Break Out Sessions
- 10:00 a.m.—Break
- 10:30 a.m.—Sub-Group Break Out Sessions
- 12:30 p.m.—IP submittals due for Friday Plenary
- 12:30 p.m.—Lunch
- 13:30 p.m.—Plenary Session (if needed, otherwise SG Break Out Session)
- 14:45 p.m.—Break
- 15:00 p.m.—Mandatory Paper Reading Session

- 17:00 p.m.—Close
- 17:00 p.m.—Executive Committee and SG Chairs/Secretaries Meeting

#### Day 5—Friday, February 12, 2010

- 08:00 a.m.—IP Comment Reply & Sub-Group Break Out Sessions (focused on finalizing any changes to papers being presented during the morning)
- 09:30 a.m.—Break
- 10:00 a.m.—Plenary Text Approval.
- 12:00 p.m.—SG1: SCWG Document Integration Sub-Group Report
- 12:05 p.m.—SG2: Issue & Rationale Sub-Group Report
- 12:10 p.m.—SG3: Tool Qualification Sub-Group Report
- 12:15 p.m.—SG4: Model Based Design & Verification Sub-Group Report
- 12:20 p.m.—SG5: Object Oriented Technology Sub-Group Report
- 12:25 p.m.—SG6: Formal Methods Sub-Group Report
- 12:30 p.m.—SG7: Special Considerations Sub-Group Report
- 12:35 p.m.—Any Other Business and Next Meeting Information
- 12:40 p.m.—Closing Remarks & Meeting Adjourned
- 12:45 p.m.—Meeting Evaluation (Round Robin)

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 11, 2010.

Francisco Estrada C.,  
RTCA Advisory Committee.

[FR Doc. 2010-845 Filed 1-15-10; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Sixteenth Plenary Meeting: RTCA Special Committee 203: Unmanned Aircraft Systems

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

**ACTION:** Notice of RTCA Special Committee 203: Unmanned Aircraft Systems.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 203: Unmanned Aircraft Systems.

**DATES:** The meeting will be held February 16–18, 2010.

**ADDRESSES:** The meeting will be held at Northrop Grumman, 16710 Via Del Campo Court, San Diego, CA 92127, Building 6 Main Conference Room.

**FOR FURTHER INFORMATION CONTACT:** RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC, 20036; telephone (202) 833-9339; fax (202) 833-9434; Web site <http://www.rtca.org>.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 203: Unmanned Aircraft Systems meeting. The agenda will include:

#### February 16, 2010

- Opening Plenary Session (Introductory Remarks and Introductions)
- Plenary #15 Minutes Approval
- Plenary Presentations
- Leadership Updates
- FAA Status Reports
- Special Committee Status Overview
- Requirements & Architecture Product Team Update
- Control & Communications Product Team Update
- Sense & Avoid Product Team Update
- Operational Safety and Environment Description (OSED)
- Comments Briefing
- Disposition/Resolution
- Achieve Consensus to Forward to Program Management Committee
- Breakout sessions Day 2 and 3 after completion of OSED comment resolution
- Closing Session

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 12, 2010.

Francisco Estrada C.,  
RTCA Advisory Committee.

[FR Doc. 2010-847 Filed 1-15-10; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2009-61]

#### Petition for Exemption; Summary of Petition Received

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

**ACTION:** Notice of petition for exemption received.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATE:** Comments on this petition must identify the petition docket number involved and must be received on or before August 10, 2010.

**ADDRESSES:** You may send comments identified by Docket Number FAA-2009-1206 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy:* We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

*Docket:* To read background documents or comments received, go to

<http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mark Forseth, ANM-113, (425) 227-2796, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98057-3356, or Ralen Gao, (202) 267-3168, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on January 13, 2010.

**Pamela Hamilton-Powell,**  
Director, Office of Rulemaking.

#### Petition for Exemption

*Docket No.:* FAA-2009-1206.

*Petitioner:* Embraer.

*Section of 14 CFR Affected:* 14 CFR 25.981(a)(3).

*Description of Relief Sought:*

The petitioner seeks relief from the requirements of fuel-tank structural lightning protection for its EMB-135BJ Enhanced model airplane.

[FR Doc. 2010-808 Filed 1-15-10; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2009-0408]

#### Pipeline Safety: Reporting Drug and Alcohol Test Results for Contractors and Multiple Operator Identification Numbers

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

**ACTION:** Notice; Issuance of Advisory Bulletin.

**SUMMARY:** This notice advises operators of gas, hazardous liquid, and carbon dioxide pipelines and liquefied natural gas facilities that the Pipeline and Hazardous Materials Safety Administration (PHMSA), Office of Pipeline Safety (OPS), is modifying the Drug & Alcohol Management Information System (DAMIS) to allow the reporting of contractor data without duplication and will begin collecting annual drug and alcohol testing data for contractor employees with Management Information System (MIS) reports due

March 15, 2010. The collection of contractor MIS reports will provide data for the entire pipeline industry to calculate the required minimum annual percent rate for random drug testing. Operators will also identify all OPS issued operator identification numbers (OpID) covered by a MIS report of operator employees.

**FOR FURTHER INFORMATION CONTACT:** Stanley T. Kastanas, Program Manager, Substance Abuse Prevention Program at 202-550-0629 or by e-mail at [Stanley.Kastanas@dot.gov](mailto:Stanley.Kastanas@dot.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under 49 CFR Part 199, each pipeline operator having more than 50 covered employees must submit an annual MIS report to OPS of its drug and alcohol testing results for covered employees by March 15 of each year for the prior calendar year. Operators with 50 or fewer covered employees may be required to submit annual MIS reports if notified by OPS in writing. A covered employee is a person employed by the operator, a contractor engaged by the operator, or a person employed by such a contractor, who performs operations, maintenance, or emergency response functions regulated by 49 CFR Parts 192, 193, and 195.

In a final rule titled "Management Information System (MIS) Standardized Data Collection and Reporting" (58 FR 68258, Dec. 23, 1993), OPS concluded that submission of contractor testing data by operators could result in duplicative reporting and inaccurate data. OPS noted that inaccuracies could affect the positive rate for the entire industry, thereby affecting the minimum annual percent rate for random drug testing. Accordingly, OPS deferred collecting contractor testing data, but stated that operators must continue to maintain the records required by 49 CFR Part 199, and ensure their pipeline contractors maintain the same. During subsequent meetings of the Technical Pipeline Safety Standards Committee and the Technical Hazardous Liquid Pipeline Safety Standards Committee, OPS discussed its intent to begin collecting contractor testing data. Comments at these meetings were supportive of the initiative to collect contractor data.

OPS does not directly regulate pipeline contract companies with respect to drug and alcohol testing, but places the responsibility on operators to ensure all covered employees are tested and, depending on the number of covered employees, the testing results are submitted to OPS either annually or

by OPS written request. Accordingly, pipeline operators monitor contractor compliance with drug and alcohol testing requirements as required by 49 CFR Part 199. Operators use a variety of methods to monitor contractor employees, such as testing of contract employees, requiring pipeline contractors to have their own testing programs, or working with pipeline contractors that belong to drug testing consortium groups. Collecting contractor testing data is essential for analyzing OPS's approach to detecting and deterring use of controlled substances. The information is also necessary to calculate the minimum annual percentage rate for random drug testing, which is based on the reported positive rate for the entire industry. Collecting this data does not require a rule amendment because 49 CFR Part 199 requires operators to report testing data for all covered employees, which includes contract employees performing work on their pipelines. The preamble to the current rule merely deferred submission of the data until the development of a methodology.

OPS is modifying DAMIS to allow the reporting of contractor data without duplication when the contractor works for multiple operators. DAMIS is also being modified to allow pipeline operators to submit a single operator employee MIS report for pipeline systems operated under more than one OPS issued OpID.

##### II. Advisory Bulletin (ADB-09-04)

*To:* Operators of Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities.

*Subject:* Reporting Drug and Alcohol Test Results for Contractors and Multiple Operator Identification Numbers.

*Advisory:* Beginning with MIS reports due by March 15, 2010, OPS will begin collecting annual drug and alcohol testing data for contractor employees. This Advisory Bulletin closes the action identified in a **Federal Register** Publication titled "Notice of Intent to Issue an Advisory Bulletin; Request for Public Comment" (70 FR 20800, April 21, 2005), for development of a methodology for collection of contractor testing data. Contractors will be identified both by name and business tax identification number (BTIN) in the MIS report. The inclusion of the BTIN will ensure employees of the same contractor are only counted once when OPS calculates the required random testing rate.

In order to verify reporting of operator employees, each MIS report for operator



employees will include each OPS issued OpID covered by the MIS report.

Under Part 199, operators who had 50 or more operator and contractor employees performing § 199.3 "covered functions" during calendar year 2009, must submit a MIS report. OPS may also request in writing, MIS reports from operators with fewer than 50 operator and contractor employees performing covered functions. In January 2010, OPS plans to notify each operator who is required, or requested, to submit a report before March 15, 2010 by mail. The notification will include detailed instructions for including all OpID and each contractor BTIN in both online and paper MIS reports.

The total number of covered employees is not limited to employees who physically worked in a maintenance, operations, or emergency response role during the previous calendar year. The definition of "performs a covered function" in Part 199.3 includes actually performing, ready to perform, or immediately available to perform a covered function. Operators need to be cognizant of this definition when calculating the number of covered employees for both the operator and contractors. Employees who "perform a covered function" as defined in § 199.3, are required to be included in the random drug testing pool. The average size of a properly maintained random drug testing pool defines the number of covered employees.

While the total number of covered employees determines if an operator must submit a MIS report, operator and contractor employee testing data must be submitted in separate MIS reports. Additionally, to ensure that contractor employees are only counted once in the entire set of calendar year 2009 MIS reports, data for each contractor with a unique BTIN will be submitted in a separate MIS report. After mailing the detailed instructions to operators, OPS will post the same information on the Drug & Alcohol Program Web site at <http://www.phmsa.dot.gov/pipeline/regs/drug>.

Operators are encouraged to submit MIS reports online. The online reporting option improves data accuracy and helps reduce the number of incomplete MIS reports. If an operator submits a paper MIS report to OPS, the operator will not receive a confirmation receipt for the MIS report. If an operator submits an online MIS report and includes an e-mail address, a confirmation receipt will be sent.

#### Submission of MIS Reports

OPS offers the following information to help operators prepare for submitting calendar year 2009 MIS reports. For clarity, the process steps are presented for single OpID reporting and multiple OpID reporting.

##### Single OpID Reporting

**Step 1:** Determine the number of operator employees performing § 199.3 covered functions during calendar year 2009.

**Step 2:** Obtain the BTIN for each contractor who provided § 199.3 covered functions during calendar year 2009. Determine the number of employees performing § 199.3 covered functions during calendar year 2009 for each contractor. Sum the number of contractor employees.

**Step 3:** Add the number of operator and contractor employees from Steps 1 and 2. If this number is less than 50, a MIS report is required only if you receive a letter from OPS requesting a MIS report.

##### Multiple OpID Reporting

**Step 1:** Determine the number of operator employees performing § 199.3 covered functions during calendar year 2009 for each reporting OpID. Sum the number of operator employees.

**Step 2:** Obtain the BTIN for each contractor who provided § 199.3 covered functions during calendar year 2009 to any reporting OpID. Determine the number of employees performing § 199.3 covered functions during calendar year 2009 for each contractor. Sum the number of contractor employees.

**Step 3:** Add the total number of operator and contractor employees from Steps 1 and 2. If this number is less than 50, a MIS report is required only if you receive a letter from OPS requesting a MIS report.

**Authority:** 49 U.S.C. chapter 601 and 49 CFR 1.53.

Issued in Washington, DC, on January 12, 2010.

**Jeffrey D. Wiese,**

*Associate Administrator for Pipeline Safety.*

[FR Doc. 2010-867 Filed 1-15-10; 8:45 am]

BILLING CODE 4910-60-P

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

#### Release of Waybill Data

The Surface Transportation Board has received a request from Sidley Austin LLP on behalf of Canadian Pacific Railway Company (WB471-12—

December 29, 2009) for permission to use certain data from the Board's Carload Waybill Samples. A copy of the request may be obtained from the Office of Economics, Environmental Analysis, and Administration.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics, Environmental Analysis, and Administration within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

**Contact:** Scott Decker, (202) 245-0330.

**Kerunie L. Cannon,**  
*Clearance Clerk.*

[FR Doc. 2010-754 Filed 1-15-10; 8:45 am]

BILLING CODE 4915-01-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Public Notice for Waiver of Aeronautical Land-Use Assurance Dupont-Lapeer Airport, Lapeer, MI

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

**ACTION:** Notice of intent of waiver with respect to land.

**SUMMARY:** The Federal Aviation Administration (FAA) is considering a proposal to change a portion of the Dupont Lapeer Airport from aeronautical use to non-aeronautical use and to authorize the sale of the airport property. The proposal consists of the sale of vacant, unimproved land owned by the Dupont-Lapeer Airport Board (Board).

The Board has requested from FAA a "Release from Federal agreement obligated land covenants" to sell one (1) parcel of property acquired by the Board with Federal funding under the Airport Improvement Program, State Block Grant No. B-26-0056-0196.

There are no impacts to the airport by allowing the Board to dispose of the vacant property. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the airport property nor a determination of eligibility for grant-in-aid funding from the FAA. The disposition of proceeds from the disposal of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the Federal Register on February 16, 1999.

In accordance with section 47107(h) of title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

**DATES:** Comments must be received on or before February 18, 2010.

**ADDRESSES:** Mr. David J. Welhouse, Program Manager, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174.

**FOR FURTHER INFORMATION CONTACT:** Mr. David J. Welhouse, Program Manager, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, Michigan 48174. Telephone Number (734) 229-2952/FAX Number (734) 229-2950. Documents reflecting this FAA action may be reviewed at this same location or at the Michigan Department of Transportation, Airports Division, 2700 Port Lansing Road, Lansing, Michigan.

**SUPPLEMENTARY INFORMATION:** Following is a legal description of the property located in Mayfield Township, Lapeer County, Michigan, and described as follows:

**Description of Parcel Being Released (4.45 Acres)**

A part of the SE ¼ of the Section 34, T.8N., R.10E., Mayfield Township, Lapeer County, Michigan; more particularly described as commencing at the south ¼ corner of said Section 34, thence south 89 degrees 47 minutes 28 seconds east 762.00 feet along the south line of said Section, thence north 00 degrees 10 minutes 20 seconds east 472.58 feet to the Point of Beginning, thence north 89 degrees 47 minutes 50 seconds west 300.00 feet, thence north 00 degrees 10 minutes 20 seconds east 647.67 feet, thence south 63 degrees 02 minutes 20 seconds east 264.38 feet, thence north 00 degrees 10 minutes 20 seconds east 1011.77 feet, thence south 89 degrees 45 minutes 52 seconds east 30.00 feet, thence south 00 degrees 10 minutes 20 seconds west 1030.22 feet, thence south 03 degrees 38 minutes 24 seconds east 511.32 feet to the Point of Beginning, containing 4.45 acres more or less.

Issued in Romulus, Michigan on December 18, 2009.

**John L. Mayfield, Jr.,**

Acting Manager, Detroit Airport, FAA, Great Lakes Region.

[FR Doc. 2010-683 Filed 1-15-10; 8:45 am]

**BILLING CODE 4910-13-M**

**DEPARTMENT OF THE TREASURY**

**Submission for OMB Review; Comment Request**

January 11, 2010.

The Department of Treasury will submit the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13, on or after the publication date of this notice. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before February 18, 2010 to be assured of consideration.

**Bureau of Public Debt (BPD)**

*OMB Number:* 1535-0068.

*Type of Review:* Extension.

*Title:* Regulations governing book-entry Treasury Bonds, Notes and Bi'lls.

*Description:* Beginning in 1986, U.S. Treasury bonds, notes and bills were offered exclusively in book-entry form.

*Respondents:* Individuals or Households.

*Estimated Total Burden Hours:* 1 hour.

*OMB Number:* 1535-0087.

*Type of Review:* Revision.

*Title:* Payment by banks and other financial institutions of U.S. Savings Bonds.

*Description:* Qualified financial institutions are authorized to redeem eligible savings bonds and receive settlement through FRB check collection system.

*Respondents:* Businesses or other for-profits.

*Estimated Total Burden Hours:* 45,896 hours.

*OMB Number:* 1535-0089.

*Type of Review:* Revision.

*Title:* Implementing Regulations: Government Securities Act of 1986, as amended.

*Description:* Regulations require gov. sec. broker/dealers to keep certain records concerning gov. sec. activities and submit financial reports.

*Respondents:* Businesses or other for-profits.

*Estimated Total Burden Hours:* 369,664 hours.

*Clearance Officer:* Judi Owens, (304) 480-8150, Bureau of the Public Debt,

200 Third Street, Parkersburg, West Virginia 26106.

*OMB Reviewer:* Shagufta Ahmed, (202) 395-7873, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Celina Elphage,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2010-765 Filed 1-15-10; 8:45 am]

**BILLING CODE 4810-39-P**

**DEPARTMENT OF THE TREASURY**

**Submission for OMB Review; Comment Request**

January 11, 2010.

The Department of Treasury will submit the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before February 18, 2010 to be assured of consideration.

**Alcohol and Tobacco Tax and Trade Bureau (TTB)**

*OMB Number:* 1513-0016.

*Type of Review:* Extension.

*Title:* Drawback on Wines Exported.

*Form:* TTB F 5120.24.

*Description:* Exporters of wines that were produced, packaged, manufactured, or bottled in the U.S. may file a claim for drawback of the taxes that have been paid or determined on the wine. This form enables TTB to protect the revenue and prevent fraudulent claims.

*Respondents:* Businesses or other for-profits.

*Estimated Total Burden Hours:* 94 hours.

*OMB Number:* 1513-0031.

*Type of Review:* Revision.

*Title:* Specific and Continuing Transportation Bond—Distilled Spirits or Wines Withdrawn for Transportation to Manufacturing Bonded Warehouse—Class Six.

*Form:* TTB F 5100.12, TTB F 5110.67.

*Description:* TTB F 5100.12 and TTB F 5110.67 are specific bonds that protect

the tax revenue on distilled spirits and wine while in transit from one type of bonded facility to another. They identify the shipment, the parties, the date, and the amount of bond coverage.

**Respondents:** Businesses or other for-profits.

**Estimated Total Burden Hours:** 10 hours.

**OMB Number:** 1513-0123.

**Type of Review:** Extension.

**Title:** Application, Permit, and Report—Wine and Beer (Puerto Rico) and Application, Permit and Report—Distilled Spirits Products (Puerto Rico).

**Form:** 5100.21, TTB F 5100.21.

**Description:** TTB Form 5100.21 is a permit to compute the tax on, tax pay, and withdraw shipments of wine or beer from Puerto Rico to the United States, as substantively required by 27 CFR 26.93. TTB Form 5110.51 is a permit to compute the tax on, tax pay, and withdraw shipments of distilled spirits products from Puerto Rico to the United States, as substantively required by 27 CFR 26.78.

**Respondents:** Businesses or other for-profits.

**Estimated Total Burden Hours:** 6 hours.

**Clearance Officer:** Frank Foote (202) 927-9347, Alcohol and Tobacco Tax and Trade Bureau, Room 200 East, 1310 G Street, NW., Washington, DC 20005.

**OMB Reviewer:** Shagufta Ahmed (202) 395-7873, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Celina Elphage,

Treasury PRA Clearance Officer.

[FR Doc. 2010-766 Filed 1-15-10; 8:45 am]

BILLING CODE 4810-31-P

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

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

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection

unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comments concerning an information collection titled "Bank Secrecy Act/Money Laundering Risk Assessment" (a.k.a. Money Laundering Risk (MLR) System). The OCC also gives notice that it has sent the information collection to OMB for review.

**DATES:** Comments must be submitted by February 18, 2010.

**ADDRESSES:** Communications Division, Office of the Comptroller of the Currency, Mailstop 2-3, Attention: 1557-0231, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874-5274, or by electronic mail to [regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov). You may personally inspect and photocopy comments at the OCC, 250 E Street, SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874-4700. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to OMB Desk Officer, 1557-0231, by mail to U.S. Office of Management and Budget, 725 17th St., NW., #10235, or by fax to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** You can request additional information or a copy of the collection and supporting documentation submitted to OMB by contacting: Mary H. Gottlieb, (202) 874-5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

**SUPPLEMENTARY INFORMATION:** The OCC is proposing to extend the approval for the following information collection:

**Title:** Bank Secrecy Act/Anti-Money Laundering Risk Assessment.

**OMB Number:** 1557-0231.

**Affected Public:** Businesses or other for-profit.

**Type of Review:** Regular review.

**Abstract:** The MLR System enhances the ability of examiners and bank management to identify and evaluate any Bank Secrecy Act/Anti-Money Laundering risks associated with the banks' products, services, customers, and locations. As new products and services are introduced, existing products and services change, and banks expand through mergers and acquisitions, management's evaluation of money laundering and terrorist

financing risks must evolve as well. Absent appropriate controls, such as this risk assessment, these lines of business, products, or entities could elevate Bank Secrecy Act/Anti-Money Laundering risks.

**Burden Estimates:**

**Estimated Number of Respondents:** 1,467.

**Estimated Number of Responses:** 1,467.

**Frequency of Response:** Annually.

**Estimated Annual Burden:** 8,802 hours.

The OCC issued a 60-day **Federal Register** notice on November 3, 2009. 74 FR 56922. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information of operation, maintenance, and purchase of services to provide information.

Dated: January 12, 2010.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2010-770 Filed 1-15-10; 8:45 am]

BILLING CODE 4810-33-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Proposed Collection; Comment Request for Form 13614-NR

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is

soliciting comments concerning Form 13614-NR, Nonresident Alien Intake and Interview Sheet.

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:**

Requests for additional information or copies of the form and instructions should be directed to Joel P. Goldberger, (202) 927-9368, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at [Joel.P.Goldberger@irs.gov](mailto:Joel.P.Goldberger@irs.gov).

**SUPPLEMENTARY INFORMATION:**

*Title:* Nonresident Alien Intake and Interview Sheet.

*OMB Number:* 1545-2075.

*Form Number:* 13614-NR.

*Abstract:* Although volunteer tax return preparers receive quality training and tools, form 13614-NR ensures they consistently collect personal information from each taxpayer to assure the returns are prepared accurately, avoiding erroneous returns. This form is critical to continued improvements in the accuracy of volunteer-prepared returns for International Students and Scholars.

*Current Actions:* There is no change in the paperwork burden previously approved by OMB.

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

*Affected Public:* Individuals or households.

*Estimated Number of Respondents:* 555,039.

*Estimated Time Per Respondent:* 15 minutes.

*Estimated Total Annual Burden Hours:* 141,260.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of

public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 17, 2009.

**R. Joseph Durbala,**  
Supervisory Tax Analyst.

[FR Doc. 2010-771 Filed 1-15-10; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

[REG-106446-98]

#### Proposed Collection; Comment Request for Regulation Project

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-106446-98 (TD 9003), Relief From Joint and Several Liability (§ 1.6015-5).

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulations should be directed to Joel Goldberger at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 927-9368, or

through the internet at [Joel.P.Goldberger@irs.gov](mailto:Joel.P.Goldberger@irs.gov).

**SUPPLEMENTARY INFORMATION:**

*Title:* Relief From Joint and Several Liability.

*OMB Number:* 1545-1719.  
*Regulation Project Number:* REG-106446-98.

*Abstract:* The regulation under section 6015 provides guidance regarding relief from the joint and several liability imposed by section 6013(d)(3). The regulations provide specific guidance on the three relief provisions of section 6015 and on how taxpayers would file a claim for such relief. In addition, the regulations provide guidance regarding Tax Court review of certain types of claims for relief, as well as information regarding the rights of the nonrequesting spouse. The regulations also clarify that, under section 6013, a return is not a joint return if one of the spouses signs the return under duress.

*Current Actions:* There is no change to this existing regulation.

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

*Affected Public:* Individuals.

The estimate of the reporting burden in § 1.6015-5 for filing a claim for relief from joint and several liability is reflected in the burden of Form 8857.

*The following paragraph applies to all of the collections of information covered by this notice:*

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection

techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 7, 2009.

**R. Joseph Durbala,**

*Supervisory Tax Analyst.*

[FR Doc. 2010-772 Filed 1-15-10; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Proposed Collection; Comment Request for Form 1099-H

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099-H, Health Coverage Tax Credit (HCTC) Advance Payments.

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Joel Goldberger at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 927-9368, or through the Internet at [Joel.P.Goldberger@irs.gov](mailto:Joel.P.Goldberger@irs.gov).

#### SUPPLEMENTARY INFORMATION:

**Title:** Health Coverage Tax Credit (HCTC) Advance Payments.

**OMB Number:** 1545-1813.

**Form Number:** Form 1099-H.

**Abstract:** Form 1099-H is used to report advance payments of health insurance premiums to qualified recipients for their use in computing the allowable health insurance credit on Form 8885.

**Current Actions:** There are no changes being made to the form at this time.

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

**Affected Public:** Business or other for-profit organizations.

**Estimated Number of Responses:** 110,000.

**Estimated Time Per Respondent:** 18 minutes.

**Estimated Total Annual Burden Hours:** 33,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Request For Comments:** Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 7, 2009.

**R. Joseph Durbala,**

*Supervisory Tax Analyst.*

[FR Doc. 2010-774 Filed 1-15-10; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Proposed Collection; Comment Request for Notice 97-66

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent

burden; invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Notice 97-66, Certain Payments Made Pursuant to a Securities Lending Transaction.

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the regulations should be directed to Joel Goldberger at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 927-9368, or through the Internet at [Joel.P.Goldberger@irs.gov](mailto:Joel.P.Goldberger@irs.gov).

#### SUPPLEMENTARY INFORMATION:

**Title:** Certain Payments Made Pursuant to a Securities Lending Transaction.

**OMB Number:** 1545-1566.

**Notice Number:** Notice 97-66.

**Abstract:** Notice 97-66 modifies final regulations which were effective November 14, 1997. The notice relaxes the statement requirement with respect to substitute interest payments relating to securities loans and sale-repurchase transactions. It also provides a withholding mechanism to eliminate excessive withholding on multiple payments in a chain of substitute dividend payments.

**Current Actions:** There are no changes being made to the notices at this time.

**Type of Review:** Extension of currently approved collection.

**Affected Public:** Business or other for-profit organizations.

**Estimated Number of Respondents:** 377,500.

**Estimated Time per Respondent:** 10 minutes.

**Estimated Total Annual Burden Hours:** 61,750.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal

revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Request For Comments:** Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

**Comments are invited on:** (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information: (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 7, 2009.

**R. Joseph Durbala,**

*Supervisory Tax Analyst.*

[FR Doc. 2010-773 Filed 1-15-10; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

[REG-116664-01]

RIN 1545-BC15

#### Proposed Collection; Comment Request for Regulation Project

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG-116664-01 (TD 9100), Guidance Necessary to Facilitate Business Electronic Filing (TD 9300(final)).

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the regulations should be directed to Joel Goldberger at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 927-9368, or through the Internet at [JoelP.Goldberger@irs.gov](mailto:JoelP.Goldberger@irs.gov).

#### SUPPLEMENTARY INFORMATION:

**Title:** Guidance Necessary to Facilitate Business Electronic Filing.

**OMB Number:** 1545-1868.

**Regulation Project Number:** REG-116664-01 (TD 9300 (final)).

**Abstract:** This document contains final regulations designed to eliminate regulatory impediments to the electronic filing of certain income tax returns and other forms. These regulations affect business taxpayers who file income tax returns electronically. This document also makes conforming changes to certain current regulations.

**Current Actions:** There is no change to this existing regulation.

**Type of Review:** Extension of currently approved collection.

**Affected Public:** Business or other for-profit organizations.

**Estimated Total Annual Reporting Burden:** 250,000 hours.

**Estimated Average Annual Burden Hours per Respondent:** .25 hours.

**Estimated Number of Respondents:** 1,000,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

**Request For Comments:** Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate

of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 7, 2009.

**R. Joseph Durbala,**

*Supervisory Tax Analyst.*

[FR Doc. 2010-773 Filed 1-15-10; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

[REG-120509-06]

RIN 1545-BF71

#### Proposed Collection; Comment Request for Regulation Project

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning final regulation, REG-120509-06, 1.882-5; Determination of Interest Expense Deduction of Foreign Corporation. (TD 9465).

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to R. Joseph Durbala, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the regulation should be directed to Joel Goldberger, at (202) 927-9368, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at [Joel.P.Goldberger@irs.gov](mailto:Joel.P.Goldberger@irs.gov).

#### SUPPLEMENTARY INFORMATION:

*Title:* Determination of Interest Expense Deduction of Foreign Corporation. (TD 9465).

*OMB Number:* 1545-2030.

*RIN:* 1545-BF71.

*Regulation Project Number:* REG-120509-06.

*Abstract:* This document contains final regulations under Section 882(c) of the Internal Revenue Code concerning the determination of the interest expense deduction of foreign corporations engaged in a trade or business within the United States. These final regulations conform the interest expense rules to recent U.S. Income Tax Treaty agreements and adopt other changes to improve compliance.

*Current Actions:* Final regulations and removal of temporary regulations. There is no change in burden.

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

*Affected Public:* Business or other for-profit institutions.

*Estimated Number of Respondents:* 75.

*Estimated Total Annual Burden Hours:* 35.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request For Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

*Comments are invited on:* (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation,

maintenance, and purchase of services to provide information.

Approved: December 28, 2009.

**R. Joseph Durbala,**

*IRS Reports Clearance Officer.*

[FR Doc. 2010-776 Filed 1-15-10; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Proposed Collection; Comment Request for Form 8879-S

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

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

**SUMMARY:** The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8879-S, IRS *e-file* Signature Authorization for Form 1120S.

**DATES:** Written comments should be received on or before March 22, 2010 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202)-622-3634, at Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at [RJoseph.Durbala@irs.gov](mailto:RJoseph.Durbala@irs.gov).

#### SUPPLEMENTARY INFORMATION:

*Title:* IRS *e-file* Signature Authorization for Form 1120S.

*OMB Number:* 1545-1863.

*Form Number:* 8879-S.

*Abstract:* Form 8879-S authorizes an officer of a corporation and an electronic return originator (ERO) to use a personal identification number (PIN) to electronically sign a corporation's electronic income tax return and, if applicable, Electronic Funds Withdrawal Consent.

*Current Actions:* There are no changes being made to the form at this time.

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

*Affected Public:* Businesses or other for-profit organizations.

*Estimated Number of Respondents:* 11,360.

*Estimated Time Per Respondent:* 6 hours, 32 minutes.

*Estimated Total Annual Burden Hours:* 74,181.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 10, 2009.

**R. Joseph Durbala,**

*Supervisory Tax Analyst.*

[FR Doc. 2010-777 Filed 1-15-10; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF THE TREASURY

### United States Mint

#### Notification of Pricing for United States Mint 2010 Native American \$1 Coin 25-Coin Rolls, 2010 Kennedy Half-Dollar Two-Roll Sets, 2010 Kennedy Half-Dollar 200-Coin Bags and 2010 Presidential \$1 Coin 25-Coin Rolls

**SUMMARY:** The United States Mint is announcing the prices of the 2010 Native American \$1 Coin 25-Coin Rolls, the 2010 Kennedy Half-Dollar Two-Roll

Sets, the 2010 Kennedy Half-Dollar 200-Coin Bags and the 2010 Presidential \$1 Coin 25-Coin Rolls.

The 2010 Native American \$1 Coin 25-Coin Rolls will be released January 22, 2010, and will be priced at \$35.95. Rolls of coins struck at both the United States Mint facilities at Philadelphia and Denver will be available.

The 2010 Kennedy Half-Dollar Two-Roll Sets will be released January 29, 2010, and will be priced at \$32.95. This set will contain two rolls of 20 coins each struck at both the United States

Mint facilities at Philadelphia and Denver.

The 2010 Kennedy Half-Dollar 200-Coin Bags will be released January 29, 2010, and will be priced at \$130.95. This bag contains coins from both the United States Mint facilities at Philadelphia and Denver.

The 2010 Presidential \$1 Coin 25-Coin Rolls, honoring Presidents Millard Fillmore, Franklin Pierce, James Buchanan and Abraham Lincoln, will be priced at \$35.95 each. Rolls of coins struck at both the United States Mint facilities at Philadelphia and Denver

will be available. Release dates for this set will be available on the United States Mint Web site.

**FOR FURTHER INFORMATION CONTACT:** B. B. Craig, Associate Director for Sales and Marketing; United States Mint; 801 9th Street, NW.; Washington, DC 20220; or call 202-354-7500.

**Authority:** 31 U.S.C. 5111, 5112, and 9701.

Dated: January 11, 2010.

**Edmund C. Moy,**  
*Director, United States Mint.*

[FR Doc. 2010-837 Filed 1-15-10; 8:45 am]

**BILLING CODE P**





# Federal Register

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Tuesday,  
January 19, 2010

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Part II

## Environmental Protection Agency

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40 CFR Parts 50, 58 and 81  
Ozone National Ambient Air Quality  
Standards; Final Rule and Proposed Rule

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 81

[EPA-HQ-OAR-2009-0476; FRL-9102-2]

#### Extension of Deadline for Promulgating Designations for the 2008 Ozone National Ambient Air Quality Standards

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

**ACTION:** Extension of deadline for promulgating designations.

**SUMMARY:** EPA is announcing that it is using its authority under the Clean Air Act (CAA) to extend by 1 year the deadline for promulgating initial area designations for the ozone national ambient air quality standards (NAAQS) that were promulgated in March 2008. The new deadline is March 12, 2011.

**DATES:** The deadline for EPA to promulgate designations for the 2008 ozone NAAQS is March 12, 2011.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding this action, contact Carla Oldham, Air Quality Planning Division, Office of Air Quality Planning and Standards, Mail Code C539-04, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: 919-541-3347; fax number: 919-541-0824; email address: [oldham.carla@epa.gov](mailto:oldham.carla@epa.gov).

**SUPPLEMENTARY INFORMATION:** This preamble is organized as follows:

#### I. General Information

- A. Does this action apply to me?
- B. Where can I get a copy of this document and other related information?

#### II. Background

- A. Designations Requirements
- B. Reconsideration of the 2008 Ozone NAAQS

#### III. Extension of Deadline for Promulgating Designations for the 2008 NAAQS

#### I. General Information

##### A. Does this action apply to me?

Entities potentially affected by this action include state, local, and tribal governments that would participate in the initial area designation process for the 2008 ozone standards.

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

EPA has established a docket for designations for the 2008 ozone NAAQS under Docket ID No. EPA-HQ-OAR-2009-0476. All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., confidential business

information or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the EPA Docket Center EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-1742.

An electronic copy of this notice is also available at <http://www.epa.gov/ozonedesignations>.

## II. Background

### A. Designations Requirements

On March 12, 2008, EPA promulgated revised 8-hour primary and secondary ozone NAAQS (73 FR 16436; March 27, 2008). The primary standard was lowered from 0.08 parts per million (ppm) to a level of 0.075 ppm. EPA also lowered the secondary standard by making it identical in all respects to the revised primary standard. (The previous ozone NAAQS were set in 1997 and remain effective.)

After EPA establishes or revises a NAAQS pursuant to CAA section 109, the CAA directs EPA and the states to begin taking steps to ensure that those NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. This step is known as the initial area designations. Section 107(d)(1) of the CAA provides that, "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall \* \* \* submit to the Administrator a list of all areas (or portions thereof) in the state" that designates those areas as nonattainment, attainment, or unclassifiable. The CAA defines an area as nonattainment if it is violating the NAAQS or if it is contributing to a violation in a nearby area. (CAA section 107(d)(1)(A)(i).)

The CAA further provides, "Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) \* \* \* as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of

the new or revised national ambient air quality standard. Such period may be extended for up to 1 year in the event the Administrator has insufficient information to promulgate the designations." (CAA section 107(d)(1)(B).)

After the states submit their recommendations, but no later than 120 days prior to promulgating designations, EPA is required to notify a state of any intended modifications to the state's recommended designation. The state then has an opportunity to demonstrate why any proposed modification is inappropriate. Whether or not a state provides a recommendation, EPA must promulgate the designation that the Agency deems appropriate within two years of promulgation of the NAAQS (or within three years if EPA extends the deadline).

For the March 2008 ozone NAAQS, the deadline for states to submit designation recommendations to EPA for their areas was March 12, 2009. EPA has been evaluating these recommendations and conducting additional analyses to determine whether it is necessary to modify any of the state recommendations. EPA was originally intending to complete the initial designations for the 2008 ozone NAAQS on a 2-year schedule, by March 12, 2010.

### B. Reconsideration of the 2008 Ozone NAAQS

On September 16, 2009, the EPA Administrator announced that EPA would take rulemaking action to reconsider the 2008 primary and secondary ozone NAAQS to ensure the standards satisfy the CAA. The EPA stated that it would sign the ozone NAAQS reconsideration proposed rule by December 21, 2009, and would sign the ozone NAAQS reconsideration final rule by August 31, 2010. In addition, EPA indicated it would work with states to accelerate the area designations process and the timeframe for submission of attainment demonstration state implementation plans for any new standards promulgated in 2010 as a result of the reconsideration. This would limit delays associated with implementing any new standards.

In a separate rulemaking action, which is being published simultaneous with this announcement, EPA is proposing to set different primary and secondary standards than those set in 2008 to provide requisite protection of public health and welfare, respectively (Ozone NAAQS Reconsideration Proposal). In that Ozone NAAQS Reconsideration Proposal, EPA is proposing that the level of the 8-hour

primary standard, which was set at 0.075 ppm in the 2008 final rule, should instead be set at a lower level to provide increased protection for children and other "at risk" populations against an array of ozone-related adverse health effects that range from decreased lung function and increased respiratory symptoms to serious indicators of respiratory morbidity.

Additionally, in the Ozone NAAQS Reconsideration Proposal, EPA is proposing that the secondary ozone standard should be a cumulative, seasonal standard. Such a standard would provide increased protection against ozone-related adverse impacts on vegetation and forested ecosystems in comparison to the secondary standard promulgated in the 2008 NAAQS final rule, which was identical to the revised primary standard.

### III. Extension of Deadline for Promulgating Designations for the 2008 NAAQS

As discussed above, in the Ozone NAAQS Reconsideration Proposal, EPA proposed to set primary and secondary ozone NAAQS that are different from and more protective than those promulgated in 2008. EPA intends to issue the final Ozone NAAQS Reconsideration Rule by August 31, 2010. If, as proposed, EPA promulgates ozone NAAQS in 2010 that differ from those promulgated in 2008, any requirements to designate areas and implement the 2008 ozone NAAQS would no longer apply. Because the ozone NAAQS reconsideration rulemaking action is a reconsideration of the 2008 ozone NAAQS, rather than a new periodic NAAQS review under CAA section 109(d)(1), a decision to promulgate different standards would result in a full replacement of the 2008

ozone NAAQS.<sup>1</sup> In other words, if as proposed, EPA concludes in the final Ozone NAAQS Reconsideration rulemaking that the 2008 ozone standards are not requisite to protect public health and welfare and promulgates different ozone standards, there would be no obligation to implement the 2008 ozone standards, which the final rule would have determined to be invalid. In this case, the designations process for the 2008 standards would be terminated. Pursuant to the CAA, states and EPA would then begin a new designations process for the newly promulgated ozone standards.

Because of the significant uncertainty that the Ozone NAAQS Reconsideration Proposal creates regarding the continued applicability of the 2008 NAAQS, EPA has determined that there is insufficient information at this time to promulgate designations. Therefore, in this action, EPA is announcing that it is using its authority under section

<sup>1</sup> EPA's action to reconsider the 2008 NAAQS is different than conducting a new "review and revise, as appropriate" action that CAA section 109(d)(1) requires EPA to take periodically. Under that statutory obligation, EPA considers the current state of knowledge, including new scientific information that has become available since promulgation of the most recent standard to consider whether the standard should be revised. Unlike a new periodic review, in this case, EPA is reconsidering the basic validity and appropriateness of the 2008 decision to promulgate the primary and secondary standards, restricting itself to consideration of the same scientific information that was before EPA when it adopted the 2008 standards. In a new periodic review, EPA evaluates the current state of knowledge, including more recent scientific information, and makes a new judgment about what standard is appropriate to protect public health (primary standard) and welfare (secondary standard) in light of the then current state of information. In that case, EPA would be required to address whether and how the implementation requirements for the replaced standard should continue to apply, *see e.g.*, CAA section 172(e).

107(d)(1)(B) of the CAA to extend by 1 year the deadline for promulgating initial area designations for the March 2008 ozone NAAQS. The new deadline is March 12, 2011. Extending the deadline for promulgating designations until March 12, 2011, will allow EPA to complete the Ozone NAAQS Reconsideration rulemaking before determining whether it is necessary to complete action to finalize designations for the 2008 ozone NAAQS or, instead, whether it is necessary to begin the designations process for different NAAQS promulgated pursuant to the reconsideration. If EPA does not timely complete its reconsideration of the 2008 ozone NAAQS, EPA will move forward to complete designations for the 2008 standards no later than March 12, 2011 pursuant to the designations recommendations that states have already submitted to EPA for the 2008 standards.

On September 16, 2009, when the EPA Administrator announced her decision to reconsider the 2008 ozone NAAQS, the Agency also stated its intention to accelerate the designations process for any 2010 ozone NAAQS resulting from the reconsideration.

EPA has proposed the designations schedule for any 2010 ozone NAAQS as part of the Ozone NAAQS Reconsideration rulemaking action.

#### List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: January 6, 2010.

**Lisa P. Jackson,**  
Administrator.

[FR Doc. 2010-349 Filed 1-15-10; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 50 and 58**

[EPA-HQ-OAR-2005-0172; FRL-9102-1]

RIN 2060-AP98

**National Ambient Air Quality Standards for Ozone**

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

**ACTION:** Proposed rule.

**SUMMARY:** Based on its reconsideration of the primary and secondary national ambient air quality standards (NAAQS) for ozone (O<sub>3</sub>) set in March 2008, EPA proposes to set different primary and secondary standards than those set in 2008 to provide requisite protection of public health and welfare, respectively. With regard to the primary standard for O<sub>3</sub>, EPA proposes that the level of the 8-hour primary standard, which was set at 0.075 ppm in the 2008 final rule, should instead be set at a lower level within the range of 0.060 to 0.070 parts per million (ppm), to provide increased protection for children and other "at risk" populations against an array of O<sub>3</sub>-related adverse health effects that range from decreased lung function and increased respiratory symptoms to serious indicators of respiratory morbidity including emergency department visits and hospital admissions for respiratory causes, and possibly cardiovascular-related morbidity as well as total non-accidental and cardiopulmonary mortality. With regard to the secondary standard for O<sub>3</sub>, EPA proposes that the secondary O<sub>3</sub> standard, which was set identical to the revised primary standard in the 2008 final rule, should instead be a new cumulative, seasonal standard expressed as an annual index of the sum of weighted hourly concentrations, cumulated over 12 hours per day (8 am to 8 pm) during the consecutive 3-month period within the O<sub>3</sub> season with the maximum index value, set at a level within the range of 7 to 15 ppm-hours, to provide increased protection against O<sub>3</sub>-related adverse impacts on vegetation and forested ecosystems.

**DATES:** Written comments on this proposed rule must be received by March 22, 2010.

**Public Hearings:** Three public hearings are scheduled for this proposed rule. Two of the public hearings will be held on February 2, 2010 in Arlington, Virginia, and Houston, Texas. The third public hearing will be held on February 4, 2010 in Sacramento, California.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2005-0172, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail:* [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov).
- *Fax:* 202-566-9744.
- *Mail:* Docket No. EPA-HQ-OAR-2005-0172, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.

- *Hand Delivery:* Docket No. EPA-HQ-OAR-2005-0172, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Public Hearings:** Three public hearings are scheduled for this proposed rule. Two of the public hearings will be held on February 2, 2010 in Arlington, Virginia and Houston, Texas. The third public hearing will be held on February 4, 2010 in Sacramento, California. The hearings will be held at the following locations:

*Arlington, Virginia—February 2, 2010*

Hyatt Regency Crystal City @ Reagan National Airport, Washington Room (located on the Ballroom Level), 2799 Jefferson Davis Highway, Arlington, Virginia 22202, Telephone: 703-418-1234.

*Houston, Texas—February 2, 2010*

Hilton Houston Hobby Airport, Moody Ballroom (located on the ground floor), 8181 Airport Boulevard, Houston, Texas 77061, Telephone: 713-645-3000.

*Sacramento, California—February 4, 2010*

Four Points by Sheraton Sacramento International Airport, Natomas Ballroom, 4900 Duckhorn Drive, Sacramento, California 95834, Telephone: 916-263-9000.

See the **SUPPLEMENTARY INFORMATION** under "Public Hearings" for further information.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-OAR-2005-0172. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business

Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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

**FOR FURTHER INFORMATION CONTACT:** Ms. Susan Lyon Stone, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-1146; fax: 919-541-0237; e-mail: [stone.susan@epa.gov](mailto:stone.susan@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## General Information

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

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

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

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

### Availability of Related Information

A number of documents relevant to this rulemaking are available on EPA web sites. The Air Quality Criteria for Ozone and Related Photochemical Oxidants (2006 Criteria Document) (two volumes, EPA/and EPA/, date) is available on EPA's National Center for Environmental Assessment Web site. To obtain this document, go to <http://www.epa.gov/ncea>, and click on Ozone in the Quick Finder section. This will open a page with a link to the March 2006 Air Quality Criteria Document. The 2007 Staff Paper, human exposure and health risk assessments, vegetation

exposure and impact assessment, and other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) web site. The updated final 2007 Staff Paper is available at: [http://epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_sp.html](http://epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_sp.html) and the exposure and risk assessments and other related technical documents are available at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_td.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_td.html). The Response to Significant Comments Document is available at: [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_rc.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_rc.html). These and other related documents are also available for inspection and copying in the EPA docket identified above.

### Public Hearings

The public hearings on February 2, 2010 and February 4, 2010 will provide interested parties the opportunity to present data, views, or arguments concerning the proposed rule. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Written comments must be received by the last day of the comment period, as specified in this proposed rulemaking.

The public hearings will begin at 9:30 a.m. and continue until 7:30 p.m. (local time) or later, if necessary, depending on the number of speakers wishing to participate. The EPA will make every effort to accommodate all speakers that arrive and register before 7:30 p.m. A lunch break is scheduled from 12:30 p.m. until 2 p.m.

If you would like to present oral testimony at the hearings, please notify Ms. Tricia Crabtree (C504-02), U.S. EPA, Research Triangle Park, NC 27711. The preferred method for registering is by e-mail ([crabtree.tricia@epa.gov](mailto:crabtree.tricia@epa.gov)). Ms. Crabtree may be reached by telephone at (919) 541-5688. She will arrange a general time slot for you to speak. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing.

Oral testimony will be limited to five (5) minutes for each commenter to address the proposal. We will not be providing equipment for commenters to show overhead slides or make computerized slide presentations unless we receive special requests in advance. Commenters should notify Ms. Crabtree if they will need specific audiovisual

(AV) equipment. Commenters should also notify Ms. Crabtree if they need specific translation services for non-English speaking commenters. The EPA encourages commenters to provide written versions of their oral testimonies either electronically on computer disk, CD-ROM, or in paper copy.

The hearing schedules, including lists of speakers, will be posted on EPA's Web site for the proposal at [http://www.epa.gov/ttn/naaqs/standards/ozone/s\\_o3\\_cr\\_fr.html](http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_fr.html) prior to the hearing. Verbatim transcripts of the hearings and written statements will be included in the rulemaking docket.

### Children's Environmental Health

Consideration of children's environmental health plays a central role in the reconsideration of the 2008 final decision on the O<sub>3</sub> NAAQS and EPA's decision to propose to set the 8-hour primary O<sub>3</sub> standard at a level within the range of 0.060 to 0.070 ppm. Technical information that pertains to children, including the evaluation of scientific evidence, policy considerations, and exposure and risk assessments, is discussed in all of the documents listed above in the section on the availability of related information. These documents include: the Air Quality Criteria for Ozone and Other Related Photochemical Oxidants; the 2007 Staff Paper; exposure and risk assessments and other related documents; and the Response to Significant Comments. All of these documents are available on the Web, as described above, and are in the public docket for this rulemaking. The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to O<sub>3</sub>.

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#### References

#### I. Background

The proposed decisions presented in this notice are based on a reconsideration of the 2008 O<sub>3</sub> NAAQS final rule (73 FR 16436, March 27, 2008), which revised the level of the 8-hour primary O<sub>3</sub> standard to 0.075 ppm and revised the secondary O<sub>3</sub> standard by making it identical to the revised primary standard. This reconsideration is based on the scientific and technical information and analyses on which the March 2008 O<sub>3</sub> NAAQS rulemaking was based. Therefore, much of the information included in this notice is drawn directly from information included in the 2007 proposed rule (72 FR 37818, July 11, 2007) and the 2008 final rule (73 FR 16436).

#### A. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list "air pollutants" that in her "judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare" and satisfy two other criteria, including "whose presence \* \* \* in the ambient air results from numerous or diverse mobile or stationary sources" and to issue air quality criteria for those that are listed. Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. \* \* \*

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public

health."<sup>1</sup> A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."<sup>2</sup>

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (DC Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (DC Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Association v. EPA*, 647 F.2d at 1156 n. 51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties

<sup>1</sup> The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level \* \* \* which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group" [S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970)].

<sup>2</sup> Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association v. EPA*, 647 F.2d at 1161-62; *Whitman v. American Trucking Associations*, 531 U.S. 457, 495 (2001).

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. *Whitman v. American Trucking Associations*, 531 U.S. 457, 473. In establishing "requisite" primary and secondary standards, EPA may not consider the costs of implementing the standards. *Id.* at 471.

Section 109(d)(1) of the CAA requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards \* \* \* and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate. \* \* \*" Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria \* \* \* and the national primary and secondary ambient air quality standards \* \* \* and shall recommend to the Administrator any new \* \* \* standards and revisions of existing criteria and standards as may be appropriate. \* \* \*" This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

#### B. Related Control Requirements

States have primary responsibility for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to emission sources.

The majority of man-made nitrogen oxides (NO<sub>x</sub>) and volatile organic compounds (VOC) emissions that contribute to O<sub>3</sub> formation in the United States come from three types of sources: Mobile sources, industrial processes (which include consumer and commercial products), and the electric

power industry.<sup>3</sup> Mobile sources and the electric power industry were responsible for 78 percent of annual NO<sub>x</sub> emissions in 2004. That same year, 99 percent of man-made VOC emissions came from industrial processes (including solvents) and mobile sources. Emissions from natural sources, such as trees, may also comprise a significant portion of total VOC emissions in certain regions of the country, especially during the O<sub>3</sub> season, which are considered natural background emissions.

The EPA has developed new emissions standards for many types of stationary sources and for nearly every class of mobile sources in the last decade to reduce O<sub>3</sub> by decreasing emissions of NO<sub>x</sub> and VOC. These programs complement State and local efforts to improve O<sub>3</sub> air quality and meet the 0.084 ppm 8-hour national standards. Under title II of the CAA, 42 U.S.C. 7521-7574), EPA has established new emissions standards for nearly every type of automobile, truck, bus, motorcycle, earth mover, and aircraft engine, and for the fuels used to power these engines. EPA also established new standards for the smaller engines used in small watercraft, lawn and garden equipment. In March 2008, EPA promulgated new standards for locomotive and marine diesel engines and in August 2009, proposed to control emissions from ocean-going vessels.

Benefits from engine standards increase modestly each year as older, more-polluting vehicles and engines are replaced with newer, cleaner models. In time, these programs will yield substantial emission reductions. Benefits from fuel programs generally begin as soon as a new fuel is available.

The reduction of VOC emissions from industrial processes has been achieved either directly or indirectly through implementation of control technology standards, including maximum achievable control technology, reasonably available control technology, and best available control technology standards; or are anticipated due to proposed or upcoming proposals based on generally available control technology or best available controls under provisions related to consumer and commercial products. These standards have resulted in VOC emission reductions of almost a million tons per year accumulated starting in 1997 from a variety of sources including combustion sources, coating categories, and chemical manufacturing. EPA has

<sup>3</sup> See EPA report, *Evaluating Ozone Control Programs in the Eastern United States: Focus on the NO<sub>x</sub> Budget Trading Program*, 2004.

also finalized emission standards and fuel requirements for new stationary engines. In the area of consumer and commercial products, EPA has finalized new national VOC emission standards for aerosol coatings and is working toward amending existing rules to establish new nationwide VOC content limits for household and institutional consumer products and architectural and industrial maintenance coatings. The aerosol coatings rule took effect in July 2009; the compliance date for both the amended consumer product rule and architectural coatings rule is anticipated to be January 2011. These actions are expected to yield significant new VOC reductions—about 200,000 tons per year. Additionally, in ozone nonattainment areas, we anticipate reductions of an additional 25,000 tons per year as States adopt rules this year implementing control techniques recommendations issued in 2008 for 4 additional categories of consumer and commercial products, typically surface coatings and adhesives used in industrial manufacturing operations. These emission reductions primarily result from solvent controls and typically occur where and when the solvent is used, such as during manufacturing processes.

The power industry is one of the largest emitters of NO<sub>x</sub> in the United States. Power industry emission sources include large electric generating units (EGU) and some large industrial boilers and turbines. The EPA's landmark Clean Air Interstate Rule (CAIR), issued on March 10, 2005, was designed to permanently cap power industry emissions of NO<sub>x</sub> in the eastern United States. The first phase of the cap was to begin in 2009, and a lower second phase cap was to begin in 2015. The EPA had projected that by 2015, the CAIR and other programs would reduce NO<sub>x</sub> emissions during the O<sub>3</sub> season by about 50 percent and annual NO<sub>x</sub> emissions by about 60 percent from 2003 levels in the Eastern U.S. However, on July 11, 2008 and December 23, 2008, the U.S. Court of Appeals for the DC Circuit issued decisions on petitions for review of the CAIR. In its July 11 opinion, the court found CAIR unlawful and decided to vacate CAIR and its associated Federal implementation plans (FIPs) in their entirety. On December 23, the court granted EPA's petition for rehearing to the extent that it remanded without vacatur for EPA to conduct further proceedings consistent with the Court's prior opinion. Under this decision, CAIR will remain in place only until replaced by EPA with a rule that is consistent with the Court's July

11 opinion. The EPA recognizes the need in our CAIR replacement effort to address the reconsidered ozone standard, and we are currently assessing our options for the best way to accomplish this. It should also be noted that new electric generating units (EGUs) are also subject to NO<sub>x</sub> limits under New Source Performance Standards (NSPS) under CAA section 111, as well as either nonattainment new source review or prevention of significant deterioration requirements.

With respect to agricultural sources, the U.S. Department of Agriculture (USDA) has approved conservation systems and activities that reduce agricultural emissions of NO<sub>x</sub> and VOC. Current practices that may reduce emissions of NO<sub>x</sub> and VOC include engine replacement programs, diesel retrofit programs, manipulation of pesticide applications including timing of applications, and animal feeding operations waste management techniques. The EPA recognizes that USDA has been working with the agricultural community to develop conservation systems and activities to control emissions of O<sub>3</sub> precursors.

These conservation activities are voluntarily adopted through the use of incentives provided to the agricultural producer. In cases where the States need these measures to attain the standard, the measures could be adopted. The EPA will continue to work with USDA on these activities with efforts to identify and/or improve the control efficiencies, prioritize the adoption of these conservation systems and activities, and ensure that appropriate criteria are used for identifying the most effective application of conservation systems and activities.

The EPA will work together with USDA and with States to identify appropriate measures to meet the primary and secondary standards, including site-specific conservation systems and activities. Based on prior experience identifying conservation measures and practices to meet the PM NAAQS requirements, the EPA will use a similar process to identify measures that could meet the O<sub>3</sub> requirements. The EPA anticipates that certain USDA-approved conservation systems and activities that reduce agricultural emissions of NO<sub>x</sub> and VOC may be able to satisfy the requirements for applicable sources to implement reasonably available control measures for purposes of attaining the primary and secondary O<sub>3</sub> NAAQS.

### *C. Review of Air Quality Criteria and Standards for O<sub>3</sub>*

In 1971, EPA first established primary and secondary NAAQS for photochemical oxidants (36 FR 8186). Both primary and secondary standards were set at a level of 0.08 parts per million (ppm), 1-hr average, total photochemical oxidants, not to be exceeded more than one hr per year. In 1977, EPA announced the first periodic review of the air quality criteria in accordance with section 109(d)(1) of the Act. The EPA published a final decision in 1979 (44 FR 8202). Both primary and secondary standard levels were revised from 0.08 to 0.12 ppm. The indicator was revised from photochemical oxidants to O<sub>3</sub>, and the form of the standards was revised from a deterministic to a statistical form, which defined attainment of the standards as occurring when the expected number of days per calendar year with maximum hourly average concentration greater than 0.12 ppm is equal to or less than one. In 1983, EPA announced that the second periodic review of the primary and secondary standards for O<sub>3</sub> had been initiated. Following review and publication of air quality criteria and a supplement, EPA published a proposed decision (57 FR 35542) in August 1992 that announced EPA's intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O<sub>3</sub> in light of emerging evidence of health effects related to 6- to 8-hr O<sub>3</sub> exposures. In March 1993, EPA concluded the review by deciding that revisions to the standards were not warranted at that time (58 FR 13008).

In August 1992 (57 FR 35542), EPA announced plans to initiate the third periodic review of the air quality criteria and O<sub>3</sub> NAAQS. On the basis of the scientific evidence contained in the 1996 CD (U.S. EPA 1996a) and the 1996 Staff Paper (U.S. EPA, 1996b), and related technical support documents, linking exposures to ambient O<sub>3</sub> to adverse health and welfare effects at levels allowed by the then existing standards, EPA proposed to revise the primary and secondary O<sub>3</sub> standards in December 1996 (61 FR 65716). The EPA proposed to replace the then existing 1-hour primary and secondary standards with 8-hour average O<sub>3</sub> standards set at a level of 0.08 ppm (equivalent to 0.084 ppm using standard rounding conventions). The EPA also proposed, in the alternative, to establish a new distinct secondary standard using a biologically based cumulative seasonal form. The EPA completed the review in July 1997 (62 FR 38856) by setting the

primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-hr average concentration, averaged over three years, and setting the secondary standard identical to the revised primary standard.

The EPA initiated the most recent periodic review of the air quality criteria and standards for O<sub>3</sub> in September 2000 with a call for information (65 FR 57810; September 26, 2000) for the development of a revised Air Quality Criteria Document for O<sub>3</sub> and Other Photochemical Oxidants (henceforth the "2006 Criteria Document"). A project work plan (EPA, 2002) for the preparation of the Criteria Document was released in November 2002 for CASAC and public review. The EPA held a series of workshops in mid-2003 on several draft chapters of the Criteria Document to obtain broad input from the relevant scientific communities. These workshops helped to inform the preparation of the first draft Criteria Document (EPA, 2005a), which was released for CASAC and public review on January 31, 2005; a CASAC meeting was held on May 4–5, 2005 to review the first draft Criteria Document. A second draft Criteria Document (EPA, 2005b) was released for CASAC and public review on August 31, 2005, and was discussed along with a first draft Staff Paper (EPA, 2005c) at a CASAC meeting held on December 6–8, 2005. In a February 16, 2006 letter to the Administrator, CASAC provided comments on the second draft Criteria Document (Henderson, 2006a), and the final 2006 Criteria Document (EPA, 2006a) was released on March 21, 2006. In a June 8, 2006 letter to the Administrator (Henderson, 2006b), CASAC provided additional advice to the Agency concerning chapter 8 of the final 2006 Criteria Document (Integrative Synthesis) to help inform the second draft Staff Paper.

A second draft Staff Paper (EPA, 2006b) was released on July 17, 2006 and reviewed by CASAC on August 24–25, 2006. In an October 24, 2006 letter to the Administrator, CASAC provided advice and recommendations to the Agency concerning the second draft Staff Paper (Henderson, 2006c). A final 2007 Staff Paper (EPA, 2007a) was released on January 31, 2007. In a March 26, 2007 letter (Henderson, 2007), CASAC offered additional advice to the Administrator with regard to recommendations and revisions to the primary and secondary O<sub>3</sub> NAAQS.

The schedule for completion of the 2008 rulemaking was governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental



and public health organizations, alleging that EPA had failed to complete the review within the period provided by statute.<sup>4</sup> The modified consent decree that governed the 2008 rulemaking, entered by the court on December 16, 2004, provided that EPA sign for publication notices of proposed and final rulemaking concerning its review of the O<sub>3</sub> NAAQS no later than March 28, 2007 and December 19, 2007, respectively. That consent decree was further modified in October 2006 to change these proposed and final rulemaking dates to no later than May 30, 2007 and February 20, 2008, respectively. These dates for signing the publication notices of proposed and final rulemaking were further extended to no later than June 20, 2007 and March 12, 2008, respectively. The proposed decision was signed on June 20, 2007 and published in the **Federal Register** on July 11, 2007 (72 FR 37818).

Public hearings on the proposed decision were held on Thursday, August 30, 2007 in Philadelphia, PA and Los Angeles, CA. On Wednesday, September 5, 2007, hearings were held in Atlanta, GA, Chicago, IL, and Houston, TX. A large number of comments were received from various commenters on the 2007 proposed revisions to the O<sub>3</sub> NAAQS. A comprehensive summary of all significant comments, along with EPA's responses (henceforth "Response to Comments"), can be found in the docket for the 2008 rulemaking, which is also the docket for this reconsideration rulemaking.

The EPA's final decision on the O<sub>3</sub> NAAQS was published in the **Federal Register** on March 27, 2008 (73 FR 16436). In the 2008 rulemaking, EPA revised the level of the 8-hour primary standard for O<sub>3</sub> to 0.075 parts per million (ppm), expressed to three decimal places. With regard to the secondary standard for O<sub>3</sub>, EPA revised the 8-hour standard by making it identical to the revised primary standard. The EPA also made conforming changes to the Air Quality Index (AQI) for O<sub>3</sub>, setting an AQI value of 100 equal to 0.075 ppm, 8-hour average, and making proportional changes to the AQI values of 50, 150 and 200.

#### *D. Reconsideration of the 2008 O<sub>3</sub> NAAQS Final Rule*

Consistent with a directive of the new Administration regarding the review of new and pending regulations (Emanuel memorandum, 74 FR 4435; January 26, 2009), the Administrator reviewed a

number of actions that were taken in the last year by the previous Administration. The 2008 final rule was included in this review in recognition of the central role that the NAAQS play in enabling EPA to fulfill its mission to protect the nation's public health and welfare. In her review, the Administrator was mindful of the need for judgments concerning the NAAQS to be based on a strong scientific foundation which is developed through a transparent and credible NAAQS review process, consistent with the core values highlighted in President Obama's memorandum on scientific integrity (March 9, 2009).

#### **1. Decision To Initiate a Rulemaking To Reconsider**

In her review of the 2008 final rule, several aspects of the final rule related to the primary and secondary standards stood out to the Administrator. As an initial matter, the Administrator noted that the 2008 final rule concluded that the 1997 primary and secondary O<sub>3</sub> standards were not adequate to protect public health and public welfare, and that revisions were necessary to provide increased protection. With respect to revision of the primary standard, the Administrator noted that the revised level established in the 2008 final rule was above the range that had been unanimously recommended by CASAC.<sup>5</sup> She also noted that EPA received comments from a large number of commenters from the medical and public health communities, including EPA's Children's Health Protection Advisory Committee, all of which endorsed levels within CASAC's recommended range.

With respect to revision of the secondary O<sub>3</sub> standard, the Administrator noted that the 2008 final rule differed substantially from CASAC's recommendations that EPA adopt a new secondary O<sub>3</sub> standard based on a cumulative, seasonal measure of exposure. The 2008 final rule revised the secondary standard to be identical to the revised primary standard, which is based on an 8-hour daily maximum measure of exposure. She also noted that EPA received comments from a number of commenters representing environmental interests, all of which endorsed CASAC's recommendation for a new cumulative, seasonal secondary standard.<sup>6</sup>

<sup>5</sup> The level of the 8-hour primary ozone standard was set at 0.075 ppm, while CASAC unanimously recommended a range between 0.060 and 0.070 ppm.

<sup>6</sup> The Administrator also noted the exchange that had occurred between EPA and the Office of

Subsequent to issuance of the 2008 final rule, in April 2008, CASAC took the unusual step of sending EPA a letter expressing strong, unanimous disagreement with EPA's decisions on both the primary and secondary standards (Henderson, 2008). The CASAC explained that it did not endorse the revised primary O<sub>3</sub> standard as being sufficiently protective of public health because it failed to satisfy the explicit stipulation of the Act to provide an adequate margin of safety. The CASAC also expressed the view that failing to revise the secondary standard to a cumulative, seasonal form was not supported by the available science. In addition to CASAC's letter, the Administrator noted a recent adverse ruling issued by the U.S. Court of Appeals for the District of Columbia Circuit on another NAAQS decision. In February 2009, the DC Circuit remanded the Agency's decisions on the primary annual and secondary standards for fine particles (PM<sub>2.5</sub>). In so doing, the Court found that EPA had not adequately explained the basis for its decisions, including why CASAC's recommendations for a more health-protective primary annual standard and for secondary standards different from the primary standards were not accepted. *American Farm Bureau v. EPA*, 559 F.3d. 512 (DC Cir. 2009).

Based on her review of the information described above, the Administrator is initiating a rulemaking to reconsider parts of the 2008 final rule. Specifically, the Administrator is reconsidering the level of the primary standard to ensure that it is sufficiently protective of public health, as discussed in section II below, and is reconsidering all aspects of the secondary standard to ensure that it appropriately reflects the available science and is sufficiently protective of public welfare, as discussed in section IV below. Based on her review, the Administrator has serious cause for concern regarding whether the revisions to the primary and secondary O<sub>3</sub> standards adopted in the 2008 final rule satisfy the requirements of the CAA, in light of the body of scientific evidence before the Agency. In addition, the importance of the O<sub>3</sub> NAAQS to public health and welfare weigh heavily in favor of reconsidering parts of the 2008 final rule as soon as possible, based on the scientific and technical information upon which the 2008 final rule was based.

Management and Budget (OMB) with regard to the final decision on the secondary standard, as discussed in the 2008 final rule (73 FR 16497).

<sup>4</sup> *American Lung Association v. Whitman* (No. 1:03CV00778, D.D.C. 2003).

Also, EPA conducted a provisional assessment of "new" scientific papers (EPA, 2009) of scientific literature evaluating health and ecological effects of O<sub>3</sub> exposure published since the close of the 2006 Criteria Document upon which the 2008 O<sub>3</sub> NAAQS were based. The Administrator notes that the provisional assessment of "new" science found that such studies did not materially change the conclusions in the 2006 Criteria Document. This provisional assessment is supportive of the Administrator's decision to reconsider parts of the 2008 final rule at this time, based on the scientific and technical information available for the 2008 final rule, as compared to foregoing such reconsideration and taking appropriate action in the future as part of the next periodic review of the air quality criteria and NAAQS, which will include such scientific and technical information.

The reconsideration of parts of the 2008 final rule discussed in this notice is based on the scientific and technical record from the 2008 rulemaking, including public comments and CASAC advice and recommendations. The information that was assessed during the 2008 rulemaking includes information in the 2006 Criteria Document (EPA, 2006a), the 2007 Policy Assessment of Scientific and Technical Information, referred to as the 2007 Staff Paper (EPA, 2007b), and related technical support documents including the 2007 REAs (U.S. EPA, 2007c; Abt Associates, 2007a,b). Scientific and technical information developed since the 2006 Criteria Document will be considered in the next periodic review, instead of this reconsideration rulemaking, allowing the new information to receive careful and comprehensive review by CASAC and the public before it is used as a basis in a rulemaking that determines whether to revise the NAAQS.

## 2. Ongoing Litigation

In May 2008, following publication of the 2008 final rule, numerous groups, including state, public health, environmental, and industry petitioners, challenged EPA's decisions in federal court. The challenges were consolidated as *State of Mississippi, et al. v. EPA* (No. 08-1200, DC Cir. 2008). On March 10, 2009, EPA filed an unopposed motion requesting that the Court vacate the briefing schedule and hold the consolidated cases in abeyance. The Agency stated its desire to allow time for appropriate officials from the new Administration to review the O<sub>3</sub> standards to determine whether they should be maintained, modified or

otherwise reconsidered. The EPA further requested that it be directed to notify the Court and all the parties of any actions it has taken or intends to take, if any, within 180 days of the Court vacating the briefing schedule. On March 19, 2009, the Court granted EPA's motion. Pursuant to the Court's order, on September 16, 2009 EPA notified the Court and the parties of its decision to initiate a rulemaking to reconsider the primary and secondary O<sub>3</sub> standards set in March 2008 to ensure they satisfy the requirements of the CAA.<sup>7</sup> In its notice to the Court, EPA stated that this notice of proposed rulemaking would be signed by December 21, 2009, and that the final rule will be signed by August 31, 2010.

## II. Rationale for Proposed Decision on the Level of the Primary Standard

As an initial matter, the Administrator notes that the 2008 final rule concluded that the 1997 primary O<sub>3</sub> standard was "not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection" (73 FR 16472). The Administrator is not reconsidering this aspect of the 2008 decision, which is based on the reasons discussed in section II.B of the 2008 final rule (73 FR 16443-16472). The Administrator also notes that the 2008 final rule concluded that it was appropriate to retain the O<sub>3</sub> indicator, the 8-hour averaging time, and form of the primary O<sub>3</sub> standard (specified as the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years), while concluding that revision of the standard level was appropriate.<sup>8</sup> The Administrator is not reconsidering these aspects of the 2008 decision, which are based on the reasons discussed in sections II.C.1-3 of the 2008 final rule, which address the indicator, averaging time, and form, respectively, of the primary O<sub>3</sub> standard (73 FR 16472-16475). For these reasons, the Administrator is not reopening the 2008

decision with regard to the need to revise the 1997 primary O<sub>3</sub> standard nor with regard to the indicator, averaging time, and form of the 2008 primary O<sub>3</sub> standard. Thus, the information that follows in this section specifically focuses on a reconsideration of level of the primary O<sub>3</sub> standard.

This section presents the rationale for the Administrator's proposed decision that the O<sub>3</sub> primary standard, which was set at a level of 0.075 ppm in the 2008 final rule, should instead be set at a lower level within the range from 0.060 to 0.070 ppm. As discussed more fully below, the rationale for the proposed range of standard levels is based on a thorough review of the latest scientific information on human health effects associated with the presence of O<sub>3</sub> in the ambient air presented in the 2006 Criteria Document. This rationale also takes into account: (1) Staff assessments of the most policy-relevant information in the 2006 Criteria Document and staff analyses of air quality, human exposure, and health risks, presented in the 2007 Staff Paper, upon which staff recommendations for revisions to the primary O<sub>3</sub> standard in the 2008 rulemaking were based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the 2006 Criteria Document and 2007 Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator both before and after the 2008 rulemaking; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately, and on the 2007 proposed rule.

In developing this rationale, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standard would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of evidence and assessments, and on the related uncertainties and limitations. Thus, in selecting standard levels to propose, and subsequently in selecting a final level, the Administrator is seeking not only to prevent O<sub>3</sub> levels that have been demonstrated to be harmful but also to prevent lower O<sub>3</sub> levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In this proposed rule, EPA has drawn upon an integrative synthesis of the entire body of evidence, published

<sup>7</sup> The EPA also separately announced that it will move quickly to implement any new standards that might result from this reconsideration. To reduce the workload for states during the interim period of reconsideration, the Agency intends to propose to defer compliance with the CAA requirement to designate areas as attainment or nonattainment. EPA will work with states, local governments and tribes to ensure that air quality is protected during that time.

<sup>8</sup> The use of O<sub>3</sub> as the indicator for photochemical oxidants was adopted in the 1979 final rule and retained in subsequent rulemaking. An 8-hour averaging time and a form based on the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years, were adopted in the 1997 final rule and retained in the 2008 rulemaking.

through early 2006, on human health effects associated with the presence of O<sub>3</sub> in the ambient air. As discussed below in section II.A, this body of evidence addresses a broad range of health endpoints associated with exposure to ambient levels of O<sub>3</sub> (EPA, 2006a, chapter 8), and includes over one hundred epidemiologic studies conducted in the U.S., Canada, and many countries around the world.<sup>9</sup> In reconsidering this evidence, EPA focuses on those health endpoints that have been demonstrated to be caused by exposure to O<sub>3</sub>, or for which the 2006 Criteria Document judges associations with O<sub>3</sub> to be causal, likely causal, or for which the evidence is highly suggestive that O<sub>3</sub> contributes to the reported effects. This rationale also draws upon the results of quantitative exposure and risk assessments, discussed below in section II.B. Section II.C focuses on the considerations upon which the Administrator's proposed conclusions on the level of the primary standard are based. Policy-relevant evidence-based and exposure/risk-based considerations are discussed, and the rationale for the 2008 final rulemaking on the primary standard and CASAC advice, given both prior to the development of the 2007 proposed rule and following the 2008 final rule, are summarized. Finally, the Administrator's proposed conclusions on the level of the primary standard are presented. Section II.D summarizes the proposed decision on the level of the primary O<sub>3</sub> standard and the solicitation of public comments.

Judgments made in the 2006 Criteria Document and 2007 Staff Paper about the extent to which relationships between various health endpoints and short-term exposures to ambient O<sub>3</sub> are likely causal have been informed by several factors. As discussed below in section II.A, these factors include the nature of the evidence (*i.e.*, controlled human exposure, epidemiological, and/or toxicological studies) and the weight of evidence, which takes into account such considerations as biological plausibility, coherence of evidence, strength of association, and consistency of evidence.

In assessing the health effects data base for O<sub>3</sub>, it is clear that human studies provide the most directly applicable information for determining causality because they are not limited

<sup>9</sup> In its assessment of the epidemiological evidence judged to be most relevant to making decisions on the level of the O<sub>3</sub> primary standard, EPA has placed greater weight on U.S. and Canadian epidemiologic studies, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

by the uncertainties of dosimetry differences and species sensitivity differences, which would need to be addressed in extrapolating animal toxicology data to human health effects. Controlled human exposure studies provide data with the highest level of confidence since they provide human health effects data under closely monitored conditions and can provide exposure-response relationships. Epidemiological data provide evidence of associations between ambient O<sub>3</sub> levels and more serious acute and chronic health effects (*e.g.*, hospital admissions and mortality) that cannot be assessed in controlled human exposure studies. For these studies the degree of uncertainty introduced by potentially confounding variables (*e.g.*, other pollutants, temperature) and other factors affects the level of confidence that the health effects being investigated are attributable to O<sub>3</sub> exposures, alone and in combination with other copollutants.

In using a weight of evidence approach to inform judgments about the degree of confidence that various health effects are likely to be caused by exposure to O<sub>3</sub>, confidence increases as the number of studies consistently reporting a particular health endpoint grows and as other factors, such as biological plausibility and strength, consistency, and coherence of evidence, increase. Conclusions regarding biological plausibility, consistency, and coherence of evidence of O<sub>3</sub>-related health effects are drawn from the integration of epidemiological studies with mechanistic information from controlled human exposure studies and animal toxicological studies. As discussed below, this type of mechanistic linkage has been firmly established for several respiratory endpoints (*e.g.*, lung function decrements, lung inflammation) but remains far more equivocal for cardiovascular endpoints (*e.g.*, cardiovascular-related hospital admissions). For epidemiological studies, strength of association refers to the magnitude of the association and its statistical strength, which includes assessment of both effects estimate size and precision. In general, when associations yield large relative risk estimates, it is less likely that the association could be completely accounted for by a potential confounder or some other bias. Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times. For example, the magnitude

of effect estimates is relatively consistent across recent studies showing association between short-term, but not long-term, O<sub>3</sub> exposure and mortality.

Based on the information discussed below in sections II.A.1–II.A.3, judgments concerning the extent to which relationships between various health endpoints and ambient O<sub>3</sub> exposures are likely causal are summarized below in section II.A.3.c. These judgments reflect the nature of the evidence and the overall weight of the evidence, and are taken into consideration in the quantitative exposure and risk assessments, discussed below in section II.B.

To put judgments about health effects that have been demonstrated to be caused by exposure to O<sub>3</sub>, or for which the 2006 Criteria Document judges associations with O<sub>3</sub> to be causal, likely causal, or for which the evidence is highly suggestive that O<sub>3</sub> contributes to the reported effects into a broader public health context, EPA has drawn upon the results of the quantitative exposure and risk assessments. These assessments provide estimates of the likelihood that individuals in particular population groups that are at risk for various O<sub>3</sub>-related physiological health effects would experience "exposures of concern" and specific health endpoints under varying air quality scenarios (*i.e.*, just meeting various standards<sup>10</sup>), as well as characterizations of the kind and degree of uncertainties inherent in such estimates.

In the 2008 final rulemaking and in this reconsideration, the term "exposures of concern" is defined as personal exposures while at moderate or greater exertion to 8-hour average ambient O<sub>3</sub> levels at and above specific benchmark levels which represent exposure levels at which O<sub>3</sub>-related health effects are known or can reasonably be inferred to occur in some individuals, as discussed below in section II.B.1.<sup>11</sup> The EPA emphasizes

<sup>10</sup> The exposure assessment done as part of the 2008 final rulemaking considered several air quality scenarios, including just meeting what was then the current standard set at a level of 0.084 ppm, as well as just meeting alternative standards at levels of 0.080, 0.074, 0.070, and 0.064 ppm.

<sup>11</sup> Exposures of concern were also considered in the 1997 review of the O<sub>3</sub> NAAQS, and were judged by EPA to be an important indicator of the public health impacts of those O<sub>3</sub>-related effects for which information was too limited to develop quantitative estimates of risk but which had been observed in humans at and above the benchmark level of 0.08 ppm for 6- to 8-hour exposures \* \* \* including increased nonspecific bronchial responsiveness (for example, aggravation of asthma), decreased pulmonary defense mechanisms (suggestive of increased susceptibility to respiratory infection), and indicators of pulmonary inflammation (related

Continued

that although the analysis of "exposures of concern" was conducted using three discrete benchmark levels (*i.e.*, 0.080, 0.070, and 0.060 ppm), the concept is more appropriately viewed as a continuum with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O<sub>3</sub> exposure levels. The EPA recognizes that there is no sharp breakpoint within the continuum ranging from at and above 0.080 ppm down to 0.060 ppm. In considering the concept of exposures of concern, it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower O<sub>3</sub> levels.

Within the context of this continuum, estimates of exposures of concern at discrete benchmark levels provide some perspective on the public health impacts of O<sub>3</sub>-related health effects that have been demonstrated in controlled human exposure and toxicological studies but cannot be evaluated in quantitative risk assessments, such as lung inflammation, increased airway responsiveness, and changes in host defenses. They also help in understanding the extent to which such impacts have the potential to be reduced by meeting various standards. These O<sub>3</sub>-related physiological effects are plausibly linked to the increased morbidity seen in epidemiological studies (*e.g.*, as indicated by increased medication use in asthmatics, school absences in all children, and emergency department visits and hospital admissions in people with lung disease). Estimates of the number of people likely to experience exposures of concern cannot be directly translated into quantitative estimates of the number of people likely to experience specific health effects, since sufficient information to draw such comparisons is not available—if such information were available, these health outcomes would have been included in the quantitative risk assessment. Due to individual variability in responsiveness, only a subset of individuals who have exposures at and above a specific benchmark level can be expected to experience such adverse health effects, and susceptible subpopulations such as those with asthma are expected to be affected more by such exposures than healthy individuals. The amount of weight to place on the estimates of exposures of concern at any of these

to potential aggravation of chronic bronchitis or long-term damage to the lungs. (62 FR 38868)

benchmark levels depends in part on the weight of the scientific evidence concerning health effects associated with O<sub>3</sub> exposures at and above that benchmark level. It also depends on judgments about the importance from a public health perspective of the health effects that are known or can reasonably be inferred to occur as a result of exposures at and above the benchmark level. Such public health policy judgments are embodied in the NAAQS standard setting criteria (*i.e.*, standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety).

As discussed below in section II.B.2, the quantitative health risk assessment conducted as part of the 2008 final rulemaking includes estimates of risks of lung function decrements in asthmatic and all school age children, respiratory symptoms in asthmatic children, respiratory-related hospital admissions, and non-accidental and cardiorespiratory-related mortality associated with recent ambient O<sub>3</sub> levels, as well as risk reductions and remaining risks associated with just meeting the then current 0.084 ppm standard and various alternative O<sub>3</sub> standards in a number of example urban areas. There are two parts to this risk assessment: one part is based on combining information from controlled human exposure studies with modeled population exposure, and the other part is based on combining information from community epidemiological studies with either monitored or adjusted ambient concentrations levels. This assessment provides estimates of the potential magnitude of O<sub>3</sub>-related health effects, as well as a characterization of the uncertainties and variability inherent in such estimates. This assessment also provides insights into the distribution of risks and patterns of risk reductions associated with meeting alternative O<sub>3</sub> standards.

As discussed below, a substantial amount of new research conducted since the 1997 review of the O<sub>3</sub> NAAQS was available to inform the 2008 final rulemaking, with important new information coming from epidemiologic studies as well as from controlled human exposure, toxicological, and dosimetric studies. The research studies newly available in the 2008 final rulemaking that were evaluated in the 2006 Criteria Document and the exposure and risk assessments presented in the 2007 Staff Paper have undergone intensive scrutiny through multiple layers of peer review and many opportunities for public review and comment. While important

uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to exposure to ambient O<sub>3</sub>, and while different interpretations of these uncertainties can result in different public health policy judgments, the review of this information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence provides an adequate basis for this reconsideration of the 2008 final rulemaking.

#### A. Health Effects Information

This section outlines key information contained in the 2006 Criteria Document (chapters 4–8) and in the 2007 Staff Paper (chapter 3) on known or potential effects on public health which may be expected from the presence of O<sub>3</sub> in ambient air. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to O<sub>3</sub>; (2) the nature of effects that have been associated directly with exposure to O<sub>3</sub> and indirectly with the presence of O<sub>3</sub> in ambient air; (3) an integrative interpretation of the evidence, focusing on the biological plausibility and coherence of the evidence; and (4) considerations in characterizing the public health impact of O<sub>3</sub>, including the identification of "at risk" populations.

The decision in the 1997 review focused primarily on evidence from short-term (*e.g.*, 1 to 3 hours) and prolonged (6 to 8 hours) controlled-exposure studies reporting lung function decrements, respiratory symptoms, and respiratory inflammation in humans, as well as epidemiology studies reporting excess hospital admissions and emergency department (ED) visits for respiratory causes. The 2006 Criteria Document prepared for the 2008 rulemaking emphasized the large number of epidemiological studies published since the last review with these and additional health endpoints, including the effects of acute (short-term and prolonged) and chronic exposures to O<sub>3</sub> on lung function decrements and enhanced respiratory symptoms in asthmatic individuals, school absences, and premature mortality. It also emphasized important new information from toxicology, dosimetry, and controlled human exposure studies. Highlights of the evidence include:

(1) Two new controlled human-exposure studies are now available that examine respiratory effects associated with prolonged O<sub>3</sub> exposures at levels below 0.080 ppm, which was the lowest

exposure level that had been examined in the 1997 review.

(2) Numerous controlled human-exposure studies have examined indicators of O<sub>3</sub>-induced inflammatory response in both the upper respiratory tract (URT) and lower respiratory tract (LRT), and increased airway responsiveness to allergens in subjects with allergic asthma and allergic rhinitis exposed to O<sub>3</sub>, while other studies have examined changes in host defense capability following O<sub>3</sub> exposure of healthy young adults.

(3) Animal toxicology studies provide new information regarding mechanisms of action, increased susceptibility to respiratory infection, and the biological plausibility of acute effects and chronic, irreversible respiratory damage.

(4) Numerous acute exposure epidemiological studies published during the past decade offer added evidence of ambient O<sub>3</sub>-related lung function decrements and respiratory symptoms in physically active healthy subjects and greater responses in asthmatic subjects, as well as evidence on new health endpoints, such as the relationships between ambient O<sub>3</sub> concentrations and asthma medication use and school absenteeism, and between ambient O<sub>3</sub> and cardiac-related physiological endpoints.

(5) Several additional studies have been published over the last decade examining the temporal associations between O<sub>3</sub> exposures and emergency department visits for asthma and other respiratory diseases and respiratory-related hospital admissions.

(6) A large number of newly available epidemiological studies have examined the effects of acute exposure to PM and O<sub>3</sub> on mortality, notably including large multicity studies that provide much more robust and credible information than was available in the 1997 review, as well as recent meta-analyses that have evaluated potential sources of heterogeneity in O<sub>3</sub>-mortality associations.

## 1. Overview of Mechanisms

Evidence on possible mechanisms by which exposure to O<sub>3</sub> may result in acute and chronic health effects is discussed in chapters 5 and 6 of the 2006 Criteria Document.<sup>12</sup> Evidence from dosimetry, toxicological, and

<sup>12</sup> While most of the available evidence addresses mechanisms for O<sub>3</sub>, O<sub>3</sub> clearly serves as an indicator for the total photochemical oxidant mixture found in the ambient air. Some effects may be caused by one or more components in the overall pollutant mix, either separately or in combination with O<sub>3</sub>. However, O<sub>3</sub> clearly dominates these other oxidants with their concentrations only being a few percent of the O<sub>3</sub> concentration.

human exposure studies has contributed to an understanding of the mechanisms that help to explain the biological plausibility and coherence of evidence for O<sub>3</sub>-induced respiratory health effects reported in epidemiological studies. More detailed information about the physiological mechanisms related to the respiratory effects of short- and long-term exposure to O<sub>3</sub> can be found in section II.A.3.b.i and II.A.3.b.iii, respectively. In the past, however, little information was available to help explain potential biological mechanisms which linked O<sub>3</sub> exposure to premature mortality or cardiovascular effects. As discussed more fully in section II.A.3.b.ii below, since the 1997 review an emerging body of animal toxicology and controlled human exposure evidence is beginning to suggest mechanisms that may mediate acute O<sub>3</sub> cardiovascular effects. While much is known about mechanisms that play a role in O<sub>3</sub>-related respiratory effects, additional research is needed to more clearly understand the role that O<sub>3</sub> may have in contributing to cardiovascular effects.

With regard to the mechanisms related to short-term respiratory effects, scientific evidence discussed in the 2006 Criteria Document (section 5.2) indicates that reactions of O<sub>3</sub> with lipids and antioxidants in the epithelial lining fluid and the epithelial cell membranes of the lung can be the initial step in mediating deleterious health effects of O<sub>3</sub>. This initial step activates a cascade of events that lead to oxidative stress, injury, inflammation, airway epithelial damage and increased alveolar permeability to vascular fluids. Inflammation can be accompanied by increased airway responsiveness, which is an increased bronchoconstrictive response to airway irritants and allergens. Continued respiratory inflammation also can alter the ability of the body to respond to infectious agents, allergens and toxins. Acute inflammatory responses to O<sub>3</sub> in some healthy people are well documented, and precursors to lung injury are observed within 3 hours after exposure in humans. Repeated respiratory inflammation can lead to a chronic inflammatory state with altered lung structure and lung function and may lead to chronic respiratory diseases such as fibrosis and emphysema (EPA, 2006a, section 8.6.2). The severity of symptoms and magnitude of response to acute exposures depend on inhaled dose, as well as on individual susceptibility to O<sub>3</sub>, as discussed below. At the same O<sub>3</sub> dose, individuals who are more susceptible to O<sub>3</sub> will have a larger

response than those who are less susceptible; among individuals with similar susceptibility, those who receive a larger dose will have a larger response to O<sub>3</sub>.

The inhaled dose is the product of O<sub>3</sub> concentration (C), minute ventilation or ventilation rate, and duration of exposure (T), or (C × ventilation rate × T). A large body of data regarding the interdependent effect of these components of inhaled dose on pulmonary responses was assessed in the 1986 and 1996 O<sub>3</sub> Criteria Documents. In an attempt to describe O<sub>3</sub> dose-response characteristics, acute responses were modeled as a function of total inhaled O<sub>3</sub> dose, which was generally found to be a better predictor of response than O<sub>3</sub> concentration, ventilation rate, or duration of exposure, alone, or as a combination of any two of these factors (EPA 2006a, section 6.2). Predicted O<sub>3</sub>-induced decrements in lung function have been shown to be a function of exposure concentration, duration and exercise level for healthy, young adults (McDonnell *et al.*, 1997). A meta-analysis of 21 studies (Mudway and Kelly, 2004) showed that markers of inflammation and increased cellular permeability in healthy subjects are associated with total O<sub>3</sub> dose.

The 2006 Criteria Document summarizes information on potentially susceptible and vulnerable groups in section 8.7. As described there, the term *susceptibility* refers to innate (*e.g.*, genetic or developmental) or acquired (*e.g.*, personal risk factors, age) factors that make individuals more likely to experience effects with exposure to pollutants. A number of population groups and lifestages have been identified as potentially susceptible to health effects as a result of O<sub>3</sub> exposure, including people with existing lung diseases, including asthma, children and older adults, and people who have larger than normal lung function responses that may be due to genetic susceptibility. In addition, some population groups and lifestages have been identified as having increased *vulnerability* to O<sub>3</sub>-related effects due to increased likelihood of exposure while at elevated ventilation rates, including healthy children and adults who are active outdoors, for example, outdoor workers, and joggers. Taken together, the susceptible and vulnerable groups are more commonly referred to as "at-risk" groups,<sup>13</sup> as discussed more fully below in section II.A.4.b.

<sup>13</sup> In previous Staff Papers and Federal Register notices announcing proposed and final decisions on the O<sub>3</sub> and other NAAQS, EPA has used the phrase

Continued

Based on a substantial body of new evidence from animal, controlled human exposure and epidemiological studies, the 2006 Criteria Document concludes that people with asthma and other preexisting pulmonary diseases are likely to be among those at increased risk from O<sub>3</sub> exposure. Altered physiological, morphological and biochemical states typical of respiratory diseases like asthma, COPD and chronic bronchitis may render people sensitive to additional oxidative burden induced by O<sub>3</sub> exposure (EPA 2006a, section 8.7). Children and adults with asthma are the group that has been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics may exhibit larger lung function decrements in response to O<sub>3</sub> exposure than healthy controls. As discussed more fully in section II.A.4.b.ii below, asthmatics present a differential response profile for cellular, molecular, and biochemical parameters (EPA, 2006a, section 8.7.1) that are altered in response to acute O<sub>3</sub> exposure. They can have larger inflammatory responses, as manifested by larger increases in markers of inflammation such as white blood cells (e.g., PMNs) or inflammatory cytokines. Asthmatics, and people with allergic rhinitis, are more likely to mount an allergic-type response upon exposure to O<sub>3</sub>, as manifested by increases in white blood cells associated with allergy (i.e., eosinophils) and related molecules, which increase inflammation in the airways. The increased inflammatory and allergic responses also may be associated with the larger late-phase responses that asthmatics can experience, which can include increased bronchoconstrictor responses to irritant substances or allergens and additional inflammation. In addition to the experimental evidence of lung function decrements, respiratory symptoms, and other respiratory effects in asthmatic populations, two large U.S. epidemiological studies as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O<sub>3</sub> concentrations and measures of lung function and daily symptoms (e.g., chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O<sub>3</sub> and increased asthma medication use (EPA, 2007a, chapter 6). These responses in

"sensitive population groups" to include both population groups that are at increased risk because they are more intrinsically susceptible and population groups that are more vulnerable due to an increased potential for exposure. In this notice, we use the phrase, "at risk" populations to include both types of population groups.

asthmatics and others with lung disease provide biological plausibility for the more serious respiratory morbidity effects observed in epidemiological studies, such as emergency department visits and hospital admissions.

Children with and without asthma were found to be particularly susceptible to O<sub>3</sub> effects on lung function and generally have greater lung function responses than older people. The American Academy of Pediatrics (2004) notes that children and infants are among the population groups most susceptible to many air pollutants, including O<sub>3</sub>. This is in part because their lungs are still developing. For example, eighty percent of alveoli are formed after birth, and changes in lung development continue through adolescence (Dietert *et al.*, 2000). Moreover, children have high minute ventilation rates and relatively high levels of physical activity which also increases their O<sub>3</sub> dose (Plunkett *et al.*, 1992). Thus, children are at-risk due to both their susceptibility and vulnerability.

Looking more broadly at age-related differences in susceptibility, several mortality studies have investigated age-related differences in O<sub>3</sub> effects (EPA, 2006a, section 7.6.7.2), primarily in the older adult population. Among the studies that observed positive associations between O<sub>3</sub> and mortality, a comparison of all age or younger age (65 years of age) O<sub>3</sub>-mortality effect estimates to that of the elderly population (>65 years) indicates that, in general, the elderly population is more susceptible to O<sub>3</sub> mortality effects. There is supporting evidence of age-related differences in susceptibility to O<sub>3</sub> lung function effects. The 2006 Criteria Document (section 7.6.7.2) concludes that the elderly population (>65 years of age) appear to be at greater risk of O<sub>3</sub>-related mortality and hospitalizations compared to all ages or younger populations, and children (<18 years of age) experience other potentially adverse respiratory health outcomes with increased O<sub>3</sub> exposure.

Controlled human exposure studies have also indicated a high degree of interindividual variability in some of the pulmonary physiological parameters, such as lung function decrements. The variable effects in individuals have been found to be reproducible, in other words, a person who has a large lung function response after exposure to O<sub>3</sub> will likely have about the same response if exposed again to the same dose of O<sub>3</sub> (EPA 2006a, section 6.1). In controlled human exposure studies, group mean responses are not representative of this segment of

the population that has much larger than average responses to O<sub>3</sub>. Recent studies, discussed in section II.A.4.b.iv below, reported a role for genetic polymorphism (i.e., the occurrence together in the same population of more than one allele or genetic marker at the same locus with the least frequent allele or marker occurring more frequently than can be accounted for by mutation alone) in observed differences in antioxidant enzymes and genes involved in inflammation to modulate pulmonary function and inflammatory responses to O<sub>3</sub> exposure. These observations suggest a potential role for these markers in the innate susceptibility to O<sub>3</sub>, however, the validity of these markers and their relevance in the context of prediction to population studies needs additional experimentation.

Controlled human exposure studies that provide information about mechanisms of the initial response to O<sub>3</sub> (e.g., lung function decrements, inflammation, and injury to the lung) also inform the selection of appropriate lag times to analyze in epidemiological studies through elucidation of the time course of these responses (EPA 2006a, section 8.4.3). Based on the results of these studies, it would be reasonable to expect that lung function decrements could be detected epidemiologically within lags of 0 (same day) or 1 to 2 days following O<sub>3</sub> exposure, given the rapid onset of lung function changes and their persistence for 24 to 48 hours among more responsive human subjects in controlled human exposure studies. Other responses take longer to develop and can persist for longer periods of time. For example, although asthmatic individuals may begin to experience symptoms soon after O<sub>3</sub> exposure, it may take anywhere from 1 to 3 days after exposure for these subjects to seek medical attention as a result of increased airway responsiveness or inflammation that may persist for 2 to 3 days. This may be reflected by epidemiologic observations of significantly increased risk for asthma-related emergency department visits or hospital admissions with 1- to 3-day lags, or, perhaps, enhanced distributed lag risks (combined across 3 days) for such morbidity indicators. Analogously, one might project increased mortality within 0- to 3-day lags as a possible consequence of O<sub>3</sub>-induced increases in clotting agents arising from the cascade of events, starting with cell injury described above, occurring within 12 to 24 hours of O<sub>3</sub> exposure. The time course for many of these initial responses to O<sub>3</sub> is highly variable.

Moreover these observations pertain only to the initial response to O<sub>3</sub>. Consequent responses can follow. For example, Jörres *et al.*, (1996) found that in subjects with asthma and allergic rhinitis, a maximum percent fall in FEV<sub>1</sub> of 27.9% and 7.8%, respectively, occurred 3 days after O<sub>3</sub> exposure when they were challenged with of the highest common dose of allergen.

## 2. Nature of Effects

The 2006 Criteria Document provides new evidence that notably enhances our understanding of short-term and prolonged exposure effects, including effects on lung function, symptoms, and inflammatory effects reported in controlled exposure studies. These studies support and extend the findings of the previous Criteria Document. There is also a significant body of new epidemiological evidence of associations between short-term and prolonged exposure to O<sub>3</sub> and effects such as premature mortality, hospital admissions and emergency department visits for respiratory (*e.g.*, asthma) causes. Key epidemiological and controlled human exposure studies are summarized below and discussed in chapter 3 of the 2007 Staff Paper, which is based on scientific evidence critically reviewed in chapters 5, 6, and 7 of the 2006 Criteria Document, as well as the Criteria Document's integration of scientific evidence contained in chapter 8.<sup>14</sup> Conclusions drawn about O<sub>3</sub>-related health effects are based upon the full body of evidence from controlled human exposure, epidemiological and toxicological data contained in the 2006 Criteria Document.

### a. Morbidity

This section summarizes scientific information on the effects of inhalation of O<sub>3</sub>, including public health effects of short-term, prolonged, and long-term exposures on respiratory morbidity and cardiovascular system effects, as discussed in chapters 6, 7 and 8 of the 2006 Criteria Document and chapter 3 of the 2007 Staff Paper. This section also summarizes the uncertainty about the potential indirect effects on public health associated with changes due to increases in UV-B radiation exposure, such as UV-B radiation-related skin cancers, that may be associated with reductions in ambient levels of ground-level O<sub>3</sub>, as discussed in chapter 10 of the 2006 Criteria Document and chapter 3 of the 2007 Staff Paper.

<sup>14</sup>Health effects discussions are also drawn from the more detailed information and tables presented in the Criteria Document's annexes.

### i. Effects on the Respiratory System From Short-term and Prolonged O<sub>3</sub> Exposures

Controlled human exposure studies have shown that O<sub>3</sub> induces a variety of health effects, including: Lung function decrements, respiratory symptoms, increased airway responsiveness, respiratory inflammation and permeability, increased susceptibility to respiratory infection, and acute morphological effects. Epidemiology studies have reported associations between O<sub>3</sub> exposures (*i.e.*, 1-hour, 8-hour and 24-hour) and a wide range of respiratory-related health effects including: pulmonary function decrements; respiratory symptoms; increased asthma medication use; increased school absences; increased emergency department visits and hospital admissions.

#### (a) Pulmonary Function Decrements, Respiratory Symptoms, and Asthma Medication Use

##### (i) Results From Controlled Human Exposure Studies

A large number of studies published prior to 1996 that investigated short-term O<sub>3</sub> exposure health effects on the respiratory system from short-term O<sub>3</sub> exposures were reviewed in the 1986 and 1996 Criteria Documents (EPA, 1986, 1996a). In the 1997 review, 0.50 ppm was the lowest O<sub>3</sub> concentration at which statistically significant reductions in forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV<sub>1</sub>) were reported in sedentary subjects. During exercise, spirometric (lung function) and symptomatic responses were observed at much lower O<sub>3</sub> exposures. When minute ventilation was considerably increased by continuous exercise (CE) during O<sub>3</sub> exposures lasting 2 hour or less at  $\geq 0.12$  ppm, healthy subjects generally experienced decreases in FEV<sub>1</sub>, FVC, and other measures of lung function; increases in specific airway resistance (sRaw), breathing frequency, and airway responsiveness; and symptoms such as cough, pain on deep inspiration, shortness of breath, throat irritation, and wheezing. When exposures were increased to 4- to 8-hours in duration, statistically significant lung function and symptom responses were reported at O<sub>3</sub> concentrations as low as 0.08 ppm and at lower minute ventilation (*i.e.*, moderate rather than high level exercise) than the shorter duration studies.

The most important observations drawn from studies reviewed in the 1996 Criteria Document were that: (1)

Young healthy adults exposed to O<sub>3</sub> concentrations  $\geq 0.080$  ppm develop significant, reversible, transient decrements in pulmonary function if minute ventilation or duration of exposure is increased sufficiently; (2) children experience similar lung function responses but report lesser symptoms from O<sub>3</sub> exposure relative to young adults; (3) O<sub>3</sub>-induced lung function responses are decreased in the elderly relative to young adults; (4) there is a large degree of intersubject variability in physiological and symptomatic responses to O<sub>3</sub> but responses tend to be reproducible within a given individual over a period of several months; (5) subjects exposed repeatedly to O<sub>3</sub> for several days show an attenuation of response upon successive exposures, but this attenuation is lost after about a week without exposure; and (6) acute O<sub>3</sub> exposure initiates an inflammatory response which may persist for at least 18 to 24 hours post exposure.

The development of these respiratory effects is time-dependent during both exposure and recovery periods, with great overlap for development and disappearance of the effects. In healthy human subjects exposed to typical ambient O<sub>3</sub> levels near 0.120 ppm, lung function responses largely resolve within 4 to 6 hours postexposure, but cellular effects persist for about 24 hours. In these healthy subjects, small residual lung function effects are almost completely gone within 24 hours, while in hyperresponsive subjects, recovery can take as much as 48 hour to return to baseline. The majority of these responses are attenuated after repeated consecutive exposures, but such attenuation to O<sub>3</sub> is lost one week postexposure.

Since 1996, there have been a number of studies published investigating lung function and symptomatic responses that generally support the observations previously drawn. Recent studies for acute exposures of 1 to 2 hours and 6 to 8 hours in duration are compiled in the 2007 Staff Paper (Appendix 3C). As summarized in more detail in the 2007 Staff Paper (section 3.3.1.1), among the more important of the recent studies that examined changes in FEV<sub>1</sub> in large numbers of subjects over a range of 1-2 hours at exposure levels of 0.080 to 0.40 ppm were studies by McDonnell *et al.* (1997) and Ultman *et al.* (2004). These studies observed considerable intersubject variability in FEV<sub>1</sub> decrements, which was consistent with findings in the 1996 Criteria Document.

For prolonged exposures (4 to 8 hours) in the range of 0.080 to 0.160 ppm-O<sub>3</sub> using moderate intermittent

exercise and typically using square-wave exposure patterns (*i.e.*, a constant exposure level during time of exposure), several pre- and post-1996 studies (Folinsbee *et al.*, 1988, 1994; Horstman *et al.*, 1990; Adams, 2002, 2003a, 2006) have reported statistically significant lung function responses and increased symptoms in healthy adults with increasing duration of exposure, O<sub>3</sub> concentration, and minute ventilation. Studies that employed triangular exposure patterns (*i.e.*, integrated exposures that begin at a low level, rise to a peak, and return to a low level during the exposure) (Hazucha *et al.*, 1992; Adams 2003a, 2006) suggest that the triangular exposure pattern can potentially lead to greater FEV<sub>1</sub> decrements and respiratory symptoms than square-wave exposures (when the overall O<sub>3</sub> doses are equal). These results suggest that peak exposures, reflective of the pattern of ambient O<sub>3</sub> concentrations in some locations, are important in terms of O<sub>3</sub> health effects.

McDonnell (1996) used data from a series of studies to investigate the frequency distributions of FEV<sub>1</sub> decrements following 6.6 hour exposures and found statistically significant, but relatively small, group mean decreases in average FEV<sub>1</sub> responses (between 5 and 10 percent) at 0.080 ppm O<sub>3</sub>.<sup>15</sup> Notably, about 26 percent of the 60 exposed subjects had lung function decrements > 10 percent, including about 8 percent of the subjects that experienced large decrements (> 20 percent) (EPA, 2007b, Figure 3-1A). These results (which were not corrected for exercise in filtered air responses) demonstrate that while average responses may be relatively small at the 0.080 ppm exposure level, some individuals experience more severe effects that may be clinically significant. Similar results at the 0.080 ppm exposure level (for 6.6 hours during intermittent exercise) were seen in more recent studies of 30 healthy young adults by Adams (2002, 2006).<sup>16</sup> In Adams (2006), relatively small but statistically significant lung function decrements and respiratory symptom responses were found (for both square-wave and triangular exposure patterns), with 17 percent of the subjects (5 of 30) experiencing ≥ 10 percent FEV<sub>1</sub>

decrements (comparing pre- and post-exposures) when the results were not corrected for the effects of exercise alone in filtered air (EPA, 2007b, Figure 3-1B) and with 23 percent of subjects (7 of 30) experiencing such effects when the results were corrected (EPA, 2007b, p. 3-6).<sup>17</sup>

These studies by Adams (2002, 2006) were notable in that they were the only controlled exposure human studies available at the time of the 2008 rulemaking that examined respiratory effects associated with prolonged O<sub>3</sub> exposures at levels below 0.080 ppm, which was the lowest exposure level that had been examined in the 1997 review. The Adams (2006) study investigated a range of exposure levels (0.000, 0.040, 0.060, and 0.080 ppm O<sub>3</sub>) using square-wave and triangular exposure patterns. The study was designed to examine hour-by-hour changes in pulmonary function (FEV<sub>1</sub>) and respiratory symptom responses (total subjective symptoms (TSS) and pain on deep inspiration (PDI)) between these various exposure protocols at six different time points within the exposure periods to investigate the effects of different patterns of exposure. At the 0.060 ppm exposure level, the author reported no statistically significant differences for FEV<sub>1</sub> decrements nor for most respiratory symptoms responses. Statistically significant responses were reported only for TSS for the triangular exposure pattern toward the end of the exposure period, with the PDI responses being noted as following a closely similar pattern (Adams, 2006, p. 131-132). EPA's reanalysis of the data from the Adams (2006) study addressed the more fundamental question of whether there were statistically significant differences in responses before and after the 6.6 hour exposure period (Brown, 2007), and used a standard statistical method appropriate for a simple before-and-after comparison. The statistical method used by EPA had been used previously by other researchers to address this same question. EPA's reanalysis of the data from the Adams (2006) study, comparing FEV<sub>1</sub> responses pre- and post-exposure at the 0.060 ppm exposure level, found small group mean differences from responses to filtered air that were statistically significant (Brown, 2007).<sup>18</sup>

Further examination of the post-exposure FEV<sub>1</sub> data and mean data at other time points and concentrations also suggest a pattern of response at 0.06 ppm that is consistent with a dose-response relationship rather than random variability. For example, the response at 5.6 hours was similar to that of the post-exposure 6.6 hour response and appeared to also differ from the FA response. At the 0.08 ppm level, the subjects in this study did not appear to be more responsive to O<sub>3</sub> than subjects in previous studies, as the observed response was similar to that of previous studies (Adams, 2003a,b; Horstman *et al.*, 1990; McDonnell *et al.*, 1991). Although of much smaller magnitude, the temporal pattern of the 0.06 ppm response was generally consistent with the temporal patterns of response to higher concentrations of O<sub>3</sub> in this and other studies. These findings are not unexpected because the previously observed group mean FEV<sub>1</sub> responses to 0.08 ppm were in the range of 6-9% suggesting that exposure to lower concentrations of O<sub>3</sub> would result in smaller, but real group mean FEV<sub>1</sub> decrements, *i.e.*, the responses to 0.060 ppm O<sub>3</sub> are consistent with the presence of a smooth exposure-response curve with responses that do not end abruptly below 0.080 ppm.

Moreover, the Adams studies (2002, 2006) also report a small percentage of subjects experiencing moderate lung function decrements (≥ 10 percent) at the 0.060 ppm exposure level. Based on study data (Adams, 2006) provided by the author, 7 percent of the subjects (2 of 30 subjects) experienced notable FEV<sub>1</sub> decrements (≥ 10 percent) with the square wave exposure pattern at the 0.060 ppm exposure level (comparing pre- and post-exposures) when the results were corrected for the effects of exercise alone in filtered air (EPA, 2007b, p. 3-6). Furthermore, in a prior publication (Adams, 2002), the author stated that, "some sensitive subjects experience notable effects at 0.06 ppm," based on the observation that 20% of subjects exposed to 0.06 ppm O<sub>3</sub> (in a face mask exposure study) had greater than a 10% decrement in FEV<sub>1</sub> even though the group mean response was not statistically different from the filtered air response. The effects described by Adams (2002), along with

exposure level in his study (Adams, 2006a) does not demonstrate a significant mean effect by ordinarily acceptable statistical analysis, but is rather in somewhat of a gray area, both in terms of a biologically meaningful response and a statistically significant response (Adams, 2007). The EPA responded to these comments in the 2008 final rule (73 FR 16455) and in the Response to Comments (EPA, 2008, pp. 26-28).

<sup>15</sup> This study and other studies (Folinsbee *et al.*, 1988; Horstman *et al.*, 1990; and McDonnell *et al.*, 1991), conducted in EPA's human studies research facility in Chapel Hill, NC, measured ozone concentrations to within +/- 5 percent or +/- 0.004 ppm at the 0.080 ppm exposure level.

<sup>16</sup> These studies, conducted at a facility at the University of California, in Davis, CA, reported O<sub>3</sub> concentrations to be accurate within +/- 0.003 ppm over the range of concentrations included in these studies.

<sup>17</sup> These distributional results presented in the Criteria Document and Staff Paper for the Adams (2006) study are based on data for square-wave exposures to 0.080 ppm that were not included in the publication but were obtained from the author.

<sup>18</sup> Dr. Adams submitted comments on EPA's reanalysis in which he concluded that the FEV<sub>1</sub> response in healthy young adults at the 0.060 ppm



the reanalysis of the Adams (2006) data as described above, demonstrate considerable inter-individual variability in responses of healthy adults at the 0.060 ppm level with some individuals experiencing greater than 10% decrements in FEV<sub>1</sub>. The observation of statistically significant small group mean lung function decrements in healthy adults at 0.060 ppm O<sub>3</sub> lowers the lowest-observed-effects level found in controlled human exposure studies for lung function decrements and respiratory symptoms.

Of potentially greater concern is the magnitude of the lung function decrements in the small group of healthy subjects who had the largest responses (*i.e.*, FEV<sub>1</sub> decrements  $\geq$  10%). This is a concern because for active healthy people, moderate levels of functional responses (*e.g.*, FEV<sub>1</sub> decrements of  $\geq$  10% but  $<$  20%) and/or moderate symptomatic responses would likely interfere with normal activity for relatively few responsive individuals. However, for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication (see section II.A.4 below).

#### (ii) Results of Epidemiological and Field Studies

A relatively large number of field studies investigating the effects of ambient O<sub>3</sub> concentrations, in combination with other air pollutants, on lung function decrements and respiratory symptoms has been published over the last decade that support the major findings of the 1996 Criteria Document that lung function changes, as measured by decrements in FEV<sub>1</sub> or peak expiratory flow (PEF), and respiratory symptoms in healthy adults and asthmatic children are closely correlated to ambient O<sub>3</sub> concentrations. Pre-1996 field studies focused primarily on children attending summer camps and found O<sub>3</sub>-related impacts on measures of lung function, but not respiratory symptoms, in healthy children. The newer studies have expanded to evaluate O<sub>3</sub>-related effects on outdoor workers, athletes, the elderly, hikers, school children, and asthmatics. Collectively, these studies confirm and extend clinical observations that prolonged (*i.e.*, 6–8 hour) exposure periods, combined with elevated levels of exertion or exercise, increase the dose of O<sub>3</sub> to the lungs at a given ambient exposure level and result in larger lung function effects. The results of one large study of hikers (Korrick *et al.*, 1998), which reported

outcome measures stratified by several factors (*e.g.*, gender, age, smoking status, presence of asthma) within a population capable of more than normal exertion, provide useful insight. In this study, lung function was measured before and after hiking, and individual O<sub>3</sub> exposures were estimated by averaging hourly O<sub>3</sub> concentrations from ambient monitors located at the base and summit. The mean 8-hour average O<sub>3</sub> concentration was 0.040 ppm (8-hour average concentration range of 0.021 ppm to 0.074 ppm O<sub>3</sub>). Decreased lung function was associated with O<sub>3</sub> exposure, with the greatest effect estimates reported for the subgroup that reported having asthma or wheezing, and for those who hiked for longer periods of time.

Asthma panel studies conducted both in the U.S. and in other countries have reported that decrements in PEF are associated with routine O<sub>3</sub> exposures among asthmatic and healthy people. One large U.S. multicity study, the National Cooperative Inner City Asthma Study or NCICAS, (Mortimer *et al.*, 2002) examined O<sub>3</sub>-related changes in PEF in 846 asthmatic children from 8 urban areas and reported that the incidence of  $\geq$  10 percent decrements in morning PEF are associated with increases in 8-hour average O<sub>3</sub> for a 5-day cumulative lag, suggesting that O<sub>3</sub> exposure may be associated with clinically significant changes in PEF in asthmatic children; however, no associations were reported with evening PEF. The mean 8-hour average O<sub>3</sub> was 0.048 ppm across the 8 cities. Excluding days when 8-hour average O<sub>3</sub> was greater than 0.080 ppm (less than 5 percent of days), the associations with morning PEF remained statistically significant. Mortimer *et al.* (2002) discussed potential biological mechanisms for delayed effects on pulmonary function in asthma, which included increased nonspecific airway responsiveness secondary to airway inflammation due to O<sub>3</sub> exposure. Two other panel studies (Romieu *et al.*, 1996, 1997) carried out simultaneously in northern and southwestern Mexico City with mildly asthmatic school children reported statistically significant O<sub>3</sub>-related reductions in PEF, with variations in effect depending on lag time and time of day. Mean 1-hour maximum O<sub>3</sub> concentrations in these locations ranged from 0.190 ppm in northern Mexico City to 0.196 ppm in southwestern Mexico City. While several studies report statistically significant associations between O<sub>3</sub> exposure and reduced PEF in asthmatics, other studies did not,

possibly due to low levels of O<sub>3</sub> exposure. EPA concludes that these studies collectively indicate that O<sub>3</sub> may be associated with short-term declines in lung function in asthmatic individuals and that the Mortimer *et al.* (2002) study showed statistically significant effects at concentrations in the range below 0.080 ppm O<sub>3</sub>.

Most of the panel studies which have investigated associations between O<sub>3</sub> exposure and respiratory symptoms or increased use of asthma medication are focused on asthmatic children. Two large U.S. studies (Mortimer *et al.*, 2002; Gent *et al.*, 2003) have reported associations between ambient O<sub>3</sub> concentrations and daily symptoms/asthma medication use, even after adjustment for copollutants. Results were more mixed, meaning that a greater proportion of studies were not both positive and statistically significant, across smaller U.S. and international studies that focused on these health endpoints.

The NCICAS reported morning symptoms in 846 asthmatic children from 8 U.S. urban areas to be most strongly associated with a cumulative 1- to 4-day lag of O<sub>3</sub> concentrations (Mortimer *et al.*, 2002). The NCICAS used standard protocols that included instructing caretakers of the subjects to record symptoms (including cough, chest tightness, and wheeze) in the daily diary by observing or asking the child. While these associations were not statistically significant in several cities, when the individual data are pooled from all eight cities, statistically significant effects were observed for the incidence of symptoms. The authors also reported that the odds ratios remained essentially the same and statistically significant for the incidence of morning symptoms when days with 8-hour O<sub>3</sub> concentrations above 0.080 ppm were excluded. These days represented less than 5 percent of days in the study.

Gent and colleagues (2003) followed 271 asthmatic children under age 12 and living in southern New England for 6 months (April through September) using a daily symptom diary. They found that mean 1-hour max O<sub>3</sub> and 8-hour max O<sub>3</sub> concentrations were 0.0586 ppm and 0.0513 ppm, respectively. The data were analyzed for two separate groups of subjects, those who used maintenance asthma medications during the follow-up period and those who did not. The need for regular medication was considered to be a proxy for more severe asthma. Not taking any medication on a regular basis and not needing to use a bronchodilator would suggest the

presence of very mild asthma. Statistically significant effects of 1-day lag  $O_3$  were observed on a variety of respiratory symptoms only in the medication user group. Both daily 1-hour max and 8-hour max  $O_3$  concentrations were similarly related to symptoms such as chest tightness and shortness of breath. Effects of  $O_3$ , but not  $PM_{2.5}$ , remained significant and even increased in magnitude in two-pollutant models. Some of the associations were noted at 1-hour max  $O_3$  levels below 0.060 ppm. In contrast, no effects were observed among asthmatics not using maintenance medication. In terms of person-days of follow-up, this is one of the larger studies currently available that address symptom outcomes in relation to  $O_3$  and provides supportive evidence for effects of  $O_3$  independent of  $PM_{2.5}$ . Study limitations include the post-hoc nature of the population stratification by medication use. Also, the study did not account for all of the important meteorological factors that might influence these results, such as relative humidity or dew point.

The multicity study by Mortimer *et al.* (2002), which examined an asthmatic population representative of the United States, and several single-city studies indicate a robust association of  $O_3$  concentrations with respiratory symptoms and increased medication use in asthmatics. While there are a number of well-conducted, albeit relatively smaller, U.S. studies which showed only limited or a lack of evidence for symptom increases associated with  $O_3$  exposure, these studies had less statistical power and/or were conducted in areas with relatively low 1-hour maximum average  $O_3$  levels, in the range of 0.03 to 0.09 ppm. The 2006 Criteria Document concludes that the asthma panel studies, as a group, and the NCI-CAS in particular, indicate a positive association between ambient concentrations and respiratory symptoms and increased medication use in asthmatics. The evidence has continued to expand since 1996 and now is considered to be much stronger than in the 1997 review of the  $O_3$  primary standard.

School absenteeism is another potential surrogate for the health implications of  $O_3$  exposure in children. The association between school absenteeism and ambient  $O_3$  concentrations was assessed in two relatively large field studies. The first study, Chen *et al.* (2000), examined total daily school absenteeism in about 28,000 elementary school students in Nevada over a 2-year period (after adjusting for  $PM_{10}$  and CO

concentrations) and found that ambient  $O_3$  concentrations with a distributed lag of 14 days were statistically significantly associated with an increased rate of school absences. The second study, Gilliland *et al.* (2001), studied  $O_3$ -related absences among about 2,000 4th grade students in 12 southern California communities and found statistically significant associations between 8-hour average  $O_3$  concentrations (with a distributed lag out to 30 days) and all absence categories, and particularly for respiratory causes. Neither  $PM_{10}$  nor  $NO_2$  were associated with any respiratory or nonrespiratory illness-related absences in single pollutant models. The 2006 Criteria Document concludes that these studies of school absences suggest that ambient  $O_3$  concentrations, accumulated over two to four weeks, may be associated with school absenteeism, and particularly illness-related absences, but further replication is needed before firm conclusions can be reached regarding the effect of  $O_3$  on school absences. In addition, more research is needed to help shed light on the implications of variation in the duration of the lag structures (*i.e.*, 1 day, 5 days, 14 days, and 30 days) found both across studies and within data sets by health endpoint and exposure metric.

#### (b) Increased Airway Responsiveness

As discussed in more detail in the 2006 Criteria Document (section 6.8) and the 2007 Staff Paper (section 3.3.1.1.2), increased airway responsiveness, also known as airway hyperresponsiveness (AHR) or bronchial hyperreactivity, refers to a condition in which the propensity for the airways to bronchoconstrict due to a variety of stimuli (*e.g.*, exposure to cold air, allergens, or exercise) becomes augmented. This condition is typically quantified by measuring the decrement in pulmonary function after inhalation exposure to specific (*e.g.*, antigen, allergen) or nonspecific (*e.g.*, methacholine, histamine) bronchoconstrictor stimuli. Exposure to  $O_3$  causes an increase in airway responsiveness as indicated by a reduction in the concentration of stimuli required to produce a given reduction in  $FEV_1$  or increase in airway obstruction. Increased airway responsiveness is an important consequence of exposure to  $O_3$  because its presence means that the airways are predisposed to narrowing on exposure to various stimuli, such as specific allergens, cold air or  $SO_2$ . Statistically significant and clinically relevant decreases in pulmonary function have

been observed in early phase allergen response in subjects with allergic rhinitis after consecutive (4-day) 3-hour exposures to 0.125 ppm  $O_3$  (Holz *et al.*, 2002). Similar increased airway responsiveness in asthmatics to house dust mite antigen 16 to 18 hours after exposure to a single dose of  $O_3$  (0.160 ppm for 7.6 hours) was observed. These observations, based on  $O_3$  exposures to levels much higher than the 0.084 ppm standard level suggest that  $O_3$  exposure may be a clinically important factor that can exacerbate the response to ambient bronchoconstrictor substances in individuals with preexisting allergic asthma or rhinitis. Further,  $O_3$  may have an immediate impact on the lung function of asthmatics as well as contribute to effects that persist for longer periods.

Kreit *et al.* (1989) found that  $O_3$  can induce increased airway responsiveness in asthmatic subjects to  $O_3$ , who typically have increased airway responsiveness at baseline. A subsequent study (Jörres *et al.*, 1996) suggested an increase in specific (*i.e.*, allergen-induced) airway reactivity in subjects with allergic asthma, and to a lesser extent in subjects with allergic rhinitis after short-term exposure to higher  $O_3$  levels; other studies reported similar results. According to one study (Folinsbee and Hazucha, 2000), changes in airway responsiveness after  $O_3$  exposure resolve more slowly than changes in  $FEV_1$  or respiratory symptoms. Other studies of repeated exposure to  $O_3$  suggest that changes in airway responsiveness tend to be somewhat less affected by attenuation with consecutive exposures than changes in  $FEV_1$  (EPA, 2006a, section 6.8).

The 2006 Criteria Document (section 6.8) concludes that  $O_3$  exposure is linked with increased airway responsiveness. Both human and animal studies indicate that increased airway responsiveness is not mechanistically associated with inflammation, and does not appear to be strongly associated with initial decrements in lung function or increases in symptoms. As a result of increased airway responsiveness induced by  $O_3$  exposure, human airways may be more susceptible to a variety of stimuli, including antigens, chemicals, and particles. Because asthmatic subjects typically have increased airway responsiveness at baseline, enhanced bronchial response to antigens in asthmatics raises potential public health concerns as they could lead to increased morbidity (*e.g.*, medication usage, school absences, emergency room visits, hospital admissions) or to more persistent alterations in airway

responsiveness (EPA 2006a, p. 8–21). As such, increased airway responsiveness after O<sub>3</sub> exposure represents a plausible link between O<sub>3</sub> exposure and increased hospital admissions.

(c) Respiratory Inflammation and Increased Permeability

Based on evidence from the 1997 review, acute inflammatory responses in the lung have been observed subsequent to 6.6 hour O<sub>3</sub> exposures to the lowest tested level—0.080 ppm—in healthy adults engaged in moderately high exercise (section 6.9 of the 2006 Criteria Document and section 3.3.1.3 of the 2007 Staff Paper). Some of these prior studies suggest that inflammatory responses may be detected in some individuals following O<sub>3</sub> exposures in the absence of O<sub>3</sub>-induced pulmonary decrements in those subjects. These studies also demonstrate that short-term exposures to O<sub>3</sub> also can cause increased permeability in the lungs of humans and experimental animals. Inflammatory responses and epithelial permeability have been seen to be independent of spirometric responses. Not only are the newer lung inflammation and increased cellular permeability findings discussed in the 2006 Criteria Document (section 8.4.2) consistent with the 1997 review, but they provide better characterization of the physiological mechanisms by which O<sub>3</sub> causes these effects.

Lung inflammation and increased permeability, which are distinct events controlled by different mechanisms, are two commonly observed effects of O<sub>3</sub> exposure observed in all of the species studied. Increased cellular permeability is a disruption of the lung barrier that leads to leakage of serum proteins, influx of polymorphonuclear leukocytes (neutrophils or PMNs), release of bioactive mediators, and movement of compounds from the airspaces into the blood.

A number of controlled human exposure studies have analyzed bronchoalveolar lavage (BAL) and nasal lavage (NL)<sup>19</sup> fluids and cells for markers of inflammation and lung damage (EPA, 2006a, Annex AX6). Increased lung inflammation is demonstrated by the presence of neutrophils found in BAL fluid in the lungs, which has long been accepted as a hallmark of inflammation. It is apparent, however, that inflammation

within airway tissues may persist beyond the point that inflammatory cells are found in the BAL fluid. Soluble mediators of inflammation, such as cytokines and arachidonic acid metabolites have been measured in the BAL fluid of humans exposed to O<sub>3</sub>. In addition to their role in inflammation, many of these compounds have bronchoconstrictive properties and may be involved in increased airway responsiveness following O<sub>3</sub> exposure. An in vitro study of epithelial cells from nonatopic and atopic asthmatics exposed to 0.010 to 0.100 ppm O<sub>3</sub> showed significantly increased permeability compared to cells from normal persons. This indicates a potentially inherent susceptibility of cells from asthmatic individuals for O<sub>3</sub>-induced permeability.

In the 1996 Criteria Document, assessment of controlled human exposure studies indicated that a single, acute (1 to 4 hours) O<sub>3</sub> exposure (≥ 0.080 to 0.100 ppm) of subjects engaged in moderate to heavy exercise could induce a number of cellular and biochemical changes suggestive of pulmonary inflammation and lung permeability (EPA, 2006a, p. 8–22). These changes persisted for at least 18 hours. Markers from BAL fluid following both 2-hour and 4-hour O<sub>3</sub> exposures repeated up to 5 days indicate that there is ongoing cellular damage irrespective of attenuation of some cellular inflammatory responses of the airways, pulmonary function, and symptom scores (EPA, 2006a, p. 8–22). Acute airway inflammation was shown in Devlin *et al.* (1990) to occur among adults exposed to 0.080 ppm O<sub>3</sub> for 6.6 hours with exercise. McBride *et al.* (1994) reported that asthmatic subjects were more sensitive than non-asthmatics to upper airway inflammation for O<sub>3</sub> exposures that did not affect pulmonary function (EPA, 2006a, p. 6–33). However, the public health significance of these changes is not entirely clear.

The studies reporting inflammatory responses and markers of lung injury have clearly demonstrated that there is significant variation in response of subjects exposed, especially to 6.6 hours O<sub>3</sub> exposures at 0.080 and 0.100 ppm. To provide some perspective on the public health impact for these effects, the 2007 Staff Paper (section 3.3.1.1.3) notes that one study (Devlin *et al.*, 1991) showed that roughly 10 to 50 percent of the 18 young healthy adult subjects experienced notable increases (*i.e.*, ≥ 2 fold increase) in most of the inflammatory and cellular injury indicators analyzed, associated with 6.6-hour exposures at 0.080 ppm. Similar,

although in some cases higher, fractions of the population of 10 healthy adults tested saw > 2 fold increases associated with 6.6-hour exposures to 0.100 ppm. The authors of this study expressed the view that “susceptible subpopulations such as the very young, elderly, and people with pulmonary impairment or disease may be even more affected” (Devlin *et al.*, 1991).

Since 1996, a substantial number of human exposure studies have been published which have provided important new information on lung inflammation and epithelial permeability. Mudway and Kelly (2004) examined O<sub>3</sub>-induced inflammatory responses and epithelial permeability with a meta-analysis of 21 controlled human exposure studies and showed that an influx in neutrophils and protein in healthy subjects is associated with total O<sub>3</sub> dose (product of O<sub>3</sub> concentration, exposure duration, and minute ventilation) (EPA, 2006a, p. 6–34). Results of the analysis suggest that the time course for inflammatory responses (including recruitment of neutrophils and other soluble mediators) is not clearly established, but there is evidence that attenuation profiles for many of these parameters are different (EPA, 2006a, p. 8–22).

The 2006 Criteria Document (chapter 8) concludes that interaction of O<sub>3</sub> with lipid constituents of epithelial lining fluid (ELF) and cell membranes and the induction of oxidative stress is implicated in injury and inflammation. Alterations in the expression of cytokines, chemokines, and adhesion molecules, indicative of an ongoing oxidative stress response, as well as injury repair and regeneration processes, have been reported in animal toxicology and human in vitro studies evaluating biochemical mediators implicated in injury and inflammation. While antioxidants in ELF confer some protection, O<sub>3</sub> reactivity is not eliminated at environmentally relevant exposures (2006 Criteria Document, p. 8–24). Further, antioxidant reactivity with O<sub>3</sub> is both species-specific and dose-dependent.

(d) Increased Susceptibility to Respiratory Infection

As discussed in more detail in the 2006 Criteria Document (sections 5.2.2, 6.9.6, and 8.4.2), short-term exposures to O<sub>3</sub> have been shown to impair physiological defense capabilities in experimental animals by depressing alveolar macrophage (AM) functions and by altering the mucociliary clearance of inhaled particles and microbes resulting in increased susceptibility to respiratory infection.

<sup>19</sup>Graham and Koren (1990) compared inflammatory mediators present in NL and BAL fluids of humans exposed to 0.4 ppm O<sub>3</sub> for 2 hours and found similar increases in PMNs in both fluids, suggesting a qualitative correlation between inflammatory changes in the lower airways (BAL) and upper respiratory tract (NL).

Short-term O<sub>3</sub> exposures also interfere with the clearance process by accelerating clearance for low doses and slowing clearance for high doses. Animal toxicological studies have reported that acute O<sub>3</sub> exposures suppress alveolar phagocytosis and immune system functions. Impairment of host defenses and subsequent increased susceptibility to bacterial lung infection in laboratory animals has been induced by short-term exposures to O<sub>3</sub> levels as low as 0.080 ppm.

A single controlled human exposure study reviewed in the 1996 Criteria Document (p. 8–26) reported that exposure to 0.080 to 0.100 ppm O<sub>3</sub> for 6.6 hours (with moderate exercise) induced decrements in the ability of AMs to phagocytose microorganisms. Integrating the recent animal study results with human exposure evidence available in the 1996 Criteria Document, the 2006 Criteria Document concludes that available evidence indicates that short-term O<sub>3</sub> exposures have the potential to impair host defenses in humans, primarily by interfering with AM function. Any impairment in AM function may lead to decreased clearance of microorganisms or nonviable particles. Compromised AM functions in asthmatics may increase their susceptibility to other O<sub>3</sub> effects, the effects of particles, and respiratory infections (EPA, 2006a, p. 8–26).

#### (e) Morphological Effects

The 1996 Criteria Document found that short-term O<sub>3</sub> exposures cause similar alterations in lung morphology in all laboratory animal species studied, including primates. As discussed in the 2007 Staff Paper (section 3.3.1.1.5), cells in the centriacinar region (CAR) of the lung (the segment between the last conducting airway and the gas exchange region) have been recognized as a primary target of O<sub>3</sub>-induced damage (epithelial cell necrosis and remodeling of respiratory bronchioles), possibly because epithelium in this region receives the greatest dose of O<sub>3</sub> delivered to the lower respiratory tract. Following chronic O<sub>3</sub> exposure, structural changes have been observed in the CAR, the region typically affected in most chronic airway diseases of the human lung (EPA, 2006a, p. 8–24).

Ciliated cells in the nasal cavity and airways, as well as Type I cells in the gas-exchange region, are also identified as targets. While short-term O<sub>3</sub> exposures can cause epithelial cell proliferation and fibrotic changes in the CAR, these changes appear to be transient with recovery occurring after exposure, depending on species and O<sub>3</sub> dose. The potential impacts of repeated

short-term and chronic morphological effects of O<sub>3</sub> exposure are discussed below in the section on effects from long-term exposures. Long-term or prolonged exposure has been found to cause chronic lesions similar to early lesions found in individuals with respiratory bronchiolitis, which have the potential to progress to fibrotic lung disease (2006 Criteria Document, p. 8–25).

Recent studies continue to show that short-term and sub-chronic exposures to O<sub>3</sub> cause similar alterations in lung structure in a variety of experimental animal species. For example, a series of new studies that used infant rhesus monkeys and simulated seasonal ambient exposure (0.5 ppm 8 hours/day for 5 days, every 14 days for 11 episodes) reported remodeling in the distal airways; abnormalities in tracheal basement membrane; eosinophil accumulation in conducting airways; and decrements in airway innervation (2006 Criteria Document, p. 8–25). Based on evidence from animal toxicological studies, short-term and sub-chronic exposures to O<sub>3</sub> can cause morphological changes in the respiratory systems, particularly in the CAR, of a number of laboratory animal species (EPA, 2006a, section 5.2.4).

#### (f) Emergency Department Visits/Hospital Admissions for Respiratory Causes

Increased summertime emergency department visits and hospital admissions for respiratory causes have been associated with ambient exposures to O<sub>3</sub>. As discussed in section 3.3.1.1.6 of the 2007 Staff Paper, numerous studies conducted in various locations in the U.S. and Canada consistently have shown a relationship between ambient O<sub>3</sub> levels and increased incidence of emergency department visits and hospital admissions for respiratory causes, even after controlling for modifying factors, such as weather and copollutants. Such associations between elevated ambient O<sub>3</sub> during summer months and increased hospital admissions have a plausible biological basis in the human and animal evidence of functional, symptomatic, and physiologic effects discussed above and in the increased susceptibility to respiratory infections observed in laboratory animals.

In the 1997 review of the O<sub>3</sub> NAAQS, the Criteria Document evaluated emergency department visits and hospital admissions as possible outcomes following exposure to O<sub>3</sub> (EPA, 2006a, section 7.3). The evidence was limited for emergency department visits, but results of several studies

generally indicated that short-term exposures to O<sub>3</sub> were associated with respiratory emergency department visits. The strongest and most consistent evidence, at both lower levels (*i.e.*, below 0.120 ppm 1-hour max O<sub>3</sub>) and at higher levels (above 0.120 ppm 1-hour max O<sub>3</sub>), was found in the group of studies which investigated summertime<sup>20</sup> daily hospital admissions for respiratory causes in different eastern North American cities. These studies consistently demonstrated that ambient O<sub>3</sub> levels were associated with increased hospital admissions and accounted for about one to three excess respiratory hospital admissions per million persons with each 0.100 ppm increase in 1-hour max O<sub>3</sub>, after adjustment for possible confounding effects of temperature and copollutants. Overall, the 1996 Criteria Document concluded that there was strong evidence that ambient O<sub>3</sub> exposures can cause significant exacerbations of preexisting respiratory disease in the general public. Excess respiratory-related hospital admissions associated with O<sub>3</sub> exposures for the New York City area (based on Thurston *et al.*, 1992) were included in the quantitative risk assessment in the 1997 review and are included in the current assessment along with estimates for respiratory-related hospital admissions in Cleveland, Detroit, and Los Angeles based on more recent studies (2007 Staff Paper, chapter 5). Significant uncertainties and the difficulty of obtaining reliable baseline incidence numbers resulted in emergency department visits not being used in the quantitative risk assessment in either the 1997 or the 2008 O<sub>3</sub> NAAQS review.

In the past decade, a number of studies have examined the temporal pattern associations between O<sub>3</sub> exposures and emergency department visits for respiratory causes (EPA, 2006a, section 7.3.2). These studies are summarized in the 2006 Criteria Document (chapter 7 Annex) and some are shown in Figure 1 (in section II.A.3). Respiratory causes for emergency department visits include asthma, bronchitis, emphysema, pneumonia, and other upper and lower respiratory infections, such as influenza, but asthma visits typically dominate the daily incidence counts. Most studies report positive associations with O<sub>3</sub>. Among studies with adequate controls for seasonal patterns, many reported at least one significant positive association involving O<sub>3</sub>.

<sup>20</sup> Discussion of the reasons for focusing on warm season studies is found in the section 2.A.3.a below.

In reviewing evidence for associations between emergency department visits for asthma and short-term O<sub>3</sub> exposures, the 2006 Criteria Document (Figure 7-8, p. 7-68) notes that in general, O<sub>3</sub> effect estimates from summer only analyses tended to be positive and larger compared to results from cool season or all year analyses. Several of the studies reported significant associations between O<sub>3</sub> concentrations and emergency department visits for respiratory causes, in particular asthma. However, inconsistencies were observed which were at least partially attributable to differences in model specifications and analysis approach among various studies. For example, ambient O<sub>3</sub> concentrations, length of the study period, and statistical methods used to control confounding by seasonal patterns and copollutants appear to affect the observed O<sub>3</sub> effect on emergency department visits.

Hospital admissions studies focus specifically on unscheduled admissions because unscheduled hospital admissions occur in response to unanticipated disease exacerbations and are more likely than scheduled admissions to be affected by variations in environmental factors, such as daily O<sub>3</sub> levels. Results of a fairly large number of these studies published during the past decade are summarized in 2006 Criteria Document (chapter 7 Annex), and results of U.S. and Canadian studies are shown in Figure 1 below (in section II.A.3). As a group, these hospital admissions studies tend to be larger geographically and temporally than the emergency department visit studies and provide results that are generally more consistent. The strongest associations of respiratory hospital admissions with O<sub>3</sub> concentrations were observed using short lag periods, in particular for a 0-day lag (same day exposure) and a 1-day lag (previous day exposure). Most studies in the United States and Canada indicated positive, statistically significant associations between ambient O<sub>3</sub> concentrations and respiratory hospital admissions in the warm season. However, not all studies found a statistically significant relationship with O<sub>3</sub>, possibly because of very low ambient O<sub>3</sub> levels. Analyses for confounding using multipollutant regression models suggest that copollutants generally do not confound the association between O<sub>3</sub> and respiratory hospitalizations. Ozone effect estimates were robust to PM adjustment in all-year and warm-season only data.

Overall, the 2006 Criteria Document concludes that positive and robust

associations were found between ambient O<sub>3</sub> concentrations and various respiratory disease hospitalization outcomes, when focusing particularly on results of warm-season analyses. Recent studies also generally indicate a positive association between O<sub>3</sub> concentrations and emergency department visits for asthma during the warm season (EPA, 2006a, p. 7-175). These positive and robust associations are supported by the controlled human exposure, animal toxicological, and epidemiological evidence for lung function decrements, increased respiratory symptoms, airway inflammation, and increased airway responsiveness. Taken together, the overall evidence supports a causal relationship between acute ambient O<sub>3</sub> exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season (EPA, 2006a, p. 8-77).

#### ii. Effects on the Respiratory System of Long-Term O<sub>3</sub> Exposures

The 1996 Criteria Document concluded that there was insufficient evidence from the limited number of studies to determine whether long-term O<sub>3</sub> exposures resulted in chronic health effects at ambient levels observed in the U.S. However, the aggregate evidence suggested that O<sub>3</sub> exposure, along with other environmental factors, could be responsible for health effects in exposed populations. Animal toxicological studies carried out in the 1980's and 1990's demonstrated that long-term exposures can result in a variety of morphological effects, including permanent changes in the small airways of the lungs, including remodeling of the distal airways and CAR and deposition of collagen, possibly representing fibrotic changes. These changes result from the damage and repair processes that occur with repeated exposure. Fibrotic changes were also found to persist after months of exposure providing a potential pathophysiologic basis for changes in airway function observed in children in some recent epidemiological studies. It appears that variable seasonal ambient patterns of exposure may be of greater concern than continuous daily exposures.

Several studies published since 1996 have investigated lung function changes over seasonal time periods (EPA, 2006a, section 7.5.3). The 2006 Criteria Document (p. 7-114) summarizes these studies which collectively indicate that seasonal O<sub>3</sub> exposure is associated with smaller growth-related increases in lung function in children than they would

have experienced living in areas with lower O<sub>3</sub> levels. There is some limited evidence that seasonal O<sub>3</sub> also may affect lung function growth in young adults, although the uncertainty about the role of copollutants makes it difficult to attribute the effects to O<sub>3</sub> alone.

Lung capacity grows during childhood and adolescence as body size increases, reaches a maximum during the twenties, and then begins to decline steadily and progressively with age. Long-term exposure to air pollution has long been thought to contribute to slower growth in lung capacity, diminished maximally attained capacity, and/or more rapid decline in lung capacity with age (EPA, 2006a, section 7.5.4). Toxicological findings evaluated in the 1996 Criteria Document demonstrated that repeated daily exposure of rats to an episodic profile of O<sub>3</sub> caused small, but significant, decrements in growth-related lung function that were consistent with early indicators of focal fibrogenesis in the proximal alveolar region, without overt fibrosis. Because O<sub>3</sub> at sufficient concentrations is a strong respiratory irritant and has been shown to cause inflammation and restructuring of the respiratory airways, it is plausible that long-term O<sub>3</sub> exposures might have a negative impact on baseline lung function, particularly during childhood when these exposures might be associated with long-term risks.

Several epidemiological studies published since 1996 have examined the relationship between lung function development and long-term O<sub>3</sub> exposure. The most extensive and robust study of respiratory effects in relation to long-term air pollution exposures among children in the U.S. is the Children's Health Study carried out in 12 communities of southern California starting in 1993. One analysis (Peters *et al.*, 1999a) examined the relationship between long-term O<sub>3</sub> exposures and self-reports of respiratory symptoms and asthma in a cross sectional analysis and found a limited relationship between outcomes of current asthma, bronchitis, cough and wheeze and a 0.040 ppm increase in 1-hour max O<sub>3</sub> (EPA, 2006a, p. 7-115). Another analysis (Peters *et al.*, 1999b) examined the relationship between lung function at baseline and levels of air pollution in the community. They reported evidence that annual mean O<sub>3</sub> levels were associated with decreases in FVC, FEV<sub>1</sub>, PEF and forced expiratory flow (FEF<sub>25-75</sub>) (the latter two being statistically significant) among females but not males. In a separate analysis (Gauderman *et al.*, 2000) of 4th, 7th, and

10th grade students, a longitudinal analysis of lung function development over four years found no association with O<sub>3</sub> exposure. The Children's Health Study enrolled a second cohort of more than 1500 fourth graders in 1996 (Gauderman *et al.*, 2002). While the strongest associations with negative lung function growth were observed with acid vapors in this cohort, children from communities with higher 4-year average O<sub>3</sub> levels also experienced smaller increases in various lung function parameters. The strongest relationship with O<sub>3</sub> was with PEF. Specifically, children from the least-polluted community had a small but statistically significant increase in PEF as compared to those from the most-polluted communities. In two-pollutant models, only 8-hour average O<sub>3</sub> and NO<sub>2</sub> were significant joint predictors of FEV<sub>1</sub> and maximal midexpiratory flow (MMEF). Although results from the second cohort of children are supportive of a weak association, the definitive 8-year follow-up analysis of the first cohort (Gauderman *et al.*, 2004a) provides little evidence that long-term exposure to ambient O<sub>3</sub> at current levels is associated with significant deficits in the growth rate of lung function in children. Avol *et al.* (2001) examined children who had moved away from participating communities in southern California to other states with improved air quality. They found that a negative, but not statistically significant, association was observed between O<sub>3</sub> and lung function parameters. Collectively, the results of these reports from the children's health cohorts provide little evidence to support an impact of long-term O<sub>3</sub> exposures on lung function development.

Evidence for a significant relationship between long-term O<sub>3</sub> exposures and decrements in maximally attained lung function was reported in a nationwide study of first year Yale students (Kinney *et al.*, 1998; Galizia and Kinney, 1999) (EPA, 2006a, p. 7–120). Males had much larger effect estimates than females, which might reflect higher outdoor activity levels and correspondingly higher O<sub>3</sub> exposures during childhood. A similar study of college freshmen at University of California at Berkeley also reported significant effects of long-term O<sub>3</sub> exposures on lung function (Künzli *et al.*, 1997; Tager *et al.*, 1998). In a comparison of students whose city of origin was either Los Angeles or San Francisco, long-term O<sub>3</sub> exposures were associated with significant changes in mid- and end-expiratory flow measures, which could be considered early

indicators for pathologic changes that might progress to COPD.

There have been a few studies that investigated associations between long-term O<sub>3</sub> exposures and the onset of new cases of asthma (EPA, 2006a, section 7.5.6). The Adventist Health and Smog (AHSMOG) study cohort of about 4,000 was drawn from nonsmoking, non-Hispanic white adult Seventh Day Adventists living in California (Greer *et al.*, 1993; McDonnell *et al.*, 1999). During the ten-year follow-up in 1987, a statistically significant increased relative risk of asthma development was observed in males, compared to a nonsignificant relative risk in females (Greer *et al.*, 1993). In the 15-year follow-up in 1992, it was reported that for males, there was a statistically significant increased relative risk of developing asthma associated with 8-hour average O<sub>3</sub> exposures, but there was no evidence of an association in females. Consistency of results in the two studies with different follow-up times provides supportive evidence of the potential for an association between long-term O<sub>3</sub> exposure and asthma incidence in adult males; however, representativeness of this cohort to the general U.S. population may be limited (EPA, 2006a, p. 7–125).

In a similar study (McConnell *et al.*, 2002) of incident asthma among children (ages 9 to 16 at enrollment), annual surveys of 3,535 children initially without asthma were used to identify new-onset asthma cases as part of the Children's Health Study. Six high-O<sub>3</sub> and six low-O<sub>3</sub> communities were identified where the children resided. There were 265 children who reported new-onset asthma during the follow-up period. Although asthma risk was no higher for all residents of the six high-O<sub>3</sub> communities versus the six low-O<sub>3</sub> communities, asthma risk was 3.3 times greater for children who played three or more sports as compared with children who played no sports within the high-O<sub>3</sub> communities. This association was absent in the communities with lower O<sub>3</sub> concentrations. No other pollutants were found to be associated with new-onset asthma (EPA, 2006a, p. 7–125). Playing sports may result in extended outdoor activity and exposure occurring during periods when O<sub>3</sub> levels are higher. It should be noted, however, that the results of the Children's Health Study were based on a small number of new-onset asthma cases among children who played three or more sports. Future replication of these findings in other cohorts would help determine whether a causal interpretation is appropriate.

In animal toxicology studies, the progression of morphological effects reported during and after a chronic exposure in the range of 0.50 to 1.00 ppm O<sub>3</sub> (well above current ambient levels) is complex, with inflammation peaking over the first few days of exposure, then dropping, then plateauing, and finally, largely disappearing (EPA, 2006a, section 5.2.4.4). By contrast, fibrotic changes in the tissue increase very slowly over months of exposure, and, after exposure ceases, the changes sometimes persist or increase. Epithelial hyperplasia peaks soon after the inflammatory response but is usually maintained in both the nose and lungs with continuous exposure; it also does not return to pre-exposure levels after the end of exposure. Patterns of exposure in this same concentration range determine effects, with 18 months of daily exposure, causing less morphologic damage than exposures on alternating months. This is important as environmental O<sub>3</sub> exposure is typically seasonal. Long-term studies by Plopper and colleagues (Evans *et al.*, 2003; Schelegle *et al.*, 2003; Chen *et al.*, 2003; Plopper and Fanucchi, 2000) investigated infant rhesus monkeys exposed to simulated, seasonal O<sub>3</sub> and demonstrated: (1) Remodeling in the distal airways, (2) abnormalities in tracheal basement membrane; (3) eosinophil accumulation in conducting airways; and (4) decrements in airway innervation (EPA, 2006a, p. 5–45). These findings provide additional information regarding possible injury-repair processes occurring with long-term O<sub>3</sub> exposures suggesting that these processes are only partially reversible and may progress following cessation of O<sub>3</sub> exposure. Further, these processes may lead to nonreversible structural damage to lung tissue; however, there is still too much uncertainty to characterize the significance of these findings to human exposure profiles and effect levels (EPA, 2006a, p. 8–25).

In summary, in the past decade, important new longitudinal studies have examined the effect of chronic O<sub>3</sub> exposure on respiratory health outcomes. Limited evidence from recent long-term morbidity studies have suggested in some cases that chronic exposure to O<sub>3</sub> may be associated with seasonal declines in lung function or reduced lung function development, increases in inflammation, and development of asthma in children and adults. Seasonal decrements or smaller increases in lung function measures have been reported in several studies; however, the extent to which these

changes are transient remains uncertain. While there is supportive evidence from animal studies involving effects from chronic exposures, large uncertainties still remain as to whether current ambient levels and exposure patterns might cause these same effects in human populations. The 2006 Criteria Document concludes that epidemiological studies of new asthma development and longer-term lung function declines remain inconclusive at present (EPA, 2006a, p. 7–134).

### iii. Effects on the Cardiovascular System of O<sub>3</sub> Exposure

At the time of the 1997 review, the possibility of O<sub>3</sub>-induced cardiovascular effects was largely unrecognized. Since then, a very limited body of evidence from animal, controlled human exposure, and epidemiologic studies has emerged that provides evidence for some potential plausible mechanisms for how O<sub>3</sub> exposures might exert cardiovascular system effects, however further research is needed to substantiate these potential mechanisms. Possible mechanisms may involve O<sub>3</sub>-induced secretions of vasoconstrictive substances and/or effects on neuronal reflexes that may result in increased arterial blood pressure and/or altered electrophysiologic control of heart rate or rhythm. Some animal toxicology studies have shown O<sub>3</sub>-induced decreases in heart rate, mean arterial pressure, and core temperature. One controlled human exposure study that evaluated effects of O<sub>3</sub> exposure on cardiovascular health outcomes found no significant O<sub>3</sub>-induced differences in ECG or blood pressure in healthy or hypertensive subjects but did observe a significant O<sub>3</sub>-induced increase the alveolar-to-arterial PO<sub>2</sub> gradient and heart rate in both groups resulting in an overall increase in myocardial work and impairment in pulmonary gas exchange (Gong *et al.*, 1998). In another controlled human exposure study, inhalation of a mixture of PM<sub>2.5</sub> and O<sub>3</sub> by healthy subjects increased brachial artery vasoconstriction and reactivity (Brook *et al.*, 2002).

The evidence from a few animal studies also includes potential direct effects such as O<sub>3</sub>-induced release from lung epithelial cells of platelet activating factor (PAF) that may contribute to blood clot formation that would have the potential to increase the risk of serious cardiovascular outcomes (e.g., heart attack, stroke, mortality). Also, interactions of O<sub>3</sub> with surfactant components in epithelial lining fluid of the lung may result in production of oxysterols and reactive oxygen species

that may exhibit PAF-like activity contributing to clotting and also may exert cytotoxic effects on lung and heart muscle cells.

Epidemiological panel and field studies that examined associations between O<sub>3</sub> and various cardiac physiologic endpoints have yielded limited evidence suggestive of a potential association between acute O<sub>3</sub> exposure and altered heart rate variability (HRV), ventricular arrhythmias, and incidence of heart attacks (myocardial infarction or MI). A number of epidemiological studies have also reported associations between short-term exposures and hospitalization for cardiovascular diseases. As shown in Figure 7–13 of the 2006 Criteria Document, many of the studies reported negative or inconsistent associations. Some other studies, especially those that examined the relationship when O<sub>3</sub> exposures were higher, have found robust positive associations between O<sub>3</sub> and cardiovascular hospital admissions (EPA, 2006a, p. 7–82). For example, one study reported a positive association between O<sub>3</sub> and cardiovascular hospital admissions in Toronto, Canada in a summer-only analysis (Burnett *et al.*, 1997b). The results were robust to adjustment for various PM indices, whereas the PM effects diminished when adjusted for gaseous pollutants. Other studies stratified their analysis by temperature (*i.e.*, by warm days versus cool days). Several analyses using warm season days consistently produced positive associations.

The epidemiologic evidence for cardiovascular morbidity is much weaker than for respiratory morbidity, with only one of several U.S. and Canadian studies showing statistically significant positive associations of cardiovascular hospitalizations with warm-season O<sub>3</sub> concentrations. Most of the available European and Australian studies, all of which conducted all-year O<sub>3</sub> analyses, did not find an association between short-term O<sub>3</sub> concentrations and cardiovascular hospitalizations. Overall, the currently available evidence is inconclusive regarding an association between cardiovascular hospital admissions and ambient O<sub>3</sub> exposure (EPA, 2006a, p. 7–83).

In summary, based on the evidence from animal toxicology, controlled human exposure, and epidemiological studies, from the 2006 Criteria Document (p. 8–77) concludes that this generally limited body of evidence is suggestive that O<sub>3</sub> can directly and/or indirectly contribute to cardiovascular-related morbidity, but that much needs to be done to more fully integrate links

between ambient O<sub>3</sub> exposures and adverse cardiovascular outcomes.

### b. Mortality

#### i. Mortality and Short-term O<sub>3</sub> Exposure

The 1996 Criteria Document concluded that an association between daily mortality and O<sub>3</sub> concentration for areas with high O<sub>3</sub> levels (e.g., Los Angeles) was suggested. However, due to a very limited number of studies available at that time, there was insufficient evidence to conclude that the observed association was likely causal.

The 2006 Criteria Document included results from numerous epidemiological analyses of the relationship between O<sub>3</sub> and mortality. Additional single city analyses have also been conducted since 1996, however, the most pivotal studies in EPA's (and CASAC's) finding of increased support for the relationship between premature mortality and O<sub>3</sub> is in part related to differences in study design—limiting analyses to warm seasons, better control for copollutants, particularly PM, and use of multicity designs (both time series and meta-analytic designs). Key findings are available from multicity time-series studies that report associations between O<sub>3</sub> and mortality. These studies include analyses using data from 90 U.S. cities in the National Mortality, Morbidity and Air Pollution (NMMAPS) study (Dominici *et al.*, 2003) and from 95 U.S. communities in an extension to the NMMAPS analyses (Bell *et al.*, 2004).

The original 90-city NMMAPS analysis, with data from 1987 to 1994, was primarily focused on investigating effects of PM<sub>10</sub> on mortality. A significant association was reported between mortality and 24-hour average O<sub>3</sub> concentrations in analyses using all available data as well as in the warm season only analyses (Dominici *et al.*, 2003). The estimate using all available data was about half that for the summer-only data at a lag of 1-day. The extended NMMAPS analysis included data from 95 U.S. cities and included an additional 6 years of data, from 1987–2000 (Bell *et al.*, 2004). Significant associations were reported between O<sub>3</sub> and mortality in analyses using all available data. The effect estimate for increased mortality was approximately 0.5 percent per 0.020 ppm change in 24-hour average O<sub>3</sub> measured on the same day, and approximately 1.04 percent per 0.020 ppm change in 24-hour average O<sub>3</sub> in a 7-day distributed lag model (EPA, 2006a, p. 7–88). In analyses using only data from the warm season, the results were not significantly different from the full-year results. The authors also report

that O<sub>3</sub>-mortality associations were robust to adjustment for PM (EPA, 2006a, p. 7–100). Using a subset of the NMMAPS data set, Huang *et al.* (2005) focused on associations between cardiopulmonary mortality and O<sub>3</sub> exposure (24-hour average) during the summer season only. The authors report an approximate 1.47 percent increase per 0.020 ppm change in O<sub>3</sub> concentration measured on the same day and an approximate 2.52 percent increase per 0.020 ppm change in O<sub>3</sub> concentration using a 7-day distributed lag model. These findings suggest that the effect of O<sub>3</sub> on mortality is immediate but also persists for several days.

As discussed below in section II.A.3.a, confounding by weather, especially temperature, is complicated by the fact that higher temperatures are associated with the increased photochemical activities that are important for O<sub>3</sub> formation. Using a case-crossover study design, Schwartz (2005) assessed associations between daily maximum concentrations and mortality, matching case and control periods by temperature, and using data only from the warm season. The reported effect estimate of approximately 0.92 percent change in mortality per 0.040 ppm O<sub>3</sub> (1-hour maximum) was similar to time-series analysis results with adjustment for temperature (approximately 0.76 percent per 0.040 ppm O<sub>3</sub>), suggesting that associations between O<sub>3</sub> and mortality were robust to the different adjustment methods for temperature.

An initial publication from APHEA, a European multicity study, reported statistically significant associations between daily maximum O<sub>3</sub> concentrations and mortality in four cities in a full year analysis (Toulomi *et al.*, 1997). An extended analysis was done using data from 23 cities throughout Europe (Gryparis *et al.*, 2004). In this report, a positive but not statistically significant association was found between mortality and 1-hour daily maximum O<sub>3</sub> in a full year analysis. Gryparis *et al.* (2004) noted that there was a considerable seasonal difference in the O<sub>3</sub> effect on mortality; thus, the small effect for the all-year data might be attributable to inadequate adjustment for confounding by seasonality. Focusing on analyses using summer measurements, the authors report statistically significant associations with total mortality, cardiovascular mortality and respiratory mortality (EPA, 2006a, p. 7–93, 7–99).

Numerous single-city analyses have also reported associations between mortality and short-term O<sub>3</sub> exposure,

especially for those analyses using warm season data. As shown in Figure 7–21 of the 2006 Criteria Document, the results of recent publications show a pattern of positive, often statistically significant associations between short-term O<sub>3</sub> exposure and mortality during the warm season. In considering results from year-round analyses, there remains a pattern of positive results but the findings are less consistent. In most single-city analyses, effect estimates were not substantially changed with adjustment for PM (EPA, 2006a, Figure 7–22).

In addition, several meta-analyses have been conducted on the relationship between O<sub>3</sub> and mortality. As described in section 7.4.4 of the 2006 Criteria Document, these analyses reported fairly consistent and positive combined effect estimates ranging from approximately 1.5 to 2.5 percent increase in mortality for a standardized change in O<sub>3</sub> (EPA, 2006a, Figure 7–20). Three recent meta-analyses evaluated potential sources of heterogeneity in O<sub>3</sub>-mortality associations (Bell *et al.*, 2005; Ito *et al.*, 2005; Levy *et al.*, 2005). The 2006 Criteria Document (p. 7–96) observes common findings across all three analyses, in that all reported that effect estimates were larger in warm season analyses, reanalysis of results using default convergence criteria in generalized additive models (GAM) did not change the effect estimates, and there was no strong evidence of confounding by PM. Bell *et al.* (2005) and Ito *et al.* (2005) both provided suggestive evidence of publication bias, but O<sub>3</sub>-mortality associations remained after accounting for that potential bias. The 2006 Criteria Document concludes that the “positive O<sub>3</sub> effects estimates, along with the sensitivity analyses in these three meta-analyses, provide evidence of a robust association between ambient O<sub>3</sub> and mortality” (EPA, 2006a, p. 7–97).

Most of the single-pollutant model estimates from single-city studies range from 0.5 to 5 percent excess deaths per standardized increments. Corresponding summary estimates in large U.S. multicity studies ranged between 0.5 to 1 percent with some studies noting heterogeneity across cities and studies (EPA, 2006a, p. 7–110).

Finally, from those studies that included assessment of associations with specific causes of death, it appears that effect estimates for associations with cardiovascular mortality are larger than those for total mortality. The meta-analysis by Bell *et al.* (2005) observed a slightly larger effect estimate for cardiovascular mortality compared to mortality from all causes. The effect

estimate for respiratory mortality was approximately one-half that of cardiovascular mortality in the meta-analysis. However, other studies have observed larger effect estimates for respiratory mortality compared to cardiovascular mortality. The apparent inconsistency regarding the effect size of O<sub>3</sub>-related respiratory mortality may be due to reduced statistical power in this subcategory of mortality (EPA, 2006a, p. 7–108).

In summary, many single- and multicity studies observed positive associations of ambient O<sub>3</sub> concentrations with total nonaccidental and cardiopulmonary mortality. The 2006 Criteria Document finds that the results from U.S. multicity time-series studies provide the strongest evidence to date for O<sub>3</sub> effects on acute mortality. Recent meta-analyses also indicate positive risk estimates that are unlikely to be confounded by PM; however, future work is needed to better understand the influence of model specifications on the risk coefficient (EPA, 2006a, p. 7–175). A meta-analysis that examined specific causes of mortality found that the cardiovascular mortality risk estimates were higher than those for total mortality. For cardiovascular mortality, the 2006 Criteria Document (Figure 7–25, p. 7–106) suggests that effect estimates are consistently positive and more likely to be larger and statistically significant in warm season analyses. The findings regarding the effect size for respiratory mortality have been less consistent, possibly because of lower statistical power in this subcategory of mortality. The 2006 Criteria Document (p. 8–78) concludes that these findings are highly suggestive that short-term O<sub>3</sub> exposure directly or indirectly contribute to non-accidental and cardiopulmonary-related mortality, but additional research is needed to more fully establish underlying mechanisms by which such effects occur.<sup>21</sup>

<sup>21</sup> In commenting on the Criteria Document, the CASAC Ozone Panel raised questions about the implications of these time-series results in a policy context, emphasizing that “\* \* \* while the time-series study design is a powerful tool to detect very small effects that could not be detected using other designs, it is also a blunt tool” (Henderson, 2006b). They note that “\* \* \* not only is the interpretation of these associations complicated by the fact that the day-to-day variation in concentrations of these pollutants is, to a varying degree, determined by meteorology, the pollutants are often part of a large and highly correlated mix of pollutants, only a very few of which are measured” (Henderson, 2006b). Even with these uncertainties, the CASAC Ozone Panel, in its review of the Staff Paper, found “\* \* \* premature total non-accidental and cardiorespiratory mortality for inclusion in the quantitative risk assessment to be appropriate.” (Henderson, 2006b)



## ii. Mortality and Long-Term O<sub>3</sub> Exposure

Little evidence was available in the 1997 review on the potential for associations between mortality and long-term exposure to O<sub>3</sub>. In the Harvard Six City prospective cohort analysis, the authors report that mortality was not associated with long-term exposure to O<sub>3</sub> (Dockery *et al.*, 1993). The authors note that the range of O<sub>3</sub> concentrations across the six cities was small, which may have limited the power of the study to detect associations between mortality and O<sub>3</sub> levels (EPA, 2006a, p. 7-127).

As discussed in section 7.5.8 of the 2006 Criteria Document, in this review there are results available from three prospective cohort studies: the American Cancer Society (ACS) study (Pope *et al.*, 2002), the Adventist Health and Smog (AHSMOG) study (Beeson *et al.*, 1998; Abbey *et al.*, 1999), and the U.S. Veterans Cohort study (Lipfert *et al.*, 2000, 2003). In addition, a major reanalysis report includes evaluation of data from the Harvard Six City cohort study (Krewski *et al.*, 2000).<sup>22</sup> This reanalysis also includes additional evaluation of data from the initial ACS cohort study report that had only reported results of associations between mortality and long-term exposure to fine particles and sulfates (Pope *et al.*, 1995). This reanalysis was discussed in the 2007 Staff Paper (section 3.3.2.2) but not in the 2006 Criteria Document.

In this reanalysis of data from the previous Harvard Six City prospective cohort study, the investigators replicated and validated the findings of the original studies, and the report included additional quantitative results beyond those available in the original report (Krewski *et al.*, 2000). In the reanalysis of data from the Harvard Six Cities study, the effect estimate for the association between long-term O<sub>3</sub> concentrations and mortality was negative and nearly statistically significant (relative risk = 0.87, 95 percent CI: 0.76, 1.00).

The ACS study is based on health data from a large prospective cohort of approximately 500,000 adults and air quality data from about 150 U.S. cities. The initial report (Pope *et al.*, 1995) focused on associations with fine particles and sulfates, for which significant associations had been reported in the earlier Harvard Six Cities study (Dockery *et al.*, 1993). As part of the major reanalysis of these

data, results for associations with other air pollutants were also reported, and the authors report that no significant associations were found between O<sub>3</sub> and all-cause mortality. However, a significant association was reported for cardiopulmonary mortality in the warm season (Krewski *et al.*, 2000). The ACS II study (Pope *et al.*, 2002) reported results of associations with an extended data base; the mortality records for the cohort had been updated to include 16 years of follow-up (compared with 8 years in the first report) and more recent air quality data were included in the analyses. Similar to the earlier reanalysis, a marginally significant association was observed between long-term exposure to O<sub>3</sub> and cardiopulmonary mortality in the warm season. No other associations with mortality were observed in both the full-year and warm season analyses.

The Adventist Health and Smog (AHSMOG) cohort includes about 6,000 adults living in California. In two studies from this cohort, a significant association has been reported between long-term O<sub>3</sub> exposure and increased risk of lung cancer mortality among males only (Beeson *et al.*, 1998; Abbey *et al.*, 1999). No significant associations were reported between long-term O<sub>3</sub> exposure and mortality from all causes or cardiopulmonary causes. Due to the small numbers of lung cancer deaths (12 for males, 18 for females) and the precision of the effect estimate (*i.e.*, the wide confidence intervals), the 2006 Criteria Document (p. 7-130) discussed concerns about the plausibility of the reported association with lung cancer.

The U.S. Veterans Cohort study (Lipfert *et al.*, 2000, 2003) of approximately 50,000 middle-aged males diagnosed with hypertension, reported some positive associations between mortality and peak O<sub>3</sub> exposures (95th percentile level for several years of data). The study included numerous analyses using subsets of exposure and mortality follow-up periods which spanned the years 1960 to 1996. In the results of analyses using deaths and O<sub>3</sub> exposure estimates concurrently across the study period, there were positive, statistically significant associations between peak O<sub>3</sub> and mortality (EPA, 2006a, p. 7-129).

Overall, the 2006 Criteria Document (p. 7-130) concludes that consistent associations have not been reported between long-term O<sub>3</sub> exposure and all-cause, cardiopulmonary or lung cancer mortality.

## c. Role of Ground-Level O<sub>3</sub> in Solar Radiation-Related Human Health Effects

Beyond the direct health effects attributable to inhalation exposure to O<sub>3</sub> in the ambient air discussed above, the 2006 Criteria Document also assesses potential indirect effects related to the presence of O<sub>3</sub> in the ambient air by considering the role of ground-level O<sub>3</sub> in mediating human health effects that may be directly attributable to exposure to solar ultraviolet radiation (UV-B). The 2006 Criteria Document (chapter 10) focuses this assessment on three key factors, including those factors that govern (1) UV-B radiation flux at the earth's surface, (2) human exposure to UV-B radiation, and (3) human health effects due to UV-B radiation. In so doing, the 2006 Criteria Document provides a thorough analysis of the current understanding of the relationship between reducing ground-level O<sub>3</sub> concentrations and the potential impact these reductions might have on increasing UV-B surface fluxes and indirectly contributing to UV-B related health effects.

There are many factors that influence UV-B radiation penetration to the earth's surface, including latitude, altitude, cloud cover, surface albedo, PM concentration and composition, and gas phase pollution. Of these, only latitude and altitude can be defined with small uncertainty in any effort to assess the changes in UV-B flux that may be attributable to any changes in tropospheric O<sub>3</sub> as a result of any revision to the O<sub>3</sub> NAAQS. Such an assessment of UV-B related health effects would also need to take into account human habits, such as outdoor activities (including age- and occupation-related exposure patterns), dress and skin care to adequately estimate UV-B exposure levels. However, little is known about the impact of these factors on individual exposure to UV-B.

Moreover, detailed information does not exist regarding other factors that are relevant to assessing changes in disease incidence, including: Type (*e.g.*, peak or cumulative) and time period (*e.g.*, childhood, lifetime, current) of exposures related to various adverse health outcomes (*e.g.*, damage to the skin, including skin cancer; damage to the eye, such as cataracts; and immune system suppression); wavelength dependency of biological responses; and interindividual variability in UV-B resistance to such health outcomes. Beyond these well recognized adverse health effects associated with various wavelengths of UV radiation, the 2006 Criteria Document (section 10.2.3.6) also

<sup>22</sup> This reanalysis report and the original prospective cohort study findings are discussed in more detail in section 8.2.3 of the *Air Quality Criteria for Particulate Matter* (EPA, 2004).

discusses protective effects of UV-B radiation. Recent reports indicate the necessity of UV-B in producing vitamin D. Vitamin D deficiency can cause metabolic bone disease among children and adults, and may also increase the risk of many common chronic diseases (e.g., type I diabetes and rheumatoid arthritis) as well as the risk of various types of cancers. Thus, the 2006 Criteria Document concludes that any assessment that attempts to quantify the consequences of increased UV-B exposure on humans due to reduced ground-level O<sub>3</sub> must include consideration of both negative and positive effects. However, as with other impacts of UV-B on human health, this beneficial effect of UV-B radiation has not been studied in sufficient detail to allow for a credible health benefits or risk assessment. In conclusion, the effect of changes in surface-level O<sub>3</sub> concentrations on UV-B-induced health outcomes cannot yet be critically assessed within reasonable uncertainty (2006 Criteria Document, p. 10–36).

The Agency last considered indirect effects of O<sub>3</sub> in the ambient air in its 2003 final response to a remand of the Agency's 1997 decision to revise the O<sub>3</sub> NAAQS. In so doing, based on the available information in the 1997 review, EPA determined that the information linking (a) changes in patterns of ground-level O<sub>3</sub> concentrations likely to occur as a result of programs implemented to attain the 1997 O<sub>3</sub> NAAQS to (b) changes in relevant exposures to UV-B radiation of concern to public health was too uncertain at that time to warrant any relaxation in the level of public health protection previously determined to be requisite to protect against the demonstrated direct adverse respiratory effects of exposure to O<sub>3</sub> in the ambient air (68 FR 614). At that time, the more recent information on protective effects of UV-B radiation was not available, such that only adverse UV-B-related effects could be considered. Taking into consideration the more recent information available for the 2008 review, the 2006 Criteria Document and 2007 Staff Paper conclude that the effect of changes in ground-level O<sub>3</sub> concentrations, likely to occur as a result of revising the O<sub>3</sub> NAAQS, on UV-B-induced health outcomes, including whether these changes would ultimately result in increased or decreased incidence of UV-B-related diseases, cannot yet be critically assessed.

### 3. Interpretation and Integration of Health Evidence

As discussed below, in assessing the health evidence, the 2006 Criteria Document integrates findings from experimental (e.g., toxicological, dosimetric and controlled human exposure) and epidemiological studies, to make judgments about the extent to which causal inferences can be made about observed associations between health endpoints and exposure to O<sub>3</sub>. In evaluating the evidence from epidemiological studies, the EPA focuses on well-recognized criteria, including: The strength of reported associations, including the magnitude and precision of reported effect estimates and their statistical significance; the robustness of reported associations, or stability in the effect estimates after considering factors such as alternative models and model specification, potential confounding by co-pollutants, and issues related to the consequences of exposure measurement error; potential aggregation bias in pooling data; and the consistency of the effects associations as observed by looking across results of multiple- and single-city studies conducted by different investigators in different places and times. Consideration is also given to evaluating concentration-response relationships observed in epidemiological studies to inform judgments about the potential for threshold levels for O<sub>3</sub>-related effects. Integrating more broadly across epidemiological and experimental evidence, the 2006 Criteria Document also focuses on the coherence and plausibility of observed O<sub>3</sub>-related health effects to reach judgments about the extent to which causal inferences can be made about observed associations between health endpoints and exposure to O<sub>3</sub> in the ambient air.

#### a. Assessment of Evidence From Epidemiological Studies

Key elements of the evaluation of epidemiological studies are briefly summarized below.

(1) The strength of associations most directly refers to the magnitude of the reported relative risk estimates. Taking a broader view, the 2006 Criteria Document draws upon the criteria summarized in a recent report from the U.S. Surgeon General, which define strength of an association as "the magnitude of the association and its statistical strength" which includes assessment of both effect estimate size and precision, which is related to the statistical power of the study (CDC, 2004). In general, when associations are

strong in terms of yielding large relative risk estimates, it is less likely that the association could be completely accounted for by a potential confounder, or some other source of bias, whereas with associations that yield small relative risk estimates it is especially important to consider potential confounding and other factors in assessing causality. Effect estimates between O<sub>3</sub> and some of the health outcomes are generally small in size and could thus be characterized as weak. For example, effect estimates for associations with mortality generally range from 0.5 to 5 percent increases per 0.040 ppm increase in 1-hour maximum O<sub>3</sub> or equivalent, whereas associations for hospitalization range up to 50 percent increases per standardized O<sub>3</sub> increment. However, the 2006 Criteria Document notes that there are large multicity studies that find small associations between short-term O<sub>3</sub> exposure and mortality or morbidity and have done so with great precision due to the statistical power of the studies (p. 8–40). That is, the power of the studies allows the authors to reliably distinguish even weak relationships from the null hypothesis with statistical confidence.

(2) In evaluating the robustness of associations, the 2006 Criteria Document (sections 7.1.3 and 8.4.4.3) and 2007 Staff Paper (section 3.4.2) have primarily considered the impact of exposure error, potential confounding by copollutants, and alternative models and model specifications.

In time-series and panel studies, the temporal (e.g., daily or hourly) changes in ambient O<sub>3</sub> concentrations measured at centrally-located ambient monitoring stations are generally used to represent a community's exposure to ambient O<sub>3</sub>. In prospective cohort or cross-sectional studies, air quality data averaged over a period of months to years are used as indicators of a community's long-term exposure to ambient O<sub>3</sub> and other pollutants. In both types of analyses, exposure error is an important consideration, as actual exposures to individuals in the population will vary across the community.

Ozone concentrations measured at central ambient monitoring sites may explain, at least partially, the variance in individual exposures to ambient O<sub>3</sub>; however, this relationship is influenced by various factors related to building ventilation practices and personal behaviors. Further, the pattern of exposure misclassification error and the influence of confounders may differ across the outcomes of interest as well as in susceptible populations. As discussed in the 2006 Criteria Document

(section 3.9), only a limited number of studies have examined the relationship between ambient O<sub>3</sub> concentrations and personal exposures to ambient O<sub>3</sub>. One of the strongest predictors of the relationship between ambient concentrations and personal exposures appears to be time spent outdoors. The strongest relationships were observed in outdoor workers (Brauer and Brook, 1995, 1997; O'Neill *et al.*, 2004). Statistically significant correlations between ambient concentrations and personal exposures were also observed for children, who likely spend more time outdoors in the warm season (Linn *et al.*, 1996; Xu *et al.*, 2005). There is some concern about the extent to which ambient concentrations are representative of personal O<sub>3</sub> exposures of another particularly susceptible group of individuals, the debilitated elderly, since those who suffer from chronic cardiovascular or respiratory conditions may tend to protect themselves more than healthy individuals from environmental threats by reducing their exposure to both O<sub>3</sub> and its confounders, such as high temperature and PM. Studies by Sarnat *et al.* (2001, 2005) that included this susceptible group reported mixed results for associations between ambient O<sub>3</sub> concentrations and personal exposures to O<sub>3</sub>. Collectively, these studies observed that the daily averaged personal O<sub>3</sub> exposures tend to be well correlated with ambient O<sub>3</sub> concentrations despite the substantial variability that existed among the personal measurements. These studies provide supportive evidence that ambient O<sub>3</sub> concentrations from central monitors may serve as valid surrogate measures for mean personal exposures experienced by the population, which is of most relevance for time-series studies. A better understanding of the relationship between ambient concentrations and personal exposures, as well as of the other factors that affect relationship will improve the interpretation of concentration-population health response associations observed.

The 2006 Criteria Document (section 7.1.3.1) also discusses the potential influence of exposure error on epidemiologic study results. Zeger *et al.* (2000) outlined the components to exposure measurement error, finding that ambient exposure can be assumed to be the product of the ambient concentration and an attenuation factor (*i.e.*, building filter) and that panel studies and time-series studies that use ambient concentrations instead of personal exposure measurements will

estimate a health risk that is attenuated by that factor. Navidi *et al.* (1999) used data from a children's cohort study to compare effect estimates from a simulated "true" exposure level to results of analyses from O<sub>3</sub> exposures determined by several methods, finding that O<sub>3</sub> exposures based on the use of ambient monitoring data overestimate the individual's O<sub>3</sub> exposure and thus generally result in O<sub>3</sub> effect estimates that are biased downward (EPA, 2006a, p. 7-8). Similarly, in a reanalysis of a study by Burnett *et al.* (1994) on the acute respiratory effects of ambient air pollution, Zidek *et al.* (1998) reported that accounting for measurement error, as well as making a few additional changes to the analysis, resulted in qualitatively similar conclusions, but the effects estimates were considerably larger in magnitude (EPA, 2006a, p. 7-8). A simulation study by Sheppard *et al.* (2005) also considered attenuation of the risk based on personal behavior, their microenvironment, and the qualities of the pollutant in time-series studies. Of particular interest is their finding that risk estimates were not further attenuated in time-series studies even when the correlations between personal exposures and ambient concentrations were weak. In addition to overestimation of exposure and the resulting underestimation of effects, the use of ambient O<sub>3</sub> concentrations may obscure the presence of thresholds in epidemiologic studies (EPA, 2006a, p. 7-9).

As discussed in the 2006 Criteria Document (section 3.9), using ambient concentrations to determine exposure generally overestimates true personal O<sub>3</sub> exposures by approximately 2- to 4-fold in available studies, resulting in attenuated risk estimates. The implication is that the effects being estimated occur at fairly low exposures and the potency of O<sub>3</sub> is greater than these effects estimates indicate. As very few studies evaluating O<sub>3</sub> health effects with personal O<sub>3</sub> exposure measurements exist in the literature, effect estimates determined from ambient O<sub>3</sub> concentrations must be evaluated and used with caution to assess the health risks of O<sub>3</sub>. In the absence of available data on personal O<sub>3</sub> exposure, the use of routinely monitored ambient O<sub>3</sub> concentrations as a surrogate for personal exposures is not generally expected to change the principal conclusions from O<sub>3</sub> epidemiologic studies. Therefore, population health risk estimates derived using ambient O<sub>3</sub> levels from currently available observational studies, with appropriate caveats about personal

exposure considerations, remain useful. The 2006 Criteria Document recommends caution in the quantitative use of effect estimates calculated using ambient O<sub>3</sub> concentrations as they may lead to underestimation of the potency of O<sub>3</sub>. However, the 2007 Staff Paper observes that the use of these risk estimates for comparing relative risk reductions between alternative ambient O<sub>3</sub> standards considered in the risk assessment (discussed below in section II.B.2) is less likely to suffer from this concern.

Confounding occurs when a health effect that is caused by one risk factor is attributed to another variable that is correlated with the causal risk factor; epidemiological analyses attempt to adjust or control for potential confounders. Copollutants (*e.g.*, PM, CO, SO<sub>2</sub> and NO<sub>2</sub>) can meet the criteria for potential confounding in O<sub>3</sub>-health associations if they are potential risk factors for the health effect under study and are correlated with O<sub>3</sub>. Effect modifiers include variables that may influence the health response to the pollutant exposure (*e.g.*, co-pollutants, individual susceptibility, smoking or age). Both are important considerations for evaluating effects in a mixture of pollutants, but for confounding, the emphasis is on controlling or adjusting for potential confounders in estimating the effects of one pollutant, while the emphasis for effect modification is on identifying and assessing the effects for different modifiers.

The 2006 Criteria Document (p. 7-148) observes that O<sub>3</sub> is generally not highly correlated with other criteria pollutants (*e.g.*, PM<sub>10</sub>, CO, SO<sub>2</sub> and NO<sub>2</sub>), but may be more highly correlated with secondary fine particles, especially during the summer months, and that the degree of correlation between O<sub>3</sub> and other pollutants may vary across seasons. For example, positive associations are observed between O<sub>3</sub> and pollutants such as fine particles during the warmer months, but negative correlations may be observed during the cooler months (EPA, 2006a, p. 7-17). Thus, the 2006 Criteria Document (section 7.6.4) pays particular attention to the results of season-specific analyses and studies that assess effects of PM in potential confounding of O<sub>3</sub>-health relationships. The 2006 Criteria Document also discussed the limitations of commonly used multipollutant models that include the difficulty in interpreting results where the copollutants are highly colinear, or where correlations between pollutants change by season (EPA, 2006a, p. 7-150). This is particularly the situation where O<sub>3</sub> and a copollutant, such as

sulfates, are formed under the same atmospheric condition; in such cases multipollutant models would produce unstable and possibly misleading results (EPA, 2006a, p. 7-152).

For mortality, the results from numerous multicity and single-city studies indicate that O<sub>3</sub>-mortality associations do not appear to be substantially changed in multipollutant models including PM<sub>10</sub> or PM<sub>2.5</sub> (EPA, 2006a, p. 7-101; Figure 7-22). Focusing on results of warm season analyses, effect estimates for O<sub>3</sub>-mortality associations are fairly robust to adjustment for PM in multipollutant models (EPA, 2006a, p. 7-102; Figure 7-23). The 2006 Criteria Document concludes that in the few multipollutant analyses conducted for these endpoints, copollutants generally do not confound the relationship between O<sub>3</sub> and respiratory hospitalization (EPA, 2006a, p. 7-79 to 7-80; Figure 7-12). Multipollutant models were not used as commonly in studies of relationships between respiratory symptoms or lung function with O<sub>3</sub>, but the 2006 Criteria Document reports that results of available analyses indicate that such associations generally were robust to adjustment for PM<sub>2.5</sub> (p. 7-154). For example, in a large multicity study of asthmatic children (Mortimer *et al.*, 2002), the O<sub>3</sub> effect was attenuated, but there was still a positive association; in Gent *et al.* (2003), effects of O<sub>3</sub>, but not PM<sub>2.5</sub>, remained statistically significant and even increased in magnitude in two-pollutant models (EPA, 2006a, p. 7-53). Considering this body of studies, the 2006 Criteria Document (p. 7-154) concludes: "Multipollutant regression analyses indicated that O<sub>3</sub> risk estimates, in general, were not sensitive to the inclusion of copollutants, including PM<sub>2.5</sub> and sulfate. These results suggest that the effects of O<sub>3</sub> on respiratory health outcomes appear to be robust and independent of the effects of other copollutants."

The 2006 Criteria Document (p. 7-14) observes that another challenge of time-series epidemiological analysis is assessing the relationship between O<sub>3</sub> and health outcomes while avoiding bias due to confounding by other time-varying factors, particularly seasonal trends and weather variables. These variables are of particular interest because O<sub>3</sub> concentrations have a well-characterized seasonal pattern and are also highly correlated with changes in temperature, such that it can be difficult to distinguish whether effects are associated with O<sub>3</sub> or with seasonal or weather variables in statistical analyses.

The 2006 Criteria Document (section 7.1.3.4) discusses statistical modeling

approaches that have been used to adjust for time-varying factors, highlighting a series of analyses that were done in a Health Effects Institute-funded reanalysis of numerous time-series studies. While the focus of these reanalyses was on associations with PM, a number of investigators also examined the sensitivity of O<sub>3</sub> coefficients to the extent of adjustment for temporal trends and weather factors. In addition, several recent studies, including U.S. multicity studies (Bell *et al.*, 2005; Huang *et al.*, 2005; Schwartz *et al.*, 2005) and a meta-analysis study (Ito *et al.*, 2005), evaluated the effect of model specification on O<sub>3</sub>-mortality associations. As discussed in the 2006 Criteria Document (section 7.6.3.1), these studies generally report that associations reported with O<sub>3</sub> are not substantially changed with alternative modeling strategies for adjusting for temporal trends and meteorologic effects. In the meta-analysis by Ito *et al.* (2005), a separate multicity analysis was presented that found that alternative adjustments for weather resulted in up to 2-fold difference in the O<sub>3</sub> effect estimate. Significant confounding can occur when strong seasonal cycles are present, suggesting that season-specific results are more generally robust than year-round results in such cases. A number of epidemiological studies have conducted season-specific analyses, and have generally reported stronger and more precise effect estimates for O<sub>3</sub> associations in the warm season than in analyses conducted in the cool seasons or over the full year.

(3) Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times (CDC, 2004). In considering results from multicity studies and single-city studies in different areas, the 2006 Criteria Document (p. 8-41) observes general consistency in effects of short-term O<sub>3</sub> exposure on mortality, respiratory hospitalization and other respiratory health outcomes. The variations in effects that are observed may be attributable to differences in relative personal exposure to O<sub>3</sub>, as well as varying concentrations and composition of copollutants present in different regions. Thus, the 2006 Criteria Document (p. 8-41) concludes that "consideration of consistency or heterogeneity of effects is appropriately understood as an evaluation of the similarity or general concordance of results, rather than an expectation of finding quantitative results with a very narrow range."

(4) The 2007 Staff Paper recognizes that it is likely that there are biological thresholds for different health effects in individuals or groups of individuals with similar innate characteristics and health status. For O<sub>3</sub> exposure, individual thresholds would presumably vary substantially from person to person due to individual differences in genetic susceptibility, pre-existing disease conditions and possibly individual risk factors such as diet or exercise levels (and could even vary from one time to another for a given person). Thus, it would be difficult to detect a distinct threshold at the population level below which no individual would experience a given effect, especially if some members of a population are unusually sensitive even down to very low concentrations (EPA, 2004, p. 9-43, 9-44).

Some studies have tested associations between O<sub>3</sub> and health outcomes after removal of days with higher O<sub>3</sub> levels from the data set; such analyses do not necessarily indicate the presence or absence of a threshold, but provide some information on whether the relationship is found using only lower-concentration data. For example, using data from 95 U.S. cities, Bell *et al.* (2004) found that the effect estimate for an association between short-term O<sub>3</sub> exposure and mortality was little changed when days exceeding 0.060 ppm (24-hour average) were excluded in the analysis. Using data from 8 U.S. cities, Mortimer and colleagues (2002) also reported that associations between O<sub>3</sub> and both lung function and respiratory symptoms remained statistically significant and of the same or greater magnitude in effect size when concentrations greater than 0.080 ppm (8-hour average) were excluded (EPA, 2006a, p. 7-46). Several single-city studies also report similar findings of associations that remain or are increased in magnitude and statistical significance when data at the upper end of the concentration range are removed (EPA, 2006a, section 7.6.5).

Other time-series epidemiological studies have used statistical modeling approaches to evaluate whether thresholds exist in associations between short-term O<sub>3</sub> exposure and mortality. As discussed in section 7.6.5 of the 2006 Criteria Document, one European multicity study included evaluation of the shape of the concentration-response curve, and observed no deviation from a linear function across the range of O<sub>3</sub> measurements from the study (Gryparis *et al.*, 2004; EPA, 2006a p. 7-154). Several single-city studies also observed a monotonic increase in associations between O<sub>3</sub> and morbidity that suggest

that no population threshold exists (EPA, 2006a, p. 7–159).

On the other hand, a study in Korea used several different modeling approaches and reported that a threshold model provided the best fit for the data. The results suggested a potential threshold level of about 0.045 ppm (1-hour maximum concentration; < 0.035 ppm, 8-hour average) for an association between mortality and short-term O<sub>3</sub> exposure during the summer months (Kim *et al.*, 2004; EPA, 2006a, p. 8–43). The authors reported larger effect estimates for the association for data above the potential threshold level, suggesting that an O<sub>3</sub>-mortality association might be underestimated in the non-threshold model. A threshold analysis recently reported by Bell *et al.* (2006) for 98 U.S. communities, including the same 95 communities in Bell *et al.* (2004), indicated that if a population threshold existed for mortality, it would likely fall below a 24-hour average O<sub>3</sub> concentration of 0.015 ppm (< 0.025 ppm, 8-hour average). In addition, Burnett and colleagues (1997a,b) plotted the relationships between air pollutant concentrations and both respiratory and cardiovascular hospitalization, and it appears in these results that the associations with O<sub>3</sub> are found in the concentration range above about 0.030 ppm (1-hour maximum; < 0.025 ppm, 8-hour average). Vedal and colleagues (2003) reported a significant association between O<sub>3</sub> and mortality in British Columbia where O<sub>3</sub> concentrations were quite low (mean 1-hour maximum concentration of 0.0273 ppm). The authors did not specifically test for threshold levels, but the fact that the association was found in an area with such low O<sub>3</sub> concentrations suggests that any potential threshold level would be quite low in this data set.

In summary, the 2006 Criteria Document finds that, taken together, the available evidence from controlled human exposure and epidemiological studies suggests that no clear conclusion can now be reached with regard to possible threshold levels for O<sub>3</sub>-related effects (EPA, 2006a, p. 8–44). Thus, the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level for effects such as increased hospital admissions and premature mortality. There are limitations in epidemiological studies that make discerning thresholds in populations difficult, including low data density in the lower concentration ranges, the possible influence of exposure measurement error, and interindividual differences in

susceptibility to O<sub>3</sub>-related effects in populations. There is the possibility that thresholds for individuals may exist in reported associations at fairly low levels within the range of air quality observed in the studies but not be detectable as population thresholds in epidemiological analyses.

#### b. Biological Plausibility and Coherence of Evidence

The body of epidemiological studies discussed in the 2007 Staff Paper emphasizes the role of O<sub>3</sub> in association with a variety of adverse respiratory and cardiovascular effects. While recognizing a variety of plausible mechanisms, there exists a general consensus suggesting that O<sub>3</sub>, could either directly or through initiation, interfere with basic cellular oxidation processes responsible for inflammation, reduced antioxidant capacity, atherosclerosis and other effects. Reasoning that O<sub>3</sub> influences cellular chemistry through basic oxidative properties (as opposed to a unique chemical interaction), other reactive oxidizing species (ROS) in the atmosphere acting either independently or in combination with O<sub>3</sub> may also contribute to a number of adverse respiratory and cardiovascular health effects. Consequently, the role of O<sub>3</sub> should be considered more broadly as O<sub>3</sub> behaves as a generator of numerous oxidative species in the atmosphere.

In considering the biological plausibility of reported O<sub>3</sub>-related effects, the 2007 Staff Paper (section 3.4.6) considers this broader question of health effects of pollutant mixtures containing O<sub>3</sub>. The potential for O<sub>3</sub>-related enhancements of PM formation, particle uptake, and exacerbation of PM-induced cardiovascular effects underscores the importance of considering contributions of O<sub>3</sub> interactions with other often co-occurring air pollutants to health effects due to O<sub>3</sub>-containing pollutant mixes. The 2007 Staff Paper summarizes some examples of important pollutant mixture effects from studies that evaluate interactions of O<sub>3</sub> with other co-occurring pollutants, as discussed in chapters 4, 5, and 6 of the 2006 Criteria Document.

All of the types of interactive effects of O<sub>3</sub> with other co-occurring gaseous and nongaseous viable and nonviable PM components of ambient air mixes noted above argue that O<sub>3</sub> acts not only alone but that O<sub>3</sub> also is a surrogate indicator for air pollution mixes which may enhance the risk of adverse effects due to O<sub>3</sub> acting in combination with other pollutants. Viewed from this perspective, those epidemiologic

findings of morbidity and mortality associations, with ambient O<sub>3</sub> concentrations extending to quite low levels in many cases, become more understandable and plausible.

The 2006 Criteria Document integrates epidemiological studies with mechanistic information from controlled human exposure studies and animal toxicological studies to draw conclusions regarding the coherence of evidence and biological plausibility of O<sub>3</sub>-related health effects to reach judgments about the causal nature of observed associations. As summarized below, coherence and biological plausibility is discussed for each of the following types of O<sub>3</sub>-related effects: Short-term effects on the respiratory system, effects on the cardiovascular system, effects related to long-term O<sub>3</sub> exposure, and short-term mortality-related health endpoints.

#### i. Coherence and Plausibility of Short-Term Effects on the Respiratory System

Acute respiratory morbidity effects that have been associated with short-term exposure to O<sub>3</sub> include such health endpoints as decrements in lung function, increased respiratory symptoms, increased airway responsiveness, airway inflammation, increased permeability related to epithelial injury, immune system effects, emergency department visits for respiratory diseases, and hospitalization due to respiratory illness.

Recent epidemiological studies have supported evidence available in the previous O<sub>3</sub> NAAQS review on associations between ambient O<sub>3</sub> exposure and decline in lung function for children. The 2006 Criteria Document (p. 8–34) concludes that exposure to ambient O<sub>3</sub> has a significant effect on lung function and is associated with increased respiratory symptoms and medication use, particularly in asthmatics. Short-term exposure to O<sub>3</sub> has also been associated with more severe morbidity endpoints, such as emergency department visits and hospital admissions for respiratory cases, including specific respiratory illness (e.g., asthma) (EPA, 2006a, sections 7.3.2 and 7.3.3). In addition, a few epidemiological studies have reported positive associations between short-term O<sub>3</sub> exposure and respiratory mortality, though the associations are not generally statistically significant (EPA, 2006a, p. 7–108).

Considering the evidence from epidemiological studies, the results described above provide evidence for coherence in O<sub>3</sub>-related effects on the respiratory system. Effect estimates from U.S. and Canadian studies are shown in

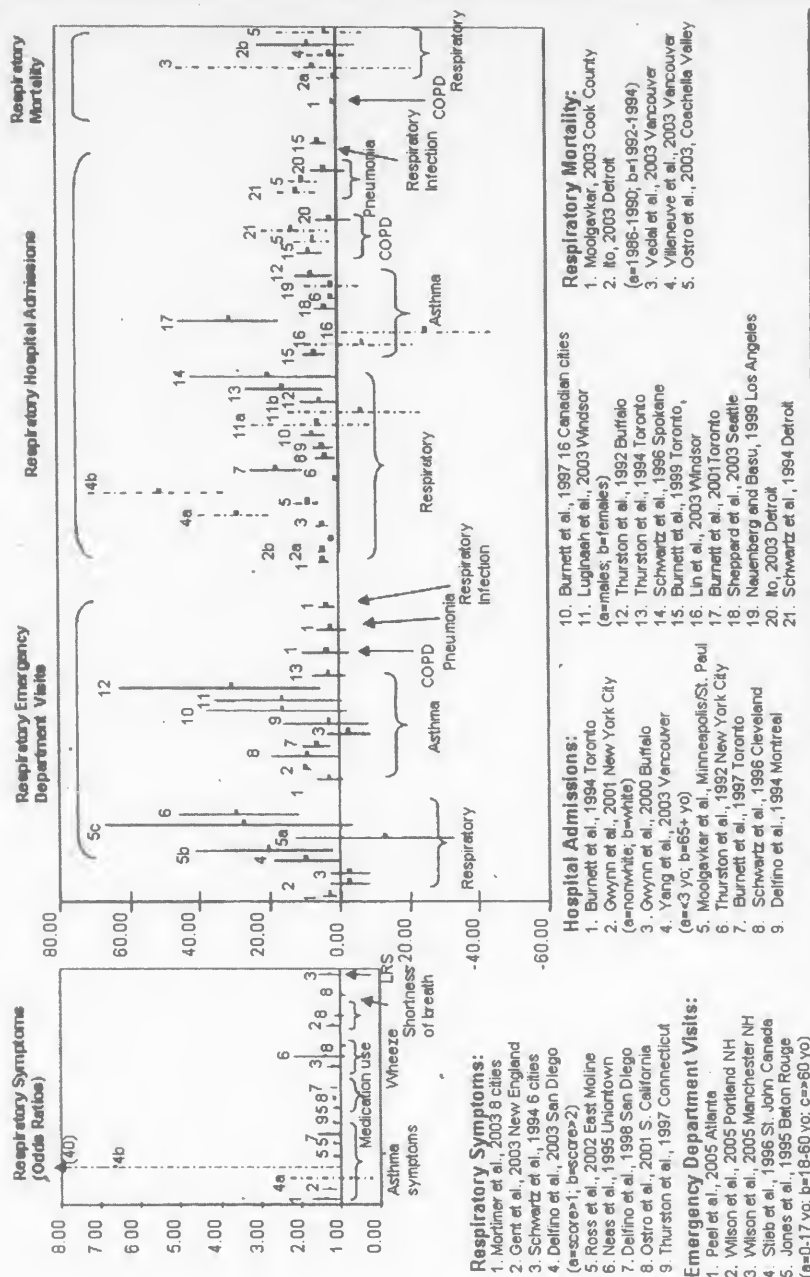
Figure 1, where it can be seen that mostly positive associations have been reported with respiratory effects ranging from respiratory symptoms, such as cough or wheeze, to hospitalization for various respiratory diseases, and there is suggestive evidence for associations with respiratory mortality. Many of the reported associations are statistically significant, particularly in the warm season. In Figure 1, the central effect estimate is indicated by a square for

each result, with the vertical bar representing the 95 percent confidence interval around the estimate. In the discussions that follow, an individual study result is considered to be statistically significant if the 95 percent confidence interval does not include zero.<sup>23</sup> Positive effect estimates indicate

<sup>23</sup> Results for studies of respiratory symptoms are presented as odds ratios; an odds ratio of 1.0 is equivalent to no effect, and thus is presented as equivalent to the zero effect estimate line.

increases in the health outcome with O<sub>3</sub> exposure. In considering these results as a whole, it is important to consider not only whether statistical significance at the 95 percent confidence level is reported in individual studies but also the general pattern of results, focusing in particular on studies with greater statistical power that report relatively more precise results.

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**Figure 1. Effect estimates (with 95% confidence intervals) for associations between short-term ozone exposure and respiratory health outcomes.**  
 Effect estimates expressed as odds ratios for associations with respiratory symptoms and % increase for other outcomes, per standardized increments: 20 ppb for 24-hr O<sub>3</sub>, 30 ppb for 8-hr O<sub>3</sub>, and 40 ppb for 1-hr O<sub>3</sub>, presented in order of decreasing statistical power from left to right in each category. Bolded line (plus) indicates all year analyses; solid line (red) indicates warm season results; LRS=lower respiratory symptoms; COPD=chronic obstructive pulmonary disease

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Considering also evidence from toxicological, controlled human exposure, and field studies, the 2006 Criteria Document (section 8.6) discusses biological plausibility and coherence of evidence for acute O<sub>3</sub>-induced respiratory health effects. Inhalation of O<sub>3</sub> for several hours while subjects are physically active can elicit both acute adverse pathophysiological changes and subjective respiratory tract symptoms (EPA, 2006a, section 8.4.2).

Acute pulmonary responses observed in healthy humans exposed to O<sub>3</sub> at ambient concentrations include: decreased inspiratory capacity; mild bronchoconstriction; rapid, shallow breathing during exercise; subjective symptoms of tracheobronchial airway irritation, including cough and pain on deep inspiration; decreases in measures of lung function; and increased airway resistance. The severity of symptoms and magnitude of response depends on inhaled dose, individual O<sub>3</sub> sensitivity,

and the degree of attenuation or enhancement of response resulting from previous O<sub>3</sub> exposures. Lung function studies of several animal species acutely exposed to relatively low O<sub>3</sub> levels from a toxicological perspective (*i.e.*, 0.25 to 0.4 ppm) show responses similar to those observed in humans, including increased breathing frequency, decreased tidal volume, increased resistance, and decreased FVC. Alterations in breathing pattern return to normal within hours of exposure, and

attenuation in functional responses following repeated O<sub>3</sub> exposures is similar to those observed in humans.

Physiological and biochemical alterations investigated in controlled human exposure and animal toxicology studies tend to support certain hypotheses of underlying pathological mechanisms which lead to the development of respiratory-related effects reported in epidemiology studies (e.g., increased hospitalization and medication use). Some of these are: (a) Decrements in lung function, (b) bronchoconstriction, (c) increased airway responsiveness, (d) airway inflammation, (e) epithelial injury, (f) immune system activation, (g) host defense impairment, and (h) sensitivity of individuals, which depends on at least a person's age, disease status, genetic susceptibility, and the degree of attenuation present due to prior exposures. The time sequence, magnitude, and overlap of these complex events, both in terms of development and recovery, illustrate the inherent difficulty of interpreting the biological plausibility of O<sub>3</sub>-induced cardiopulmonary health effects (EPA, 2006a, p. 8–48).

The interaction of O<sub>3</sub> with airway epithelial cell membranes and ELF to form lipid ozonation products and ROS is supported by numerous human, animal and in vitro studies. Ozonation products and ROS initiate a cascade of events that lead to oxidative stress, injury, inflammation, airway epithelial damage and increased epithelial damage and increased alveolar permeability to vascular fluids. Repeated respiratory inflammation can lead to a chronic inflammatory state with altered lung structure and lung function and may lead to chronic respiratory diseases such as fibrosis and emphysema (EPA, 2006a, section 8.6.2). Continued respiratory inflammation also can alter the ability to respond to infectious agents, allergens and toxins. Acute inflammatory responses to O<sub>3</sub> are well documented, and lung injury appears within 3 hours after exposure in humans.

Taken together, the 2006 Criteria Document concludes that the evidence from experimental human and animal toxicology studies indicates that acute O<sub>3</sub> exposure is causally associated with respiratory system effects. These effects include O<sub>3</sub>-induced pulmonary function decrements; respiratory symptoms; lung inflammation and increased lung permeability; airway hyperresponsiveness; increased uptake of nonviable and viable particles; and consequent increased susceptibility to PM-related toxic effects and respiratory infections (EPA, 2006a, p. 8–48).

#### ii. Coherence and Plausibility of Effects on the Cardiovascular System

There is very limited experimental evidence of animals and humans that has evaluated possible mechanisms or physiological pathways by which acute O<sub>3</sub> exposures may induce cardiovascular system effects. Ozone induces lung injury, inflammation, and impaired mucociliary clearance, with a host of associated biochemical changes all leading to increased lung epithelial permeability. As noted above in section II.A.2.a, the generation of lipid ozonation products and ROS in lung tissues can influence pulmonary hemodynamics, and ultimately the cardiovascular system. Other potential mechanisms by which O<sub>3</sub> exposure may be associated with cardiovascular disease outcomes have been described. Laboratory animals exposed to relatively high O<sub>3</sub> concentrations ( $\geq 0.5$  ppm) demonstrate tissue edema in the heart and lungs. Ozone-induced changes in heart rate, edema of heart tissue, and increased tissue and serum levels of ANF found with 8-hour 0.5 ppm O<sub>3</sub> exposure in animal toxicology studies (Vesely *et al.*, 1994a,b,c) also raise the possibility of potential cardiovascular effects of acute ambient O<sub>3</sub> exposures.

Animal toxicology studies have found both transient and persistent ventilatory responses with and without progressive decreases in heart rate (Arito *et al.*, 1997). Observations of O<sub>3</sub>-induced vasoconstriction in a controlled human exposure study by Brook *et al.* (2002) suggests another possible mechanism for O<sub>3</sub>-related exacerbations of preexisting cardiovascular disease. One controlled human study (Gong *et al.*, 1998) evaluated potential cardiovascular health effects of O<sub>3</sub> exposure. The overall results did not indicate acute cardiovascular effects of O<sub>3</sub> in either the hypertensive or control subjects. The authors observed an increase in rate-pressure product and heart rate, a decrement for FEV<sub>1</sub>, and a > 10 mm Hg increase in the alveolar/arterial pressure difference for O<sub>2</sub> following O<sub>3</sub> exposure. Foster *et al.* (1993) demonstrated that even in relatively young healthy adults, O<sub>3</sub> exposure can cause ventilation to shift away from the well-perfused basal lung. This effect of O<sub>3</sub> on ventilation distribution may persist beyond 24-hours post-exposure (Foster *et al.*, 1997). These findings suggest that O<sub>3</sub> may exert cardiovascular effects indirectly by impairing alveolar-arterial O<sub>2</sub> transfer and potentially reducing O<sub>2</sub> supply to the myocardium. Ozone exposure may increase myocardial work and impair pulmonary gas exchange to a degree that could perhaps be clinically

important in persons with significant preexisting cardiovascular impairment.

As noted above in section II.A.2.a, a limited number of new epidemiological studies have reported associations between short-term O<sub>3</sub> exposure and effects on the cardiovascular system. Among these studies, three were population-based and involved relatively large cohorts; two of these studies evaluated associations between O<sub>3</sub> and HRV and the other study evaluated the association between O<sub>3</sub> levels and the relative risk of MI or heart attack. Such studies may offer more informative results based on their large subject-pool and design. Results from these three studies were suggestive of an association between O<sub>3</sub> exposure and the cardiovascular endpoints studied. In other recent studies on the incidence of heart attacks and some more subtle cardiovascular health endpoints, such as changes in HRV or cardiac arrhythmia, some but not all studies reported associations with short-term exposure to O<sub>3</sub> (EPA, 2006a, section 7.2.7.1). From these studies, the 2006 Criteria Document concludes that the "current evidence is rather limited but suggestive of a potential effect on HRV, ventricular arrhythmias, and MI incidence" (EPA, 2006a, p. 7–65).

An increasing number of studies have evaluated the association between O<sub>3</sub> exposure and cardiovascular hospital admissions. As discussed in section 7.3.4 of the 2006 Criteria Document, many reported negative or inconsistent associations, whereas other studies, especially those that examined the relationship when O<sub>3</sub> exposures were higher, have found positive and robust associations between O<sub>3</sub> and cardiovascular hospital admissions. The 2006 Criteria Document (p. 7–83) finds that the overall evidence from these studies remains inconclusive regarding the effect of O<sub>3</sub> on cardiovascular hospitalizations. The 2006 Criteria Document notes that the suggestive positive epidemiologic findings of O<sub>3</sub> exposure on cardiac autonomic control, including effects on HRV, ventricular arrhythmias and heart attacks, and reported associations between O<sub>3</sub> exposure and cardiovascular hospitalizations generally in the warm season gain credibility and scientific support from the results of experimental animal toxicology and controlled human exposure studies, which are indicative of plausible pathways by which O<sub>3</sub> may exert cardiovascular effects (EPA, 2006a, section 8.6.1).



### iii. Coherence and Plausibility of Effects Related to Long-Term O<sub>3</sub> Exposure

Controlled human exposure studies cannot evaluate effects of long-term exposures to O<sub>3</sub>; there is some evidence available from toxicological studies. While early animal toxicology studies of long-term O<sub>3</sub> exposures were conducted using continuous exposures, more recent studies have focused on exposures which mimic diurnal and seasonal patterns and more realistic O<sub>3</sub> exposure levels (EPA, 2006a, p. 8–50). Studies of monkeys that compared these two exposure scenarios found increased airway pathology only with the latter design. Persistent and irreversible effects reported in chronic animal toxicology studies suggest that additional complementary human data are needed from epidemiologic studies (EPA, 2006a, p. 8–50).

There is limited evidence from human studies for long-term O<sub>3</sub>-induced effects on lung function. As discussed in section 8.6.2 of the 2006 Criteria Document, previous epidemiological studies have provided only inconclusive evidence for either mortality or morbidity effects of long-term O<sub>3</sub> exposure. The 2006 Criteria Document (p. 8–50) observes that the inconsistency in findings may be due to a lack of precise exposure information, the possibility of selection bias, and the difficulty of controlling for confounders. Several new longitudinal epidemiology studies have evaluated associations between long-term O<sub>3</sub> exposures and morbidity and mortality and suggest that these long-term exposures may be related to changes in lung function in children; however, little evidence is available to support a relationship between chronic O<sub>3</sub> exposure and mortality or lung cancer incidence (EPA, 2006a, p. 8–50).

The 2006 Criteria Document (p. 8–51) concludes that evidence from animal toxicology studies strongly suggests that chronic O<sub>3</sub> exposure is capable of damaging the distal airways and proximal alveoli, resulting in lung tissue remodeling leading to apparent irreversible changes. Such structural changes and compromised lung function caused by persistent inflammation may exacerbate the progression and development of chronic lung disease. Together with the limited evidence available from epidemiological studies, these findings offer some insight into potential biological mechanisms for suggested associations between long-term or seasonal exposures to O<sub>3</sub> and reduced lung function development in children which have been observed in

epidemiologic studies (EPA, 2006a, p. 8–51).

### iv. Coherence and Plausibility of Short-Term Mortality-Related Health Endpoints

An extensive epidemiological literature on air pollution related mortality risk estimates from the U.S., Canada, and Europe is discussed in the 2006 Criteria Document (sections 7.4 and 8.6.3). These single- and multicity mortality studies coupled with results from meta-analyses generally indicate associations between acute O<sub>3</sub> exposure and elevated risk for all-cause mortality, even after adjustment for the influence of season and PM exposure. Several single-city studies that specifically evaluated the relationship between O<sub>3</sub> exposure and cardiopulmonary mortality also reported results suggestive of a positive association (EPA, 2006a, p. 8–51). These mortality studies suggest a pattern of effects for causality that have biologically plausible explanations, but our knowledge regarding potential underlying mechanisms is very limited at this time and requires further research. Most of the physiological and biochemical parameters investigated in human and animal studies suggest that O<sub>3</sub>-induced biochemical effects are relatively transient and attenuate over time. The 2006 Criteria Document (p. 8–52) hypothesizes a generic pathway of O<sub>3</sub>-induced lung damage, potentially involving oxidative lung damage with subsequent inflammation and/or decline in lung function leading to respiratory distress in some sensitive population groups (e.g., asthmatics), or other plausible pathways noted below that may lead to O<sub>3</sub>-related contributions to cardiovascular effects that ultimately increase risk of mortality.

The third National Health and Nutrition Examination Survey follow-up data analysis indicates that about 20 percent of the adult population has reduced FEV<sub>1</sub> values, suggesting impaired lung function in a significant portion of the population. Most of these individuals have COPD, asthma or fibrotic lung disease (Manino *et al.*, 2003), which are associated with persistent low-grade inflammation. Furthermore, patients with COPD are at increased risk for cardiovascular disease. Also, lung disease with underlying inflammation may be linked to low-grade systemic inflammation associated with atherosclerosis, independent of cigarette smoking (EPA, 2006a, p. 8–52). Lung function decrements in persons with cardiopulmonary disease have been associated with inflammatory markers,

such as C-reactive protein (CRP) in the blood. At a population level it has been found that individuals with the lowest FEV<sub>1</sub> values have the highest levels of CRP, and those with the highest FEV<sub>1</sub> values have the lowest CRP levels (Manino *et al.*, 2003; Sin and Man, 2003). This complex series of physiological and biochemical reactions following O<sub>3</sub> exposure may tilt the biological homeostasis mechanisms which could lead to adverse health effects in people with compromised cardiopulmonary systems.

Several other types of newly available data also support reasonable hypotheses that may help to explain the findings of O<sub>3</sub>-related increases in cardiovascular mortality observed in some epidemiological studies. These include the direct effect of O<sub>3</sub> on increasing PAF in lung tissue that can then enter the general circulation and possibly contribute to increased risk of blood clot formation and the consequent increased risk of heart attacks, cerebrovascular events (stroke), or associated cardiovascular-related mortality. Ozone reactions with cholesterol in lung surfactant to form epoxides and oxysterols that are cytotoxic to lung and heart muscles and that contribute to atherosclerotic plaque formation in arterial walls represent another potential pathway. Stimulation of airway irritant receptors may lead to increases in tissue and serum levels of ANF, changes in heart rate, and edema of heart tissue. A few new field and panel studies of human adults have reported associations between ambient O<sub>3</sub> concentrations and changes in cardiac autonomic control (e.g., HRV, ventricular arrhythmias, and MI). These represent plausible pathways that may lead to O<sub>3</sub>-related contributions to cardiovascular effects that ultimately increase the risk of mortality.

In addition, O<sub>3</sub>-induced increases in lung permeability allow more ready entry for inhaled PM into the blood stream, and thus O<sub>3</sub> exposure may increase the risk of PM-related cardiovascular effects. Furthermore, increased ambient O<sub>3</sub> levels contribute to ultrafine PM formation in the ambient air and indoor environments. Thus, the contributions of elevated ambient O<sub>3</sub> concentrations to ultrafine PM formation and human exposure, along with the enhanced uptake of inhaled fine particles, consequently may contribute to exacerbation of PM-induced cardiovascular effects in addition to those more directly induced by O<sub>3</sub> (EPA, 2006a, p. 8–53).

### c. Summary

Judgments concerning the extent to which relationships between various health endpoints and ambient O<sub>3</sub> exposures are likely to be causal are informed by the conclusions and discussion in the 2006 Criteria Document as discussed above and summarized in section 3.7.5 of the 2007 Staff Paper. These judgments reflect the nature of the evidence and the overall weight of the evidence, and are taken into consideration in the quantitative risk assessment discussed below in section II.B.2.

For example, there is a very high level of confidence that O<sub>3</sub> induces lung function decrements in healthy adults and children due in part to the dozens of controlled human exposure and epidemiological studies consistently showing such effects. The 2006 Criteria Document (p. 8–74) states that these studies provide clear evidence of causality for associations between short-term O<sub>3</sub> exposures and statistically significant declines in lung function in children, asthmatics and adults who exercise outdoors. An increase in respiratory symptoms (e.g., cough, shortness of breath) has been observed in controlled human exposure studies of short-term O<sub>3</sub> exposures, and significant associations between ambient O<sub>3</sub> exposures and a wide variety of respiratory symptoms have been reported in epidemiology studies (EPA, 2006a, p. 8–75). Population time-series studies showing robust associations between O<sub>3</sub> exposures and respiratory hospital admissions and emergency department visits are strongly supported by controlled human exposure, animal toxicological, and epidemiological evidence for O<sub>3</sub>-related lung function decrements, respiratory symptoms, airway inflammation, and airway hyperreactivity. The 2006 Criteria Document (p. 8–77) concludes that, taken together, the overall evidence supports the inference of a causal relationship between acute ambient O<sub>3</sub> exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season. Further, recent epidemiologic evidence has been characterized in the 2006 Criteria Document (p. 8–78) as highly suggestive that O<sub>3</sub> directly or indirectly contributes to non-accidental and cardiopulmonary-related mortality.

### 4. O<sub>3</sub>-Related Impacts on Public Health

The following discussion draws from chapters 6 and 7 and section 8.7 of the 2006 Criteria Document and section 3.6 of the 2007 Staff Paper to characterize

factors which modify responsiveness to O<sub>3</sub>, populations potentially at risk for O<sub>3</sub>-related health effects, the adversity of O<sub>3</sub>-related effects, and the size of the at-risk populations in the U.S. These considerations are all important elements in characterizing the potential public health impacts associated with exposure to ambient O<sub>3</sub>.

#### a. Factors That Modify Responsiveness to Ozone

There are numerous factors that can modify individual responsiveness to O<sub>3</sub>. These include: influence of physical activity; age; gender and hormonal influences; racial, ethnic and socioeconomic status (SES) factors; environmental factors; and oxidant-antioxidant balance. These factors are discussed in more detail in section 6.5 of the 2006 Criteria Document.

It is well established that physical activity increases an individual's minute ventilation and will thus increase the dose of O<sub>3</sub> inhaled (EPA, 2006a, section 6.5.4). Increased physical activity results in deeper penetration of O<sub>3</sub> into more distal regions of the lungs, which are more sensitive to acute O<sub>3</sub> response and injury. This will result in greater lung function decrements for acute exposures of individuals during increased physical activity. Research has shown that respiratory effects are observed at lower O<sub>3</sub> concentrations if the level of exertion is increased and/or duration of exposure and exertion are extended. Predicted O<sub>3</sub>-induced decrements in lung function have been shown to be a function of exposure concentration, duration and exercise level for healthy, young adults (McDonnell *et al.*, 1997).

Most of the studies investigating the influence of age have used lung function decrements and symptoms as measures of response. For healthy adults, lung function and symptom responses to O<sub>3</sub> decline as age increases. The rate of decline in O<sub>3</sub> responsiveness appears greater in those 18 to 35 years old compared to those 35 to 55 years old, while there is very little change after age 55. In one study (Seal *et al.*, 1996) analyzing a large data set, a 5.4% decrement in FEV<sub>1</sub> on average was estimated for 20-year-old individuals exposed to 0.12 ppm O<sub>3</sub> for 2.3 hours, whereas similar exposure of 35-year-old individuals resulted in a 2.6% decrement on average. While healthy children tend not to report respiratory symptoms when exposed to low levels of O<sub>3</sub>, for subjects 18 to 36 years old symptom responses induced by O<sub>3</sub> are observed but tend to decrease with increasing age within this range (McDonnell *et al.*, 1999).

Limited evidence of gender differences in response to O<sub>3</sub> exposure has suggested that females may be predisposed to a greater susceptibility to O<sub>3</sub>. Lower plasma and NL fluid levels of the most prevalent antioxidant, uric acid, in females relative to males may be a contributing factor. Consequently, reduced removal of O<sub>3</sub> in the upper airways may promote deeper penetration. However, most of the evidence on gender differences appears to be equivocal, with one study (Hazucha *et al.*, 2003) suggesting that physiological responses of young healthy males and females may be comparable (EPA, 2006a, section 6.5.2).

A few studies have suggested that ethnic minorities might be more responsive to O<sub>3</sub> than Caucasian population groups (EPA, 2006a, section 6.5.3). This may be more the result of a lack of adequate health care and socioeconomic status (SES) than any differences in sensitivity to O<sub>3</sub>. The limited data available, which have investigated the influence of race, ethnic or other related factors on responsiveness to O<sub>3</sub>, prevent drawing any clear conclusions at this time.

Few human studies have examined the potential influence of environmental factors such as the sensitivity of individuals who voluntarily smoke tobacco (*i.e.*, smokers) and the effect of high temperatures on O<sub>3</sub> responsiveness. New controlled human exposure studies have confirmed that smokers are less responsive to O<sub>3</sub> than nonsmokers; however, time course of development and recovery of these effects, as well as reproducibility, was not different from nonsmokers (EPA, 2006a, section 6.5.5). Influence of ambient temperature on pulmonary effects induced by O<sub>3</sub> has been studied very little, but additive effects of heat and O<sub>3</sub> exposure have been reported.

Antioxidants, which scavenge free radicals and limit lipid peroxidation in the ELF, are the first line of defense against oxidative stress. Ozone exposure leads to absorption of O<sub>3</sub> in the ELF with subsequent depletion of antioxidant in the nasal ELF, but concentration and antioxidant enzyme activity in ELF or plasma do not appear related to O<sub>3</sub> responsiveness (EPA 2006a, section 6.5.6). Controlled studies of dietary antioxidant supplements have shown some protective effects on lung function decrements but not on symptoms and airway inflammatory responses. Dietary antioxidant supplements have provided some protection to asthmatics by attenuating post-exposure airway hyperresponsiveness. Animal studies

have also supported the protective effects of ELF antioxidants.

#### b. At-Risk Subgroups for O<sub>3</sub>-Related Effects

Several characteristics may increase the extent to which a population group shows increased susceptibility or vulnerability. Information on potentially susceptible and vulnerable groups is summarized in section 8.7 of the 2006 Criteria Document. As described there, the term *susceptibility* refers to innate (e.g., genetic or developmental) or acquired (e.g., personal risk factors, age) factors that make individuals more likely to experience effects with exposure to pollutants. A number of population groups have been identified as potentially susceptible to health effects as a result of O<sub>3</sub> exposure, including people with existing lung diseases, including asthma, children and older adults, and people who have larger than normal lung function responses that may be due to genetic susceptibility. In addition, some population groups have been identified as having increased vulnerability to O<sub>3</sub>-related effects due to increased likelihood of exposure while at elevated ventilation rates, including healthy children and adults who are active outdoors, for example, outdoor workers and joggers. Taken together, the susceptible and vulnerable groups make up "at-risk" groups.<sup>24</sup>

##### i. Active People

A large group of individuals at risk from O<sub>3</sub> exposure consists of outdoor workers and children, adolescents, and adults who engage in outdoor activities involving exertion or exercise during summer daylight hours when ambient O<sub>3</sub> concentrations tend to be higher. This conclusion is based on a large number of controlled-human exposure studies and several epidemiologic field/panel studies which have been conducted with healthy children and adults and those with preexisting respiratory diseases (EPA 2006a, sections 6.2, 6.3, 7.2, and 8.4.4). The controlled human exposure studies show a clear O<sub>3</sub> exposure-response relationship with increasing spirometric and symptomatic response as exercise level increases. Furthermore, O<sub>3</sub>-induced response increases as time of exposure increases. Studies of outdoor workers and others who participate in outdoor activities indicate that extended exposures to O<sub>3</sub> at elevated exertion

levels can produce marked effects on lung function, as discussed above in section IIA.2 (Brauer *et al.*, 1996; Höppe *et al.*, 1995; Korrick *et al.*, 1998; McConnell *et al.*, 2002).

These field studies with subjects at elevated exertion levels support the extensive evidence derived from controlled human exposure studies. The majority of controlled human exposure studies has examined the effects of O<sub>3</sub> exposure in subjects performing continuous or intermittent exercise for variable periods of time and has reported significant O<sub>3</sub>-induced respiratory responses. The epidemiologic studies discussed above also indicate that prolonged exposure periods, combined with elevated levels of exertion or exercise, may magnify O<sub>3</sub> effects on lung function. Thus, outdoor workers and others who participate in higher exertion activities outdoors during the time of day when high peak O<sub>3</sub> concentrations occur appear to be particularly vulnerable to O<sub>3</sub> effects on respiratory health. Although these studies show a wide variability of response and sensitivity among subjects and the factors contributing to this variability continue to be incompletely understood, the effect of increased exertion is consistent. It should be noted that this wide variability of response and sensitivity among subjects may be in part due to the wide range of other highly reactive photochemical oxidants coexisting with O<sub>3</sub> in the ambient air.

##### ii. People With Lung Disease

People with preexisting pulmonary disease are among those at increased risk from O<sub>3</sub> exposure. Altered physiological, morphological, and biochemical states typical of respiratory diseases like asthma, COPD, and chronic bronchitis may render people sensitive to additional oxidative burden induced by O<sub>3</sub> exposure. At the time of the 1997 review, it was concluded that these groups were at greater risk because the impact of O<sub>3</sub>-induced responses on already-compromised respiratory systems would noticeably impair an individual's ability to engage in normal activity or would be more likely to result in increased self-medication or medical treatment. At that time there was little evidence that people with preexisting disease were more responsive than healthy individuals in terms of the magnitude of lung function decrements or symptomatic responses. The new results from controlled exposure and epidemiologic studies continue to indicate that individuals with preexisting pulmonary disease are a sensitive population for O<sub>3</sub>-related health effects.

Several controlled human exposure studies reviewed in the 1996 Criteria Document on atopic and asthmatic subjects have suggested but not clearly demonstrated enhanced responsiveness to acute O<sub>3</sub> exposure compared to healthy subjects. The majority of the newer studies reviewed in Chapter 6 of the 2006 Criteria Document indicate that asthmatics are more sensitive than normal subjects in manifesting O<sub>3</sub>-induced lung function decrements. In one key study (Horstman *et al.*, 1995), the FEV<sub>1</sub> decrement observed in the asthmatics was significantly larger than in the healthy subjects (19% versus 10%, respectively). There was also a notable tendency for a greater group mean O<sub>3</sub>-induced decrease in FEF<sub>25-75</sub> in asthmatics relative to the healthy subjects (24% versus 15%, respectively). A significant positive correlation in asthmatics was also reported between the magnitude of O<sub>3</sub>-induced spirometric responses and baseline lung function, *i.e.*, responses increased with severity of disease.

Asthmatics present a differential response profile for cellular, molecular, and biochemical parameters (2006 Criteria Document, Figure 8-1) that are altered in response to acute O<sub>3</sub> exposure. Ozone-induced increases in neutrophils, IL-8 and protein were found to be significantly higher in the BAL fluid from asthmatics compared to healthy subjects, suggesting mechanisms for the increased sensitivity of asthmatics (Basha *et al.*, 1994; McBride *et al.*, 1994; Scannell *et al.*, 1996; Hiltermann *et al.*, 1999; Holz *et al.*, 1999; Bosson *et al.*, 2003). Neutrophils, or PMNs, are the white blood cells most associated with inflammation. IL-8 is an inflammatory cytokine with a number of biological effects, primarily on neutrophils. The major role of this cytokine is to attract and activate neutrophils. Protein in the airways is leaked from the circulatory system, and is a marker for increased cellular permeability.

Bronchial constriction following provocation with O<sub>3</sub> and/or allergens presents a two-phase response. The early response is mediated by release of histamine and leukotrienes that leads to contraction of smooth muscle cells in the bronchi, narrowing the lumen and decreasing the airflow. In people with allergic airway disease, including people with rhinitis and asthma, these mediators also cause accumulation of eosinophils in the airways (Bascom *et al.*, 1990; Jorres *et al.*, 1996; Peden *et al.*, 1995 and 1997; Frampton *et al.*, 1997; Michelson *et al.*, 1999; Hiltermann *et al.*, 1999; Holz *et al.*, 2002; Vagaggini *et al.*, 2002). In asthma, the eosinophil.

<sup>24</sup>In the Staff Paper and documents from previous O<sub>3</sub> NAAQS reviews, "at-risk" groups have also been called "sensitive" groups, to mean both groups with greater inherent susceptibility and those more likely to be exposed.

which increases inflammation and allergic responses, is the cell most frequently associated with exacerbations of the disease. A study by Bosson *et al.* (2003) evaluated the difference in O<sub>3</sub>-induced bronchial epithelial cytokine expression between healthy and asthmatic subjects. After O<sub>3</sub> exposure the epithelial expression of IL-5 and GM-CSF increased significantly in asthmatics, compared to healthy subjects. Asthma is associated with Th2-related airway response (allergic response), and IL-5 is an important Th2-related cytokine. The O<sub>3</sub>-induced increase in IL-5, and also in GM-CSF, which affects the growth, activation and survival of eosinophils, may indicate an effect on the Th2-related airway response and on airway eosinophils. The authors reported that the O<sub>3</sub>-induced Th2-related cytokine responses that were found within the asthmatic group may indicate a worsening of their asthmatic airway inflammation and thus suggest a plausible link to epidemiological data indicating O<sub>3</sub>-associated increases in bronchial reactivity and hospital admissions.

The accumulation of eosinophils in the airways of asthmatics is followed by production of mucus and a late-phase bronchial constriction and reduced airflow. In a study of 16 intermittent asthmatics, Hiltermann *et al.* (1999) found that there was a significant inverse correlation between the O<sub>3</sub>-induced change in the percentage of eosinophils in induced sputum and the change in PC<sub>20</sub>, the concentration of methacholine causing a 20% decrease in FEV<sub>1</sub>. Characteristic O<sub>3</sub>-induced inflammatory airway neutrophilia at one time was considered a leading mechanism of airway hyperresponsiveness. However, Hiltermann *et al.* (1999) determined that the O<sub>3</sub>-induced change in percentage neutrophils in sputum was not significantly related to the change in PC<sub>20</sub>. These results are consistent with the results of Zhang *et al.* (1995), which found neutrophilia in a murine model to be only coincidentally associated with airway hyperresponsiveness, *i.e.*, there was no cause and effect relationship. (2006 Criteria Document, AX 6–26). Hiltermann *et al.* (1999) concluded that the results point to the role of eosinophils in O<sub>3</sub>-induced airway hyperresponsiveness. Increases in O<sub>3</sub>-induced nonspecific airway responsiveness incidence and duration could have important clinical implications for asthmatics.

Two studies (Jörres *et al.*, 1996; Holz *et al.*, 2002) observed increased airway responsiveness to O<sub>3</sub> exposure with bronchial allergen challenge in subjects

with preexisting allergic airway disease. Jörres *et al.* (1996) found that O<sub>3</sub> causes an increased response to bronchial allergen challenge in subjects with allergic rhinitis and mild allergic asthma. The subjects were exposed to 0.25 ppm O<sub>3</sub> for 3 hours with IE. Airway responsiveness to methacholine was determined 1 hour before and after exposure; responsiveness to allergen was determined 3 hours after exposure. Statistically significant decreases in FEV<sub>1</sub> occurred in subjects with allergic rhinitis (13.8%) and allergic asthma (10.6%), and in healthy controls (7.3%). Methacholine responsiveness was statistically increased in asthmatics, but not in subjects with allergic rhinitis or healthy controls. Airway responsiveness to an individual's historical allergen (either grass and birch pollen, house dust mite, or animal dander) was significantly increased after O<sub>3</sub> exposure when compared to FA exposure. In subjects with asthma and allergic rhinitis, a maximum percent fall in FEV<sub>1</sub> of 27.9% and 7.8%, respectively, occurred 3 days after O<sub>3</sub> exposure when they were challenged with of the highest common dose of allergen. The authors concluded that subjects with asthma or allergic rhinitis, without asthma, could be at risk if a high O<sub>3</sub> exposure is followed by a high dose of allergen. Holz *et al.* (2002) reported an early phase lung function response in subjects with rhinitis after a consecutive 4-day exposure to 0.125 ppm O<sub>3</sub> that resulted in a clinically relevant (>20%) decrease in FEV<sub>1</sub>. Ozone-induced exacerbation of airway responsiveness persists longer and attenuates more slowly than O<sub>3</sub>-induced lung function decrements and respiratory symptom responses and can have important clinical implications for asthmatics.

A small number of in vitro studies corroborate the differences in the responses of asthmatic and healthy subject generally found in controlled human exposure studies. In vitro studies (Schierhorn *et al.*, 1999) of nasal mucosal biopsies from atopic and nonatopic subjects exposed to 0.1 ppm O<sub>3</sub> found significant differences in release of IL-4, IL-6, IL-8, and TNF- $\alpha$ . Another study by Schierhorn *et al.* (2002) found significant differences in the O<sub>3</sub>-induced release of the neuropeptides neurokinin A and substance P for allergic patients in comparison to nonallergic controls, suggesting increased activation of sensory nerves by O<sub>3</sub> in the allergic tissues. Another study by Bayram *et al.* (2002) using in vitro culture of bronchial epithelial cells recovered from atopic and nonatopic asthmatics also

found significant increases in epithelial permeability in response to O<sub>3</sub> exposure.

The new data on airway responsiveness, inflammation, and various molecular markers of inflammation and bronchoconstriction indicate that people with asthma and allergic rhinitis (with or without asthma) comprise susceptible groups for O<sub>3</sub>-induced adverse effects. This body of evidence indicates that controlled human exposure and epidemiological panel studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O<sub>3</sub> exposure on asthmatics and other susceptible populations. The effects of O<sub>3</sub> on lung function, inflammation, and increased airway responsiveness demonstrated in subjects with asthma and other allergic airway diseases, provide plausible mechanisms underlying the more serious respiratory morbidity effects, such as emergency department visits and hospital admissions, and respiratory mortality effects.

A number of epidemiological studies have been conducted using asthmatic study populations. The majority of epidemiological panel studies that evaluated respiratory symptoms and medication use related to O<sub>3</sub> exposures focused on children. These studies suggest that O<sub>3</sub> exposure is associated with increased respiratory symptoms and medication use in children with asthma. Other reported effects include respiratory symptoms, lung function decrements, and emergency department visits, as discussed in the 2006 Criteria Document (section 7.6.7.1). Strong evidence from a large multicity study (Mortimer *et al.*, 2002), along with support from several single-city studies indicate that O<sub>3</sub> exposure is associated with increased respiratory symptoms and medication use in children with asthma. With regard to ambient O<sub>3</sub> levels and increased hospital admissions and emergency department visits for asthma and other respiratory causes, strong and consistent evidence establishes a correlation between O<sub>3</sub> exposure and increased exacerbations of preexisting respiratory disease for 1-hour maximum O<sub>3</sub> concentrations <0.12 ppm. As discussed above and in the 2006 Criteria Document, section 7.3, several hospital admission and emergency department visit studies in the U.S., Canada, and Europe have reported positive associations between increase in O<sub>3</sub> and increased risk of emergency department visits and hospital admissions for asthma other

respiratory diseases, especially during the warm season.

In summary, based on a substantial new body of evidence from animal, controlled human exposure and epidemiological studies the 2006 Criteria Document (section x.x) concludes that people with asthma and other preexisting pulmonary diseases are among those at increased risk from O<sub>3</sub> exposure. Evidence from controlled human exposure studies indicates that asthmatics may exhibit larger lung function decrements and can have larger inflammatory responses in response to O<sub>3</sub> exposure than healthy controls. Asthmatics present a different response profile for cellular, molecular, and biochemical parameters that are altered in response to acute O<sub>3</sub> exposure. Asthmatics, and people with allergic rhinitis, are more likely to mount an allergic-type response upon exposure to O<sub>3</sub>, as manifested by increases in white blood cells associated with allergy and related molecules, which increase inflammation in the airways. The increased inflammatory and allergic responses also may be associated with the larger late-phase responses that asthmatics can experience, which can include increased bronchoconstrictor responses to irritant substances or allergens and additional inflammation. Epidemiological studies have reported fairly robust associations between ambient O<sub>3</sub> concentrations and measures of lung function and daily respiratory symptoms (e.g., chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O<sub>3</sub> and increased asthma medication use. These more serious responses in asthmatics and others with lung disease provide biological plausibility for the respiratory morbidity effects observed in epidemiological studies, such as emergency department visits and hospital admissions. The body of evidence from controlled human exposure and epidemiological studies, which includes asthmatic as well as non-asthmatic subjects, indicates that controlled human exposure studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O<sub>3</sub> exposure on asthmatics and other susceptible populations.

Newly available reports from controlled human exposure studies (see chapter 6 in the 2006 Criteria Document) utilized subjects with preexisting cardiopulmonary diseases such as COPD, asthma, allergic rhinitis, and hypertension. The data generated from these studies that evaluated

changes in spirometry did not find clear differences between filtered air and O<sub>3</sub> exposure in COPD subjects. However, the new data on airway responsiveness, inflammation, and various molecular markers of inflammation and bronchoconstriction indicate that people with atopic asthma and allergic rhinitis comprise susceptible groups for O<sub>3</sub>-induced adverse health effects.

Although controlled human exposure studies have not found evidence of larger spirometric responses to O<sub>3</sub> in people with COPD relative to healthy subjects, this may be due to the fact that most people with COPD are older adults who would not be expected to be as responsive based on their age. However, in section 8.7.1, the 2006 Criteria Document notes that new epidemiological evidence indicates that people with COPD may be more likely to experience other effects, including emergency room visits, hospital admissions, or premature mortality. For example, results from an analysis of five European cities indicated strong and consistent O<sub>3</sub> effects on unscheduled respiratory hospital admissions, including COPD (Anderson *et al.*, 1997). Also, an analysis of a 9-year data set for the whole population of the Netherlands provided risk estimates for more specific causes of mortality, including COPD (Hoek *et al.*, 2000, 2001; reanalysis Hoek, 2003); a positive, but nonsignificant, excess risk of COPD-related mortality was found to be associated with short-term O<sub>3</sub> concentrations. Moreover, as indicated by Gong *et al.* (1998), the effects of O<sub>3</sub> exposure on alveolar-arterial oxygen gradients may be more pronounced in patients with preexisting obstructive lung diseases. Relative to healthy elderly subjects, COPD patients have reduced gas exchange and low SaO<sub>2</sub>. Any inflammatory or edematous responses due to O<sub>3</sub> delivered to the well-ventilated regions of the lung in COPD subjects could further inhibit gas exchange and reduce oxygen saturation. In addition, O<sub>3</sub>-induced vasoconstriction could also acutely induce pulmonary hypertension. Inducing pulmonary vasoconstriction and hypertension in these patients would perhaps worsen their condition, especially if their right ventricular function was already compromised (EPA, 2006a, section 6.10). These controlled human exposure and epidemiological studies indicate that people with pre-existing lung diseases other than asthma are also at greater risk from O<sub>3</sub> exposure than people without lung disease.

### iii. Children and Older Adults

Supporting evidence exists for heterogeneity in the effects of O<sub>3</sub> by age. As discussed in section 6.5.1 of the 2006 Criteria Document, children, adolescents, and young adults (<18 yrs of age) appear, on average, to have nearly equivalent spirometric responses to O<sub>3</sub>, but have greater responses than middle-aged and older adults when exposed to comparable O<sub>3</sub> doses. Symptomatic responses to O<sub>3</sub> exposure, however, do not appear to occur in healthy children, but are observed in asthmatic children, particularly those who use maintenance medications. For adults (>17 yrs of age) symptoms gradually decrease with increasing age. In contrast to young adults, the diminished symptomatic responses in children and the diminished symptomatic and spirometric responses in older adults increases the likelihood that these groups continue outdoor activities leading to greater O<sub>3</sub> exposure and dose.

As described in the section 7.6.7.2 of the 2006 Criteria Document, many epidemiological field studies focused on the effect of O<sub>3</sub> on the respiratory health of school children. In general, children experienced decrements in lung function parameters, including PEF, FEV<sub>1</sub>, and FVC. Increases in respiratory symptoms and asthma medication use were also observed in asthmatic children. In one German study, children with and without asthma were found to be particularly susceptible to O<sub>3</sub> effects on lung function. Approximately 20 percent of the children, both with and without asthma, experienced a greater than 10 percent change in FEV<sub>1</sub>, compared to only 5 percent of the elderly population and athletes (Höppe *et al.*, 2003).

The American Academy of Pediatrics (2004) notes that children and infants are among the population groups most susceptible to many air pollutants, including O<sub>3</sub>. This is in part because their lungs are still developing. For example, eighty percent of alveoli are formed after birth, and changes in lung development continue through adolescence (Dieter *et al.*, 2000). Children are also likely to spend more time outdoors than adults, which results in increased exposure to air pollutants (Wiley *et al.*, 1991a,b). Moreover, children have high minute ventilation rates and high levels of physical activity which also increases their dose (Plunkett *et al.*, 1992).

Several mortality studies have investigated age-related differences in O<sub>3</sub> effects (EPA, 2006a, section 7.6.7.2). Older adults are also often classified as

being particularly susceptible to air pollution. The 2006 Criteria Document (p. 8–60) concludes that the basis for increased O<sub>3</sub> sensitivity among the elderly is not known, but one hypothesis is that it may be related to changes in the respiratory tract lining fluid antioxidant defense network (Kelly *et al.*, 2003). Older adults have lower baseline lung function than younger people, and are also more likely to have preexisting lung and heart disease. Increased susceptibility of older adults to O<sub>3</sub> health effects is most clearly indicated in the newer mortality studies. Among the studies that observed positive associations between O<sub>3</sub> and mortality, a comparison of all age or younger age (≤ 65 years of age) O<sub>3</sub>-mortality effect estimates to that of the elderly population (> 65 years) indicates that, in general, the elderly population is more susceptible to O<sub>3</sub> mortality effects. The meta-analysis by Bell *et al.* (2005) found a larger mortality effect estimate for the elderly than for all ages. In the large U.S. 95 communities study (Bell *et al.*, 2004), mortality effect estimates were slightly higher for those aged 65 to 74 years, compared to individuals less than 65 years and 75 years or greater. The absolute effect of O<sub>3</sub> on premature mortality may be substantially greater in the elderly population because of higher rates of preexisting respiratory and cardiac diseases. The 2006 Criteria Document (p. 7–177) concludes that the elderly population (>65 years of age) appear to be at greater risk of O<sub>3</sub>-related mortality and hospitalizations compared to all ages or younger populations.

The 2006 Criteria Document notes that, collectively, there is supporting evidence of age-related differences in susceptibility to O<sub>3</sub> lung function effects. The elderly population (> 65 years of age) appear to be at increased risk of O<sub>3</sub>-related mortality and hospitalizations, and children (< 18 years of age) experience other potentially adverse respiratory health outcomes with increased O<sub>3</sub> exposure (EPA, 2006a, section 7.6.7.2).

#### iv. People With Increased Responsiveness to Ozone

New animal toxicology studies using various strains of mice and rats have identified O<sub>3</sub>-sensitive and resistant strains and illustrated the importance of genetic background in determining O<sub>3</sub> susceptibility (EPA, 2006a, section 8.7.4). Controlled human exposure studies have also indicated a high degree of variability in some of the pulmonary physiological parameters. The variable effects in individuals have been found to be reproducible, in other

words, a person who has a large lung function response after exposure to O<sub>3</sub> will likely have about the same response if exposed again to the same dose of O<sub>3</sub>. In controlled human exposure studies, group mean responses are not representative of this segment of the population that has much larger than average responses to O<sub>3</sub>. Recent studies of asthmatics by David *et al.* (2003) and Romieu *et al.* (2004) reported a role for genetic polymorphism in observed differences in antioxidant enzymes and genes involved in inflammation to modulate lung function and inflammatory responses to O<sub>3</sub> exposure.<sup>25</sup>

Biochemical and molecular parameters extensively evaluated in these experiments were used to identify specific loci on chromosomes and, in some cases, to relate the differential expression of specific genes to biochemical and physiological differences observed among these species. Utilizing O<sub>3</sub>-sensitive and O<sub>3</sub>-resistant species, it has been possible to identify the involvement of increased airway reactivity and inflammation processes in O<sub>3</sub> susceptibility. However, most of these studies were carried out using relatively high doses of O<sub>3</sub>, making the relevance of these studies questionable in human health effects assessment. The genes and genetic loci identified in these studies may serve as useful biomarkers in the future.

#### v. Other Population Groups

There is limited, new evidence supporting associations between short-term O<sub>3</sub> exposures and a range of effects on the cardiovascular system. Some but not all, epidemiological studies have reported associations between short-term O<sub>3</sub> exposures and the incidence of heart attacks and more subtle cardiovascular health endpoints, such as changes in HRV and cardiac arrhythmia. Others have reported associations with hospitalization or emergency department visits for cardiovascular diseases, although the results across the studies are not consistent. Studies also report associations between short-term O<sub>3</sub> exposure and mortality from cardiovascular or cardiopulmonary causes. The 2006 Criteria Document (p. 7–65) concludes that current

cardiovascular effects evidence from some field studies is rather limited but supportive of a potential effect of short-term O<sub>3</sub> exposure and HRV, cardiac arrhythmia, and heart attack incidence. In the 2006 Criteria Document's evaluation of studies of hospital admissions for cardiovascular disease (EPA 2006a, section 7.3.4), it is concluded that evidence from this growing group of studies is generally inconclusive regarding an association with O<sub>3</sub> in studies conducted during the warm season (EPA 2006a, p. 7–83). This body of evidence suggests that people with heart disease may be at increased risk from short-term exposures to O<sub>3</sub>; however, more evidence is needed to conclude that people with heart disease are a susceptible population.

Other groups that might have enhanced sensitivity to O<sub>3</sub>, but for which there is currently very little evidence, include groups based on race, gender and SES, and those with nutritional deficiencies, which presents factors which modify responsiveness to O<sub>3</sub>.

#### c. Adversity of Effects

In the 2008 rulemaking, in making judgments as to when various O<sub>3</sub>-related effects become regarded as adverse to the health of individuals, EPA looked to guidelines published by the American Thoracic Society (ATS) and the advice of CASAC. While recognizing that perceptions of "medical significance" and "normal activity" may differ among physicians, lung physiologists and experimental subjects, the ATS (1985)<sup>26</sup> defined adverse respiratory health effects as "medically significant physiologic changes generally evidenced by one or more of the following: (1) Interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3) incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction." During the 1997 review, it was concluded that there was evidence of causal associations from controlled human exposure studies for effects in the first of these five ATS-defined categories, evidence of statistically significant associations from epidemiological studies for effects in the second and third categories, and evidence from animal toxicology

<sup>25</sup> Similar to animal toxicology studies referred above, a polymorphism in a specific proinflammatory cytokine gene has been implicated in O<sub>3</sub>-induced lung function changes in healthy, mild asthmatics and individuals with rhinitis. These observations suggest a potential role for these markers in the innate susceptibility to O<sub>3</sub>, however, the validity of these markers and their relevance in the context of prediction to population studies requires additional research.

<sup>26</sup> In 2000, the American Thoracic Society (ATS) published an official statement on "What Constitutes an Adverse Health Effect of Air Pollution?" (ATS, 2000), which updated its earlier guidance (ATS, 1985). Overall, the new guidance does not fundamentally change the approach previously taken to define adversity, nor does it suggest a need at this time to change the structure or content of the tables describing gradation of severity and adversity of effects described below.

studies, which could be extrapolated to humans only with a significant degree of uncertainty, for the last two categories.

For ethical reasons, clear causal evidence from controlled human exposure studies still covers only effects in the first category. However, for this review there are results from epidemiological studies, upon which to base judgments about adversity, for effects in all of the categories. Statistically significant and robust associations have been reported in epidemiology studies falling into the second and third categories. These more serious effects include respiratory events (e.g., triggering asthma attacks) that may require medication (e.g., asthma), but not necessarily hospitalization, as well as respiratory hospital admissions and emergency department visits for respiratory causes. Less conclusive, but still positive associations have been reported for school absences and cardiovascular hospital admissions. Human health effects for which associations have been suggested through evidence from epidemiological and animal toxicology studies, but have not been conclusively demonstrated still fall primarily into the last two categories. In the 1997 review of the O<sub>3</sub> standard, evidence for these more serious effects came from studies of effects in laboratory animals. Evidence from animal studies evaluated in the 2006 Criteria Document strongly suggests that O<sub>3</sub> is capable of damaging the distal airways and proximal alveoli, resulting in lung tissue remodeling leading to apparently irreversible changes. Recent advancements of dosimetry modeling also provide a better basis for extrapolation from animals to humans. Information from epidemiological studies provides supporting, but limited evidence of irreversible respiratory effects in humans than was available in the prior review. Moreover, the findings from single-city and multicity time-series epidemiology studies and meta-analyses of these epidemiological studies are highly suggestive of an association between short-term O<sub>3</sub> exposure and mortality particularly in the warm season.

While O<sub>3</sub> has been associated with effects that are clearly adverse, application of these guidelines, in particular to the least serious category of effects related to ambient O<sub>3</sub> exposures, involves judgments about which medical experts on the CASAC panel and public commenters have expressed diverse views in the past. To help frame such judgments, EPA staff have defined specific ranges of functional responses

(e.g., decrements in FEV<sub>1</sub> and airway responsiveness) and symptomatic responses (e.g., cough, chest pain, wheeze), together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses, that have been used in previous NAAQS reviews. These ranges of pulmonary responses and their associated potential impacts are summarized in Tables 3-2 and 3-3 of the 2007 Staff Paper.

For active healthy people, moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements of  $\geq 10$  percent but  $< 20$  percent, lasting up to 24 hours) and/or moderate symptomatic responses (e.g., frequent spontaneous cough, marked discomfort on exercise or deep breath, lasting up to 24 hours) would likely interfere with normal activity for relatively few responsive individuals. On the other hand, EPA staff determined that large functional responses (e.g., FEV<sub>1</sub> decrements  $\geq 20$  percent, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, lasting longer than 24 hours) would likely interfere with normal activities for many responsive individuals. EPA staff determined that these would be considered adverse under ATS guidelines. In the context of standard setting, CASAC indicated that a focus on the mid to upper end of the range of moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements  $\geq 15$  percent but  $< 20$  percent) is appropriate for estimating potentially adverse lung function decrements in active healthy people. However, for people with lung disease, even moderate functional (e.g., FEV<sub>1</sub> decrements  $\geq 10$  percent but  $< 20$  percent, lasting up to 24 hours) or symptomatic responses (e.g., frequent spontaneous cough, marked discomfort on exercise or with deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. For people with lung disease, large functional responses (e.g., FEV<sub>1</sub> decrements  $\geq 20$  percent, lasting longer than 24 hours) and/or severe symptomatic responses (e.g., persistent uncontrollable cough, severe discomfort on exercise or deep breath, persistent wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most individuals and would increase the likelihood that these individuals would seek medical treatment. In the context of standard

setting, the CASAC indicated (Henderson, 2006c) that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements  $\geq 10$  percent) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease.

In judging the extent to which these impacts represent effects that should be regarded as adverse to the health status of individuals, an additional factor that has been considered in previous NAAQS reviews is whether such effects are experienced repeatedly during the course of a year or only on a single occasion. While some experts would judge single occurrences of moderate responses to be a "nuisance," especially for healthy individuals, a more general consensus view of the adversity of such moderate responses emerges as the frequency of occurrence increases.

The new guidance builds upon and expands the 1985 definition of adversity in several ways. There is an increased focus on quality of life measures as indicators of adversity. There is also a more specific consideration of population risk. Exposure to air pollution that increases the risk of an adverse effect to the entire population is adverse, even though it may not increase the risk of any individual to an unacceptable level. For example, a population of asthmatics could have a distribution of lung function such that no individual has a level associated with significant impairment. Exposure to air pollution could shift the distribution to lower levels that still do not bring any individual to a level that is associated with clinically relevant effects. However, this would be considered to be adverse because individuals within the population would have diminished reserve function, and therefore would be at increased risk if affected by another agent.

Of the various effects of O<sub>3</sub> exposure that have been studied, many would meet the ATS definition of adversity. Such effects include, for example, any detectable level of permanent lung function loss attributable to air pollution, including both reductions in lung growth or acceleration of the age-related decline of lung function; exacerbations of disease in individuals with chronic cardiopulmonary diseases; reversible loss of lung function in combination with the presence of symptoms; as well as more serious effects such as those requiring medical care including hospitalization and, obviously, mortality.

#### d. Size of At-Risk Populations

Although O<sub>3</sub>-related health risk estimates may appear to be small, their significance from an overall public health perspective is determined by the large numbers of individuals in the population groups potentially at risk for O<sub>3</sub>-related health effects discussed above. For example, a population of concern includes people with respiratory disease, which includes approximately 11 percent of U.S. adults and 13 percent of children who have been diagnosed with asthma and 6 percent of adults with chronic obstructive pulmonary disease (chronic bronchitis and/or emphysema) in 2002 and 2003 (Table 8-4 in the 2006 Criteria Document, section 8.7.5.2). More broadly, individuals with preexisting cardiopulmonary disease may constitute an additional population of concern, with potentially tens of millions of people included in each disease category. In addition, populations based on age group also comprise substantial segments of the population that may be potentially at risk for O<sub>3</sub>-related health impacts. Based on U.S. census data from 2003, about 26 percent of the U.S. population are under 18 years of age and 12 percent are 65 years of age or older. Hence, large proportions of the U.S. population are included in life stages that are most likely to have increased susceptibility to the health effects of O<sub>3</sub> and/or those with the highest ambient O<sub>3</sub> exposures.

The 2006 Criteria Document (section 8.7.5.2) notes that the health statistics data illustrate what is known as the "pyramid" of effects. At the top of the pyramid, there are approximately 2.5 millions deaths from all causes per year in the U.S. population, with about 100,000 deaths from chronic lower respiratory diseases. For respiratory health diseases, there are nearly 4 million hospital discharges per year, 14 million emergency department visits, 112 million ambulatory care visits, and an estimated 700 million restricted activity days per year due to respiratory conditions from all causes per year. Applying small risk estimates for the O<sub>3</sub>-related contribution to such health effects with relatively large baseline levels of health outcomes can result in quite large public health impacts related to ambient O<sub>3</sub> exposure. Thus, even a small percentage reduction in O<sub>3</sub> health impacts on cardiopulmonary diseases would reflect a large number of avoided cases. In considering this information together with the concentration-response relationships that have been observed between exposure to O<sub>3</sub> and various health endpoints, the 2006

Criteria Document (section 8.7.5.2) concludes that exposure to ambient O<sub>3</sub> likely has a significant impact on public health in the U.S.

#### B. Human Exposure and Health Risk Assessments

To put judgments about health effects that are adverse for individuals into a broader public health context, EPA has developed and applied models to estimate human exposures and health risks. This broader context includes consideration of the size of particular population groups at risk for various effects, the likelihood that exposures of concern will occur for individuals in such groups under varying air quality scenarios, estimates of the number of people likely to experience O<sub>3</sub>-related effects, the variability in estimated exposures and risks, and the kind and degree of uncertainties inherent in assessing the exposures and risks involved.

As discussed below there are a number of important uncertainties that affect the exposure and health risk estimates. It is also important to note that there have been significant improvements in both the exposure and health risk model. CASAC expressed the view that the exposure analysis represents a state-of-the-art modeling approach and that the health risk assessment was "well done, balanced and reasonably communicated" (Henderson, 2006c). While recognizing and considering the kind and degree of uncertainties in both the exposure and health risk estimates, the 2007 Staff Paper (pp. 6-20 to 6-21) judged that the quality of the estimates is such that they are suitable to be used as an input to the Administrator's decisions on the O<sub>3</sub> primary standard.

In modeling exposures and health risks associated with just meeting the current and alternative O<sub>3</sub> standards, EPA has simulated air quality to represent conditions just meeting these standards based on O<sub>3</sub> air quality patterns in several recent years and on how the shape of the O<sub>3</sub> air quality distribution has changed over time based on historical trends in monitored O<sub>3</sub> air quality data. As described in the 2007 Staff Paper (EPA, 2007b, section 4.5.8) and discussed below, recent O<sub>3</sub> air quality distributions have been statistically adjusted to simulate just meeting the current and selected alternative standards. These simulations do not reflect any consideration of specific control programs or strategies designed to achieve the reductions in emissions required to meet the specified standards. Further, these simulations do not represent predictions of when,

whether, or how areas might meet the specified standards.<sup>27</sup>

As noted in section I.C above, around the time of the release of the final 2007 Staff Paper in January 2007, EPA discovered a small error in the exposure model that when corrected resulted in slight increases in the simulated exposures. Since the exposure estimates are an input to the lung function portion of the health risk assessment, this correction also resulted in slight increases in the lung function risk estimates as well. The exposure and risk estimates discussed in this notice reflect the corrected estimates, and thus are slightly different than the exposure and risk estimates cited in the January 31, 2007 Staff Paper.<sup>28</sup>

#### 1. Exposure Analyses

##### a. Overview

As part of the 2008 rulemaking, the EPA conducted exposure analyses using a simulation model to estimate O<sub>3</sub> exposures for the general population, school age children (ages 5-18), and school age children with asthma living in 12 U.S. metropolitan areas representing different regions of the country where the then current 8-hour O<sub>3</sub> standard is not met. The emphasis on children reflects the finding of the 1997 O<sub>3</sub> NAAQS review that children are an important at-risk group. The 12 modeled areas combined represent a significant fraction of the U.S. urban population, 89 million people, including 18 million school age children of whom approximately 2.6 million have asthma. The selection of urban areas to include in the exposure analysis took into consideration the location of O<sub>3</sub> epidemiological studies, the availability of ambient O<sub>3</sub> data, and the desire to represent a range of geographic areas, population demographics, and O<sub>3</sub> climatology. These selection criteria are discussed further in chapter 5 of the 2007 Staff Paper (EPA, 2007b). The geographic extent of each modeled area consists of the census tracts in the combined statistical area (CSA) as defined by OMB (OMB, 2005).<sup>29</sup>

<sup>27</sup> Modeling that projects whether and how areas might attain alternative standards in a future year is presented in the Regulatory Impact Analysis being prepared in connection with this rulemaking.

<sup>28</sup> EPA made available corrected versions of the final 2007 Staff Paper, and human exposure and health risk assessment technical support documents in July 2007 on the EPA Web site listed in the Availability of Related Information section of this notice.

<sup>29</sup> The 12 CSAs modeled are: Atlanta-Sandy Springs-Gainesville, GA-AL; Boston-Worcester-Manchester, MA-NH; Chicago-Naperville-Michigan City, IL-IN-WI; Cleveland-Akron-Elyria, OH; Detroit-Warren-Flint, MI; Houston-Baytown-Huntsville, TX; Los Angeles-Long Beach-Riverside,



Exposure estimates were developed using a probabilistic exposure model that is designed to explicitly model the numerous sources of variability that affect people's exposures. As discussed below, the model estimates population exposures by simulating human activity patterns, air conditioning prevalence, air exchange rates, and other factors. The modeled exposure estimates were developed for three recent years of ambient O<sub>3</sub> concentrations (2002, 2003, and 2004), as well as for O<sub>3</sub> concentrations adjusted to simulate conditions associated with just meeting the then current NAAQS and various alternative 8-hour standards based on the three year period 2002–2004.<sup>30</sup> This exposure assessment is more fully described and presented in the 2007 Staff Paper and in a technical support document, *Ozone Population Exposure Analysis for Selected Urban Areas* (EPA, 2007c; hereafter Exposure Analysis TSD). The scope and methodology for this exposure assessment were developed over the last few years with considerable input from the CASAC Ozone Panel and the public.<sup>31</sup>

The goals of the O<sub>3</sub> exposure assessment were: (1) To provide estimates of the size of at-risk populations exposed to various levels associated with recent O<sub>3</sub> concentrations, and with just meeting the current O<sub>3</sub> NAAQS and alternative O<sub>3</sub> standards, in specific urban areas; (2) to provide distributions of exposure estimates over the entire range of ambient O<sub>3</sub> concentrations as an important input to the lung function risk assessment summarized below in section II.B.2; (3) to develop a better understanding of the influence of various inputs and assumptions on the exposure estimates; and (4) to gain insight into the distribution of exposures and patterns of exposure

reductions associated with meeting alternative O<sub>3</sub> standards.

The EPA recognizes that there are many sources of variability and uncertainty inherent in the inputs to this assessment and that there is uncertainty in the resulting O<sub>3</sub> exposure estimates. With respect to variability, the exposure modeling approach accounts for variability in ambient O<sub>3</sub> levels, demographic characteristics, physiological attributes, activity patterns, and factors affecting microenvironmental (e.g., indoor) concentrations. In EPA's judgment, the most important uncertainties affecting the exposure estimates are related to the modeling of human activity patterns over an O<sub>3</sub> season, the modeling of variations in ambient concentrations near roadways, and the modeling of air exchange rates that affect the amount of O<sub>3</sub> that penetrates indoors. Another important uncertainty that affects the estimation of how many exposures are associated with moderate or greater exertion is the characterization of energy expenditure for children engaged in various activities. As discussed in more detail in the 2007 Staff Paper (EPA, 2007b, section 4.3.4.7), the uncertainty in energy expenditure values carries over to the uncertainty of the modeled breathing rates, which are important since they are used to classify exposures occurring at moderate or greater exertion which are the relevant exposures since O<sub>3</sub>-related effects observed in controlled human exposure studies only are observed when individuals are engaged in some form of exercise. The uncertainties in the exposure model inputs and the estimated exposures have been assessed using quantitative uncertainty and sensitivity analyses. Details are discussed in the 2007 Staff Paper (section 4.6) and in a technical memorandum describing the exposure modeling uncertainty analysis (Langstaff, 2007).

#### b. Scope and Key Components

Population exposures to O<sub>3</sub> are primarily driven by ambient outdoor concentrations, which vary by time of day, location, and peoples' activities. Outdoor O<sub>3</sub> concentration estimates used in the exposure assessment are provided by measurements and statistical adjustments to the measured concentrations. The current exposure analysis allows comparisons of population exposures to O<sub>3</sub> within each urban area, associated with current O<sub>3</sub> levels and with O<sub>3</sub> levels just meeting several potential alternative air quality standards or scenarios. Human exposure, regardless of the pollutant,

depends on where individuals are located and what they are doing. Inhalation exposure models are useful in realistically estimating personal exposures to O<sub>3</sub> based on activity-specific breathing rates, particularly when recognizing that large scale population exposure measurement studies have not been conducted that are representative of the overall population or at risk subpopulations.

The model EPA used to simulate O<sub>3</sub> population exposure is the Air Pollutants Exposure Model (APEX), the human inhalation exposure model within the Total Risk Integrated Methodology (TRIM) framework (EPA, 2006c,d). APEX is conceptually based on the probabilistic NAAQS exposure model for O<sub>3</sub> (pNEM/O<sub>3</sub>) used in the last O<sub>3</sub> NAAQS review. Since that time the model has been restructured, improved, and expanded to reflect conceptual advances in the science of exposure modeling and newer input data available for the model. Key improvements to algorithms include replacement of the cohort approach with a probabilistic sampling approach focused on individuals, accounting for fatigue and oxygen debt after exercise in the calculation of breathing rates, and a new approach for construction of longitudinal activity patterns for simulated persons. Major improvements to data input to the model include updated air exchange rates, more recent census and commuting data, and a greatly expanded daily time-activities database.

APEX is a probabilistic model designed to explicitly model the numerous sources of variability that affect people's exposures. APEX simulates the movement of individuals through time and space and estimates their exposures to O<sub>3</sub> in indoor, outdoor, and in-vehicle microenvironments. The exposure model takes into account the most significant factors contributing to total human O<sub>3</sub> exposure, including the temporal and spatial distribution of people and O<sub>3</sub> concentrations throughout an urban area, the variation of O<sub>3</sub> levels within each microenvironment, and the effects of exertion on breathing rate in exposed individuals. A more detailed description of APEX and its application is presented in chapter 4 of the 2007 Staff Paper and associated technical documents (EPA, 2006b,c,d).

Several methods have been used to evaluate the APEX model and to characterize the uncertainty of the model estimates. These include conducting model evaluation, sensitivity analyses, and a detailed uncertainty analysis for one urban area.

CA: New York-Newark-Bridgeport, NY-NJ-CT-PA; Philadelphia-Camden-Vineland, PA-NJ-DE-MD; Sacramento-Arden-Arcade-Truckee, CA-NV; St. Louis-St. Charles-Farmington, MO-IL; Washington-Baltimore-N. Virginia, DC-MD-VA-WV.

<sup>30</sup> All 12 of the CSAs modeled did not meet the 0.084 ppm O<sub>3</sub> NAAQS for the three year period examined.

<sup>31</sup> The general approach used in the human exposure assessment was described in the draft Health Assessment Plan (EPA, 2005d) that was released to the CASAC and general public in April 2005 and was the subject of a consultation with the CASAC O<sub>3</sub> Panel on May 5, 2005. In October 2005, OAQPS released the first draft of the Staff Paper containing a chapter discussing the exposure analyses and first draft of the Exposure Analyses TSD for CASAC consultation and public review on December 8, 2005. In July 2006, OAQPS released the second draft of the Staff Paper and second draft of the Exposure Analyses TSD for CASAC review and public comment which was held by the CASAC O<sub>3</sub> Panel on August 24–25, 2006.

These are discussed fully in the 2007 Staff Paper (section 4.6) and in Langstaff (2007). The uncertainty of model structure was judged to be of lesser importance than the uncertainties of the model inputs and parameters. Model structure refers to the algorithms in APEX designed to simulate the processes that result in people's exposures, for example, the way that APEX models exposures to individuals when they are near roads. The uncertainties in the model input data (e.g., measurement error, ambient concentrations, air exchange rates, and activity pattern data) have been assessed individually, and their impact on the uncertainty in the modeled exposure estimates was assessed in a unified quantitative analysis with results expressed in the form of estimated confidence ranges around the estimated measures of exposure. This uncertainty analysis was conducted for one urban area (Boston) using the observed 2002 O<sub>3</sub> concentrations and 2002 concentrations adjusted to simulate just meeting the current standard, with the expectation that the results would be similar for other cities and years. One significant source of uncertainty, due to limitations in the database used to model peoples' daily activities, was not included in the unified analysis, and was assessed through separate sensitivity analyses. This analysis indicates that the uncertainty of the exposure results is relatively small. For example, 95 percent uncertainty intervals were calculated for the APEX estimates of the percent of children or asthmatic children with exposures above 0.060, 0.070, or 0.080 ppm under moderate exertion, for two air quality scenarios (current 2002 and 2002 adjusted to simulate just meeting the current standard) in Boston (Langstaff, 2007, Tables 26 and 27). The 95 percent uncertainty intervals for this set of 12 exposure estimates indicate the possibility of underpredictions of the exposure estimates ranging from 3 to 25 percent of the modeled estimates, and overpredictions ranging from 4 to 11 percent of the estimates. For example, APEX estimates the percent of asthmatic children with exposures above 0.070 ppm under moderate exertion to be 24 percent, for Boston 2002 O<sub>3</sub> concentrations adjusted to simulate just meeting the current standard. The 95 percent uncertainty interval for this estimate is 23–30 percent, or –4 to +25 percent of the estimate. These uncertainty intervals do not include the uncertainty engendered by limitations of the activity database, which is in the range of one to ten percent.

The exposure periods modeled here are the O<sub>3</sub> seasons in 2002, 2003, and 2004. The O<sub>3</sub> season in each area includes the period of the year where elevated O<sub>3</sub> levels tend to be observed and for which routine hourly O<sub>3</sub> monitoring data are available. Typically this period spans from March or April through September or October, or in some areas, spanning the entire year. Three years were modeled to reflect the substantial year-to-year variability that occurs in O<sub>3</sub> levels and related meteorological conditions, and because the standard is specified in terms of a three-year period. The year-to-year variability observed in O<sub>3</sub> levels is due to a combination of different weather patterns and the variation in emissions of O<sub>3</sub> precursors. Nationally, 2002 was a relatively high year with respect to the 4th highest daily maximum 8-hour O<sub>3</sub> levels observed in urban areas across the U.S. (EPA, 2007b, Figure 2–16), with the mean of the distribution of O<sub>3</sub> levels for the urban monitors being in the upper third among the years 1990 through 2006. In contrast, on a national basis, 2004 is the lowest year on record through 2006 for this same air quality statistic, and 8-hour daily maximum O<sub>3</sub> levels observed in most, but not all of the 12 urban areas included in the exposure and risk analyses were relatively low compared to other recent years. The 4th highest daily maximum 8-hour O<sub>3</sub> levels observed in 2003 in the 12 urban areas and nationally generally were between those observed in 2002 and 2004.

Regulatory scenarios examined in the 2008 rulemaking include the then current 0.08 ppm, average of the 4th daily maximum 8-hour averages over a three year period standard; standards with the same form but with alternative levels of 0.080, 0.074, 0.070, and 0.064 ppm; standards specified as the average of the 3rd highest daily maximum 8-hour averages over a three year period with alternative levels of 0.084 and 0.074 ppm; and a standard specified as the average of the 5th highest daily maximum 8-hour averages over a three year period with a level of 0.074 ppm.<sup>32</sup> The then current standard used a rounding convention that allows areas to have an average of the 4th daily maximum 8-hour averages as high as

<sup>32</sup> The 8-hour O<sub>3</sub> standard established in 1997 was 0.08 ppm, but the rounding convention specified that the average of the 4th daily maximum 8-hour average concentrations over a three-year period must be at 0.084 ppm or lower to be in attainment of this standard. When EPA staff selected alternative standards to analyze, it was presumed that the same type of rounding convention would be used, and thus alternative standards of 0.084, 0.074, 0.064 ppm were chosen.

0.084 ppm and still meet the standard. All alternative standards analyzed were intended to reflect improved precision in the measurement of ambient concentrations (in ppm), where the precision would extend to three instead of two decimal places.

The then current standard and all alternative standards were modeled using a quadratic rollback approach to adjust the hourly concentrations observed in 2002–2004 to yield a design value<sup>33</sup> corresponding to the standard being analyzed. The quadratic rollback technique reduces higher concentrations near ambient background levels.<sup>34</sup> This procedure was considered in a sensitivity analysis in the 1997 review of the O<sub>3</sub> standard and has been shown to be more realistic than a linear, proportional rollback method, where all of the ambient concentrations are reduced by the same factor.

#### c. Exposure Estimates and Key Observations

The exposure assessment, which provides estimates of the number of people exposed to different levels of ambient O<sub>3</sub> while at specified exertion levels,<sup>35</sup> serve two purposes. First, the entire range of modeled personal exposures to ambient O<sub>3</sub> is an essential input to the portion of the health risk assessment based on exposure-response functions from controlled human exposure studies, discussed in the next section. Second, estimates of personal exposures to ambient O<sub>3</sub> concentrations at and above specific benchmark levels provide some perspective on the public

<sup>33</sup> A design value is a statistic that describes the air quality status of a given area relative to the level of the NAAQS. Design values are often based on multiple years of data, consistent with specification of the NAAQS in Part 50 of the CFR. For the 8-hour O<sub>3</sub> NAAQS, the 3-year average of the annual 4th-highest daily maximum 8-hour average concentrations, based on the monitor within (or downwind of) an urban area yielding the highest 3-year average, is the design value.

<sup>34</sup> The quadratic rollback approach and evaluation of this approach are described by Johnson (1997), Duff *et al.* (1998) and Rizzo (2005, 2006).

<sup>35</sup> As discussed above in Section II.A, O<sub>3</sub> health responses observed in controlled human exposure studies are associated with exposures while engaged in moderate or greater exertion and, therefore, these are the exposure measures of interest. The level of exertion of individuals engaged in particular activities is measured by an equivalent ventilation rate (EVR), ventilation normalized by body surface area (BSA, in m<sup>2</sup>), which is calculated as VE/BSA, where VE is the ventilation rate (liters/minute). Moderate and greater exertion levels were defined as EVR > 13 liters/min-m<sup>2</sup> (Whitfield *et al.*, 1996) to correspond to the exertion levels measured in most subjects studied in the controlled human exposure studies that reported health effects associated with 6.6 hour O<sub>3</sub> exposures.

health impacts of health effects that cannot currently be evaluated in quantitative risk assessments that may occur at current air quality levels, and the extent to which such impacts might be reduced by meeting the current and alternative standards. This is especially true when there are exposure levels at which it is known or can reasonably be inferred that specific O<sub>3</sub>-related health effects are occurring. In this notice, exposures at and above these benchmark concentrations are referred to as "exposures of concern."

It is important to note that although the analysis of "exposures of concern" was conducted using three discrete benchmark levels (*i.e.*, 0.080, 0.070, and 0.060 ppm), the concept is more appropriately viewed as a continuum with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O<sub>3</sub> exposure levels. The EPA recognizes that there is no sharp breakpoint within the continuum ranging from at and above 0.080 ppm down to 0.060 ppm. In considering the concept of exposures of concern, it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower O<sub>3</sub> levels.

Within the context of this continuum, estimates of exposures of concern at discrete benchmark levels provide some perspective on the public health impacts of O<sub>3</sub>-related health effects that have been demonstrated in controlled human exposure and toxicological studies but cannot be evaluated in quantitative risk assessments, such as lung inflammation, increased airway responsiveness, and changes in host defenses. They also help in understanding the extent to which such impacts have the potential to be reduced by meeting the current and alternative standards. In the selection of specific benchmark concentrations for this analysis, staff first considered the exposure level of 0.080 ppm, at which there is a substantial amount of controlled human exposure evidence demonstrating a range of O<sub>3</sub>-related health effects including lung inflammation and airway responsiveness in healthy individuals. Thus, as in the 1997 review, this level was selected as a benchmark level for this assessment of exposures of concern. Evidence newly available in this review is the basis for identifying additional, lower benchmark levels of 0.070 and 0.060 ppm for this assessment.

More specifically, as discussed above in section II.A.2, evidence available from controlled human exposure and epidemiological studies indicates that people with asthma have larger and more serious effects than healthy individuals, including lung function, respiratory symptoms, increased airway responsiveness, and pulmonary inflammation, which has been shown to be a more sensitive marker than lung function responses. Further, a substantial new body of evidence from epidemiological studies shows associations with serious respiratory morbidity and cardiopulmonary mortality effects at O<sub>3</sub> levels that extend below 0.080 ppm. Additional, but very limited new evidence from controlled human exposure studies shows lung function decrements and respiratory symptoms in healthy subjects at an O<sub>3</sub> exposure level of 0.060 ppm. The selected benchmark level of 0.070 ppm reflects the new information that asthmatics have larger and more serious effects than healthy people and therefore controlled human exposure studies done with healthy subjects may underestimate effects in this group, as well as the substantial body of epidemiological evidence of associations with O<sub>3</sub> levels below 0.080 ppm. The selected benchmark level of 0.060 ppm additionally reflects the very limited new evidence from controlled human exposure studies that show lung function decrements and respiratory symptoms in some healthy subjects at the 0.060 ppm exposure level, recognizing that asthmatics are likely to have more serious responses and that lung function is not likely to be as sensitive a marker for O<sub>3</sub> effects as is lung inflammation.

The estimates of exposures of concern were reported in terms of both "people exposed" (the number and percent of people who experience a given level of O<sub>3</sub> concentrations, or higher, at least one time during the O<sub>3</sub> season in a given year) and "occurrences of exposure" (the number of times a given level of pollution is experienced by the population of interest, expressed in terms of person-days of occurrences). Estimating exposures of concern is important because it provides some indication of the potential public health impacts of a range of O<sub>3</sub>-related health outcomes, such as lung inflammation, increased airway responsiveness, and changes in host defenses. These particular health effects have been demonstrated in controlled human exposure studies of healthy individuals to occur at levels as low as 0.080 ppm O<sub>3</sub>, but have not been evaluated at lower

levels in controlled human exposure studies. The EPA did not include these effects in the quantitative risk assessment due to a lack of adequate information on the exposure-response relationships.

The 1997 O<sub>3</sub> NAAQS review estimated exposures associated with 1-hour heavy exertion, 1-hour moderate exertion, and 8-hour moderate exertion for children, outdoor workers, and the general population. The EPA's analysis in the 1997 Staff Paper showed that exposure estimates based on the 8-hour moderate exertion scenario for children yielded the largest number of children experiencing exposures at or above exposures of concern. Consequently, EPA chose to focus on the 8-hour moderate and greater exertion exposures in all and asthmatic school age children in the current exposure assessment. While outdoor workers and other adults who engage in moderate or greater exertion for prolonged durations while outdoors during the day in areas experiencing elevated O<sub>3</sub> concentrations also are at risk for experiencing exposures associated with O<sub>3</sub>-related health effects, EPA did not focus on quantitative estimates for these populations due to the lack of information about the number of individuals who regularly work or exercise outdoors. Thus, the exposure estimates presented here and in the 2007 Staff Paper are most useful for making relative comparisons across alternative air quality scenarios and do not represent the total exposures in all children or other groups within the general population associated with the air quality scenarios.

Population exposures to O<sub>3</sub> were estimated in 12 urban areas for 2002, 2003, and 2004 air quality, and also using O<sub>3</sub> concentrations adjusted to just meet the then current and several alternative standards. The estimates of 8-hour exposures of concern at and above benchmark levels of 0.080, 0.070, and 0.060 ppm aggregated across all 12 areas are shown in Table 1 for air quality scenarios just meeting the current and four alternative 8-hour average standards.<sup>36</sup> Table 1 provides estimates of the number and percent of school age children and asthmatic school age children exposed, with daily 8-hour maximum exposures at or above each O<sub>3</sub> benchmark level of exposures of concern, while at intermittent moderate or greater exertion and based on O<sub>3</sub> concentrations observed in 2002 and

<sup>36</sup>The full range of quantitative exposure estimates associated with just meeting the 0.084 ppm and alternative O<sub>3</sub> standards are presented in chapter 4 and Appendix 4A of the 2007 Staff Paper.

2004. Table 1 summarizes estimates for 2002 and 2004 because these years reflect years that bracket relatively higher and lower O<sub>3</sub> levels, with year 2003 generally containing O<sub>3</sub> levels in between when considering the 12 urban areas modeled. This table also reports the percent change in the number of persons exposed when a given alternative standard is compared with the then current standard.

Key observations important in comparing exposure estimates associated with just meeting the current NAAQS and alternative standards under consideration include:

(1) As shown in Table 6-1 of the 2007 Staff Paper, the patterns of exposure in

terms of percentages of the population exceeding a given exposure level are very similar for the general population and for asthmatic and all school age (5-18) children, although children are about twice as likely to be exposed, based on the percent of the population exposed, at any given level.

(2) As shown in Table 1 below, the number and percentage of asthmatic and all school-age children aggregated across the 12 urban areas estimated to experience one or more exposures of concern decline from simulations of just meeting the then current 0.084 ppm standard to simulations of alternative 8-hour standards by varying amounts

depending on the benchmark level, the population subgroup considered, and the year chosen. For example, the estimated percentage of school age children experiencing one or more exposures  $\geq 0.070$  ppm, while engaged in moderate or greater exertion, during an O<sub>3</sub> season is about 18 percent of this population when the 0.084 ppm standard is met using the 2002 simulation; this is reduced to about 12, 4, 1, and 0.2 percent of children upon meeting alternative standards of 0.080, 0.074, 0.070, and 0.064 ppm, respectively (all specified in terms of the 4th highest daily maximum 8-hour average), using the 2002 simulation.

TABLE 1—NUMBER AND PERCENT OF ALL AND ASTHMATIC SCHOOL AGE CHILDREN IN 12 URBAN AREAS ESTIMATED TO EXPERIENCE 8-HOUR OZONE EXPOSURES ABOVE 0.080, 0.070, AND 0.060 PPM WHILE AT MODERATE OR GREATER EXERTION, ONE OR MORE TIMES PER SEASON, AND THE NUMBER OF OCCURRENCES ASSOCIATED WITH JUST MEETING ALTERNATIVE 8-HOUR STANDARDS BASED ON ADJUSTING 2002 AND 2004 AIR QUALITY DATA<sup>1, 2</sup>

Benchmark levels of exposures of concern (ppm)	8-Hour air quality standards <sup>3</sup> (ppm)	All children, ages 5-18 Aggregate for 12 urban areas Number of children exposed (% of all) [% reduction from 0.084 ppm standard]		Asthmatic children, ages 5-18 Aggregate for 12 urban areas Number of children exposed (% of group) [% reduction from 0.084 ppm standard]	
		2002	2004	2002	2004
		0.080	0.084	700,000 (4%)	30,000 (0%)
	0.080	290,000 (2%) [70%]	10,000 (0%) [67%]	50,000 (2%) [54%]	0 (0%)
	0.074	60,000 (0%) [91%]	0 (0%) [100%]	10,000 (0%) [91%]	0 (0%)
	0.070	10,000 (0%) [98%]	0 (0%) [100%]	0 (0%) [100%]	0 (0%)
	0.064	0 (0%) [100%]	0 (0%) [100%]	0 (0%) [100%]	0 (0%)
0.070	0.084	3,340,000 (18%)	260,000 (1%)	520,000 (20%)	40,000 (1%)
	0.080	2,160,000 (12%) [35%]	100,000 (1%) [62%]	330,000 (13%) [36%]	10,000 (0%) [75%]
	0.074	770,000 (4%) [77%]	20,000 (0%) [92%]	120,000 (5%) [77%]	0 (0%) [100%]
	0.070	270,000 (1%) [92%]	0 (0%) [100%]	50,000 (2%) [90%]	0 (0%) [100%]
	0.064	30,000 (0.2%) [99%]	0 (0%) [100%]	10,000 (0.2%) [98%]	0 (0%) [100%]
0.060	0.084	7,970,000 (44%)	1,800,000 (10%)	1,210,000 (47%)	270,000 (11%)
	0.080	6,730,000 (37%) [16%]	1,050,000 (6%) [42%]	1,020,000 (40%) [16%]	150,000 (6%) [44%]
	0.074	4,550,000 (25%) [43%]	350,000 (2%) [80%]	700,000 (27%) [42%]	50,000 (2%) [81%]
	0.070	3,000,000 (16%) [62%]	110,000 (1%) [94%]	460,000 (18%) [62%]	10,000 (1%) [96%]
	0.064	950,000 (5%) [88%]	10,000 (0%) [99%]	150,000 (6%) [88%]	0 (0%) [100%]

<sup>1</sup> Moderate or greater exertion is defined as having an 8-hour average equivalent ventilation rate  $\geq 13$  l-min/m<sup>2</sup>.

<sup>2</sup> Estimates are the aggregate results based on 12 combined statistical areas (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington, DC). Estimates are for the ozone season which is all year in Houston, Los Angeles and Sacramento and March or April to September or October for the remaining urban areas.

<sup>3</sup> All standards summarized here have the same form as the 8-hour standard established in 1997 which is specified as the 3-year average of the annual 4th highest daily maximum 8-hour average concentrations must be at or below the concentration level specified. As described in the 2007 Staff Paper (EPA, 2007b, section 4.5.8), recent O<sub>3</sub> air quality distributions have been statistically adjusted to simulate just meeting the 0.084 ppm standard and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards.

(3) Substantial year-to-year variability in exposure estimates is observed over the three-year modeling period. For example, the estimated number of school age children experiencing one or more exposures  $\geq 0.070$  ppm during an O<sub>3</sub> season when a 0.084 ppm standard is met in the 12 urban areas included in the analysis is 3.3, 1.0, or 0.3 million for the 2002, 2003, and 2004 simulations, respectively.

(4) There is substantial variability observed across the 12 urban areas in the percent of the population subgroups

estimated to experience exposures of concern. For example, when 2002 O<sub>3</sub> concentrations are simulated to just meet a 0.084 ppm standard, the aggregate 12 urban area estimate is 18 percent of all school age children are estimated to experience O<sub>3</sub> exposures  $\geq 0.070$  ppm (Table 1 below), while the range of exposure estimates in the 12 urban areas considered separately for all children range from 1 to 38 percent (EPA, 2007b, p. 4-48, Exhibit 2). There was also variability in exposure estimates among the modeled areas

when using the 2004 air quality simulation for the same scenario; however it was reduced and ranged from 0 to 7 percent in the 12 urban areas (EPA, 2007b, p. 4-60, Exhibit 8).

(5) Of particular note, as discussed above in section II.A of this notice, high inter-individual variability in responsiveness means that only a subset of individuals in these groups who are exposed at and above a given benchmark level would actually be expected to experience such adverse health effects.

(6) In considering these observations, it is important to take into account the variability, uncertainties, and limitations associated with this assessment, including the degree of uncertainty associated with a number of model inputs and uncertainty in the model itself, as discussed above.

## 2. Quantitative Health Risk Assessment

This section discusses the approach used to develop quantitative health risk estimates associated with exposures to O<sub>3</sub> building upon a more limited risk assessment that was conducted during the last review.<sup>37</sup> As part of the 1997 review, EPA conducted a health risk assessment that produced risk estimates for the number and percent of children and outdoor workers experiencing lung function and respiratory symptoms associated with O<sub>3</sub> exposures for 9 urban areas.<sup>38</sup> The risk assessment for the 1997 review also included risk estimates for excess respiratory-related hospital admissions related to O<sub>3</sub> concentrations for New York City. In the last review, the risk estimates played a significant role in both the staff recommendations and in the proposed and final decisions to revise the O<sub>3</sub> standards. The health risk assessment conducted for the current review builds upon the methodology and lessons learned from the prior review.

### a. Overview

The updated health risk assessment conducted as part of the 2008 rulemaking includes estimates of (1) risks of lung function decrements in all and asthmatic school age children, respiratory symptoms in asthmatic children, respiratory-related hospital admissions, and non-accidental and cardiorespiratory-related mortality associated with recent ambient O<sub>3</sub> levels; (2) risk reductions and remaining risks associated with just meeting the then current 0.084 ppm 8-hour O<sub>3</sub> NAAQS; and (3) risk reductions and remaining risks associated with just meeting various alternative 8-hour O<sub>3</sub> NAAQS in a number of example urban areas. This risk assessment is more fully described and presented in chapter 5 of the 2007 Staff Paper and in a technical support document (TSD), *Ozone Health Risk Assessment for Selected Urban*

*Areas* (Abt Associates, 2007a, hereafter referred to as "Risk Assessment TSD"). The scope and methodology for this risk assessment were developed over the last few years with considerable input from the CASAC O<sub>3</sub> Panel and the public.<sup>39</sup> The information contained in these documents included specific criteria for the selection of health endpoints, studies, and locations to include in the assessment. In a peer review letter sent by CASAC to the Administrator documenting its advice in October 2006 (Henderson, 2006c), the CASAC O<sub>3</sub> Panel concluded that the risk assessment was "well done, balanced, and reasonably communicated" and that the selection of health endpoints for inclusion in the quantitative risk assessment was appropriate.

The goals of the risk assessment are: (1) To provide estimates of the potential magnitude of several morbidity effects and mortality associated with current O<sub>3</sub> levels, and with meeting the then current 0.084 ppm standard and alternative 8-hour O<sub>3</sub> standards in specific urban areas; (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to gain insights into the distribution of risks and patterns of risk reductions associated with meeting alternative O<sub>3</sub> standards. The health risk assessment is intended to be dependent on and reflect the overall weight and nature of the health effects evidence discussed above in section II.A and in more detail in the 2006 Criteria Document and 2007 Staff Paper. While not independent of the overall evaluation of the health effects evidence, the quantitative health risk assessment provides additional insights regarding the relative public health implications associated with just meeting a 0.084 ppm standard and several alternative 8-hour standards.

The risk assessment covers a variety of health effects for which there is adequate information to develop quantitative risk estimates. However, as noted by CASAC (Henderson, 2007) and in the 2007 Staff Paper, there are a number of health endpoints (e.g., increased lung inflammation, increased

airway responsiveness, impaired host defenses, increased medication usage for asthmatics, increased emergency department visits for respiratory causes, and increased school absences) for which there currently is insufficient information to develop quantitative risk estimates, but which are important to consider in assessing the overall public health impacts associated with exposures to O<sub>3</sub>. These additional health endpoints are discussed above in section II.A.2 and are also taken into account in considering the level of exposures of concern in populations particularly at risk, discussed above in this notice.

There are two parts to the health risk assessment: One based on combining information from controlled human exposure studies with modeled population exposure and the other based on combining information from community epidemiological studies with either monitored or adjusted ambient concentrations levels. Both parts of the risk assessment were implemented within a new probabilistic version of TRIM.Risk, the component of EPA's Total Risk Integrated Methodology (TRIM) model framework that estimates human health risks.

The EPA recognizes that there are many sources of uncertainty and variability in the inputs to this assessment and that there is significant variability and uncertainty in the resulting O<sub>3</sub> risk estimates. As discussed in chapters 2, 5, and 6 of the 2007 Staff Paper, there is significant year-to-year and city-to-city variability related to the air quality data that affects both the controlled human exposure studies-based and epidemiological studies-based parts of the risk assessment. There are also uncertainties associated with the air quality adjustment procedure used to simulate just meeting various alternative standards. In the prior review, different statistical approaches using alternative functional forms (i.e., quadratic, proportional, Weibull) were used to reflect how O<sub>3</sub> air quality concentrations have historically changed. Based on sensitivity analyses conducted in the prior review, the choice of alternative air quality adjustment procedures had only a modest impact on the risk estimates (EPA, 2007b, p. 6–20). With respect to uncertainties about estimated background concentrations, as discussed below and in the 2007 Staff Paper (section 5.4.3), alternative assumptions about background levels have a variable impact depending on the location, standard, and health endpoint analyzed.

<sup>37</sup> The methodology, scope, and results from the risk assessment conducted in the last review are described in Chapter 6 of the 1996 Staff Paper (EPA, 1996) and in several technical reports (Whitfield *et al.*, 1996; Whitfield, 1997) and publication (Whitfield *et al.*, 1998).

<sup>38</sup> The 9 urban study areas included in the exposure and risk analyses conducted during the last review were: Chicago, Denver, Houston, Los Angeles, Miami, New York City, Philadelphia, St. Louis, and Washington, DC.

<sup>39</sup> The general approach used in the health risk assessment was described in the draft Health Assessment Plan (EPA, 2005d) that was released to the CASAC and general public in April 2005 and was the subject of a consultation with the CASAC O<sub>3</sub> Panel on May 5, 2005. In October 2005, OAQPS released the first draft of the Staff Paper containing a chapter discussing the risk assessment and first draft of the Risk Assessment TSD for CASAC consultation and public review on December 8, 2005. In July 2006, OAQPS released the second draft of the Staff Paper and second draft of the Risk Assessment TSD for CASAC review and public comment which was held by the CASAC O<sub>3</sub> Panel on August 24–25, 2006.

With respect to the lung function part of the health risk assessment, key uncertainties include uncertainties in the exposure estimates, discussed above, and uncertainties associated with the shape of the exposure-response relationship, especially at levels below 0.08 ppm, 8-hour average, where only very limited data are available down to 0.04 ppm and there is an absence of data below 0.04 ppm (EPA, 2007b, pp. 6–20 to 6–21). Concerning the part of the risk assessment based on effects reported in epidemiological studies, important uncertainties include uncertainties (1) surrounding estimates of the O<sub>3</sub> coefficients for concentration-response relationships used in the assessment, (2) involving the shape of the concentration-response relationship and whether or not a population threshold or non-linear relationship exists within the range of concentrations examined in the studies, (3) related to the extent to which concentration-response relationships derived from studies in a given location and time when O<sub>3</sub> levels were higher or behavior and/or housing conditions were different provide accurate representations of the relationships for the same locations with lower air quality distributions and/or different behavior and/or housing conditions, and (4) concerning the possible role of co-pollutants which also may have varied between the time of the studies and the current assessment period. An important additional uncertainty for the mortality risk estimates is the extent to which the associations reported between O<sub>3</sub> and non-accidental and cardiorespiratory mortality actually reflect causal relationships.

As discussed below, some of these uncertainties have been addressed quantitatively in the form of estimated confidence ranges around central risk estimates; others are addressed through separate sensitivity analyses (e.g., the influence of alternative estimates for policy-relevant background levels) or are characterized qualitatively. For both parts of the health risk assessment, statistical uncertainty due to sampling error has been characterized and is expressed in terms of 95 percent credible intervals. The EPA recognizes that these credible intervals do not reflect all of the uncertainties noted above.

#### b. Scope and Key Components

The health risk assessment is based on the information evaluated in the 2006 Criteria Document. The risk assessment includes several categories of health effects and estimates risks associated with just meeting a 0.084

ppm standard and alternative 8-hour O<sub>3</sub> NAAQS and with several individual recent years of air quality (i.e., 2002, 2003, and 2004). The risk assessment considers the same alternative air quality scenarios that were examined in the human exposure analyses described above. Risk estimates were developed for up to 12 urban areas selected to illustrate the public health impacts associated with these air quality scenarios.<sup>40</sup> As discussed above in section II.B.1, the selection of urban areas was largely determined by identifying areas in the U.S. which represented a range of geographic areas, population demographics, and climatology; with an emphasis on areas that did not meet the then current 0.084 ppm 8-hour O<sub>3</sub> NAAQS and which included the largest areas with O<sub>3</sub> nonattainment problems. The selection criteria also included whether or not there were acceptable epidemiological studies available that reported concentration-response relationships for the health endpoints selected for inclusion in the assessment.

The short-term exposure related health endpoints selected for inclusion in the quantitative risk assessment include those for which the 2006 Criteria Document or the 2007 Staff Paper concluded that the evidence as a whole supports the general conclusion that O<sub>3</sub>, acting alone and/or in combination with other components in the ambient air pollution mix, is either clearly causal or is judged to be likely causal. Some health effects met this criterion of likely causality, but were not included in the risk assessment for other reasons, such as insufficient exposure-response data or lack of baseline incidence data.

As discussed in the section above describing the exposure analysis, in order to estimate the health risks associated with just meeting various alternative 8-hour O<sub>3</sub> NAAQS, it is necessary to estimate the distribution of hourly O<sub>3</sub> concentrations that would occur under any given standard. Since compliance is based on a 3-year average, the amount of control has been applied to each year of data (i.e., 2002 to 2004) to estimate risks for a single O<sub>3</sub> season or single warm O<sub>3</sub> season, depending on the health effect, based on a simulation that adjusted each of these individual

<sup>40</sup>The 12 urban areas are the same urban areas evaluated in the exposure analysis discussed in the prior section. However, for most of the health endpoints based on findings from epidemiological studies, the geographic areas and populations examined in the health risk assessment were limited to those counties included in the original epidemiological studies that served as the basis for the concentration-response relationships.

years so that the three year period would just meet the specified standard.

Consistent with the risk assessment approach used in the last review, the risk estimates developed for both recent air quality levels and just meeting the then current 0.084 ppm standard and selected alternative 8-hour standards represent risks associated with O<sub>3</sub> levels attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above “policy-relevant background”). Policy-relevant background O<sub>3</sub> concentrations used in the O<sub>3</sub> risk assessment were defined in chapter 2 of the 2007 Staff Paper (pp. 2–48–2–55) as the O<sub>3</sub> concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of precursors (e.g., VOC, NO<sub>x</sub>, and CO) in the U.S., Canada, and Mexico. The results of a global tropospheric O<sub>3</sub> model (GEOS-CHEM) have been used to estimate monthly background daily diurnal profiles for each of the 12 urban areas for each month of the O<sub>3</sub> season using meteorology for the year 2001. Based on the results of the GEOS-CHEM model, the Criteria Document indicates that background O<sub>3</sub> concentrations are generally predicted to be in the range of 0.015 to 0.035 ppm in the afternoon, and they are generally lower under conditions conducive to man-made O<sub>3</sub> episodes.<sup>41</sup>

This approach of estimating risks in excess of background is judged to be more relevant to policy decisions regarding ambient air quality standards than risk estimates that include effects potentially attributable to uncontrollable background O<sub>3</sub> concentrations. Sensitivity analyses examining the impact of alternative estimates for background on lung function and mortality risk estimates have been developed and are included in the 2007 Staff Paper and Risk Assessment TSD and key observations are discussed below. Further, CASAC noted the difficulties and complexities associated with available approaches to estimating policy-relevant background concentrations (Henderson, 2007).

In the first part of the risk assessment, lung function decrement, as measured by FEV<sub>1</sub>, is the only health response that is based on data from controlled human exposure studies. As discussed above, there is clear evidence of a causal relationship between lung function decrements and O<sub>3</sub> exposures for school age children engaged in moderate

<sup>41</sup>EPA notes that the estimated level of policy-relevant background O<sub>3</sub> used in the prior risk assessment was a single concentration of 0.04 ppm, which was the midpoint of the range of levels for policy-relevant background that was provided in the 1996 Criteria Document.

exertion based on numerous controlled human exposure and summer camp field studies conducted by various investigators. Risk estimates have been developed for O<sub>3</sub>-related lung function decrements (measured as changes in FEV<sub>1</sub>) for all school age children (ages 5 to 18) and a subset of this group, asthmatic school age children (ages 5 to 18), whose average exertion over an 8-hour period was moderate or greater. The exposure period and exertion level were chosen to generally match the exposure period and exertion level used in the controlled human exposure studies that were the basis for the exposure-response relationships. A combined data set including individual level data from the Folinsbee *et al.* (1988), Horstman *et al.* (1990), and McDonnell *et al.* (1991) studies, used in the previous risk assessment, and more recent data from Adams (2002, 2003a, 2006) have been used to estimate probabilistic exposure-response relationships for 8-hour exposures under different definitions of lung function response (*i.e.*,  $\geq 10$ , 15, and 20 percent decrements in FEV<sub>1</sub>). As discussed in the 2007 Staff Paper (p. 5-27), while these specific controlled human exposure studies only included healthy adults aged 18-35, findings from other controlled human exposure studies and summer camp field studies involving school age children in at least six different locations in the northeastern United States, Canada, and Southern California indicated changes in lung function in healthy children similar to those observed in healthy adults exposed to O<sub>3</sub> under controlled chamber conditions.

Consistent with advice from CASAC (Henderson, 2006c), EPA has considered both linear and logistic functional forms in estimating the probabilistic exposure-response relationships for lung function responses. A Bayesian Markov Chain Monte Carlo approach, described in more detail in the Risk Assessment TSD, has been used that incorporates both model uncertainty and uncertainty due to sample size in the combined data set that served as the basis for the assessment. The EPA has chosen a model reflecting a 90 percent weighting on a logistic form and a 10 percent weighting on a linear form as the base case for the risk assessment. The basis for this choice is that the logistic form provides a very good fit to the combined data set, but a linear model cannot be entirely ruled out since there are only very limited data (*i.e.*, 30 subjects) at the two lowest exposure levels (*i.e.*, 0.040 and 0.060 ppm). The EPA has conducted a sensitivity analysis which

examines the impact on the lung function risk estimates of two alternative choices, an 80 percent logistic/20 percent linear split and a 50 percent logistic/50 percent linear split.

As noted above, risk estimates have been developed for three measures of lung function response (*i.e.*,  $\geq 10$ , 15, and 20 percent decrements in FEV<sub>1</sub>). However, the 2007 Staff Paper and risk estimates summarized below focus on FEV<sub>1</sub> decrements  $\geq 15$  percent for all school age children and  $\geq 10$  percent for asthmatic school age children, consistent with the advice from CASAC (Henderson, 2006c) that these levels of response represent indicators of adverse health effects in these populations. The Risk Assessment TSD and 2007 Staff Paper present the broader range of risk estimates including all three measures of lung function response.

Developing risk estimates for lung function decrements involved combining probabilistic exposure-response relationships based on the combined data set from several controlled human exposure studies with population exposure distributions for all and asthmatic school age children associated with recent air quality and air quality simulated to just meet the then current 0.084 ppm standard and alternative 8-hour O<sub>3</sub> NAAQS based on the results from the exposure analysis described in the previous section. The risk estimates have been developed for 12 large urban areas for the O<sub>3</sub> season.<sup>42</sup> These 12 urban areas include approximately 18.3 million school age children, of which 2.6 million are asthmatic school age children.<sup>43</sup>

In addition to uncertainties arising from sample size considerations, which are quantitatively characterized and presented as 95 percentile credible intervals, there are additional uncertainties and caveats associated with the lung function risk estimates. These include uncertainties about the shape of the exposure-response relationship, particularly at levels below 0.080 ppm, and about policy-relevant background levels, for which sensitivity analyses have been conducted. Additional important caveats and uncertainties concerning the lung function portion of the health risk assessment include: (1) The

<sup>42</sup> As discussed above in section II.B.1, the urban areas were defined using the consolidated statistical areas definition and the total population residing in the 12 urban areas was approximately 88.5 million people.

<sup>43</sup> For 9 of the 12 urban areas, the O<sub>3</sub> season is defined as a period running from March or April to September or October. In 3 of the urban areas (Houston, Los Angeles, and Sacramento), the O<sub>3</sub> season is defined as the entire year.

uncertainties and limitations associated with the exposure estimates discussed above and (2) the inability to account for some factors which are known to affect the exposure-response relationships (*e.g.*, assigning healthy and asthmatic children the same responses as observed in healthy adult subjects and not adjusting response rates to reflect the increase and attenuation of responses that have been observed in studies of lung function responses upon repeated exposures). A more complete discussion of assumptions and uncertainties is contained in chapter 5 of the 2007 Staff Paper and in the Risk Assessment TSD.

The second part of the risk assessment is based on health effects observed in epidemiological studies. Based on a review of the evidence evaluated in the 2006 Criteria Document and 2007 Staff Paper, as well as the criteria discussed in chapter 5 of the 2007 Staff Paper, the following categories of health endpoints associated with short-term exposures to ambient O<sub>3</sub> concentrations were included in the risk assessment: respiratory symptoms in moderate to severe asthmatic children, hospital admissions for respiratory causes, and non-accidental and cardiorespiratory mortality. As discussed above, there is strong evidence of a causal relationship for the respiratory morbidity endpoints included in the risk assessment. With respect to nonaccidental and cardiorespiratory mortality, the 2006 Criteria Document concludes that there is strong evidence which is highly suggestive of a causal relationship between nonaccidental and cardiorespiratory-related mortality and O<sub>3</sub> exposures during the warm O<sub>3</sub> season. As discussed in the 2007 Staff Paper (chapter 5), EPA also recognizes that for some of the effects observed in epidemiological studies, such as increased respiratory-related hospital admissions and nonaccidental and cardiorespiratory mortality, O<sub>3</sub> may be serving as an indicator for reactive oxidant species in the overall photochemical oxidant mix and that these other constituents may be responsible in whole or part for the observed effects.

Risk estimates for each health endpoint category were only developed for areas that were the same or close to the location where at least one concentration-response function for the health endpoint had been estimated.<sup>44</sup>

<sup>44</sup> The geographic boundaries for the urban areas included in this portion of the risk assessment were generally matched to the geographic boundaries used in the epidemiological studies that served as the basis for the concentration-response functions. In most cases, the urban areas were defined as

Continued

Thus, for respiratory symptoms in moderate to severe asthmatic children only the Boston urban area was included and four urban areas were included for respiratory-related hospital admissions. Nonaccidental mortality risk estimates were developed for 12 urban areas and 8 urban areas were included for cardiorespiratory mortality.

The concentration-response relationships used in the assessment are based on findings from human epidemiological studies that have relied on fixed-site ambient monitors as a surrogate for actual ambient O<sub>3</sub> exposures. In order to estimate the incidence of a particular health effect associated with recent air quality in a specific county or set of counties attributable to ambient O<sub>3</sub> exposures in excess of background, as well as the change in incidence corresponding to a given change in O<sub>3</sub> levels resulting from just meeting various 8-hour O<sub>3</sub> standards, three elements are required for this part of the risk assessment. These elements are: (1) Air quality information (including recent air quality data for O<sub>3</sub> from ambient monitors for the selected location, estimates of background O<sub>3</sub> concentrations appropriate for that location, and a method for adjusting the recent data to reflect patterns of air quality estimated to occur when the area just meets a given O<sub>3</sub> standard); (2) relative risk-based concentration-response functions that provide an estimate of the relationship between the health endpoints of interest and ambient O<sub>3</sub> concentration; and (3) annual or seasonal baseline health effects incidence rates and population data, which are needed to provide an estimate of the seasonal baseline incidence of health effects in an area before any changes in O<sub>3</sub> air quality.

A key component in the portion of the risk assessment based on epidemiological studies is the set of concentration-response functions which provide estimates of the relationships between each health endpoint of interest and changes in ambient O<sub>3</sub> concentrations. Studies often report more than one estimated concentration-response function for the same location and health endpoint. Sometimes models include different sets of co-pollutants and/or different lag periods between the ambient concentrations and reported health responses. For some health endpoints, there are studies that estimated multicity and single-city O<sub>3</sub> concentration-response functions. While the Risk Assessment TSD and chapter 5

either a single county or a few counties for this portion of the risk assessment.

of the 2007 Staff Paper present a more comprehensive set of risk estimates, EPA has focused on estimates based on multicity studies where available. As discussed in chapter 5 of the 2007 Staff Paper, the advantages of relying more heavily on concentration-response functions based on multicity studies include: (1) More precise effect estimates due to larger data sets, reducing the uncertainty around the estimated coefficient; (2) greater consistency in data handling and model specification that can eliminate city-to-city variation due to study design; and (3) less likelihood of publication bias or exclusion of reporting of negative or nonsignificant findings. Where studies reported different effect estimates for varying lag periods, consistent with the 2006 Criteria Document, single day lag periods of 0 to 1 days were used for associations with respiratory hospital admissions and mortality. For mortality associated with exposure to O<sub>3</sub> which may result over a several day period after exposure, distributed lag models, which take into account the contribution to mortality effects over several days, were used where available.

One of the most important elements affecting uncertainties in the epidemiological-based portion of the risk assessment is the concentration-response relationships used in the assessment. The uncertainty resulting from the statistical uncertainty associated with the estimate of the O<sub>3</sub> coefficient in the concentration-response function was characterized either by confidence intervals or by Bayesian credible intervals around the corresponding point estimates of risk. Confidence and credible intervals express the range within which the true risk is likely to fall if the only uncertainty surrounding the O<sub>3</sub> coefficient involved sampling error. Other uncertainties, such as differences in study location, time period (*i.e.*, the years in which the study was conducted), and model uncertainties are not represented by the confidence or credible intervals presented, but were addressed by presenting estimates for different urban areas, by including risk estimates based on studies using different time periods and models, where available, and/or are discussed throughout section 5.3 of the 2007 Staff Paper. Because O<sub>3</sub> effects observed in the epidemiological studies have been more clearly and consistently shown for warm season analyses, all analyses for this portion of the risk assessment were carried out for the same time period, April through September.

The 2006 Criteria Document (p. 8–44) finds that no definitive conclusion can

be reached with regard to the existence of population thresholds in epidemiological studies. The EPA recognizes, however, the possibility that thresholds for individuals may exist for reported associations at fairly low levels within the range of air quality observed in the studies, but not be detectable as population thresholds in epidemiological analyses. Based on the 2006 Criteria Document's conclusions, EPA judged and CASAC concurred, that there is insufficient evidence to support use of potential population threshold levels in the quantitative risk assessment. However, EPA recognizes that there is increasing uncertainty about the concentration-response relationship at lower concentrations which is not captured by the characterization of the statistical uncertainty due to sampling error. Therefore, the risk estimates for respiratory symptoms in moderate to severe asthmatic children, respiratory-related hospital admissions, and premature mortality associated with exposure to O<sub>3</sub> must be considered in light of uncertainties about whether or not these O<sub>3</sub>-related effects occur in these populations at very low O<sub>3</sub> concentrations.

With respect to variability within this portion of the risk assessment, there is variability among concentration-response functions describing the relation between O<sub>3</sub> and both respiratory-related hospital admissions and nonaccidental and cardiorespiratory mortality across urban areas. This variability is likely due to differences in population (*e.g.*, age distribution), population activities that affect exposure to O<sub>3</sub> (*e.g.*, use of air conditioning), levels and composition of co-pollutants, baseline incidence rates, and/or other factors that vary across urban areas. The risk assessment incorporates some of the variability in key inputs to the analysis by using location-specific inputs (*e.g.*, location-specific concentration-response functions, baseline incidence rates, and air quality data). Although spatial variability in these key inputs across all U.S. locations has not been fully characterized, variability across the selected locations is imbedded in the analysis by using, to the extent possible, inputs specific to each urban area.

#### c. Risk Estimates and Key Observations

The 2007 Staff Paper (chapter 5) and Risk Assessment TSD present risk estimates associated with just meeting the then current 0.084 ppm standard and several alternative 8-hour standards, as well as three recent years of air quality as represented by 2002,



2003, and 2004 monitoring data. As discussed in the exposure analysis section above, there is considerable city-to-city and year-to-year variability in the O<sub>3</sub> levels during this period, which results in significant variability in both portions of the health risk assessment.

In the 1997 risk assessment, risks for lung function decrements associated with 1-hour heavy exertion, 1-hour moderate exertion, and 8-hour moderate exertion exposures were estimated. Since the 8-hour moderate exertion exposure scenario for children clearly resulted in the greatest health risks in terms of lung function decrements, EPA

chose to include only the 8-hour moderate exertion exposures in the risk assessment for this health endpoint.

Thus, the risk estimates presented here and in the 2007 Staff Paper are most useful for making relative comparisons across alternative air quality scenarios and do not represent the total risks for lung function decrements in children or other groups within the general population associated with any of the air quality scenarios. Thus, some outdoor workers and adults engaged in moderate exertion over multi-hour periods (e.g., 6–8 hour exposures) also

would be expected to experience similar lung function decrements. However, the percentage of each of these other subpopulations expected to experience these effects is expected to be smaller than all school age children who tend to spend more hours outdoors while active based on the exposure analyses conducted during the prior review.

Table 2 presents a summary of the risk estimates for lung function decrements for the 0.084 ppm standard set in 1997 and several alternative 8-hour standard levels with the same form.

TABLE 2—NUMBER AND PERCENT OF ALL AND ASTHMATIC SCHOOL AGE CHILDREN IN SEVERAL URBAN AREAS ESTIMATED TO EXPERIENCE MODERATE OR GREATER LUNG FUNCTION RESPONSES ONE OR MORE TIMES PER SEASON ASSOCIATED WITH 8-HOUR OZONE EXPOSURES ASSOCIATED WITH JUST MEETING ALTERNATIVE 8-HOUR STANDARDS BASED ON ADJUSTING 2002 AND 2004 AIR QUALITY DATA<sup>1 2</sup>

8-Hour air quality standards <sup>3</sup>	All children, ages 5–18 FEV <sub>1</sub> ≥ 15 percent Aggregate for 12 urban areas Number of children affected (% of all) [% reduction from 0.084 ppm standard]		Asthmatic Children, ages 5–18 FEV <sub>1</sub> ≥ 10 percent Aggregate for 5 urban areas Number of children affected (% of group) [% reduction from 0.084 ppm standard]	
	2002	2004	2002	2004
0.084 ppm (Standard set in 1997)	610,000 (3.3%)	230,000 (1.2%)	130,000 (7.8%)	70,000 (4.2%)
0.080 ppm	490,000 (2.7%) [20% reduction]	180,000 (1.0%) [22% reduction]	NA <sup>4</sup>	NA
0.074 ppm	340,000 (1.9%) [44% reduction]	130,000 (0.7%) [43% reduction]	90,000 (5.0%) [31% reduction]	40,000 (2.7%) [43% reduction]
0.070 ppm	260,000 (1.5%) [57% reduction]	100,000 (0.5%) [57% reduction]	NA	NA
0.064 ppm	180,000 (1.0%) [70% reduction]	70,000 (0.4%) [70% reduction]	50,000 (3.0%) [62% reduction]	20,000 (1.5%) [71% reduction]

<sup>1</sup> Associated with exposures while engaged in moderate or greater exertion, which is defined as having an 8-hour average equivalent ventilation rate ≥ 13 l-min/m<sup>2</sup>.

<sup>2</sup> Estimates are the aggregate central tendency results based on either 12 urban areas (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington, DC) or 5 urban areas (Atlanta, Chicago, Houston, Los Angeles, New York). Estimates are for the O<sub>3</sub> season which is all year in Houston, Los Angeles and Sacramento and March or April to September or October for the remaining urban areas.

<sup>3</sup> All standards summarized here have the same form as the 8-hour standard set in 1997, which is specified as the 3-year average of the annual 4th highest daily maximum 8-hour average concentrations. As described in the 2007 Staff Paper (section 4.5.8), recent O<sub>3</sub> air quality distributions have been statistically adjusted to simulate just meeting the 0.084 ppm standard set in 1997 and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards.

<sup>4</sup> NA (not available) indicates that EPA did not develop risk estimates for these scenarios for the asthmatic school age children population.

The estimates are for the aggregate number and percent of all school age children across 12 urban areas and the aggregate number and percent of asthmatic school age children across 5 urban areas<sup>45</sup> who are estimated to have at least 1 moderate or greater lung function response (defined as FEV<sub>1</sub> ≥ 15 percent in all children and ≥ 10 percent in asthmatic children) associated with 8-hour exposures to O<sub>3</sub> while engaged in moderate or greater exertion on average over the 8-hour period. The lung function risk estimates summarized in

Table 2 illustrate the year-to-year variability in both remaining risk associated with a relatively high year (i.e., based on adjusting 2002 O<sub>3</sub> air quality data) and relatively low year (based on adjusting 2004 O<sub>3</sub> air quality data) as well as the year-to-year variability in the risk reduction estimated to occur associated with various alternative standards relative to just meeting the then current 0.084 ppm standard. For example, it is estimated that about 610,000 school age children (3.2 percent of school age children) would experience 1 or more moderate lung function decrements for the 12 urban areas associated with O<sub>3</sub> levels just meeting a 0.084 ppm standard based on 2002 air quality data compared to 230,000 (1.2 percent of children)

associated with just meeting a 0.084 ppm standard based on 2004 air quality data.

As discussed in the 2007 Staff Paper, a child may experience multiple occurrences of a lung function response during the O<sub>3</sub> season. For example, upon meeting a 0.084 ppm 8-hour standard, the median estimates are that about 610,000 children would experience a moderate or greater lung function response 1 or more times for the aggregate of the 12 urban areas over a single O<sub>3</sub> season (based on the 2002 simulation), and that there would be almost 3.2 million total occurrences. Thus, on average it is estimated that there would be about 5 occurrences per O<sub>3</sub> season per responding child for air quality just meeting a 0.084 ppm 8-hour

<sup>45</sup> Due to time constraints, lung function risk estimates for asthmatic school age children were developed for only 5 of the 12 urban areas, and the areas were selected to represent different geographic regions. The 5 areas were: Atlanta, Chicago, Houston, Los Angeles, and New York City.

standard across the 12 urban areas. While the estimated number of occurrences per O<sub>3</sub> season is lower when based on the 2004 simulation than for the 2002 simulation, the estimated number of occurrences per responding child is similar. The EPA recognizes that some children in the population might have only 1 or 2 occurrences while others may have 6 or more occurrences per O<sub>3</sub> season. Risk estimates based on adjusting 2003 air quality to simulate just meeting the a 0.084 ppm standard and alternative 8-hour standards are intermediate to the estimates presented in Table 2 above in this notice and are presented in the 2007 Staff Paper (chapter 5) and Risk Assessment TSD.

For just meeting a 0.084 ppm 8-hour standard, Table 5–8 in the 2007 Staff Paper shows that median estimates across the 12 urban areas for all school age children experiencing 1 or more moderate lung function decrements ranges from 0.9 to 5.4 percent based on the 2002 simulation and from 0.8 to 2.2 percent based on the 2004 simulation. Risk estimates for each urban area included in the assessment, for each of the three years analyzed, and for additional alternative standards are presented in chapter 5 of the 2007 Staff Paper and in the Risk Assessment TSD.

For just meeting a 0.084 ppm 8-hour standard, the median estimates across the 5 urban areas for asthmatic school age children range from 3.4 to 10.9 percent based on the 2002 simulation and from 3.2 to 6.9 percent based on the 2004 simulation.

Key observations important in comparing estimated lung function risks associated with just meeting the 0.084 ppm NAAQS and alternative standards under consideration include:

(1) As discussed above, there is significant year to year variability in the range of median estimates of the number of school age children (ages 5–18) estimated to experience at least one FEV<sub>1</sub> decrement  $\geq$  15 percent due to 8-hour O<sub>3</sub> exposures across the 12 urban areas analyzed, and similarly across the 5 urban areas analyzed for asthmatic school age children (ages 5–18) estimated to experience at least one FEV<sub>1</sub> decrement  $\geq$  10 percent, when various 8-hour standards are just met.

(2) For asthmatic school age children, the median estimates of occurrences of FEV<sub>1</sub> decrements  $\geq$  10% range from 52,000 to nearly 510,000 responses associated with just meeting a 0.084 ppm standard (based on the 2002 simulation) and range from 61,000 to about 240,000 occurrences (based on the 2004 simulation). These risk estimates would be reduced to a range of 14,000

to about 275,000 occurrences (2002 simulation) and to about 18,000 to nearly 125,000 occurrences (2004 simulation) upon just meeting the most stringent alternative 8-hour standard (0.064 ppm, 4th highest). The average number of occurrences per asthmatic child in an O<sub>3</sub> season ranged from about 6 to 11 associated with just meeting a 0.084 ppm standard (2002 simulation). The average number of occurrences per asthmatic child ranged from 4 to 12 upon meeting the most stringent alternative examined (0.064 ppm, 4th-highest) based on the 2002 simulation. The number of occurrences per asthmatic child is similar for the scenarios based on the 2004 simulation.

As discussed above, several epidemiological studies have reported increased respiratory morbidity outcomes (e.g., respiratory symptoms in moderate to severe asthmatic children, respiratory-related hospital admissions) and increased nonaccidental and cardiorespiratory mortality associated with exposure to ambient O<sub>3</sub> concentrations. The results and key observations from this portion of the risk assessment are presented below:

(1) Estimates for increased respiratory symptoms (*i.e.*, chest tightness, shortness of breath, and wheeze) in moderate/severe asthmatic children (ages 0–12) were developed for the Boston urban area only. The median estimated number of days involving chest tightness (using the concentration-response relationship with only O<sub>3</sub> in the model) is about 6,100 (based on the 2002 simulation) and about 4,500 (based on the 2004 simulation) upon meeting a 0.084 ppm 8-hour standard and this is reduced to about 4,600 days (2002 simulation) and 3,100 days (2004 simulation) upon meeting the most stringent alternative examined (0.064 ppm, 4th-highest daily maximum 8-hour average). This corresponds to 11 percent (2002 simulation) and 8 percent (2004 simulation) of total incidence of chest tightness upon meeting a 0.084 ppm 8-hour standard and to about 8 percent (2002 simulation) and 5.5 percent (2004 simulation) of total incidence of chest tightness upon meeting a 0.064 ppm, 4th-highest daily maximum 8-hour average standard. Similar patterns of effects and reductions in effects are observed for each of the respiratory symptoms examined.

(2) The 2007 Staff Paper and Risk Assessment TSD present unscheduled hospital admission risk estimates for respiratory illness and asthma in New York City associated with short-term exposures to O<sub>3</sub> concentrations in excess of background levels from April

through September for several recent years (2002, 2003, and 2004) and upon just meeting a 0.084 ppm standard and alternative 8-hour standards based on simulating O<sub>3</sub> levels using 2002–2004 O<sub>3</sub> air quality data. For total respiratory illness, EPA estimates about 6.4 cases per 100,000 relevant population (2002 simulation) and about 4.6 cases per 100,000 relevant population (2004 simulation), which represents 1.5 percent (2002 simulation) and 1.0 percent (2004 simulation) of total incidence or about 510 cases (2002 simulation) and about 370 cases (2004 simulation) upon just meeting a 0.084 ppm 8-hour standard. For asthma-related hospital admissions, which are a subset of total respiratory illness admissions, the estimates are about 5.5 cases per 100,000 relevant population (2002 simulation) and about 3.9 cases per 100,000 relevant population (2004 simulation), which represents about 3.3 percent (2002 simulation) and 2.4 percent (2004 simulation) of total incidence or about 440 cases (2002) and about 310 cases (2004) for this same air quality scenario.

For increasingly more stringent alternative 8-hour standards, there is a gradual reduction in respiratory illness cases per 100,000 relevant population from 6.4 cases per 100,000 upon just meeting a 0.084 ppm 8-hour standard to 4.6 cases per 100,000 under the most stringent 8-hour standard (*i.e.*, 0.064 ppm, average 4th-highest daily maximum) analyzed based on the 2002 simulation. Similarly, based on the 2004 simulation there is a gradual reduction from 4.6 cases per 100,000 relevant population upon just meeting a 0.084 ppm 8-hour standard to 3.0 cases per 100,000 under a 0.064 ppm, average 4th-highest daily maximum standard.

Additional respiratory-related hospital admission estimates for three other locations are provided in the Risk Assessment TSD. The EPA notes that the concentration-response functions for each of these locations examined different outcomes in different age groups (e.g., > age 30 in Los Angeles, > age 64 in Cleveland and Detroit, vs. all ages in New York City), making comparison of the risk estimates across the areas very difficult.

(3) Based on the median estimates for incidence for nonaccidental mortality (based on the Bell *et al.* (2004) 95 cities concentration-response function), meeting the most stringent standard (0.064 ppm) is estimated to reduce mortality by 40 percent of what it would be associated with just meeting a 0.084 ppm standard (based on the 2002 simulation). The patterns for cardiorespiratory mortality are similar.

The aggregate O<sub>3</sub>-related cardiorespiratory mortality upon just meeting the most stringent standard shown is estimated to be about 42 percent of what it would be upon just meeting a 0.084 ppm standard, using simulated O<sub>3</sub> concentrations that just meet a 0.084 ppm standard and alternative 8-hour standards based on the 2002 simulation. Using the 2004 simulation, the corresponding reductions show a similar pattern but are somewhat greater.

(4) Much of the contribution to the risk estimates for non-accidental and cardiorespiratory mortality upon just meeting a 0.084 ppm 8-hour standard is associated with 24-hour O<sub>3</sub> concentrations between background and 0.040 ppm. Based on examining relationships between 24-hour concentrations averaged across the monitors within an urban area and 8-hour daily maximum concentrations, 8-hour daily maximum levels at the highest monitor in an urban area associated with these averaged 24-hour levels are generally about twice as high as the 24-hour levels. Thus, most O<sub>3</sub>-related nonaccidental mortality is estimated to occur when O<sub>3</sub> concentrations are between background and when the highest monitor in the urban area is at or below 0.080 ppm, 8-hour average concentration.

The discussion below highlights additional observations and insights from the O<sub>3</sub> risk assessment, together with important uncertainties and limitations.

(1) As discussed in the 2007 Staff Paper (section 5.4.5), EPA has greater confidence in relative comparisons in risk estimates between alternative standards than in the absolute magnitude of risk estimates associated with any particular standard.

(2) Significant year-to-year variability in O<sub>3</sub> concentrations combined with the use of a 3-year design value to determine the amount of air quality adjustment to be applied to each year analyzed, results in significant year-to-year variability in the annual health risk estimates upon just meeting various 8-hour standards.

(3) There is noticeable city-to-city variability in estimated O<sub>3</sub>-related incidence of morbidity and mortality across the 12 urban areas analyzed for both recent years of air quality and for air quality adjusted to simulate just meeting a 0.084 ppm standard and selected potential alternative standards. This variability is likely due to differences in air quality distributions, differences in exposure related to many factors including varying activity patterns and air exchange rates,

differences in baseline incidence rates, and differences in susceptible populations and age distributions across the 12 urban areas.

(4) With respect to the uncertainties about estimated policy-relevant background concentrations, as discussed in the 2007 Staff Paper (section 5.4.3), alternative assumptions about background levels had a variable impact depending on the health effect considered and the location and standard analyzed in terms of the absolute magnitude and relative changes in the risk estimates. There was relatively little impact on either absolute magnitude or relative changes in lung function risk estimates due to alternative assumptions about background levels. With respect to O<sub>3</sub>-related non-accidental mortality, while notable differences (*i.e.*, greater than 50 percent)<sup>46</sup> were observed for nonaccidental mortality in some areas, particularly for more stringent standards, the overall pattern of estimated reductions, expressed in terms of percentage reduction relative to the 0.084 ppm standard, was significantly less impacted.

### C. Reconsideration of the Level of the Primary Standard

#### 1. Evidence and Exposure/Risk-Based Considerations

The approach used in the 2007 Staff Paper as a basis for staff recommendations on standard levels builds upon and broadens the general approach used by EPA in the 1997 review. This approach reflects the more extensive and stronger body of evidence available for the 2008 rulemaking on a broader range of health effects associated with exposure to O<sub>3</sub>, including: (1) Additional respiratory-related endpoints; (2) new information about the mechanisms underlying respiratory morbidity effects supporting a judgment that the link between O<sub>3</sub> exposure and these effects is causal; (3) newly identified cardiovascular-related health endpoints from animal toxicology and controlled human exposures studies that are highly suggestive that O<sub>3</sub> can directly or indirectly contribute to cardiovascular morbidity, and (4) new U.S. multicity time series studies, single city studies, and several meta-analyses of these

studies that provide relatively strong evidence for associations between short-term O<sub>3</sub> exposures and all-cause (nonaccidental) mortality, at levels below the current primary standard: As well as (5) a substantial body of new evidence of increased susceptibility in people with asthma and other lung diseases. In evaluating evidence-based and exposure/risk-based considerations, the 2007 Staff Paper considered: (1) The ranges of levels of alternative standards that are supported by the evidence, and the uncertainties and limitations in that evidence and (2) the extent to which specific levels of alternative standards reduce the estimated exposures of concern and risks attributable to O<sub>3</sub> and other photochemical oxidants, and the uncertainties associated with the estimated exposure and risk reductions.

#### a. Evidence-Based Considerations

In taking into account evidence-based considerations, the 2007 Staff Paper evaluated available evidence from controlled human exposure studies and epidemiological studies, as well as the uncertainties and limitations in that evidence. In particular, it focused on the extent to which controlled human exposure studies provide evidence of lowest-observed-effects levels and the extent to which epidemiological studies provide evidence of associations that extend down to the lower levels of O<sub>3</sub> concentrations observed in the studies or some indication of potential effect thresholds in terms of 8-hour average O<sub>3</sub> concentrations.

The most certain evidence of adverse health effects from exposure to O<sub>3</sub> comes from the controlled human exposure studies, as discussed above in section II.A.2, and the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above. At those levels, there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of inflammation and other medically significant airway responses.

Two studies by Adams (2002, 2006), newly available for consideration in the 2008 rulemaking, are the only available controlled human exposure studies that examine respiratory effects associated with prolonged O<sub>3</sub> exposures at levels below 0.080 ppm, which was the lowest exposure level that had been examined in the 1997 review. As discussed above in section II.A.2.a.i.(a)(i), the Adams (2006) study investigated a range of exposure levels, including 0.060 and 0.080 ppm O<sub>3</sub>, and analyzed hour-by-hour changes in responses, including lung function (measured in term of decrements in FEV<sub>1</sub>) and respiratory

<sup>46</sup> For example, assuming lower background levels resulted in increased estimates of non-accidental mortality incidence per 100,000 that were often 50 to 100 percent greater than the base case estimates; assuming higher background levels resulted in decreased estimates of non-accidental mortality incidence per 100,000 that were less than the base case estimates by 50 percent or more in many of the areas.

symptoms, to investigate the effects of different patterns of exposure. At the 0.060 ppm exposure level, the author reported no statistically significant differences for lung function decrements; statistically significant responses were reported for total subjective respiratory symptoms toward the end of the exposure period for one exposure pattern. The EPA's reanalysis (Brown, 2007) of the data from the Adams (2006) study addressed the more fundamental question of whether there were statistically significant changes in lung function from a 6.6-hour exposure to 0.060 ppm O<sub>3</sub> versus filtered air and used a standard statistical method appropriate for a simple paired comparison. This reanalysis found small group mean lung function decrements in healthy adults at the 0.060 ppm exposure level to be statistically significantly different from responses associated with filtered air exposure.

Moreover, the Adams' studies also report a small percentage of subjects (7 to 20 percent) experienced lung function decrements (> 10 percent) at the 0.060 ppm exposure level. This is a concern because, for active healthy people, moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements of > 10% but < 20%) and/or moderate respiratory symptom responses would likely interfere with normal activity for relatively few responsive individuals. However, for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. In the context of standard setting, the CASAC indicated (Henderson, 2006c) that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements  $\geq$  10%) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease. Therefore, the results of the Adams studies which indicate that a small percentage of healthy, non-asthmatic subjects are likely to experience FEV<sub>1</sub> decrements  $\geq$  10% when exposed to 0.060 ppm O<sub>3</sub> have implications for setting a standard that protects public health, including the health of sensitive populations such as asthmatics, with an adequate margin of safety.

In considering these most recent controlled human exposure studies, the 2007 Staff Paper concluded that these studies provide evidence of a lowest-observed-effects level of 0.060 ppm for potentially adverse lung function decrements and respiratory symptoms in some healthy adults while at prolonged moderate exertion. It further

concluded that since people with asthma, particularly children, have been found to be more sensitive and to experience larger decrements in lung function in response to O<sub>3</sub> exposures than would healthy adults, the 0.060 ppm exposure level also can be interpreted as representing a level likely to cause adverse lung function decrements and respiratory symptoms in children with asthma and more generally in people with respiratory disease.

In considering controlled human exposure studies of pulmonary inflammation, airway responsiveness, and impaired host defense capabilities, discussed above in section II.A.2.a.i, the 2007 Staff Paper noted that these studies provide evidence of a lowest-observed-effects level for such effects in healthy adults at prolonged moderate exertion of 0.080 ppm, the lowest level tested. Moreover there is no evidence that the 0.080 ppm level is a threshold for these effects. Studies reporting inflammatory responses and markers of lung injury have clearly demonstrated that there is significant variation in response of subjects exposed, even to O<sub>3</sub> exposures at 0.080 ppm. One study showed notable interindividual variability in young healthy adult subjects in most of the inflammatory and cellular injury indicators analyzed at 0.080 ppm. This inter-individual variability suggests that some portion of the population would likely experience such effects at exposure levels extending well below 0.080 ppm.

As discussed above, these physiological effects have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions. Further, pulmonary inflammation is related to increased cellular permeability in the lung, which may be a mechanism by which O<sub>3</sub> exposure can lead to cardiovascular system effects, and to potential chronic effects such as chronic bronchitis or long-term damage to the lungs that can lead to reduced quality of life. These are all indicators of adverse O<sub>3</sub>-related morbidity effects, which are consistent with and lend plausibility to the adverse morbidity effects and mortality effects observed in epidemiological studies.

Significant associations between ambient O<sub>3</sub> exposures and a wide variety of respiratory symptoms and other morbidity outcomes (e.g., asthma medication use, school absences, emergency department visits, and

hospital admissions) have been reported in epidemiological studies, as discussed above in section II.A.2.a.i. Overall, the 2006 Criteria Document concludes that positive and robust associations were found between ambient O<sub>3</sub> concentrations and various respiratory disease hospitalization outcomes, when focusing particularly on results of warm-season analyses. Recent studies also generally indicate a positive association between O<sub>3</sub> concentrations and emergency department visits for asthma during the warm season. These positive and robust associations are supported by the controlled human exposure, animal toxicological, and epidemiological evidence for lung function decrements, increased respiratory symptoms, airway inflammation, and increased airway responsiveness. Taken together, the overall evidence supports a causal relationship between acute ambient O<sub>3</sub> exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season (EPA, 2006a, p. 8-77).

Moreover, many single- and multicity epidemiological studies observed positive associations of ambient O<sub>3</sub> concentrations with total nonaccidental and cardiopulmonary mortality. As discussed above in section II.A.2.b.i, the 2006 Criteria Document finds that the results from U.S. multicity time-series studies provide the strongest evidence to date for O<sub>3</sub> effects on acute mortality. Recent meta-analyses also indicate positive risk estimates that are unlikely to be confounded by PM; however, future work is needed to better understand the influence of model specifications on the magnitude of risk. The 2006 Criteria Document concludes that the "positive O<sub>3</sub> effects estimates, along with the sensitivity analyses in these three meta-analyses, provide evidence of a robust association between ambient O<sub>3</sub> and mortality" (EPA, 2006a, p. 7-97). In summary, the 2006 Criteria Document (p. 8-78) concludes that these findings are highly suggestive that short-term O<sub>3</sub> exposure directly or indirectly contribute to non-accidental and cardiopulmonary-related mortality, but additional research is needed to more fully establish underlying mechanisms by which such effects occur.

The 2007 Staff Paper considered the epidemiological studies to evaluate evidence related to potential effects thresholds at the population level for morbidity and mortality effects. As discussed above in section II.A.3.a (and more fully in the 2007 Staff Paper in chapter 3 and the 2006 Criteria

Document in chapter 7), a number of time-series studies have used statistical modeling approaches to evaluate potential thresholds at the population level. A few such studies reported some suggestive evidence of possible thresholds for morbidity and mortality outcomes in terms of 24-hour, 8-hour, and 1-hour averaging times. These results, taken together, provide some indication of possible 8-hour average threshold levels from below about 0.025 to 0.035 ppm (within the range of background concentrations) up to approximately 0.050 ppm. Other studies, however, observe linear concentration-response functions suggesting no effect threshold. The 2007 Staff Paper (p.6–60) concluded that the statistically significant associations between ambient O<sub>3</sub> concentrations and lung function decrements, respiratory symptoms, indicators of respiratory morbidity including increase emergency department visits and hospital admissions, and possibly mortality reported in a large number of studies likely extend down to ambient O<sub>3</sub> concentrations that are well below the level of the then current standard (0.084 ppm). These associations also extend well below the level of the standard set in 2008 (0.075 ppm) in that the highest level at which there is any indication of a threshold is approximately 0.050 ppm. Toward the lower end of the range of O<sub>3</sub> concentrations observed in such studies, ranging down to background levels (*i.e.*, 0.035 to 0.015 ppm), however, the 2007 Staff Paper stated that there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O<sub>3</sub>, rather than to the broader mix of air pollutants present in the ambient atmosphere.

The 2007 Staff Paper also considered studies that did subset analyses, which included only days with ambient O<sub>3</sub> concentrations below the level of the then current standard, or below even lower O<sub>3</sub> concentrations, and continue to report statistically significant associations. Notably, as discussed above, Bell *et al.* (2006) conducted a subset analysis that continued to show statistically significant mortality associations even when only days with a maximum 8-hour average O<sub>3</sub> concentration below a value of approximately 0.061 ppm were included.<sup>47</sup> Also of note is the large multicity NCICAS (Mortimer *et al.*,

2002) that reported statistically significant associations between ambient O<sub>3</sub> concentrations and lung function decrements even when days with 8-hour average O<sub>3</sub> levels greater than 0.080 ppm were excluded (which consisted of less than 5 percent of the days in the eight urban areas in the study).

Further, as discussed above in section II.A.3.a, there are limitations in epidemiological studies that make discerning thresholds in populations difficult, including low data density in the lower concentration ranges, the possible influence of exposure measurement error, and interindividual differences in susceptibility to O<sub>3</sub>-related effects in populations. There is the possibility that thresholds for individuals may exist in reported associations at fairly low levels within the range of air quality in the studies but not be detectable as population thresholds in epidemiological analyses.

Based on the above considerations, the 2007 Staff Paper recognized that the available evidence neither supports nor refutes the existence of effect thresholds at the population level for morbidity and mortality effects, and that if a population threshold level does exist, it would likely be well below the level of the then current standard and possibly within the range of background levels. Taken together, these considerations also support the conclusion that if a population threshold level does exist, it would likely be well below the level of the 0.075 ppm, 8-hour average, standard set in 2008.

In looking more broadly at evidence from animal toxicological, controlled human exposure, and epidemiological studies, the 2006 Criteria Document found substantial evidence, newly available in the 2008 rulemaking, that people with asthma and other preexisting pulmonary diseases are among those at increased risk from O<sub>3</sub> exposure. Altered physiological, morphological, and biochemical states typical of respiratory diseases like asthma, COPD, and chronic bronchitis may render people sensitive to additional oxidative burden induced by O<sub>3</sub> exposure (EPA, 2006a, section 8.7). Children and adults with asthma are the groups that have been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics may exhibit larger lung function decrements in response to O<sub>3</sub> exposure than healthy controls. As discussed more fully in section II.A.4 above, asthmatics present a different response profile for cellular, molecular, and biochemical parameters (EPA,

2006a, Figure 8–1) that are altered in response to acute O<sub>3</sub> exposure. They can have larger inflammatory responses, as manifested by larger increases in markers of inflammation such as white blood cells (*e.g.*, PMNs) or inflammatory cytokines. Asthmatics, and people with allergic rhinitis, are more likely to have an allergic-type response upon exposure to O<sub>3</sub>, as manifested by increases in white blood cells associated with allergy (*i.e.*, eosinophils) and related molecules, which increase inflammation in the airways. The increased inflammatory and allergic responses also may be associated with the larger late-phase responses that asthmatics can experience, which can include increased bronchoconstrictor responses to irritant substances or allergens and additional inflammation.

In addition to the experimental evidence of lung function decrements, respiratory symptoms, and other respiratory effects in asthmatic populations, two large U.S. epidemiological studies as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O<sub>3</sub> concentrations and measures of lung function and daily respiratory symptoms (*e.g.*, chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O<sub>3</sub> and increased asthma medication use (EPA, 2007a, chapter 6). These more serious responses in asthmatics and others with lung disease provide biological plausibility for the respiratory morbidity effects observed in epidemiological studies, such as emergency department visits and hospital admissions.

The body of evidence from controlled human exposure and epidemiological studies, which includes asthmatic as well as non-asthmatic subjects, indicates that controlled human exposure studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O<sub>3</sub> exposure on asthmatics and other susceptible populations. Therefore, relative to the healthy, non-asthmatic subjects used in most controlled human exposure studies, including the Adams (2002, 2006) studies, a greater proportion of people with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses at ambient exposures to 0.060 ppm O<sub>3</sub>. This indicates that the lowest-observed-effects levels demonstrated in controlled human exposure studies that use only healthy subjects may not

<sup>47</sup> Bell *et al.* (2006) referred to this level as being approximately equivalent to 120 µg/m<sup>3</sup>, daily 8-hour maximum, the World Health Organization guideline and European Commission target value for O<sub>3</sub>.

reflect the lowest levels at which people with asthma or other lung diseases may respond.

Being mindful of the uncertainties and limitations inherent in interpreting the available evidence, the 2007 Staff Paper stated the view that the range of alternative O<sub>3</sub> standards for consideration should take into account information on lowest-observed-effects levels in controlled human exposure studies as well as indications of possible effects thresholds reported in some epidemiological studies and questions of biological plausibility in attributing associations observed down to background levels to O<sub>3</sub> exposures alone. Based on the evidence and these considerations, it concluded that the upper end of the range of consideration should be somewhat below 0.080 ppm, the lowest-observed-effects level for effects such as pulmonary inflammation, increased airway responsiveness and impaired host-defense capabilities in healthy adults while at prolonged moderate exertion. The 2007 Staff Paper also concluded that the lower end of the range of alternative O<sub>3</sub> standards appropriate for consideration should be the lowest-observed-effects level for potentially adverse lung function decrements and respiratory symptoms in some healthy adults, 0.060 ppm.

#### b. Exposure and Risk-Based Considerations

In addition to the evidence-based considerations informing staff recommendations on alternative levels, as discussed above in section II.B, the 2007 Staff Paper also evaluated quantitative exposures and health risks estimated to occur upon meeting the then current 0.084 ppm standard and alternative standards.<sup>48</sup> In so doing, it presented the important uncertainties and limitations associated with these exposure and risk assessments (discussed above in section II.B and more fully in chapters 4 and 5 of the 2007 Staff Paper).

The 2007 Staff Paper (and the CASAC) also recognized that the exposure and risk analyses could not provide a full picture of the O<sub>3</sub> exposures and O<sub>3</sub>-related health risks

posed nationally. The EPA did not have sufficient information to evaluate all relevant at-risk groups (e.g., outdoor workers) or all O<sub>3</sub>-related health outcomes (e.g., increased medication use, school absences, and emergency department visits that are part of the broader pyramid of effects discussed above in section II.A.4.d), and the scope of the 2007 Staff Paper analyses was generally limited to estimating exposures and risks in 12 urban areas across the U.S., and to only five or just one area for some health effects included in the risk assessment. Thus, national-scale public health impacts of ambient O<sub>3</sub> exposures are clearly much larger than the quantitative estimates of O<sub>3</sub>-related incidences of adverse health effects and the numbers of children likely to experience exposures of concern associated with meeting the 0.084 ppm standard or alternative standards. On the other hand, inter-individual variability in responsiveness means that only a subset of individuals in each group estimated to experience exposures exceeding a given benchmark exposure of concern level would actually be expected to experience such adverse health effects.

The 2007 Staff Paper focused on alternative standards with the same form as the then current 0.084 ppm O<sub>3</sub> standard (i.e. the 0.074/4, 0.070/4 and 0.064/4 scenarios).<sup>49</sup> Having concluded in the 2007 Staff Paper that it was appropriate to consider a range of standard levels from somewhat below 0.080 ppm down to as low as 0.060 ppm, the 2007 Staff Paper looked to results of the analyses of exposure and risk for the 0.074/4 scenario to represent the public health impacts of selecting a standard in the upper part of the range, the results of analyses of the 0.070/4 scenario to represent the impacts in the middle part of the range, and the results of the analyses of the 0.064/4 scenario to represent the lower part of the range.

As discussed in section II.B.1 of this notice, the exposure estimates presented in the 2007 Staff Paper are for the number and percent of all children and asthmatic children exposed, and the number of person-days (occurrences) of exposures, with daily 8-hour maximum exposures at or above several benchmark levels while at intermittent, moderate or greater exertion. Exposures above selected benchmark levels provide some perspective on the public

health impacts of health effects that cannot currently be evaluated in quantitative risk assessments but that may occur at existing air quality levels, and the extent to which such impacts might be reduced by meeting alternative standard levels. As described in section II.B.1.c above, the 2007 Staff Paper refers to exposures at and above these benchmark levels as "exposures of concern." The 2007 Staff Paper notes that exposures of concern, and the health outcomes they represent, likely occur across a range of O<sub>3</sub> exposure levels, such that there is no one exposure level that addresses all public health concerns. As noted above in section II.B., EPA also has acknowledged that the concept is more appropriately viewed as a continuum with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O<sub>3</sub> exposure levels.

Consistent with advice from CASAC, the 2007 Staff Paper estimates exposures of concern not only at 0.080 ppm O<sub>3</sub>, a level at which there are clearly demonstrated effects, but also at 0.070 and 0.060 ppm O<sub>3</sub> levels where there is some evidence that health effects are likely to occur in some individuals. The 2007 Staff Paper recognizes that there will be varying degrees of concern about exposures at each of these levels, based in part on the population groups experiencing them. Given that there is clear evidence of inflammation, increased airway responsiveness, and changes in host defenses in healthy people exposed to 0.080 ppm and reason to infer that such effects will continue at lower exposure levels, but with increasing uncertainty about the extent to which such effects occur at lower O<sub>3</sub> concentrations, the 2007 Staff Paper and discussion below, focus on exposures of concern at or above benchmark levels of 0.070 and 0.060 ppm O<sub>3</sub> for purposes of evaluating alternative standards. The focus on these two benchmark levels reflects the following evidence-based considerations, discussed above in section II.C.1, that raise concerns about adverse health effects likely occurring at levels below 0.080 ppm: (1) That there is limited, but important, new evidence from controlled human exposure studies showing lung function decrements and respiratory symptoms in some healthy subjects at 0.060 ppm; (2) that asthmatics are likely to have more serious responses than healthy individuals; (3) that lung function is not likely to be as sensitive a marker for O<sub>3</sub>

<sup>48</sup> As described in the 2007 Staff Paper (section 4.5.8) and discussed above in section II.B, recent O<sub>3</sub> air quality distributions have been statistically adjusted to simulate just meeting the then current 0.084 ppm standard and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards. Modeling that projects whether and how areas might attain alternative standards in a future year is presented in the Regulatory Impact Analysis being prepared in connection with this rulemaking.

<sup>49</sup> The abbreviated notation used to identify the then current 0.084 ppm standard and alternative standards in this section and in the risk assessment section of the Staff Paper is in terms of ppm and the nth highest daily maximum 8-hour average. For example, the 8-hour standard established in 1997 is identified as "0.084/4."

effects as lung inflammation; and (4) that there is epidemiological evidence which reports associations with O<sub>3</sub> levels that extend well below 0.080 ppm.

Table 3 below summarizes the exposure estimates for all children and asthmatic children for the 0.060 and 0.070 ppm health effect benchmark levels associated with O<sub>3</sub> levels adjusted to just meet 0.074/4, 0.070/4, and 0.064/4 alternative 8-hour standards based on a generally poorer year of air quality (2002) and based on a generally better year of air quality (2004). This table includes exposure estimates reflecting the aggregate estimate for the 12 urban areas as well as the range across these same 12 areas. As shown in Table 3 below, the percent of population exposed over the selected benchmark levels is very similar for all and asthmatic school age children. Thus, the following discussion focuses primarily on the exposure estimates for asthmatic children, recognizing that the pattern of exposure estimates is similar for all children when expressed in terms of percentage of the population.

As noted in section II.B.2 and shown in Tables 1 and 3 of this notice, substantial year-to-year variability is observed, ranging to over an order of magnitude at the higher alternative standard levels, in estimates of the number of children and the number of occurrences of exposures of concern at both the 0.060 and 0.070 ppm benchmark levels. As shown in Table 3, and discussed more fully below, aggregate estimates of exposures of concern for the 12 urban areas included in the assessment are considerably larger for the benchmark level of  $\geq 0.060$  ppm O<sub>3</sub>, compared to the 0.070 ppm benchmark, while the pattern of year-to-year variability is fairly similar.

As shown in Table 3, aggregate estimates of exposures of concern for a 0.060 ppm benchmark level vary considerably among the three alternative standards included in this table, particularly for the 2002 simulations (a year with generally poorer air quality in most, but not all areas). For air quality just meeting a 0.074/4 standard approximately 27% of asthmatic children, based on the 2002 simulation, and approximately 2% of asthmatic children based on the 2004 simulation (a year with better air quality in most but not all areas), are estimated to experience one or more exposures of concern at the benchmark level of  $\geq 0.060$  ppm O<sub>3</sub>. Considering a 0.070/4 standard using the same benchmark level (0.060 ppm), about 18% of asthmatic children are estimated to experience one or more exposures of

concern, in a year with poorer air quality (2002), and only about 1% in a year with better air quality (2004). For the most stringent standard examined (a 0.064/4 standard), about 6% of asthmatic children are estimated to experience one or more exposures of concern in the simulation based on the year with poorer air quality (2002), and exposures of concern at the 0.060 ppm benchmark level are essentially eliminated based on a year with better air quality (2004).

Table 3 also provides aggregate exposure estimates for the 12 urban areas where a benchmark level of  $\geq 0.070$  ppm is used. Based on the year with poorer air quality (2002), the estimate of the percent of asthmatic children exposed one or more times is about 5% when a 0.074/4 standard is just met; based on a year with better air quality (2004), exposures of concern are essentially eliminated. For this same benchmark (0.070 ppm), when a 0.070/4 standard is just met, estimates range from about 2% of asthmatic children exposed one or more times over this benchmark based on a year with poorer air quality (2002), and exposures of concern are essentially eliminated based on a year with better air quality (2004). At the 0.070 ppm benchmark, just meeting a 0.064/4 standard essentially eliminates exposures of concern regardless of the year that is used as the basis for the analysis.

The 2007 Staff Paper also notes that there is substantial city-to-city variability in these estimates, and notes that it is appropriate to consider not just the aggregate estimates across all cities, but also to consider the public health impacts in cities that receive relatively less protection from the alternative standards. As shown in Table 3, in considering the benchmark level of  $\geq 0.060$  ppm, while the aggregate percentage of asthmatic children estimated to experience one or more exposures of concern across all 12 cities for a 0.074/4 standard is about 27% based on the year with poorer air quality (2002), it ranges up to approximately 51% for asthmatic children in the city with the least degree of protection from that alternative standard. Similarly, for air quality just meeting a 0.070/4 standard, the aggregate percentage of asthmatic children estimated to experience one or more exposures of concern across all 12 cities is 18% based on the year with poorer air quality, but it ranges up to about 41% in the city with the least degree of protection associated with just meeting that alternative standard. For just meeting a 0.064/4 standard, the aggregate estimate of asthmatic children experiencing

exposures of concern for the 0.060 ppm benchmark is about 6% based on the year with poorer air quality and ranges up to 16% in the city with the least degree of protection.

This pattern of city-to-city variability also occurs at the benchmark level of  $\geq 0.070$  ppm associated with air quality just meeting these same three alternative standards (i.e., 0.074/4, 0.070/4, and 0.064/4). While the aggregate percentage of asthmatic children estimated to experience such exposures of concern across all 12 cities is about 5% based on the year with poorer air quality for just meeting the 0.074/4 standard, it ranges up to 14% in the city with the least degree of protection associated with that alternative standard. For just meeting a 0.070/4 standard the aggregate estimate is 2% of asthmatic children experiencing exposures of concern for the 0.070 ppm benchmark based on the year with poorer air quality and ranges up to 6% in the city with the least degree of protection. The aggregate estimate for exposures of concern is further reduced to 0.2% of asthmatic children for this same benchmark level for air quality just meeting a 0.064/4 standard based on the year with poorer air quality and ranges up to 1% in the city with the least degree of protection.

In addition to observing the fraction of the population estimated to experience exposures of concern associated with just meeting alternative standards, EPA also took into consideration in the 2007 Staff Paper the percent reduction in exposures of concern and health risks associated with alternative standards relative to just meeting the then current 0.084/4 standards. For the current decision it is also informative to consider the incremental reductions in exposures of concern associated with more stringent alternative standards relative to the 0.075 ppm standard. As shown in Table 1 above, at the  $\geq 0.060$  ppm benchmark level based on a year with poorer air quality, the reduction in exposures of concern for asthmatic children in going from the 0.074/4 standard (which approximates the 0.075 ppm standard adopted in 2008) down to a 0.064/4 standard is observed to be very similar to the reduction estimated to occur in going from then current 0.084/4 standard down to a 0.074/4 standard. More specifically, the estimates for asthmatic children are reduced from 47% (about 1.2 million children) associated with meeting a 0.084/4 standard down to 27% (about 700,000 children) for just meeting a 0.074/4 standard and the estimates are reduced further to about 6% (about 150,000 children) associated with just meeting a

0.064/4 standard in the 12 urban areas included in the assessment. In a year with better air quality (2004), exposures estimated to exceed the 0.060 ppm benchmark in asthmatic children one or more times in a year are reduced from 11% associated with just meeting a 0.084/4 standard down to about 2% for a 0.074/4 standard and are essentially eliminated when a 0.064/4 standard is just met.

Turning to consideration of the risk assessment estimates, Table 2 above summarizes the risk estimates for moderate lung function decrements in both all school age children and asthmatic school age children associated with just meeting several alternative standards based on simulations involving a year with relatively poorer air quality (2002) and a year with relatively better air quality (2004). As shown in Table 2, for the 2002 simulation the reduction in the number of asthmatic children estimated to experience one or more moderate lung function decrements going from a 0.074/4 standard down to a 0.064/4 standard is roughly equivalent to the additional health protection afforded associated with just meeting a 0.074/4 standard relative to then current 0.084/4 standard. More specifically, for just 5 urban areas, it is estimated that nearly 8% of asthmatic children (130,000 children) would experience one or more occurrences of moderate lung function decrements per year at a 0.084/4 standard and this would be reduced to about 5% (90,000 children) at a 0.074/4 standard and further reduced down to about 3% (50,000 children) at a 0.064/4 standard. Based on the 2002 simulations, the percent reduction associated with just meeting a 0.064/4 standard relative to then current 0.084/4 standard is about 62% which is about twice the reduction in risk compared to the estimated 31% reduction associated

with just meeting a 0.074/4 standard. As shown in Table 2 above, similar patterns were observed in reductions in lung function risk for all school age children in 12 urban areas associated with these alternative standards.

Figures 6-5 and 6-6 in the 2007 Staff Paper (EPA, 2007b) show the percent reduction in non-accidental mortality risk estimates associated with just meeting the same alternative standards discussed above relative to just meeting the then current 0.084/4 standard for 12 urban areas, based on adjusting 2002 and 2004 air quality data. These figures also provide perspective on the extent to which the risks in these years (*i.e.*, 2002 and 2004) are greater than those estimated to occur upon meeting the then current 0.084/4 standard (in terms of a negative percent reduction relative to a 0.084/4 standard). Based on the 2002 simulations (EPA, 2007b, Figure 6-5), the estimated reduction in non-accidental mortality is about 30 to 70% across the 12 urban areas for just meeting a 0.064/4 standard relative to the then current 0.084/4 standard. This reduction is roughly twice the 15 to 30% estimated reduction across the 12 urban areas associated with just meeting a 0.074/4 standard relative to a 0.084/4 standard. While the estimated incidence is lower based on the 2004 simulations (EPA, 2007b, Figure 6-6), the pattern of risk reductions among alternative standards is roughly similar to that observed for the 2002 simulations.

In addition to the risk estimates for lung function decrements in all school age children and non-accidental mortality that were estimated for 12 urban areas and lung function decrements in asthmatic children for 5 urban areas, a similar pattern of incremental reductions in health risks was shown for two health outcomes where risks were estimated in one city only for each of these outcomes. These

included reductions in respiratory symptoms in asthmatic children (EPA, 2007b; Boston, Table 6-9) and respiratory-related hospital admissions (EPA, 2007a; New York City, Table 6-10) associated with just meeting alternative 8-hour standards set at 0.074 ppm, 0.070 ppm, and 0.064 ppm relative to just meeting the then current 0.084 ppm standard. Using the 2002 simulation, a standard set at 0.074/4 is estimated to reduce the incidence of symptom days in children with moderate to severe asthma in the Boston area by about 15 percent relative to a 0.084/4 standard. With this reduction, it is estimated that about 1 respiratory symptom day in 8 during the O<sub>3</sub> season would be attributable to O<sub>3</sub> exposure. A standard set at 0.064/4 is estimated, based on the 2002 simulation, to reduce the incidence of symptom days in children with moderate to severe asthma in the Boston area by about a 25 to 30 percent reduction relative to a 0.084 ppm standard, which is roughly twice the reduction compared to that provided by a 0.074/4 standard. But even with this reduction, it is estimated that 1 respiratory symptom day in 10 during the O<sub>3</sub> season is attributable to O<sub>3</sub> exposure.

As shown in Table 6-10 (EPA, 2007b) estimated incidence of respiratory-related hospital admissions in one urban area (New York City) was reduced by 14 to 17 percent by a standard set at 0.074/4 relative to then current 0.084/4 standard, in the year with relatively high and relatively low O<sub>3</sub> air quality levels, respectively. Similar to the pattern observed for the other health outcomes discussed above, the reduction in incidence of respiratory-related hospital admissions for a 0.064/4 standard relative to a 0.084/4 standard is about twice that associated with a 0.074/4 standard relative to a 0.084/4 standard.

TABLE 3—NUMBER AND PERCENT OF ALL AND ASTHMATIC SCHOOL AGE CHILDREN IN 12 URBAN AREAS ESTIMATED TO EXPERIENCE 8-HOUR OZONE EXPOSURES ABOVE 0.060 AND 0.070 PPM WHILE AT MODERATE OR GREATER EXERTION, ONE OR MORE TIMES PER SEASON ASSOCIATED WITH JUST MEETING ALTERNATIVE 8-HOUR STANDARDS BASED ON ADJUSTING 2002 AND 2004 AIR QUALITY DATA<sup>1, 2</sup>

Benchmark levels of exposures of concern (ppm)	8-Hour air quality standards <sup>3</sup> (ppm)	All children, ages 5-18 Aggregate for 12 urban areas Number of children exposed (% of all children) [Range across 12 cities, % of all children]		Asthmatic children, ages 5-18 Aggregate for 12 urban areas Number of children exposed (% of group) [Range across 12 cities, % of group]	
		2002	2004	2002	2004
		0.070	0.074	770,000 (4%) [0-13%]	20,000 (0%) [0-1%]
	0.070	270,000 (1%) [0-5%]	0 (0%) [0%]	50,000 (2%) [0-6%]	0 (0%) [0%]
	0.064	30,000 (0.2%) [0-1%]	0 (0%) [0%]	10,000 (0.2%) [0-1%]	0 (0%) [0%]



TABLE 3—NUMBER AND PERCENT OF ALL AND ASTHMATIC SCHOOL AGE CHILDREN IN 12 URBAN AREAS ESTIMATED TO EXPERIENCE 8-HOUR OZONE EXPOSURES ABOVE 0.060 AND 0.070 PPM WHILE AT MODERATE OR GREATER EXERCISE, ONE OR MORE TIMES PER SEASON ASSOCIATED WITH JUST MEETING ALTERNATIVE 8-HOUR STANDARDS BASED ON ADJUSTING 2002 AND 2004 AIR QUALITY DATA<sup>1,2</sup>—Continued

Benchmark levels of exposures of concern (ppm)	8-Hour air quality standards <sup>3</sup> (ppm)	All children, ages 5–18 Aggregate for 12 urban areas Number of children exposed (% of all children) [Range across 12 cities, % of all children]		Asthmatic children, ages 5–18 Aggregate for 12 urban areas Number of children exposed (% of group) [Range across 12 cities, % of group]	
		2002	2004	2002	2004
		0.060	0.074	4,550,000 (25%) [1–48%]	350,000 (2%) [0–9%]
	0.070	3,000,000 (16%) [1–36%]	110,000 (1%) [0–4%]	460,000 (18%) [0–41%]	10,000 (1%) [0–3%]
	0.064	950,000 (5%) [0–17%]	10,000 (0%) [0–1%]	150,000 (6%) [0–16%]	0 (0%) [0–1%]

<sup>1</sup> Moderate or greater exertion is defined as having an 8-hour average equivalent ventilation rate  $\geq 13$  l-min/m<sup>2</sup>.

<sup>2</sup> Estimates are the aggregate results based on 12 combined statistical areas (Atlanta, Boston, Chicago, Cleveland, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington, DC). Estimates are for the ozone season which is all year in Houston, Los Angeles and Sacramento and March or April to September or October for the remaining urban areas.

<sup>3</sup> All standards summarized here have the same form as the 8-hour standard established in 1997 which is specified as the 3-year average of the annual 4th highest daily maximum 8-hour average concentrations must be at or below the concentration level specified. As described in the 2007 Staff Paper (EPA, 2007b, section 4.5.8), recent O<sub>3</sub> air quality distributions have been statistically adjusted to simulate just meeting the 0.084 ppm standard and selected alternative standards. These simulations do not represent predictions of when, whether, or how areas might meet the specified standards.

## 2. CASAC Views Prior to 2008 Decision

In comments on the second draft Staff Paper, CASAC stated in its letter to the Administrator, “the CASAC unanimously recommends that the current primary ozone NAAQS be revised and that the level that should be considered for the revised standard be from 0.060 to 0.070 ppm” (Henderson, 2006c, p. 5). This recommendation followed from its more general recommendation that the 0.084 ppm standard needed to be substantially reduced to be protective of human health, particularly in at-risk subpopulations.

The CASAC Panel noted that beneficial reductions in some adverse health effects were estimated to occur upon meeting the lowest standard level (0.064 ppm) considered in the risk assessment (Henderson, 2006c, p. 4). The lower end of this range reflects CASAC’s views that “[w]hile data exist that adverse health effects may occur at levels lower than 0.060 ppm, these data are less certain and achievable gains in protecting human health can be accomplished through lowering the ozone NAAQS to a level between 0.060 and 0.070 ppm.” (id.).

In a subsequent letter sent specifically to offer advice to aid the Administrator and Agency staff in developing the O<sub>3</sub> proposal, the CASAC reiterated that the Panel members “were unanimous in recommending that the level of the current primary ozone standard should be lowered from 0.08 ppm to no greater than 0.070 ppm” (Henderson, 2007, p. 2). Further, the CASAC Panel expressed

the view that the 2006 Criteria Document and 2007 Staff Paper, together with the information in its earlier letter, provide “overwhelming scientific evidence for this recommendation,” and emphasized the Clean Air Act requirement that the primary standard must be set to protect the public health with an adequate margin of safety (id.).

## 3. Basis for 2008 Decision on the Primary Standard

This section presents the rationale for the 2008 final decision on the primary O<sub>3</sub> standard as presented in the 2008 final rule (73 FR 16475). The EPA’s conclusions on the level of the standard began by noting that, having carefully considered the public comments on the appropriate level of the O<sub>3</sub> standard, EPA concluded that the fundamental scientific conclusions on the effects of O<sub>3</sub> reached in the 2006 Criteria Document and 2007 Staff Paper remained valid. In considering the level at which the primary O<sub>3</sub> standard should be set, EPA placed primary consideration on the body of scientific evidence available in the 2008 final rulemaking on the health effects associated with O<sub>3</sub> exposure, while viewing the results of exposure and risk assessments as providing information in support of the decision. In considering the available scientific evidence, EPA concluded that a focus on the proposed range of 0.070 to 0.075 ppm was appropriate in light of the large body of controlled human exposure and epidemiological and other scientific

evidence. The notice stated that this body of evidence did not support retaining the then current 0.084 ppm 8-hour O<sub>3</sub> standard, as suggested by some commenters, nor did it support setting a level just below 0.080 ppm, because, based on the entire body of evidence, such a level would not provide a significant increase in protection compared to the 0.084 ppm standard. Further, such a level would not be appreciably below the level in controlled human exposure studies at which adverse effects have been demonstrated (i.e., 0.080 ppm). The notice also stated that the body of evidence did not support setting a level of 0.060 ppm or below, as suggested by other commenters. In evaluating the information from the exposure assessment and the risk assessment, EPA judged that this information did not provide a clear enough basis for choosing a specific level within the range of 0.075 to 0.070 ppm.

In making a final judgment about the level of the primary O<sub>3</sub> standard, EPA noted that the level of 0.075 ppm is above the range recommended by the CASAC (i.e., 0.070 to 0.060 ppm). The notice stated that in placing great weight on the views of CASAC, careful consideration had been given to CASAC’s stated views and the scientific basis and policy views for the range it recommended. In so doing, EPA fully agreed that the scientific evidence supports the conclusion that the current standard was not adequate and must be revised.

With respect to CASAC's recommended range of standard levels, EPA observed that the basis for CASAC's recommendation appeared to be a mixture of scientific and policy considerations. While in general agreement with CASAC's views concerning the interpretation of the scientific evidence, EPA noted that there was no bright line clearly directing the choice of level, and the choice of what was appropriate was clearly a public health policy judgment entrusted to the EPA Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. In reviewing the basis for the CASAC Panel's recommendation for the range of the O<sub>3</sub> standard, EPA observed that it reached a different policy judgment than the CASAC Panel based on apparently placing different weight in two areas: The role of the evidence from the Adams studies and the relative weight placed on the results from the exposure and risk assessments. While EPA found the evidence reporting effects at the 0.060 ppm level from the Adams studies to be too limited to support a primary focus at this level, EPA observed that the CASAC Panel appeared to place greater weight on this evidence, as indicated by its recommendation of a range down to 0.060 ppm. It was noted that while the CASAC Panel supported a level of 0.060 ppm, they also supported a level above 0.060, which indicated that they did not believe that the results of Adams studies meant that the level of the standard had to be set at 0.060 ppm. The EPA also observed that the CASAC Panel appeared to place greater weight on the results of the risk assessment as a basis for its recommended range. In referring to the risk assessment results for lung function, respiratory symptoms, hospital admissions and mortality, the CASAC Panel concluded that: "beneficial effects in terms of reduction of adverse health effects were calculated to occur at the lowest concentration considered (*i.e.*, 0.064 ppm)" (Henderson, 2006c, p. 4). However, EPA more heavily weighed the implications of the uncertainties associated with the Agency's quantitative human exposure and health risk assessments. Given these uncertainties, EPA did not agree that these assessment results appropriately served as a primary basis for concluding that levels at or below 0.070 ppm were required for the 8-hour O<sub>3</sub> standard.

The notice stated that after carefully taking the above comments and

considerations into account, and fully considering the scientific and policy views of the CASAC, EPA decided to revise the level of the primary 8-hour O<sub>3</sub> standard to 0.075 ppm. The EPA judged, based on the available evidence, that a standard set at this level would be requisite to protect public health with an adequate margin of safety, including the health of sensitive subpopulations, from serious health effects including respiratory morbidity, that were judged to be causally associated with short-term and prolonged exposures to O<sub>3</sub>, and premature mortality. The EPA also judged that a standard set at this level provides a significant increase in protection compared to the 0.084 ppm standard, and is appreciably below 0.080 ppm, the level in controlled human exposure studies at which adverse effects have been demonstrated. At a level of 0.075 ppm, exposures at and above the benchmark of 0.080 ppm are essentially eliminated, and exposures at and above the benchmark of 0.070 are substantially reduced or eliminated for the vast majority of people in at-risk groups. A standard set at a level lower than 0.075 would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with 8-hour average O<sub>3</sub> concentrations that are well below the concentrations observed in the key controlled human exposure studies and if the reported associations observed in epidemiological studies are, in fact, causally related to O<sub>3</sub> at those lower levels. Based on the available evidence, EPA was not prepared to make these assumptions. Taking into account the uncertainties that remained in interpreting the evidence from available controlled human exposure and epidemiological studies at very low levels, EPA noted that the likelihood of obtaining benefits to public health decreased with a standard set below 0.075 ppm O<sub>3</sub>, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increased. The EPA judged that the appropriate balance to be drawn, based on the entire body of evidence and information available in the 2008 final rulemaking, was to set the 8-hour primary standard at 0.075 ppm. The EPA expressed the belief that a standard set at 0.075 ppm would be sufficient to protect public health with an adequate margin of safety, and did not believe that a lower standard was needed to provide this degree of protection. The EPA further asserted that this judgment appropriately considered the

requirement for a standard that was neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

#### 4. CASAC Advice Following 2008 Decision

Following the 2008 decision on the O<sub>3</sub> standard, serious questions were raised as to whether the standard met the requirements of the CAA. In April 2008, the members of the CASAC Ozone Review Panel sent a letter to EPA stating "In our most-recent letters to you on this subject—dated October 2006 and March 2007—the CASAC unanimously recommended selection of an 8-hour average Ozone NAAQS within the range of 0.060 to 0.070 parts per million for the primary (human health-based) Ozone NAAQS" (Henderson, 2008). The letter continued: "The CASAC now wishes to convey, by means of this letter, its additional, unsolicited advice with regard to the primary and secondary Ozone NAAQS. In doing so, the participating members of the CASAC Ozone Review Panel are unanimous in strongly urging you or your successor as EPA Administrator to ensure that these recommendations be considered during the next review cycle for the Ozone NAAQS that will begin next year" (*id.*). Moreover, the CASAC Panel noted that "numerous medical organizations and public health groups have also expressed their support of these CASAC recommendations." (*id.*) The letter further stated the following strong, unanimous view:

[the CASAC did] "not endorse the new primary ozone standard as being sufficient protective of public health. The CASAC—as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards—unanimously recommended decreasing the primary standard to within the range of 0.060–0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations" (Henderson, 2008).

#### 5. Administrator's Proposed Conclusions

For the reasons discussed below, the Administrator proposes to set a new level for the 8-hour primary O<sub>3</sub> within

the range from 0.060 to 0.070 ppm.<sup>50</sup> In reaching this proposed decision, the Administrator has considered: the evidence-based considerations from the 2006 Criteria Document and the 2007 Staff Paper; the results of the exposure and risk assessments discussed above and in the 2007 Staff Paper; CASAC advice and recommendations provided in CASAC's letters to the Administrator both during and following the 2008 rulemaking; EPA staff recommendations; and public comments received in conjunction with review of drafts of these documents and on the 2007 proposed rule. In considering what level of an 8-hour O<sub>3</sub> standard is requisite to protect public health with an adequate margin of safety, the Administrator is mindful that this choice requires judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information.

The Administrator notes that the most certain evidence of adverse health effects from exposure to O<sub>3</sub> comes from the controlled human exposure studies, and that the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above. At those levels, there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of O<sub>3</sub>-induced pulmonary inflammation, airway responsiveness, impaired host defense capabilities, and other medically significant airway responses. Moreover, there is no evidence that the 0.080 ppm exposure level is a threshold for any of these types of respiratory effects. Rather, there is now controlled human exposure evidence, including studies of lung function decrements and respiratory symptoms at the 0.060 ppm exposure level, that strengthens our previous understanding that this array of respiratory responses are likely to occur in some healthy adults at such lower levels.

In particular, the Administrator notes two studies by Adams (2002, 2006), newly available in the 2008 rulemaking, that examined lung function and respiratory symptom effects associated with prolonged O<sub>3</sub> exposures at levels below 0.080 ppm, as well as EPA's

reanalysis of the data from the Adams (2006) study at a 0.060 ppm exposure level. As discussed above, while the author's analysis focused on hour-by-hour comparisons of effects, for the purpose of exploring responses associated with different patterns of exposure, EPA's reanalysis focused on addressing the more fundamental question of whether the pre- to post-exposure change in lung function differed between a 6.6-hour exposure to 0.060 ppm O<sub>3</sub> versus a 6.6 hour exposure to clean filtered air. The Administrator notes that this reanalysis found small, but statistically significant group mean differences in lung function decrements in healthy adults at the 0.060 ppm exposure level, which is now the lowest-observed-effects level for these effects. Moreover, these studies also report a small percentage of subjects (7 to 20 percent) experienced moderate lung function decrements ( $\geq 10$  percent) at the 0.060 ppm exposure level. While for active healthy people, moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements of  $\geq 10\%$  but  $< 20\%$ ) and/or moderate respiratory symptom responses would likely interfere with normal activity for relatively few responsive individuals, the Administrator notes that for people with lung disease, even moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. Further, she notes that CASAC indicated that a focus on the lower end of the range of moderate levels of functional responses (e.g., FEV<sub>1</sub> decrements  $\geq 10\%$ ) is most appropriate for estimating potentially adverse lung function decrements in people with lung disease (Henderson, 2006c).

The Administrator also notes that many public commenters on the 2007 proposed rule raised a number of questions about the weight that should be placed on the Adams studies and EPA's reanalysis of data from the Adams (2006) study. Some commenters expressed the view that the results of these studies and EPA's reanalysis provided support for setting a standard level below the proposed range, while others raised questions about EPA's reanalysis and generally expressed the view that the study results were not robust enough to reach conclusions about respiratory effects at the 0.060 ppm exposure level.<sup>51</sup>

Based on all the above considerations, the Administrator concludes that the Adams studies provide limited but

important evidence which adds to the overall body of evidence that informs her proposed decision on the range of levels within which a standard could be set that would be requisite to protect public health with an adequate margin of safety, including the health of at-risk populations such as people with lung disease.

In considering controlled human exposure studies reporting O<sub>3</sub>-induced pulmonary inflammation, airway responsiveness, and impaired host defense capabilities at exposure levels down to 0.080 ppm, the lowest level at which these effects have been tested, the Administrator notes that these physiological effects have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions, especially in people with lung disease. These physiological effects are all indicators of potential adverse O<sub>3</sub>-related morbidity effects, which are consistent with and lend plausibility to the associations observed between O<sub>3</sub> and adverse morbidity effects and mortality effects in epidemiological studies.

With regard to epidemiological studies, the Administrator observes that statistically significant associations between ambient O<sub>3</sub> levels and a wide array of respiratory symptoms and other morbidity outcomes including school absences, emergency department visits, and hospital admissions have been reported in a large number of studies. More specifically, positive and robust associations were found between ambient O<sub>3</sub> concentrations and respiratory hospital admissions and emergency department visits, when focusing particularly on the results of warm season analyses. Taken together, the overall body of evidence from controlled human exposure, toxicological, and epidemiological studies supports the inference of a causal relationship between acute ambient O<sub>3</sub> exposures and increased respiratory morbidity outcomes resulting in increased emergency department visits and hospitalizations during the warm season. Further, the Administrator notes that recent epidemiological evidence is highly suggestive that O<sub>3</sub> directly or indirectly contributes to non-accidental and cardiopulmonary-related mortality.

The Administrator also considered the epidemiological evidence with regard to considering potential effects thresholds at the population level for

<sup>50</sup> As discussed above at the beginning of section II, the Administrator has focused her reconsideration of the primary O<sub>3</sub> standard set in the 2008 final rule on the level of the standard, having decided not to reopen the 2008 final rule with regard to the need to revise the 1997 primary O<sub>3</sub> standard to provide increased public health protection nor with regard to the indicator, averaging period, and form of the 2008 standard.

<sup>51</sup> The EPA responded to these comments in the 2008 final rule (73 FR 16454-5).

morbidity and mortality effects. As discussed above, while some studies provide some indication of possible 8-hour average threshold levels from below about 0.025 to 0.035 ppm (within the range of background concentrations) up to approximately 0.050 ppm, other studies observe linear concentration-response functions suggesting that there may be no effects thresholds at the population level above background concentrations. In addition, other studies conducted subset analyses that included only days with ambient O<sub>3</sub> concentrations below the level of the then current standard, or below even lower O<sub>3</sub> concentrations, including a level as low as 0.061 ppm, and continue to report statistically significant associations. The Administrator notes that the relationships between ambient O<sub>3</sub> concentrations and lung function decrements, respiratory symptoms, indicators of respiratory morbidity including increased respiratory-related emergency department visits and hospital admissions, and possibly mortality reported in a large number of studies likely extend down to ambient O<sub>3</sub> concentrations well below the level of the standard set in 2008 (0.075 ppm), in that the highest level at which there is any indication of a threshold is approximately 0.050 ppm. The Administrator notes as well that toward the lower end of the range of O<sub>3</sub> concentrations observed in such studies, ranging down to background levels (*i.e.*, 0.035 to 0.015 ppm), there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O<sub>3</sub>, rather than to the broader mix of air pollutants present in the ambient atmosphere. She also notes that there are limitations in epidemiological studies that make discerning population thresholds difficult, as discussed above, such that there is the possibility that thresholds for individuals may exist in reported associations at fairly low levels within the range of air quality observed in the studies but not be detectable as population thresholds in epidemiological analyses.

In looking more broadly at evidence from animal toxicological, controlled human exposure, and epidemiological studies, the Administrator finds substantial evidence, newly available for consideration in the 2008 rulemaking, that people with asthma and other preexisting pulmonary diseases are among those at increased risk from O<sub>3</sub> exposure. As discussed above, altered physiological, morphological, and biochemical states typical of respiratory diseases like

asthma, COPD, and chronic bronchitis may render people sensitive to additional oxidative burden induced by O<sub>3</sub> exposure. Children and adults with asthma are the group that has been studied most extensively. Evidence from controlled human exposure studies indicates that asthmatics and people with allergic rhinitis may exhibit larger lung function decrements in response to O<sub>3</sub> exposure than healthy subjects and that they can have larger inflammatory responses. The Administrator also notes that two large U.S. epidemiological studies, as well as several smaller U.S. and international studies, have reported fairly robust associations between ambient O<sub>3</sub> concentrations and measures of lung function and daily symptoms (*e.g.*, chest tightness, wheeze, shortness of breath) in children with moderate to severe asthma and between O<sub>3</sub> and increased asthma medication use. These more serious responses in asthmatics and others with lung disease provide biological plausibility for the respiratory morbidity effects observed in epidemiological studies, such as respiratory-related emergency department visits and hospital admissions.

The Administrator also observes that a substantial body of evidence from controlled human exposure and epidemiological studies indicates that relative to the healthy, non-asthmatic subjects used in most controlled human exposure studies, a greater proportion of people with asthma may be affected, and those who are affected may have as large or larger lung function and symptomatic responses to O<sub>3</sub> exposures. Thus, the Administrator concludes that controlled human exposure studies of lung function decrements and respiratory symptoms that evaluate only healthy, non-asthmatic subjects likely underestimate the effects of O<sub>3</sub> exposure on asthmatics and other susceptible populations.

In addition to the evidence-based considerations discussed above, the Administrator also considered quantitative exposures and health risks estimated to occur associated with air quality simulated to just meet various standard levels to help inform judgments about a range of standard levels for consideration that could provide an appropriate degree of public health protection. In so doing, she is mindful of the important uncertainties and limitations that are associated with the exposure and risk assessments, as discussed in more detail in the 2007 Staff Paper, and above in sections II.B and II.C.1.b. Beyond these uncertainties, the Administrator also recognized important limitations related to the

exposure and risk analyses. For example, EPA did not have sufficient information to evaluate all relevant at-risk groups (*e.g.*, outdoor workers) or all O<sub>3</sub>-related health outcomes (*e.g.*, increased medication use, school absences, emergency department visits), and the scope of the analyses was generally limited to estimating exposures and risks in 12 urban areas across the U.S., and to only five or just one area for some health effects. Thus, it is clear that national-scale public health impacts of ambient O<sub>3</sub> exposures are much larger than the quantitative estimates of O<sub>3</sub>-related incidences of adverse health effects and the numbers of children likely to experience exposures of concern associated with meeting the then current standard or alternative standards. Taking these limitations into account, the CASAC advised EPA not to rely solely on the results of the exposure and risk assessments in considering alternative standards, but also to place significant weight on the body of evidence of O<sub>3</sub>-related health effects in drawing conclusions about an appropriate range of levels for consideration. The Administrator agrees with this advice.

Turning first to the results of the exposure assessment, the Administrator focused on the extent to which alternative standard levels, approximately at and below the 0.075 ppm O<sub>3</sub> standard set in the 2008 final rule, are estimated to reduce exposures over the 0.060 and 0.070 ppm health effects benchmark levels, for all and asthmatic school age children in the 12 urban areas included in the assessment.<sup>52</sup> The Administrator also took note that the lowest standard level included in the exposure and health risk assessments was 0.064 ppm and that additional reductions in exposures over the selected health benchmark levels would be anticipated for just meeting a 0.060 ppm standard.

As an initial matter, the Administrator recognized that the concept of "exposures of concern" is more appropriately viewed as a continuum, with greater confidence and less uncertainty about the existence of health effects at the upper end and less confidence and greater uncertainty as one considers increasingly lower O<sub>3</sub> exposure levels. In considering the concept of exposures of concern, the Administrator also noted that it is important to balance concerns about the potential for health effects and their

<sup>52</sup> As noted in section II.C.1.b. above, the Administrator focused on alternative standards with different levels but the same form and averaging time as the primary standard set in 2008.

severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower O<sub>3</sub> levels. Within the context of this continuum, estimates of exposures of concern at discrete benchmark levels provide some perspective on the public health impacts of O<sub>3</sub>-related physiological effects that have been demonstrated in controlled human exposure and toxicological studies but cannot be evaluated in quantitative risk assessments, such as lung inflammation, increased airway responsiveness, and changes in host defenses. They also help in understanding the extent to which such impacts have the potential to be reduced by meeting alternative standards. As discussed in II.C.1.a above, these O<sub>3</sub>-related physiological effects are plausibly linked to the increased morbidity seen in epidemiological studies (e.g., as indicated by increased medication use in asthmatics, school absences in all children, and emergency department visits and hospital admissions in people with lung disease).

Estimates of the number of people likely to experience exposures of concern cannot be directly translated into quantitative estimates of the number of people likely to experience specific health effects, since sufficient information to draw such comparisons is not available—if such information were available, these health outcomes would have been included in the quantitative risk assessment. Due to individual variability in responsiveness, only a subset of individuals who have exposures at and above a specific benchmark level are expected to experience such adverse health effects, and susceptible population groups such as those with asthma are expected to be affected more by such exposures than healthy individuals.

For the reasons discussed in section II.C.1.b above, the Administrator has concluded that it is appropriate to focus on both the 0.060 and 0.070 ppm health effect benchmarks for her decision on the primary standard. In summary, the focus on these two benchmark levels reflects the following evidence-based considerations, discussed above in section II.C.1.a, that raise concerns about adverse health effects likely occurring at levels below 0.080 ppm: (1) That there is limited, but important, new evidence from controlled human exposure studies showing lung function decrements and respiratory symptoms in some healthy subjects at 0.060 ppm; (2) that asthmatics are likely to have more serious responses than healthy individuals; (3) that lung function is not likely to be as sensitive a marker for O<sub>3</sub>

effects as lung inflammation; and (4) that there is epidemiological evidence which reports associations between ambient O<sub>3</sub> concentrations and respiratory symptoms, ED visits, hospital admissions, and premature mortality in areas with O<sub>3</sub> levels that extend well below 0.080 ppm.

Based on the exposure and risk considerations discussed in detail in the 2007 Staff Paper and presented in sections II.B and II.C.1.b above, the Administrator notes the following important observations from these assessments: (1) There is a similar pattern for all children and asthmatic school age children in terms of exposures of concern over selected benchmark levels when estimates are expressed in terms of percentage of the population; (2) the aggregate estimates of exposures of concern reflecting estimates for the 12 urban areas included in the assessment are considerably larger for the benchmark level of 0.060 ppm compared to the 0.070 ppm benchmark; (3) there is notable year-to-year variability in exposure and risk estimates with higher exposure and risk estimates occurring in simulations involving a year with generally poorer air quality in most areas (2002) compared to a year with generally better air quality (2004); and (4) there is significant city-to-city variability in exposure and risk estimates, with some cities receiving considerably less protection associated with air quality just meeting the same standard. As discussed above, the Administrator believes that it is appropriate to consider not just the aggregate estimates across all cities, but also to consider the public health impacts in cities that receive relatively less protection from alternative standards under consideration. Similarly, the Administrator believes that year-to-year variability should also be considered in making judgments about which standards will protect public health with an adequate margin of safety.

In addition, significant reductions in exposures of concern and risk have been estimated to occur across standard levels analyzed. The magnitudes of exposure and risk reductions estimated to occur in going from a 0.074 ppm standard to a 0.064 ppm standard are as large as those estimated to occur in going from the then current 0.084 ppm standard to a 0.074 ppm standard. Consequently, the reduction in risk that can be achieved by going from a standard of 0.074 ppm to a standard of 0.064 ppm is comparable to the risk reduction that can be achieved by moving from the 1997 O<sub>3</sub> standard,

effectively a 0.084 ppm standard, to a standard very close to the 2008 standard of 0.075 ppm.

The Administrator also observes that estimates of exposures of concern associated with air quality just meeting the alternative standards below 0.080 ppm (i.e., 0.074, 0.070, and 0.064 ppm, the levels included in the assessment) are notably lower than estimates for alternative standards set at and above 0.080 ppm. As shown in Table 6–8 in the 2007 Staff Paper, just meeting a 0.080 ppm standard is associated with an aggregate estimate of exposures of concern of about 13% of asthmatic children at the 0.070 ppm benchmark level, ranging up to 31% in the city with the least degree of protection in a year with generally poorer air quality, and an aggregate estimate of exposures of concern of about 40% of asthmatic children, ranging up to 63% in the city with the least degree of protection at the 0.060 ppm benchmark level. Based on the exposure estimates presented in Table 3 in this notice, she observes that standards included in the assessment below 0.080 ppm (i.e., 0.074, 0.070, and 0.064 ppm), are estimated to have substantially lower estimates of exposures of concern at the 0.070 ppm benchmark level. Similarly, she notes that exposures of concern at the 0.060 ppm benchmark associated with alternative standards below 0.080 ppm are appreciably lower than exposures associated with standards at or above 0.080 ppm, especially for standards set at 0.064 and 0.070 ppm.

As noted previously, the Administrator also recognizes that the risk estimates for health outcomes included in the risk assessment are limited and that the overall health effects evidence is indicative of a much broader array of O<sub>3</sub>-related health effects that are part of a “pyramid of effects” that include various indicators of morbidity that could not be included in the risk assessment (e.g., school absences, increased medication use, doctor's visits, and emergency department visits), some of which have a greater impact on at-risk groups. Consideration of such unquantified risks for this array of health effects, taken together with the estimates of exposures of concern and the quantified health risks discussed above, supports the Administrator's evidence-based conclusion that revising the standard level to a level well below 0.080 ppm will provide important increased public health protection, especially for at-risk groups such as people with asthma or other lung disease, as well as children and older adults, particularly those active outdoors, and outdoor workers.

Based on the evidence- and exposure/ risk-based considerations discussed above, the Administrator concludes that it is appropriate to set the level of the primary O<sub>3</sub> standard to a level well below 0.080 ppm, a level at which the evidence provides a high degree of certainty about the adverse effects of O<sub>3</sub> exposure in healthy people, to provide an adequate margin of safety for at-risk groups. In selecting a proposed range of levels, the Administrator believes it is appropriate to consider the following information: (1) The strong body of evidence from controlled human exposure studies evaluating healthy people at exposure levels of 0.080 ppm and above that demonstrated lung function decrements, respiratory symptoms, pulmonary inflammation, and other medically significant airway responses, as well as limited but important evidence of lung function decrements and respiratory symptoms in healthy people down to O<sub>3</sub> exposure levels of 0.060 ppm; (2) the substantial body of evidence from controlled human exposure and epidemiological studies indicating that people with asthma are likely to experience larger and more serious effects than healthy people; (3) the body of epidemiological evidence indicating associations are observed for a wide range of serious health effects, including respiratory-related emergency department visits and hospital admissions and premature mortality, across distributions of ambient O<sub>3</sub> concentrations that extend below the current standard level of 0.075 ppm, as well as questions of biological plausibility in attributing the observed effects to O<sub>3</sub> alone at the lower end of the concentration ranges extending down to background levels; and (4) the estimates of exposures of concern and risks for a range of health effects that indicate that important improvements in public health are very likely associated with O<sub>3</sub> levels just meeting alternative standards, especially for standards set at 0.070 and 0.064 ppm (the lowest levels included in the assessment), relative to standards set at and above 0.080 ppm.

The Administrator next considered what standard level well below 0.080 ppm would be requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety that is sufficient but not more than necessary to achieve that result. The assessment of a standard level calls for consideration of both the degree of risk to public health at alternative levels of the standard as well as the certainty that such risk will occur at any specific level. Based on the information

available in the 2008 rulemaking, there is no evidence-based bright line that indicates a single appropriate level. Instead there is a combination of scientific evidence and other information that needs to be considered as a whole in making this public health policy judgment, and selecting a standard level from a range of potentially reasonable values.

As an initial matter, the Administrator considered whether the standard level of 0.075 ppm set in the 2008 final rule is sufficiently below 0.080 ppm to be requisite to protect public health with an adequate margin of safety. In considering this standard level, the Administrator looked to the rationale for selecting this level presented in the 2008 final rule, as summarized above in section II.C.3. In that rationale, EPA observed that a level of 0.075 ppm is above the range of 0.060 to 0.070 ppm recommended by CASAC, and that the CASAC Panel appeared to place greater weight on the evidence from the Adams studies and on the results of the exposure and risk assessments, whereas EPA placed greater weight on the limitations and uncertainties associated with that evidence and the quantitative exposure and risk assessments. Additionally, EPA's rationale did not discuss and thus placed no weight on exposures of concern relative to the 0.060 ppm benchmark. Further, EPA concluded that "[a] standard set at a lower level than 0.075 ppm would only result in significant further public health protection if, in fact, there is a continuum of health risks in areas with 8-hour average O<sub>3</sub> concentrations that are well below the concentrations observed in the key controlled human exposure studies and if the reported associations observed in epidemiological studies are, in fact, causally related to O<sub>3</sub> at those lower levels. Based on the available evidence, [EPA] is not prepared to make these assumptions" (73 FR 16483).

In reconsidering the entire body of evidence available in the 2008 rulemaking, including the Agency's own assessment of the epidemiological evidence in the 2006 Criteria Document, and placing significant weight on the views of CASAC, the Administrator now concludes that important and significant risks to public health are likely to occur at a standard level of 0.075 ppm. She judges that a standard level of 0.075 ppm is not sufficient to provide protection with an adequate margin of safety. In support of this conclusion, the Administrator finds that setting a standard that would protect public health, including the health of at-risk populations, with an adequate margin of

safety should reasonably depend upon giving some weight to the results of the Adams studies and EPA's reanalysis of the Adams's data, and to how effectively alternative standard levels would serve to limit exposures of concern relative to the 0.060 ppm benchmark level as well as to the 0.070 ppm benchmark level. The Administrator notes that EPA's risk assessment estimates comparable risk reductions in going from a 0.074 ppm standard to a 0.064 ppm standard as were estimated in going from the then current 0.084 ppm standard down to a 0.074 ppm standard for an array of health effects analyzed. These estimates include reductions in risk for lung function decrements in all and asthmatic school age children, respiratory symptoms in asthmatic children, respiratory-related hospital admissions, and non-accidental mortality.

Further, based on the exposure assessment estimates discussed above, the Administrator notes that for air quality just meeting a 0.074 ppm standard, approximately 27% of asthmatic school age children and 25% of all school age children are estimated to experience one or more exposures of concern over the 0.060 ppm benchmark level based on simulations for a year with generally poorer air quality; this estimate increases to about 50% of asthmatic and all children in the city with the least degree of protection. The Administrator judges that these estimates are large and strongly suggest significant public health impacts would likely remain in many areas with air quality just meeting a 0.075 ppm O<sub>3</sub> standard.

In light of these estimates and the available evidence, the Administrator agrees with CASAC's conclusion that important public health protections can be achieved by a standard set below 0.075 ppm, within the range of 0.060 to 0.070 ppm. In addition, based on both the evidence- and exposure/risk-based considerations summarized above, the Administrator concludes that a standard set as high as 0.075 would not be considered requisite to protect public health with an adequate margin of safety, and that consideration of lower levels is warranted. In considering such lower levels, the Administrator recognizes that the CAA requires her to reach a public health policy judgment as to what standard would be requisite to protect public health with an adequate margin of safety, based on scientific evidence and technical assessments that have inherent uncertainties and limitations. This judgment requires making reasoned decisions as to what weight to place on various types of

evidence and assessments and on the related uncertainties and limitations.

In selecting a level below 0.075 ppm that would serve as an appropriate upper end for a range of levels to propose, the Administrator has considered a more cautious approach to interpreting the available evidence and exposure/risk-based information—that is, an approach that places significant weight on uncertainties and limitations in the information so as to avoid potentially overestimating public health risks and protection likely to be associated with just meeting a particular standard level. In so doing, she notes that the most certain evidence of adverse health effects from exposure to O<sub>3</sub> comes from the controlled human exposure studies, and that the large bulk of this evidence derives from studies of exposures at levels of 0.080 ppm and above. At those levels, there is consistent evidence of lung function decrements and respiratory symptoms in healthy young adults, as well as evidence of inflammation and other medically significant airway responses. Further, she takes note of the limited but important evidence from controlled human exposure studies indicating that lung function decrements and symptoms can occur in healthy people at levels as low as 0.060 ppm, while also recognizing the limitations in that evidence, as discussed above in sections II.A.1 and II.C.1.a. She also notes that some people with asthma are likely to experience larger and more serious effects than the healthy subjects evaluated in the controlled exposure studies, while recognizing that there is uncertainty about the magnitude of such differences. In considering the available epidemiological studies, she recognizes that they provide evidence of serious respiratory morbidity effects, including respiratory-related emergency department visits and hospital admissions, and non-accidental mortality at levels well below 0.080 ppm, while also recognizing that there is increasing uncertainty associated with the likelihood that such effects occur at decreasing O<sub>3</sub> levels down to background levels. Considering the exposure/risk information, as shown in Table 3, the Administrator observes that a standard set at 0.070 ppm would likely substantially limit exposures of concern relative to the 0.070 ppm benchmark level, while affording far less protection against exposures of concern relative to the 0.060 ppm benchmark level. To the extent that more weight is placed on protection relative to the higher benchmark level, and more weight is placed on the

uncertainties associated with the epidemiological evidence, a standard set at 0.070 ppm might be considered to be adequately protective. Taken together, this type of cautious approach to interpreting the evidence and the exposure/risk information serves as the basis for the Administrator's conclusion that the upper end of the proposed range should be set at 0.070 ppm O<sub>3</sub>.

In selecting a level that would serve as an appropriate lower end for a range of levels to propose, the Administrator has considered a more precautionary approach to interpreting the available evidence and exposure/risk-based information—that is, an approach that places less weight on uncertainties and limitations in the information so as to avoid potentially underestimating public health improvements likely to be associated with just meeting a particular standard level. In so doing, the Administrator notes the limited, but important evidence of a lowest-observed-effects level at 0.060 ppm O<sub>3</sub> from controlled human exposure studies reporting lung function decrements and respiratory symptoms in healthy subjects. Notably, these studies also report that a small percentage of subjects (7 to 20 percent) experienced moderate lung function decrements (≥ 10 percent) at the 0.060 ppm exposure level, recognizing that for people with lung disease, such moderate functional or symptomatic responses would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication. In addition, a substantial body of evidence indicates that people with asthma are likely to experience larger and more serious effects than healthy people and therefore controlled human exposure studies done with healthy subjects likely underestimate effects in this at-risk population.

Moreover, epidemiological studies provide evidence of serious respiratory morbidity effects, including respiratory-related emergency department visits and hospital admissions, and non-accidental mortality at O<sub>3</sub> levels that may plausibly extend down to at least 0.060 ppm even when considering the uncertainties inherent in such studies. The Administrator notes that the controlled human exposure studies conducted at 0.060 ppm provide some biological plausibility for associations between respiratory morbidity and mortality effects found in epidemiological studies and O<sub>3</sub> exposures down to 0.060 ppm. Considering the exposure information, as shown in Table 3, the Administrator observes that a standard set at 0.064 ppm would likely essentially eliminate

exposures of concern relative to the 0.070 ppm benchmark level, while appreciably limiting exposures of concern relative to the 0.060 ppm benchmark level to approximately 6 percent of asthmatic children in the aggregate across 12 cities and up to 16 percent in the city that would receive the least protection. While not addressed in the exposure assessment done as part of the 2008 rulemaking, a standard set at 0.060 ppm would be expected to provide somewhat greater protection from such exposures, which is important to the extent that more weight is placed on providing protection relative to the lower benchmark level. Taken together, the Administrator concludes that this precautionary approach to interpreting the evidence and the exposure/risk information supports a level of 0.060 ppm as the lower end of the proposed range.

The Administrator has also concluded that the lower end of the proposed range should not extend below 0.060 ppm O<sub>3</sub>. In reaching this conclusion, she gives significant weight to the recommendation of the CASAC panel that 0.060 ppm should be the lower end of the range for consideration (Henderson, 2006c). In the Administrator's view, the evidence from controlled human exposure studies at the 0.060 ppm exposure level, the lowest level tested, is not robust enough to support consideration of a lower level. While some epidemiological studies provide evidence of serious respiratory morbidity effects and non-accidental mortality with no evidence of a threshold, the Administrator notes that other studies provide evidence of a potential threshold somewhat below 0.060 ppm. Moreover, there are limitations in epidemiological studies that make discerning population thresholds difficult, including fewer observations in the range of lower concentrations, concerns related to exposure measurement error, the possible role of copollutants and effects modifiers, and interindividual differences in susceptibility to O<sub>3</sub>-related effects. In the Administrator's judgment, these limitations in epidemiological studies, including the limitations in judging the causality of observed associations at lower O<sub>3</sub> levels, and the lack of robust controlled human exposure data at 0.060 ppm make it difficult to interpret this evidence as a basis for a standard level set below 0.060 ppm. Thus, in selecting 0.060 ppm as the lower end of the range for the proposed level of the O<sub>3</sub> standard, the Administrator has taken into

account information on the lowest-observed-effects levels in controlled human exposure studies, indications of possible thresholds reported in some epidemiological studies, the increasing uncertainty in the epidemiological evidence at even lower levels, as well as evidence about increased susceptibility of people with asthma and also other lung diseases. In so doing, she concludes that a primary O<sub>3</sub> standard set below 0.060 ppm would be more than is necessary to protect public health with an adequate margin of safety for at-risk groups.

In reaching her proposed decision, the Administrator has also considered the public comments that were received on the 2007 proposed rule (72 FR 37818). The Administrator notes that there were sharply divergent views expressed by two general sets of commenters with regard to considering the health effects evidence, results of exposure and risk assessments, and the advice of the CASAC panel. On one hand, medical groups, health effects researchers, public health organizations, environmental groups, and some state, tribal and local air pollution control agencies strongly supported a standard set within the range recommended by the CASAC. These commenters generally placed significant weight on the more recent evidence from controlled human exposure studies, down to the 0.060 ppm exposure level, as well as on the epidemiological studies and the results of the exposure and risk assessment conducted for the 2008 rulemaking. Many of these commenters took a more precautionary view and supported a standard set at 0.060 ppm O<sub>3</sub>, the lower end of the CASAC recommended range. The Administrator notes that these views are generally consistent with her proposed conclusions. On the other hand, another group of commenters primarily representing industry associations and businesses and some state environmental agencies, primarily expressed the view that the more recent evidence from controlled human exposure, the epidemiological studies, and the results of exposure and human health risk assessments were so uncertain that they did not provide a basis for making any changes to the then current 0.084 ppm O<sub>3</sub> standard set in 1997. This group of commenters generally argued that the health effects evidence newly available in the 2008 rulemaking, the results of the exposure and health risk assessments, and the advice of the CASAC were flawed. For the reasons discussed above, the Administrator does not agree with the

later group of commenters that essentially no weight should be placed on any of the new evidence or assessments that were available for consideration in the 2008 rulemaking.

Based on consideration of the entire body of evidence and information available in the 2008 rulemaking, including exposure and risk estimates, as well as the recommendations of CASAC, the Administrator proposes to set the level of the primary 8-hour O<sub>3</sub> standard to a level within the range of 0.060 to 0.070 ppm. A standard level within this range would reduce the risk of a variety of health effects associated with exposure to O<sub>3</sub>, including the respiratory symptoms and lung function effects demonstrated in the controlled human exposure studies, and the respiratory-related emergency department visits, hospital admissions and mortality effects observed in the epidemiological studies. All of these effects are indicative of a much broader array of O<sub>3</sub>-related health endpoints, such as school absences and increased medication use, that are plausibly linked to these observed effects. Depending on the weight placed on the evidence and information available in the 2008 rulemaking, as well as the uncertainties and limitations in the evidence and information, a standard could be set within this range at a level that would be requisite to protect public health with an adequate margin of safety.

In reaching this proposed decision, as discussed above, the Administrator has focused on the nature of the increased public health protection that would be afforded by a standard set within the proposed range of levels relative to the protection afforded by the standard set in 2008. Having considered the public comments received on the 2007 proposed rule in reaching this proposed decision that reconsiders the 2008 final rule, the Administrator is interested in again receiving public comment on the benefits to public health associated with a standard set at specific levels within the proposed range relative to the benefits associated with the standard set in 2008.

#### *D. Proposed Decision on the Level of the Primary Standard*

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of CASAC, and public comments received during the 2008 rulemaking, the Administrator proposes to set a new level for the 8-hour primary O<sub>3</sub> standard. Specifically, the

Administrator proposes to set the level of the 8-hour primary O<sub>3</sub> standard to within a range of 0.060 to 0.070 ppm. The proposed 8-hour primary standard would be met at an ambient air monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentration is less than or equal to the level of the standard that is promulgated. Thus, the Administrator proposes to set a standard with a level within this range. She solicits comment on this range and on the appropriate weight to place on the various types of available evidence, the exposure and risk assessment results, and the uncertainties and limitations related to this information, as well as on the benefits to public health associated with a standard set within this range relative to the benefits associated with the standard set in 2008.

### **III. Communication of Public Health Information**

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. The current Air Quality Index has been in use since its inception in 1999 (64 FR 42530). It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for O<sub>3</sub>, carbon monoxide, nitrogen dioxide, particulate matter and sulfur dioxide. The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location are characterized as good (0-50), moderate (51-100), unhealthy for sensitive groups (101-150), unhealthy (151-200), very unhealthy (201-300), or hazardous (300-500). The AQI index value of 100 typically corresponds to the level of the short-term NAAQS for each pollutant. An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (*i.e.*, unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day; whereas an AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (*i.e.*, moderate or good). Decisions about the pollutant concentrations at which to set the various AQI breakpoints, that delineate the various AQI categories, draw directly from the underlying health information that supports the NAAQS review.



In the 2008 rulemaking, the AQI for O<sub>3</sub> was revised by setting an AQI value of 100 equal to 0.075 ppm, 8-hour average, the level of the revised primary O<sub>3</sub> standard. The other AQI breakpoints were also revised as follows: An AQI value of 50 is set at 0.059 ppm; an AQI value of 150 was set at 0.095 ppm; and an AQI value of 200 was set at 0.115 ppm. All these levels are averaged over 8 hours. These levels were developed by making proportional adjustments to the other AQI breakpoints (i.e., AQI values of 50, 150 and 200).

The Agency recognizes the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS. Therefore, having proposed to set a new level for the 2008 primary 8-hour O<sub>3</sub> standard in this action, EPA also proposes to finalize conforming changes to the AQI in connection with the Agency's final decision on the level of the primary O<sub>3</sub> standard. These conforming changes would include setting the 100 level of the AQI at the same level as that set for the primary O<sub>3</sub> standard resulting from this rulemaking, and also making proportional adjustments to AQI breakpoints at the lower end of the range (i.e., AQI values of 50, 150 and 200). EPA does not propose to change breakpoints at the higher end of the range (from 300 to 500), which would apply to state contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this reconsideration of the 2008 final rule does not inform decisions about breakpoints at those higher levels.

With respect to reporting requirements (40 CFR Part 58, § 58.50),

EPA proposes to require that the AQI be reported in all metropolitan and micropolitan statistical areas where O<sub>3</sub> monitoring is required, as discussed below in section VI. The Agency solicits comments on our proposed approach to AQI reporting requirements. We are also revising 40 CFR Part 58, § 58.50(c) to require the reporting requirements to be based on the latest available census figures, rather than the most recent decennial U.S. census. This change is consistent with our current practice of using the latest population figures to make monitoring requirements more responsive to changes in population.

#### IV. Rationale for Proposed Decision on the Secondary Standard

As an initial matter, the Administrator notes that the 2008 final rule concluded that (1) the protection afforded by the 1997 secondary O<sub>3</sub> standard was "not sufficient and that the standard needs to be revised to provide additional protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems, and that such a revised standard could also be expected to provide additional protection to sensitive ornamental vegetation" and (2) "that there is not adequate information to establish a separate secondary standard based on other effects of O<sub>3</sub> on public welfare" (73 FR 16497). The Administrator is not reconsidering these aspects of the 2008 decision, which are based on the reasons discussed in section IV.B of the 2008 final rule (73 FR 16489-16497). The Administrator also notes that the 2008 final rule concluded that it was appropriate to retain the O<sub>3</sub> indicator for

the secondary O<sub>3</sub> standard. The Administrator is not reconsidering this aspect of the 2008 decision, which was based on the reasons discussed in sections IV.B and IV.C of the 2008 final rule (73 FR 16489-16497). For these reasons, the Administrator is not reopening the 2008 decision with regard to the need to revise the 1997 secondary O<sub>3</sub> standard to provide additional protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems, nor with regard to the appropriate indicator for the secondary standard. Thus, the information that follows in this section specifically focuses on a reconsideration of the 8-hour secondary O<sub>3</sub> standard set in the 2008 final rule for the purpose of determining whether and, if so, how to revise the form, averaging time, and level of the standard to provide appropriate protection from known and anticipated adverse effects on sensitive natural vegetation and sensitive ecosystems.

This section presents the rationale for the Administrator's proposed decision that the secondary O<sub>3</sub> standard, which was set identical to the revised primary standard in the 2008 final rule, should instead be a new cumulative, seasonal standard. This standard is expressed in terms of a concentration-weighted form commonly called W126, which uses a sigmoidal weighting function to assign a weight to each hourly O<sub>3</sub> concentration within the 12-hour daylight period (8 am to 8 pm). This daily ozone index is defined as follows:

$$\text{daily } W126 = \sum_{i=8\text{am}}^{i<8\text{pm}} w_{C_i} C_i, \text{ where } C_i = \text{hourly } O_3 \text{ at hour } i, \text{ and } w_{C_i} = \frac{1}{1 + 4403e^{-126C}}$$

The daily index values are then summed over each month within the O<sub>3</sub> season, and the annual highest consecutive three month sum is determined. The proposed standard consists of the three-year average of this highest three-month statistic, set at a level within the range of 7 to 15 ppb-hours.

As discussed more fully below, the rationale for this proposed new standard is based on a thorough review, in the 2006 Criteria Document, of the latest scientific information on vegetation, ecological and other public welfare effects associated with the presence of O<sub>3</sub> in the ambient air. This rationale also takes into account and is consistent with: (1) Staff assessments of the most

policy-relevant information in the 2006 Criteria Document and staff analyses of air quality, vegetation effects evidence, exposure, and risks, presented in the 2007 Staff Paper, upon which staff recommendations for revisions to the secondary O<sub>3</sub> standard are based; (2) CASAC advice and recommendations as reflected in discussions of drafts of the 2006 Criteria Document and 2007 Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator, both before and after the 2008 rulemaking, and (3) public comments received during development of these documents, either in conjunction with CASAC meetings or separately; and on the 2007 proposed

rule, and (4) consideration of the degree of protection to vegetation potentially afforded by the 2008 8-hour standard.

In developing this rationale, the Administrator has again focused on direct O<sub>3</sub> effects on vegetation, specifically drawing upon an integrative synthesis of the entire body of evidence (EPA, 2006a, chapter 9), published through early 2006, on the broad array of vegetation effects associated with the presence of O<sub>3</sub> in the ambient air. In addition, because O<sub>3</sub> can also indirectly affect other ecosystem components such as soils, water, and wildlife, and their associated ecosystem goods and services, through its effects on vegetation, a qualitative discussion of these other indirect impacts is also

included, though these effects were not quantifiable at the time of the 2008 rulemaking. As discussed below in section IV.A, the peer-reviewed literature includes studies conducted in the U.S., Canada, Europe, and many other countries around the world.<sup>53</sup> In reconsidering this evidence, as was concluded in the 2008 rulemaking, and based on the body of scientific literature assessed in the 2006 Criteria Document, the Administrator continues to believe that it is reasonable to conclude that a secondary standard protecting the public welfare from known or anticipated adverse effects to trees and native vegetation would also afford increased protection from adverse effects to other environmental components relevant to the public welfare, including ecosystem services and function. Section IV.B focuses on considerations related to biologically relevant exposure indices. This rationale also draws upon the results of quantitative exposure and risk assessments, discussed below in section IV.C. Section IV.D focuses on the considerations upon which the Administrator's proposed conclusions are based. Considerations regarding a cumulative seasonal standard as well as an 8-hour standard are discussed, and the rationale for the 2008 decision on the secondary standard and CASAC advice, given both prior to the development of the 2007 proposed rule and following the 2008 final rule, are summarized. Finally, the Administrator's proposed conclusions on the secondary standard are presented. Section IV.E summarizes the proposed decision on the secondary O<sub>3</sub> standard and the solicitation of public comments.

As with virtually any policy-relevant vegetation effects research, there is uncertainty in the characterization of vegetation effects attributable to exposure to ambient O<sub>3</sub>. As discussed below, however, research conducted since the 1997 review provides important information coming from field-based exposure studies, including free air, gradient, and biomonitoring surveys, in addition to the more traditional open top chamber (OTC) studies. Moreover, the newly available studies evaluated in the 2006 Criteria Document have undergone intensive scrutiny through multiple layers of peer review and many opportunities for public review and comment. While

<sup>53</sup> In its assessment of the evidence judged to be most relevant to making decisions on the level of the O<sub>3</sub> secondary standard, however, EPA has placed greater weight on U.S. studies, due to the often species-, site- and climate-specific nature of O<sub>3</sub>-related vegetation response.

important uncertainties remain, the review of the vegetation effects information has been extensive and deliberate. In the judgment of the Administrator, the intensive evaluation of the scientific evidence that has occurred provides an adequate basis for this reconsideration of the 2008 rulemaking.

#### A. Vegetation Effects Information

This section outlines key information contained in the 2006 Criteria Document (chapter 9) and in the 2007 Staff Paper (chapter 7) on known or anticipated effects on public welfare associated with the presence of O<sub>3</sub> in ambient air. The information highlighted here summarizes: (1) New information available in the 2008 rulemaking on potential mechanisms for vegetation effects associated with exposure to O<sub>3</sub>; (2) the nature of effects on vegetation that have been associated with exposure to O<sub>3</sub> and consequent potential impacts on ecosystems; and (3) considerations in characterizing what constitutes an adverse welfare impact of O<sub>3</sub>.

Exposures to O<sub>3</sub> have been associated quantitatively and qualitatively with a wide range of vegetation effects. The decision in the 1997 review to set a more protective secondary standard primarily reflected consideration of the quantitative information on vegetation effects available at that time, particularly growth impairment (e.g., biomass loss) in sensitive forest tree species during the seedling growth stage and yield loss in important commercial crops. This information, derived mainly using the open top chamber (OTC) exposure method, found cumulative, seasonal O<sub>3</sub> exposures were most strongly associated with observed vegetation response. The 2006 Criteria Document discusses a number of additional studies that support and strengthen key conclusions regarding O<sub>3</sub> effects on vegetation and ecosystems found in the previous Criteria Document (EPA, 1996a, 2006a), including further clarification of the underlying mechanistic and physiological processes at the sub-cellular, cellular, and whole system levels within the plant. More importantly, however, in the context of this review, new quantitative information is now available across a broader array of vegetation effects (e.g., growth impairment during seedlings, saplings and mature tree growth stages, visible foliar injury, and yield loss in annual crops) and across a more diverse set of exposure methods, including chamber, free air, gradient, model, and field-based observation. The non-chambered, field-based study results

begin to address one of the key data gaps cited by EPA in the 1997 review.

The following discussion of the policy-relevant science regarding vegetation effects associated with cumulative, seasonal exposures to ambient levels of O<sub>3</sub> integrates information from the 2006 Criteria Document (chapter 9) and the 2007 Staff Paper (chapter 7).

#### 1. Mechanisms

Scientific understanding regarding O<sub>3</sub> impacts at the genetic, physiological, and mechanistic levels helps to explain the biological plausibility and coherence of the evidence for O<sub>3</sub>-induced vegetation effects and informs the interpretation of predictions of risk associated with vegetation response at ambient O<sub>3</sub> exposure levels. In most cases, the mechanisms of response are similar regardless of the degree of sensitivity of the species. The evidence assessed in the 2006 Criteria Document (EPA, 2006a) regarding the O<sub>3</sub>-induced changes in physiology continues to support the information discussed in the 1997 review (EPA, 1996a, 2006a). In addition, during the last decade understanding of the cellular processes within plants has been further clarified and enhanced. This section reviews the key scientific conclusions identified in 1996 Criteria Document (EPA, 1996a), and incorporates recent information from the Criteria Document (EPA, 2006a). This section describes: (1) Plant uptake of O<sub>3</sub>, (2) O<sub>3</sub>-induced cellular to systemic response, (3) plant compensation and detoxification mechanisms, (4) O<sub>3</sub>-induced changes to plant metabolism, and (5) plant response to chronic O<sub>3</sub> exposures.

##### a. Plant Uptake of Ozone

To cause injury, O<sub>3</sub> must first enter the plant through openings in the leaves called stomata. Leaves exist in a three dimensional environment called the plant canopy, where each leaf has a unique orientation and receives a different exposure to ambient air, microclimatological conditions, and sunlight. In addition, a plant may be located within a stand of other plants which further modifies ambient air exchange with individual leaves. Not all O<sub>3</sub> entering a plant canopy is absorbed into the leaf stomata, but may be adsorbed to other surfaces e.g., leaf cuticles, stems, and soil (termed non-stomatal deposition) or scavenged by reactions with intra-canopy biogenic VOCs and naturally occurring NO<sub>x</sub> emissions from soils. Because O<sub>3</sub> does not typically penetrate the leaf's cuticle, it must reach the stomatal openings in the leaf for absorption to occur. The

movement of O<sub>3</sub> and other gases such as CO<sub>2</sub> into and out of leaves is controlled by stomatal guard cells that regulate the size of the stomatal apertures. These guard cells respond to a variety of internal species-specific factors as well as external site specific environmental factors such as light, temperature, humidity, CO<sub>2</sub> concentration, soil fertility, water status, and in some cases, the presence of air pollutants, including O<sub>3</sub>. These modifying factors produce stomatal conductances that vary between leaves of the same plant, individuals and genotypes within a species as well as diurnally and seasonally.

#### b. Cellular to Systemic Response

Once inside the leaf, O<sub>3</sub> can react with a variety of biochemical compounds that are exposed to the air spaces within the leaf or it can be dissolved into the water lining the cell wall of the air spaces. Once in the aqueous phase, O<sub>3</sub> can be rapidly altered to form oxidative products that can diffuse more readily into and through the cell and react with many biochemical compounds. Early steps in a series of O<sub>3</sub>-induced events that can lead to leaf injury seems to involve alteration in cell membrane function, including membrane transport properties (EPA, 2006a) and/or reactions with organic molecules that in certain circumstances result in the generation of signaling compounds. The generation of such signaling compounds can lead to a cascade of events. One such signaling molecule is hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>). The presence of higher-than-normal levels of H<sub>2</sub>O<sub>2</sub> within the leaf is a potential trigger for a set of metabolic reactions that include those typical of the well documented "wounding" response or pathogen defense pathway generated by cutting of the leaf or by pathogen/insect attack. Ethylene is another compound produced when plants are subjected to biotic or abiotic stressors. Increased ethylene production by plants exposed to O<sub>3</sub> stress was identified as a consistent marker for O<sub>3</sub> exposure in studies conducted decades ago (Tingey *et al.*, 1976).

#### c. Compensation and Detoxification

Ozone injury will not occur if (1) the rate and amount of O<sub>3</sub> uptake is small enough for the plant to detoxify or metabolize O<sub>3</sub> or its metabolites or (2) the plant is able to repair or compensate for the O<sub>3</sub> impacts (Tingey and Taylor, 1982; U.S. EPA, 1996a). With regard to the first, a few studies have documented direct stomatal closure or restriction in the presence of O<sub>3</sub> in some species, which limits O<sub>3</sub> uptake and potential subsequent injury. This response may

be initiated ranging from within minutes to hours or days of exposure (Moldau *et al.*, 1990; Dann and Pell, 1989; Weber *et al.*, 1993). However, exclusion of O<sub>3</sub> simultaneously restricts the uptake of CO<sub>2</sub>, which also limits photosynthesis and growth. In addition, antioxidants present in plants can effectively protect tissue against damage from low levels of oxidants by dissipating excess oxidizing power. Since 1996, the role of detoxification in providing a level of resistance to O<sub>3</sub> has been further investigated. A number of antioxidants have been found in plants. However, the pattern of changes in the amounts of these antioxidants varies greatly among different species and conditions. Most recent reports indicate that ascorbate within the cell wall provides the first significant opportunity for detoxification to occur. In spite of the new research, however, it is still not clear as to what extent detoxification protects against O<sub>3</sub> injury. Specifically, data are needed on potential rates of antioxidant production, sub-cellular location(s) of antioxidants, and whether generation of these antioxidants in response to O<sub>3</sub>-induced stress potentially diverts resources and energy away from other vital uses. Thus, the 2006 Criteria Document concludes that scientific understanding of the detoxification mechanisms is not yet complete and requires further investigation (EPA, 2006a).

Regarding the second, once O<sub>3</sub> injury has occurred in leaf tissue, some plants are able to repair or compensate for the impacts. In general, plants have a variety of compensatory mechanisms for low levels of stress including reallocation of resources, changes in root/shoot ratio, production of new tissue, and/or biochemical shifts, such as increased photosynthetic capacity in new foliage and changes in respiration rates, indicating possible repair or replacement of damaged membranes or enzymes. Since these mechanisms are genetically determined, not all plants have the same complement of compensatory mechanisms or degree of tolerance, and these may vary over the life of the plant as not all stages of a plant's development are equally sensitive to O<sub>3</sub>. At higher levels or over longer periods of O<sub>3</sub> stress, some of these compensatory mechanisms, such as a reallocation of resources away from storage in the roots in favor of leaves or shoots, could occur at a cost to the overall health of the plant. However, it is not yet clear to what degree or how the use of plant resources for repair or compensatory processes affects the

overall carbohydrate budget or subsequent plant response to O<sub>3</sub> or other stresses (EPA, 1996a, EPA, 2006a).

#### d. Changes to Plant Metabolism

Ozone inhibits photosynthesis, the process by which plants produce energy rich compounds (e.g., carbohydrates) in the leaves. This impairment can result from direct impact to chloroplast function and/or O<sub>3</sub>-induced stomatal closure resulting in reduced uptake of CO<sub>2</sub>. A large body of literature published since 1996 has further elucidated the mechanism of effect of O<sub>3</sub> within the chloroplast. Pell *et al.* (1997) showed that O<sub>3</sub> exposure results in a loss of the central carboxylating enzyme that plays an important role in the production of carbohydrates. Due to its central importance, any decrease in this enzyme may have severe consequences for the plant's productivity. Several recent studies have found that O<sub>3</sub> has a greater effect as leaves age, with the greatest impact of O<sub>3</sub> occurring on the oldest leaves (Fiscus *et al.*, 1997; Reid and Fiscus, 1998; Noormets *et al.*, 2001; Morgan *et al.*, 2004). The loss of this key enzyme as a function of increasing O<sub>3</sub> exposure is also linked to an early senescence or a speeding up of normal development leading to senescence. If total plant photosynthesis is sufficiently reduced, the plant will respond by reallocating the remaining carbohydrate at the level of the whole organism (EPA, 1996a, 2006a). This reallocation of carbohydrate away from the roots into above ground vegetative components can have serious implications for perennial species, as discussed below.

#### e. Plant Response to Chronic Ozone Exposures

Though many changes that occur with O<sub>3</sub> exposure can be observed within hours, or perhaps days, of the exposure, including those connected with wounding, other effects take longer to occur and tend to become most obvious after chronic seasonal exposures to low O<sub>3</sub> concentrations. These lower chronic exposures have been linked to senescence or some other physiological response very closely linked to senescence. In perennial plant species, a reduction in carbohydrate storage in one year may result in the limitation of growth the following year (Andersen *et al.*, 1997). Such "carry-over" effects have been documented in the growth of tree seedlings (Hogsett *et al.*, 1989; Sasek *et al.*, 1991; Temple *et al.*, 1993; EPA, 1996a) and in roots (Andersen *et al.*, 1991; EPA, 1996a). Though it is not fully understood how chronic seasonal O<sub>3</sub> exposure affects long-term growth and resistance to other biotic and abiotic

insults in long-lived trees, accumulation of these carry-over effects over time could affect survival and reproduction.

## 2. Nature of Effects

Ozone injury at the cellular level can accumulate sufficiently to induce effects at the level of a whole leaf or plant. These larger scale effects can include: Reduced carbohydrate production and/or reallocation; reduced growth and/or reproduction; visible foliar injury and/or premature senescence; and reduced plant vigor. Much of what is now known about these O<sub>3</sub>-related effects, as summarized below, is based on research that was available in the 1997 review. Studies available in the 2008 rulemaking continue to support and expand this knowledge (EPA, 2006a).

### a. Carbohydrate Production and Allocation

When total plant photosynthesis is sufficiently reduced, the plant will respond by reallocating the remaining carbohydrate at the level of the whole organism. Many studies have demonstrated that root growth is more sensitive to O<sub>3</sub> exposure than stem or leaf growth (EPA, 2006a). When fewer carbohydrates are present in the roots, less energy is available for root-related functions such as acquisition of water and nutrients. In addition, by inhibiting photosynthesis and the amount of carbohydrates available for transfer to the roots, O<sub>3</sub> can disrupt the association between soil fungi and host plants. Fungi in the soil form a symbiotic relationship with many terrestrial plants. For host plants, these fungi improve the uptake of nutrients, protect the roots against pathogens, produce plant growth hormones, and may transport carbohydrates from one plant to another (EPA, 1996a). These below ground effects have recently been documented in the field (Grunke *et al.*, 1998; Grunke and Balduman, 1999). Data from a long-studied pollution gradient in the San Bernardino Mountains of southern California suggest that O<sub>3</sub> substantially reduces root growth in natural stands of Ponderosa pine (*Pinus ponderosa*). Root growth in mature trees was decreased at least 87 percent in a high-pollution site as compared to a low-pollution site (Grunke *et al.*, 1998), and a similar pattern was found in a separate study with whole-tree harvest along this gradient (Grunke and Balduman, 1999). Though effects on other ecosystem components were not examined, a reduction of root growth of this magnitude could have significant implications for the below-ground communities at those sites. Because effects on leaf and needle carbohydrate

content under O<sub>3</sub> stress can range from a reduction (Barnes *et al.*, 1990; Miller *et al.*, 1989), to no effect (Alscher *et al.*, 1989), to an increase (Luethy-Krause and Landolt, 1990), studies that examine only above-ground vegetative components may miss important O<sub>3</sub>-induced changes below ground. These below-ground changes could signal a shift in nutrient cycling with significance at the ecosystem level (Young and Sanzone, 2002).

### b. Growth Effects on Trees

Studies comparing the O<sub>3</sub>-related growth response of different vegetation types (coniferous and deciduous) and growth stages (*e.g.*, seedling and mature) have established that on average, individual coniferous trees are less sensitive than deciduous trees, and deciduous trees are generally less sensitive to O<sub>3</sub> than most annual plants, with the exception of a few fast growing deciduous tree species (*e.g.*, quaking aspen, black cherry, and cottonwood), which are highly sensitive and, in some cases, as much or more sensitive to O<sub>3</sub> than sensitive annual plants. In addition, studies have shown that the relationship between O<sub>3</sub> sensitivity in seedling and mature growth stages of trees can vary widely, with seedling growth being more sensitive to O<sub>3</sub> exposures in some species, while in others, the mature growth stage is the more O<sub>3</sub> sensitive. In general, mature deciduous trees are likely to be more sensitive to O<sub>3</sub> than deciduous seedlings, and mature evergreen trees are likely to be less sensitive to O<sub>3</sub> than their seedling counterparts. Based on these results, stomatal conductance, O<sub>3</sub> uptake, and O<sub>3</sub> effects cannot be assumed to be equivalent in seedlings and mature trees.

In the 1997 review (EPA, 1996b), analyses of the effects of O<sub>3</sub> on trees were limited to 11 tree species for which concentration-response (C-R) functions for the seedling growth stage had been developed from OTC studies conducted by the National Health and Environmental Effects Research Lab, Western Ecology Division (NHEERL-WED). A number of replicate studies were conducted on these species, leading to a total of 49 experimental cases. The 2007 Staff Paper presented a graph of the composite regression equation that combines the results of the C-R functions developed for each of the 49 cases. The NHEERL-WED study predicted relative biomass loss at various exposure levels in terms of a 12-hour W126. For example, 50 percent of the tree seedling cases would be protected from greater than 10 percent biomass loss at a 3-month, 12-hour

W126 of approximately 24 ppm-hour, while 75 percent of cases would be protected from 10 percent biomass loss at a 3-month, 12-hour W126 level of approximately 16 ppm-hour.

Since the 1997 review, only a few studies have developed C-R functions for additional tree seedling species (EPA, 2006a). One such study is of particular importance because it documented growth effects in the field of a similar magnitude as those previously seen in OTC studies but without the use of chambers or other fumigation methods (Gregg *et al.*, 2003). This study placed eastern cottonwood (*Populus deltoides*) saplings at sites along a continuum of ambient O<sub>3</sub> exposures that gradually increased from urban to rural areas in the New York City area (Gregg *et al.*, 2003). Eastern cottonwood is a fast growing O<sub>3</sub> sensitive tree species that is important ecologically along streams and commercially for pulpwood, furniture manufacturing, and as a possible new source for energy biomass (Burns and Hankola, 1990). Gregg *et al.* (2003) found that the cottonwood saplings grown in urban New York City grew faster than saplings grown in downwind rural areas. Because these saplings were grown in pots with carefully controlled soil nutrient and moisture levels, the authors were able to control for most of the differences between sites. After carefully considering these and other factors, the authors concluded the primary explanation for the difference in growth was the gradient of cumulative O<sub>3</sub> exposures that increased as one moved downwind from urban to less urban and more rural sites. It was determined that the lower O<sub>3</sub> exposure within the city center was due to NO<sub>x</sub> titration reactions which removed O<sub>3</sub> from the ambient air. The authors were able to reproduce the growth responses observed in the field in a companion OTC experiment, confirming O<sub>3</sub> as the stressor inducing the growth loss response (Gregg *et al.*, 2003).

Another recent set of studies employed a modified Free Air CO<sub>2</sub> Enrichment (FACE) methodology to expose vegetation to elevated O<sub>3</sub> without the use of chambers. This exposure method was originally developed to expose vegetation to elevated levels of CO<sub>2</sub>, but was later modified to include O<sub>3</sub> exposure in Illinois (SoyFACE) and Wisconsin (AspenFACE) for soybean and deciduous trees, respectively (Dickson *et al.*, 2000; Morgan *et al.*, 2004). The FACE method releases gas (*e.g.*, CO<sub>2</sub>, O<sub>3</sub>) from a series of orifices placed along the length of the vertical pipes surrounding a circular field plot and uses the

prevailing wind to distribute it. This exposure method has many characteristics that differ from those associated with the OTC. Most significantly, this exposure method more closely replicates conditions in the field than do OTCs. This is because, except for O<sub>3</sub> levels which are varied across co-located plots, plants are exposed to the same ambient growing conditions that occur naturally in the field (e.g., location-specific pollutant mixtures; climate conditions such as light, temperature and precipitation; insect pests, pathogens). By using one of several co-located plots as a control (e.g., receives no additional O<sub>3</sub>), and by exposing the other rings to differing levels of elevated O<sub>3</sub>, the growth response signal that is due solely to the change in O<sub>3</sub> exposure can be clearly determined. Furthermore, the FACE system can expand vertically with the growth of trees, allowing for exposure experiments to span numerous years, an especially useful capability in forest research.

On the other hand, the FACE methodology also has the undesirable characteristic of potentially creating hotspots near O<sub>3</sub> gas release orifices or gradients of exposure in the outer ring of trees within the plots, such that averaging results across the entire ring potentially overestimates the response. In recognition of this possibility, researchers at the AspenFACE experimental site only measured trees in the center core of each ring (e.g., at least 5–6 meters away from the emission sites of O<sub>3</sub>) (Dickson *et al.*, 2000; Karnosky *et al.*, 2005). By taking this precaution, it is unlikely that their measurements were influenced by any potential hotspots or gradients of exposure within the FACE rings. Taking all of the above into account, results from the Wisconsin FACE site on quaking aspen appear to demonstrate that the detrimental effects of O<sub>3</sub> exposure seen on tree growth and symptom expression in OTCs can be observed in the field using this exposure method (Karnosky *et al.*, 1999; 2005).

The 2007 Staff Paper thus concluded that the combined evidence from the AspenFACE and Gregg *et al.* (2003) field studies provide compelling and important support for the appropriateness of continued use of the C–R functions derived using OTC from the NHEERL–WED studies to estimate risk to these tree seedlings under ambient field exposure conditions. These studies make a significant contribution to the coherence of the weight of evidence available in this review and provide additional evidence that O<sub>3</sub>-induced effects observed in chambers also occur in the field.

Trees and other perennials, in addition to cumulating the effects of O<sub>3</sub> exposures over the annual growing season, can also cumulate effects across multiple years. It has been reported that effects can “carry over” from one year to another (EPA, 2006a). Growth affected by a reduction in carbohydrate storage in one year may result in the limitation of growth in the following year (Andersen *et al.*, 1997). Carry-over effects have been documented in the growth of some tree seedlings (Hogsett *et al.*, 1989; Simini *et al.*, 1992; Temple *et al.*, 1993) and in roots (Andersen *et al.*, 1991; EPA, 1996a). On the basis of past and recent OTC and field study data, ambient O<sub>3</sub> exposures that occur during the growing season in the United States are sufficient to potentially affect the annual growth of a number of sensitive seedling tree species. However, because most studies do not take into account the possibility of carry over effects on growth in subsequent years, the true implication of these annual biomass losses may be missed. It is likely that under ambient exposure conditions, some sensitive trees and perennial plants could experience compounded impacts that result from multiple year exposures.

#### c. Visible Foliar Injury

Cellular injury to leaves due to exposure to O<sub>3</sub> can and often does become visible. Acute injury usually appears within 24 hours after exposure to O<sub>3</sub> and, depending on species, can occur under a range of exposures and durations from 0.040 ppm for a period of 4 hours to 0.410 ppm for 0.5 hours for crops and 0.060 ppm for 4 hours to 0.510 ppm for 1 hour for trees and shrubs (Jacobson, 1977). Chronic injury may be mild to severe. In some cases, cell death or premature leaf senescence may occur. The significance of O<sub>3</sub> injury at the leaf and whole plant levels depends on how much of the total leaf area of the plant has been affected, as well as the plant's age, size, developmental stage, and degree of functional redundancy among the existing leaf area. As a result, it is not presently possible to determine, with consistency across species and environments, what degree of injury at the leaf level has significance to the vigor of the whole plant.

The presence of visible symptoms due to O<sub>3</sub> exposures can, however, by itself, represent an adverse impact to the public welfare. Specifically, it can reduce the market value of certain leafy crops (such as spinach, lettuce), impact the aesthetic value of ornamentals (such as petunia, geranium, and poinsettia) in urban landscapes, and affect the

aesthetic value of scenic vistas in protected natural areas such as national parks and wilderness areas. Many businesses rely on healthy looking vegetation for their livelihoods (e.g., horticulturalists, landscapers, Christmas tree growers, farmers of leafy crops) and a variety of ornamental species have been listed as sensitive to O<sub>3</sub> (Abt Associates Inc., 1995). Though not quantified, there is likely some level of economic impact to businesses and homeowners from O<sub>3</sub>-related injury on sensitive ornamental species due to the cost associated with more frequent replacement and/or increased maintenance (fertilizer or pesticide application). In addition, because O<sub>3</sub> not only results in discoloration of leaves but can lead to more rapid senescence (early shedding of leaves) there potentially could be some lost tourist dollars at sites where fall foliage is less available or attractive.

The use of sensitive plants as biological indicators to detect phytotoxic levels of O<sub>3</sub> is a longstanding and effective methodology (Chappelka and Samuelson, 1998; Manning and Krupa, 1992). Each bioindicator exhibits typical O<sub>3</sub> injury symptoms when exposed under appropriate conditions. These symptoms are considered diagnostic as they have been verified in exposure-response studies under experimental conditions. In recent years, field surveys of visible foliar injury symptoms have become more common, with greater attention to the standardization of methods and the use of reliable indicator species (Campbell *et al.*, 2000; Smith *et al.*, 2003). Specifically, the United States Forest Service (USFS) through the Forest Health Monitoring Program (FHM) (1990–2001) and currently the Forest Inventory and Analysis (FIA) Program collects data regarding the incidence and severity of visible foliar injury on a variety of O<sub>3</sub> sensitive plant species throughout the U.S. (Coulston *et al.*, 2003, 2004; Smith *et al.*, 2003).

Since the conclusion of the 1997 review, the FIA monitoring program network and database has continued to expand. This network continues to document foliar injury symptoms in the field under ambient exposure conditions. Recent survey results show that O<sub>3</sub>-induced foliar injury incidence is widespread across the country. The visible foliar injury indicator has been identified as a means to track O<sub>3</sub> exposure stress trends in the nation's natural plant communities as highlighted in EPA's most recent Report on the Environment (EPA, 2003a; <http://www.epa.gov/indicators/roe>).

Previous Criteria Documents have noted the difficulty in relating visible foliar injury symptoms to other vegetation effects such as individual tree growth, stand growth, or ecosystem characteristics (EPA, 1996a) and this difficulty remains to the present day (EPA, 2006a). It is important to note that direct links between O<sub>3</sub> induced visible foliar injury symptoms and other adverse effects are not always found. Therefore, visible foliar injury cannot serve as a reliable surrogate measure for other O<sub>3</sub>-related vegetation effects because other effects (e.g., biomass loss) have been reported with and without visible injury. In some cases, visible foliar symptoms have been correlated with decreased vegetative growth (Karnosky *et al.*, 1996; Peterson *et al.*, 1987; Somers *et al.*, 1998) and with impaired reproductive function (Black *et al.*, 2000; Chappelka, 2002). Therefore, the lack of visible injury should not be construed to indicate a lack of phytotoxic concentrations of O<sub>3</sub> nor absence of other non-visible O<sub>3</sub> effects.

#### d. Reduced Plant Vigor

Though O<sub>3</sub> levels over most of the U.S. are not high enough to kill vegetation directly, current levels have been shown to reduce the ability of many sensitive species and genotypes within species to adapt to or withstand other environmental stresses. These O<sub>3</sub> effects may include increased susceptibility to freezing temperatures, increased vulnerability to pest infestations and/or root disease, and compromised ability to compete for available resources. As an example of the latter, when species with differing O<sub>3</sub>-sensitivities occur together, O<sub>3</sub>-sensitive species may experience a greater reduction in growth than more O<sub>3</sub>-tolerant species, which then can better compete for available resources. The result of such above effects can produce a loss in plant vigor in O<sub>3</sub>-sensitive species that over time may lead to premature plant death.

#### e. Ecosystems

Ecosystems are comprised of complex assemblages of organisms and the physical environment with which they interact. Each level of organization within an ecosystem has functional and structural characteristics. At the ecosystem level, functional characteristics include, but are not limited to, energy flow; nutrient, hydrologic, and biogeochemical cycling; and maintenance of food chains. The sum of the functions carried out by ecosystem components provides many benefits to humankind, as in the case of

forest ecosystems (Smith, 1992). Some of these benefits, also termed "ecosystem goods and services", include food, fiber production, aesthetics, genetic diversity, maintenance of water quality, air quality, and climate, and energy exchange. A conceptual framework for discussing the effects of stressors, including air pollutants such as O<sub>3</sub>, on ecosystems was developed by the EPA Science Advisory Board (Young and Sanzone, 2002). In this report, the authors identify six essential ecological attributes (EEAs) of ecosystems including landscape condition, biotic condition, chemical/physical condition, ecological processes, hydrology/geomorphology, and natural disturbance regime. Each EEA is depicted as one of six triangles that together build a hexagon. On the outside of each triangle is a list of stressors that can act on the EEA. Tropospheric O<sub>3</sub> is listed as a stressor of both biotic condition and the chemical/physical condition of ecosystems. As each EEA is linked to all the others, it is clearly envisioned in this framework that O<sub>3</sub> could either directly or indirectly impact all of the EEAs associated with an ecosystem that is being stressed by O<sub>3</sub>.

Vegetation often plays an influential role in defining the structure and function of an ecosystem, as evidenced by the use of dominant vegetation forms to classify many types of natural ecosystems, e.g., tundra, wetland, deciduous forest, and conifer forest. Plants simultaneously inhabit both above- and below-ground environments, integrating and influencing key ecosystem cycles of energy, water, and nutrients. When a sufficient number of individual plants within a community have been affected, O<sub>3</sub>-related effects can be propagated up to ecosystem-level effects. Thus, through its impact on vegetation, O<sub>3</sub> can be an important ecosystem stressor.

#### i. Potential Ozone Alteration of Ecosystem Structure and Function

The 2006 Criteria Document outlines seven case studies where O<sub>3</sub> effects on ecosystems have either been documented or are suspected. The oldest and clearest example involves the San Bernardino Mountain forest ecosystem in California. This system experienced chronic high O<sub>3</sub> exposures over a period of 50 or more years. The O<sub>3</sub>-sensitive and co-dominant species of ponderosa and Jeffrey pine demonstrated severe levels of foliar injury, premature senescence, and needle fall that decreased the photosynthetic capacity of stressed pines and reduced the production of carbohydrates resulting in a decrease in

radial growth and in the height of stressed trees. It was also observed that ponderosa and Jeffrey pines with slight to severe crown injury lost basal area in relation to competing species that are more tolerant to O<sub>3</sub>. Due to a loss of vigor, these trees eventually succumbed to the bark beetle, leading to elevated levels of tree death. Increased mortality of susceptible trees shifted the community composition towards white fir and incense cedar, effectively reversing the development of the normal fire climax mixture dominated by ponderosa and Jeffrey pines, and leading to increased fire susceptibility. At the same time, numerous other organisms and processes were also affected either directly or indirectly, including successional patterns of fungal microflora and their relationship to the decomposer community. Nutrient availability was influenced by the heavy litter and thick needle layer under stands with the most severe needle injury and defoliation. In this example, O<sub>3</sub> appeared to be a predisposing factor that led to increased drought stress, windthrow, root diseases, and insect infestation (Takemoto *et al.*, 2001). Thus, through its effects on tree water balance, cold hardiness, tolerance to wind, and susceptibility to insect and disease pests, O<sub>3</sub> potentially impacted the ecosystem-related EEA of natural disturbance regime (e.g., fire, erosion). Although the role of O<sub>3</sub> was extremely difficult to separate from other confounding factors, such as high nitrogen deposition, there is evidence that this shift in species composition has altered the structure and dynamics of associated food webs (Pronos *et al.*, 1999) and carbon (C) and nitrogen (N) cycling (Arbaugh *et al.*, 2003). Ongoing and new research in this important ecosystem is needed to reveal the extent to which ecosystem services have been affected and to what extent strong causal linkages between historic and/or current ambient O<sub>3</sub> exposures and observed ecosystem-level effects can be made.

Ozone has also been reported to be a selective pressure among sensitive tree species (e.g., eastern white pine) in the east. The nature of community dynamics in eastern forests is different, however, than in the west, consisting of a wider diversity of species and uneven aged stands, and the O<sub>3</sub> levels are less severe. Therefore, lower level chronic O<sub>3</sub> stress in the east is more likely to produce subtle long-term forest responses such as shifts in species composition, rather than wide-spread community degradation.

Some of the best-documented studies of population and community response

to O<sub>3</sub> effects are the long-term studies of common plantain (*Plantago major*) in native plant communities in the United Kingdom (Davison and Reiling, 1995; Lyons *et al.*, 1997; Reiling and Davison, 1992c). Elevated O<sub>3</sub> significantly decreased the growth of sensitive populations of common plantain (Pearson *et al.*, 1996; Reiling and Davison, 1992a, b; Whitfield *et al.*, 1997) and reduced its fitness as determined by decreased reproductive success (Pearson *et al.*, 1996; Reiling and Davison, 1992a). While spatial comparisons of population responses to O<sub>3</sub> are complicated by other environmental factors, rapid changes in O<sub>3</sub> resistance were imposed by ambient levels and variations in O<sub>3</sub> exposure (Davison and Reiling, 1995). Specifically, in this case study, it appeared that O<sub>3</sub>-sensitive individuals are being removed by O<sub>3</sub> stress and the genetic variation represented in the population could be declining. If genetic diversity and variation is lost in ecosystems, there may be increased vulnerability of the system to other biotic and abiotic stressors, and ultimately a change in the EEAs and associated services provided by those ecosystems.

Recent free-air exposure experiments have also provided new insight into how O<sub>3</sub> may be altering ecosystem structure and function (Karnosky *et al.*, 2005). For example, a field O<sub>3</sub> exposure experiment at the AspenFACE site in Wisconsin (described in section IV.A.2.b. above) was designed to examine the effects of both elevated CO<sub>2</sub> and O<sub>3</sub> on mixed stands of aspen (*Populus tremuloides*), birch (*Betula papyrifera*), and sugar maple (*Acer saccharum*) that are characteristic of Great Lakes aspen-dominated forests (Karnosky *et al.*, 2003; Karnosky *et al.*, 1999). They found evidence that the effects on above- and below-ground growth and physiological processes have cascaded through the ecosystem, even affecting microbial communities (Larson *et al.*, 2002; Phillips *et al.*, 2002). This study also confirmed earlier observations of O<sub>3</sub>-induced changes in trophic interactions involving keystone tree species, as well as important insect pests and their natural enemies (Awmack *et al.*, 2004; Holton *et al.*, 2003; Percy *et al.*, 2002).

Collectively these examples suggest that O<sub>3</sub> is an important stressor in natural ecosystems, but it is difficult to quantify the contribution of O<sub>3</sub> due to the combination of other stresses present in ecosystems. In most cases, because only a few components in each of these ecosystems have been examined and characterized for O<sub>3</sub> effects, the full

extent of ecosystem changes in these example ecosystems is not fully understood. Clearly, there is a need for highly integrated ecosystem studies that specifically investigate the effect of O<sub>3</sub> on ecosystem structure and function in order to fully determine the extent to which O<sub>3</sub> is altering ecosystem services. Continued research, employing new approaches, will be necessary to fully understand the extent to which O<sub>3</sub> is affecting ecosystem services.

#### ii. Effects on Ecosystem Services and Carbon Sequestration

Since it has been established that O<sub>3</sub> affects photosynthesis and growth of plants, O<sub>3</sub> is most likely affecting the productivity of forest ecosystems. Therefore, it is desirable to link effects on growth and productivity to essential ecosystem services. However, it is very difficult to quantify ecosystem-level productivity losses because of the amount of complexity in scaling from the leaf-level or individual plant to the ecosystem level, and because not all organisms in an ecosystem are equally affected by O<sub>3</sub>.

Terrestrial ecosystems are important in the Earth's carbon (C) balance and could help offset emissions of CO<sub>2</sub> by humans if anthropogenic C is sequestered in vegetation and soils. The annual increase in atmospheric CO<sub>2</sub> is less than the total inputs from fossil fuel burning and land use changes (Prentice *et al.*, 2001), and much of this discrepancy is thought to be attributable to CO<sub>2</sub> uptake by plant photosynthesis (Tans & White, 1998). Temperate forests of the northern hemisphere have been estimated to be a net sink of about 0.6 to 0.7 petagrams (Pg) C per year (Goodale *et al.* 2002). Ozone interferes with photosynthesis, causes some plants to senesce leaves prematurely, and in some cases, reduces allocation to stem and root tissue. Thus, O<sub>3</sub> decreases the potential for C sequestration. For the purposes of this discussion, C sequestration is defined as the net exchange of carbon by the terrestrial biosphere. However, long-term storage in the soil organic matter is considered to be the most stable form of C storage in ecosystems.

In a study including all ecosystem types, Felzer *et al.* (2004), estimated that U.S. net primary production (net flux of C into an ecosystem) was decreased by 2.6–6.8 percent due to O<sub>3</sub> pollution in the late 1980s to early 1990s. Ozone not only reduces C sequestration in existing forests, it can also affect reforestation projects (Beedlow *et al.* 2004). This effect, in turn, has been found to ultimately inhibit C sequestration in forest soils which act as long-term C

storage (Loya *et al.*, 2003; Beedlow *et al.* 2004). The interaction of rising O<sub>3</sub> pollution and rising CO<sub>2</sub> concentrations in the coming decades complicates predictions of future sequestration potential. Models generally predict that, in the future, C sequestration will increase with increasing CO<sub>2</sub>, but often do not account for the decrease in productivity due to the local effects of current or potentially increasing levels of tropospheric O<sub>3</sub>. In the presence of high O<sub>3</sub> levels, the stimulatory effect of rising CO<sub>2</sub> concentrations on forest productivity has been estimated to be reduced by more than 20 percent (Tingey *et al.*, 2001; Ollinger *et al.* 2002; Karnosky *et al.*, 2003).

In summary, it would be anticipated that meeting lower O<sub>3</sub> standards would increase the amount of CO<sub>2</sub> uptake by many ecosystems in the U.S. However, the amount of this improvement would be heavily dependent on the species composition of those ecosystems. Many ecosystems in the U.S. do have O<sub>3</sub> sensitive plants. For example, forest ecosystems with dominant species such as aspen or ponderosa pine would be expected to increase CO<sub>2</sub> uptake more with lower O<sub>3</sub> than forests with more O<sub>3</sub> tolerant species.

A recent critique of the secondary NAAQS review process published in the report by the National Academy of Sciences on Air Quality Management in the United States (NRC, 2004) stated that "EPA's current practice for setting secondary standards for most criteria pollutants does not appear to be sufficiently protective of sensitive crops and ecosystems \* \* \*". This report made several specific recommendations for improving the secondary NAAQS process and concluded that "There is growing evidence that tighter standards to protect sensitive ecosystems in the United States are needed. \* \* \*". An effort has been recently initiated within the Agency to identify indicators of ecological condition whose responses can be clearly linked to changes in air quality that are attributable to Agency environmental programs. Using a single indicator to represent the complex linkages and dynamic cycles that define ecosystem condition will always have limitations. With respect to O<sub>3</sub>-related impacts on ecosystem condition, only two candidate indicators, foliar injury (as described above) and radial growth in trees, have been suggested. Thus, while at the present time, most O<sub>3</sub>-related effects on ecosystems must be inferred from observed or predicted O<sub>3</sub>-related effects on individual plants, additional research at the ecosystem level could identify new indicators and/or establish stronger causal linkages

between O<sub>3</sub>-induced plant effects and ecosystem condition.

#### f. Yield Reductions in Crops

Ozone can interfere with carbon gain (photosynthesis) and allocation of carbon with or without the presence of visible foliar injury. As a result of decreased carbohydrate availability, fewer carbohydrates are available for plant growth, reproduction, and/or yield. Recent studies have further confirmed and demonstrated O<sub>3</sub> effects on different stages of plant reproduction, including pollen germination, pollen tube growth, fertilization, and abortion of reproductive structures, as reviewed by Black *et al.* (2000). For seed-bearing plants, these reproductive effects will culminate in reduced seed production or yield.

As described in the 1997 review and again in the 2006 Criteria Document and 2007 Staff Paper, the National Crop Loss Assessment Network (NCLAN) studies undertaken in the early to mid-1980s provide the largest, most uniform database on the effects of O<sub>3</sub> on agricultural crop yields. The NCLAN protocol was designed to produce crop exposure-response data representative of the areas in the U.S. where the crops were typically grown. In total, 15 species (*e.g.*, corn, soybean, winter wheat, tobacco, sorghum, cotton, barley, peanuts, dry beans, potato, lettuce, turnip, and hay [alfalfa, clover, and fescue]), accounting for greater than 85 percent of U.S. agricultural acreage planted at that time, were studied. Of these 15 species, 13 species including 38 different cultivars were combined in 54 cases representing unique combinations of cultivars, sites, water regimes, and exposure conditions. Crops were grown under typical farm conditions and exposed in open-top chambers to ambient O<sub>3</sub>, sub-ambient O<sub>3</sub>, and above ambient O<sub>3</sub>. Robust C-R functions were developed for each of these crop species. These results showed that 50 percent of the studied cases would be protected from greater than 10 percent yield loss at a W126 level of 21 ppm-hour, while a W126 of 13 ppm-hour would provide protection for 75 percent of the cases studied from greater than 10 percent yield loss.

Recent studies continue to find yield loss levels in crop species studied previously under NCLAN that reflect the earlier findings. In other words, there has been no evidence that crops are becoming more tolerant of O<sub>3</sub> (EPA, 2006a). For cotton, some newer varieties have been found to have higher yield loss due to O<sub>3</sub> compared to older varieties (Olszyk *et al.*, 1993, Grantz and

McCool, 1992). In a meta-analysis of 53 studies, Morgan *et al.* (2003) found consistent deleterious effects of O<sub>3</sub> exposures on soybean from studies published between 1973 and 2001. Further, early results from the field-based exposure experiment SoyFACE in Illinois indicate a lack of any apparent difference in the O<sub>3</sub> tolerance of old and recent cultivars of soybean in a study of 22 soybean varieties (Long *et al.*, 2002). Thus, the 2007 Staff Paper concluded that the recent scientific literature continues to support the conclusions of the 1996 Criteria Document that ambient O<sub>3</sub> concentrations are reducing the yield of major crops in the U.S.

In addition to the effects described on annual crop species, several studies published since the 1997 review have focused on perennial forage crops (EPA, 2006a). These recent results confirm that O<sub>3</sub> is also impacting yields and quality of multiple-year forage crops at sufficient magnitude to have nutritional and possibly economic implications to their use as ruminant animal feed at O<sub>3</sub> exposures that occur in some years over large areas of the U.S.

#### 3. Adversity of Effects

The 2007 Staff Paper recognized that the statute requires that a secondary standard be protective against "adverse" O<sub>3</sub> effects, not all identifiable O<sub>3</sub>-induced effects. In considering what constitutes a vegetation effect that is adverse to the public welfare, the 2007 Staff Paper recognizes that O<sub>3</sub> can cause a variety of vegetation effects, beginning at the level of the individual cell and accumulating up to the level of whole leaves, plants, plant populations, communities and whole ecosystems, not all of which have been classified in past reviews as "adverse" to public welfare.

Previous reviews have classified O<sub>3</sub> vegetation effects as either "injury" or "damage" to help in determining adversity. Specifically, "injury" is defined as encompassing all plant reactions, including reversible changes or changes in plant metabolism (*e.g.*, altered photosynthetic rate), altered plant quality, or reduced growth, that does not impair the intended use or value of the plant (Guderian, 1977). In contrast, "damage" has been defined to include those injury effects that reach sufficient magnitude as to also reduce or impair the intended use or value of the plant. Examples of effects that are classified as damage include reductions in aesthetic values (*e.g.*, foliar injury in ornamental species) as well as losses in terms of weight, number, or size of the plant part that is harvested (reduced yield or biomass production). Yield loss also may include changes in crop

quality, *i.e.*, physical appearance, chemical composition, or the ability to withstand storage, while biomass loss includes slower growth in species harvested for timber or other fiber uses. While this construct has proved useful in the past, it appears to be most useful in the context of evaluating effects on single plants or species grown in monocultures such as agricultural crops or managed forests. It is less clear how it might apply to potential effects on natural forests or entire ecosystems when O<sub>3</sub>-induced species level impacts lead to shifts in species composition and/or associated ecosystem services such as nutrient cycling or hydrologic cycles, where the intended use or value of the system has not been specifically identified.

A more recent construct for assessing risks to forests described in Hogsett *et al.* (1997) suggests that "adverse effects could be classified into one or more of the following categories: (1) Economic production, (2) ecological structure, (3) genetic resources, and (4) cultural values." This approach expands the context for evaluating the adversity of O<sub>3</sub>-related effects beyond the species level. Another recent publication, *A Framework for Assessing and Reporting on Ecological Condition: An SAB report* (Young and Sanzone, 2002), provides additional support for expanding the consideration of adversity beyond the species level by making explicit the linkages between stress-related effects (*e.g.*, O<sub>3</sub> exposure) at the species level and at higher levels within an ecosystem hierarchy. Taking this recent literature into account, the 2007 Staff Paper concludes that a determination of what constitutes an "adverse" welfare effect in the context of the secondary NAAQS review can appropriately occur within this broader paradigm.

#### B. Biologically Relevant Exposure Indices

The 2006 Criteria Document concluded that O<sub>3</sub> exposure indices that cumulate differentially weighted hourly concentrations are the best candidates for relating exposure to plant growth responses. This conclusion follows from the extensive evaluation of the relevant studies in the 1996 Criteria Document (EPA, 1996a) and the recent evaluation of studies that have been published since that time. The following selections, taken from the 1996 Criteria Document (EPA, 1996a, section 5.5), further elucidate the depth and strength of these conclusions. Specifically, with respect to the importance of taking into account exposure duration, the 1996 Criteria Document stated, "when O<sub>3</sub> effects are the primary cause of variation



in plant response, plants from replicate studies of varying duration showed greater reductions in yield or growth when exposed for the longer duration" and "the mean exposure index of unspecified duration could not account for the year-to-year variation in response" (EPA, 1996a, pg. 5–96). Further, "because the mean exposure index treats all concentrations equally and does not specifically include an exposure duration component, the use of a mean exposure index for characterizing plant exposures appears inappropriate for relating exposure with vegetation effects" (EPA, 1996a, pg. 5–88). Regarding the relative importance of higher concentrations than lower in determining plant response, the 1996 Criteria Document concluded that "the ultimate impact of long-term exposures to O<sub>3</sub> on crops and seedling biomass response depends on the integration of repeated peak concentrations during the growth of the plant" (EPA, 1996a, pg. 5–104). Further, "at this time, exposure indices that weight the hourly O<sub>3</sub> concentrations differentially appear to be the best candidates for relating exposure with predicted plant response" (EPA, 1996a, pgs. 5–136).

At the conclusion of the 1997 review, the biological basis for a cumulative, seasonal form was not in dispute. There was general agreement between EPA and CASAC, based on their review of the air quality criteria, that a cumulative, seasonal form was more biologically based than the then current 1-hour and newly proposed 8-hour average form. However, in selecting a specific form appropriate for a secondary standard, there was less agreement. An evaluation of the performance of several cumulative seasonal forms in predicting plant response data taken from OTC experiments had found that all performed about equally well and was unable to distinguish between them (EPA, 1996a). In selecting between two of these cumulative forms, the SUM06<sup>54</sup> and W126, in the absence of biological evidence to distinguish between them, EPA based its decision on both science and policy considerations. Specifically, these were: (1) All cumulative, peak-weighted exposure indices considered, including W126 and SUM06, were about equally good as exposure measures to predict exposure-response relationships reported in the NCLAN crop studies; and (2) the SUM06 form would not be influenced by PRB O<sub>3</sub> concentrations (defined at the time as

0.03 to 0.05 ppm) under many typical air quality distributions. On the basis of these considerations, EPA chose the SUM06 as the most appropriate cumulative, seasonal form to consider when proposing an alternative secondary standard form (61 FR 65716).

Though the scientific justification for a cumulative, seasonal form was generally accepted in the 1997 review, an analysis undertaken by EPA at that time had shown that there was considerable overlap between areas that would be expected not to meet the range of alternative 8-hour standards being considered for the primary NAAQS and those expected not to meet the range of values (expressed in terms of the seasonal SUM06 index) of concern for vegetation. This result suggested that improvements in national air quality expected to result from attaining an 8-hour primary standard within the recommended range of levels would also be expected to significantly reduce levels of concern for vegetation in those same areas. Thus, in the 1996 proposed rule, EPA proposed two alternatives for consideration: one alternative was to make the secondary standard equal in every way to the proposed 8-hour, 0.08 ppm primary standard; and the second was to establish a cumulative, seasonal secondary standard in terms of a SUM06 form as also appropriate to protect public welfare from known or anticipated adverse effects given the available scientific knowledge and that such a seasonal standard " \* \* \* is more biologically relevant \* \* \*" (61 FR 65716).

In the 1997 final rule, EPA decided to make the secondary standard identical to the primary standard. The EPA acknowledged, however, that "it remained uncertain as to the extent to which air quality improvements designed to reduce 8-hr average O<sub>3</sub> concentrations averaged over a 3-year period would reduce O<sub>3</sub> exposures measured by a seasonal SUM06 index." (62 FR 38876) In other words, it was uncertain as to whether the 8-hour average form would, in practice, provide sufficient protection for vegetation from the cumulative, seasonal and concentration-weighted exposures described in the scientific literature as of concern.

On the basis of that history, the 2007 Staff Paper (chapter 7) revisited the issue of whether the SUM06 was still the most appropriate choice of cumulative, seasonal form for a secondary standard to protect the public welfare from known and anticipated adverse vegetation effects in light of the new information available in this review. Specifically, the 2007 Staff

Paper considered: (1) The continued lack of evidence within the vegetation effects literature of a biological threshold for vegetation exposures of concern; and (2) new estimates of PRB that were lower than in the 1997 review. The W126 form, also evaluated in the 1997 review, was again selected for comparison with the SUM06 form. Regarding the first consideration, the 2007 Staff Paper noted that the W126 form, by its incorporation of a continuous sigmoidal weighting scheme, does not create an artificially imposed concentration threshold, yet also gives proportionally more weight to the higher and typically more biologically potent concentrations, as supported by the scientific evidence. Second, the index value is not significantly influenced by O<sub>3</sub> concentrations within the range of estimated PRB, as the weights assigned by the sigmoidal weighting scheme to concentrations in this range are near zero. Thus, it would also provide a more appropriate target for air quality management programs designed to reduce emissions from anthropogenic sources contributing to O<sub>3</sub> formation. On the basis of these considerations, the 2007 Staff Paper concluded that the W126 form was the most biologically-relevant cumulative, seasonal form appropriate to consider in the context of the 2008 rulemaking.

### C. Vegetation Exposure and Impact Assessment

The vegetation exposure and impact assessment conducted for the 2008 rulemaking and described in the 2007 Staff paper, consisted of exposure, risk and benefits analyses and improved and built upon similar analyses performed in the 1997 review (EPA 1996b). The vegetation exposure assessment was performed using interpolation and included information from ambient monitoring networks and results from air quality modeling. The vegetation risk assessment included both tree and crop analyses. The tree risk analysis includes three distinct lines of evidence: (1) Observations of visible foliar injury in the field linked to monitored O<sub>3</sub> air quality for the years 2001–2004; (2) estimates of seedling growth loss under then current and alternative O<sub>3</sub> exposure conditions; and (3) simulated mature tree growth reductions using the TREGRO model to simulate the effect of meeting alternative air quality standards on the predicted annual growth of a single western species (ponderosa pine) and two eastern species (red maple and tulip poplar). The crop analysis includes estimates of the risks to crop yields from then current and alternative

<sup>54</sup> The SUM06 index is defined as the sum of all hourly O<sub>3</sub> concentrations greater or equal to 0.06 ppm over a specified time.

O<sub>3</sub> exposure conditions and the associated change in economic benefits expected to accrue in the agriculture sector upon meeting the levels of various alternative standards. Each element of the assessment is described below, including discussions of known sources and ranges of uncertainties associated with the elements of this assessment.

### 1. Exposure Characterization

Though numerous effects of O<sub>3</sub> on vegetation have been documented as discussed above, it is important in considering risk to examine O<sub>3</sub> air quality patterns in the U.S. relative to the location of O<sub>3</sub> sensitive species that have a known concentration-response in order to predict whether adverse effects are occurring at current levels of air quality, and whether they are likely to occur under alternative standard forms and levels.

The most important information about exposure to vegetation comes from the O<sub>3</sub> monitoring data that are available from two national networks: (1) Air Quality System (AQS; <http://www.epa.gov/ttn/airs/airsaqs>) and (2) Clean Air Status and Trends Network (CASTNET; <http://www.epa.gov/castnet/>). The AQS monitoring network currently has over 1100 active O<sub>3</sub> monitors which are generally sited near population centers. However, this network also includes approximately 36 monitors located in national parks. CASTNET is the nation's primary source for data on dry acidic deposition and rural, ground-level O<sub>3</sub>. It consists of over 80 sites across the eastern and western U.S. and is cooperatively operated and funded with the National Park Service. In the 1997 O<sub>3</sub> NAAQS final rule, it was acknowledged that because the national air quality surveillance network for O<sub>3</sub> was designed principally to monitor O<sub>3</sub> exposure in populated areas, there was limited measured data available to characterize O<sub>3</sub> air quality in rural and remote sites. Since the 1997 review, there has been a small increase in the number of CASTNET sites (from approximately 52 sites in 1992 to 84 sites in 2004), however these monitors are not used for attainment designations.

National parks represent areas of nationally recognized ecological and public welfare significance, which have been afforded a high level of protection by Congress. Two recent reports presented some discussion of O<sub>3</sub> trends in a subset of national parks: The Ozone Report: Measuring Progress Through 2003 (EPA, 2004), and 2005 Annual Performance and Progress Report: Air

Quality in National Parks (NPS, 2005). Unfortunately, much of this information is presented only in terms of the current 8-hr average form. The 2007 Staff Paper analyzed available air quality data in terms of the cumulative 12-hour W126 form from 2001 to 2005 for a subset of national parks and other significant natural areas representing 4 general regions of the U.S. Many of these national parks and natural areas have monitored O<sub>3</sub> levels above concentrations that have been shown to decrease plant growth and above the 12-hour W126 levels analyzed in this review. For example, the Great Smokey Mountain, Rocky Mountain, Grand Canyon, Yosemite and Sequoia National Parks all had more than one year within the 2001–2005 period with a 12-hour W126 above 21 ppm-hour. This level of exposure has been associated with approximately no more than 10 percent biomass loss in 50 percent of the 49 tree seedling cases studied in the NHEERL–WED experiments (Lee and Hogsett, 1996). Black cherry (*Prunus serotina*), an important O<sub>3</sub>-sensitive tree species in the eastern U.S., occurs in the Great Smoky Mountain National Park and is estimated to have O<sub>3</sub>-related seedling biomass loss of approximately 40 percent when exposed to a 3 month, 12-hour W126 O<sub>3</sub> level greater than 21 ppm-hour. Ponderosa pine (*Pinus ponderosa*) which occurs in the Grand Canyon, Yosemite and Sequoia National Parks has been reported to have approximately 10 percent biomass losses at 3 month, 12 hour W126 O<sub>3</sub> levels as low as 17 ppm-hour (Lee and Hogsett, 1996). Impacts on seedlings may potentially affect long-term tree growth and survival, ultimately affecting the competitiveness of O<sub>3</sub>-sensitive tree species and genotypes within forest stands.

In order to characterize exposures to vegetation at the national scale, however, the 2007 Staff Paper concluded that it could not rely solely on limited site-specific monitoring data, and that it was necessary to select an interpolation method that could be used to characterize O<sub>3</sub> air quality over broad geographic areas. The 2007 Staff Paper therefore investigated the appropriateness of using the O<sub>3</sub> outputs from the EPA/NOAA Community Multi-scale Air Quality (CMAQ)<sup>55</sup> model

<sup>55</sup> The CMAQ model is a multi-pollutant, multiscale air quality model that contains state-of-the-science techniques for simulating atmospheric and land processes that affect the transport, transformation, and deposition of atmospheric pollutants and/or their precursors on both regional and urban scales. It is designed as a science-based modeling tool for handling many major pollutants (including photochemical oxidants/O<sub>3</sub>, particulate

system (<http://www.epa.gov/asmdnerl/CMAQ>, Byun and Ching, 1999; Arnold *et al.* 2003, Eder and Yu, 2005) to improve spatial interpolations based solely on existing monitoring networks. Due to the significant resources required to run CMAQ, model outputs were only available for a limited number of years. For the 2008 rulemaking, the most recent outputs available at the time from CMAQ version 4.5 were for the year 2001.

Based on the significant difference in monitor network density between the eastern and western U.S., the 2007 Staff Paper concluded that it was appropriate to use separate interpolation techniques in these two regions. Only AQS and CASTNET monitoring data were used for the eastern interpolation, since it was determined that enhancing the interpolation with CMAQ data did not add much information to the eastern U.S. interpolation. In the western U.S., however, where rural monitoring is more sparse, O<sub>3</sub> values generated by the CMAQ model were used to develop scaling factors to augment the interpolation.

In order to characterize uncertainties associated with the interpolation method, monitored O<sub>3</sub> concentrations were systematically compared to interpolated O<sub>3</sub> concentrations in areas where monitors were located. In general, the interpolation method used in the current review performed well in many areas in the U.S., although it under-predicted higher 12-hour W126 exposures in rural areas. Due to the important influence of higher exposures in determining risks to plants, this feature of the interpolated surface could result in an under-estimation of risks to vegetation in some areas. Taking these uncertainties into account, and given the absence of more complete rural monitoring data, this approach was used in developing national vegetation exposure and risk assessments that estimate relative changes in risk for the various alternative standards analyzed.

To evaluate changing vegetation exposures and risks under selected air quality scenarios, the 2007 Staff Paper utilized 2001 base year O<sub>3</sub> air quality distributions that had been adjusted with a rollback method (Horst and Duff, 1995; Rizzo, 2005, 2006) to reflect meeting the then current and alternative secondary standard options. This technique combines both linear and quadratic elements to reduce higher O<sub>3</sub>

matter, and nutrient deposition) holistically. The CMAQ model can generate estimates of hourly O<sub>3</sub> concentrations for the contiguous U.S., making it possible to express model outputs in terms of a variety of exposure indices (e.g., W126, 8-hour average).

concentrations more than lower ones. In this regard, the rollback method attempts to account for reductions in emissions without greatly affecting lower concentrations. The following O<sub>3</sub> air quality scenarios were analyzed: (1) 4th-highest daily maximum 8-hour average: 0.084 ppm (the effective level of the then current standard) and 0.070 ppm levels; (2) 3-month, 12-hour. SUM06: 25 ppm-hour (proposed in the 1997 review) and 15 ppm-hour levels; and (3) 3-month, 12-hour W126: 21 ppm-hour and 13 ppm-hour levels.

The two 8-hour average levels were chosen as possible alternatives of the then current form for comparison with the cumulative, seasonal alternative forms. The SUM06 scenarios were very similar to the W126 scenarios. Since the W126 was judged to be the more biologically-relevant cumulative, seasonal form, only the results for the W126 scenarios are summarized below. For the W126 form, the two levels were selected on the basis of the associated levels of tree seedling biomass loss and crop yield loss protection identified in the NHEERL-WED and NCLAN studies, respectively. Specifically, the upper level of W126 (21 ppm-hour) was associated with a level of tree and crop protection of approximately no more than 10 percent growth or yield loss in 50 percent of cases studied. Alternatively, the lower level of W126 (13 ppm-hour) was associated with a level of tree seedling and crop protection of approximately no more than 10 percent growth or yield loss in 75 percent of studied cases.

The following discussion highlights key observations drawn from comparing predicted changes in interpolated air quality under each alternative standard form and level scenario for the base year, 2001:

(1) Under the base year (2001) "as is" air quality, a large portion of California had 12-hr W126 O<sub>3</sub> levels above 31 ppm-hour, which has been associated with approximately no more than 14 percent biomass loss in 50 percent of tree seedling cases studies. Broader multi-state regions in the east (NC, TN, KY, IN, OH, PA, NJ, NY, DE, MD, VA) and west (CA, NV, AZ, OK, TX) are predicted to have levels of air quality above the W126 level of 21 ppm-hour, which is approximately equal to the secondary standard proposed in 1996 and is associated with approximately no more than 10 percent biomass loss in 50 percent of tree seedling cases studied. Much of the east and Arizona and California have 12-hour W126 O<sub>3</sub> levels above 13 ppm-hour, which has been associated with approximately no more than 10 percent biomass loss in 75

percent of tree seedling cases studied. The results of the exposure assessment indicate that current air quality levels could result in significant impacts to vegetation in some areas.

(2) When 2001 air quality was rolled back to meet the then current 8-hour, 0.084 ppm secondary standard, the overall 3-month 12-hour W126 O<sub>3</sub> levels were somewhat improved, but not substantially. Under this scenario, there were still many areas in California with 12-hour W126 O<sub>3</sub> levels above 31 ppm-hour. A broad multi-state region in the east (NC, TN, KY, IN, OH, PA, MD) and west (CA, NV, AZ, OK, TX) were still predicted to have O<sub>3</sub> levels above the W126 level of 21 ppm-hour.

(3) Exposures generated for just meeting a 0.070 ppm, 4th-highest maximum 8-hour average alternative standard showed substantially improved O<sub>3</sub> air quality when compared to just meeting the then current 8-hour standard. Most areas were predicted to have O<sub>3</sub> levels below the W126 level of 21 ppm-hour, although some areas in the east (KY, TN, MI, AR, MO, IL) and west (CA, NV, AZ, UT, NM, CO, OK, TX) were still predicted to have O<sub>3</sub> levels above the W126 level of 13 ppm-hour.

These results suggest that meeting a 0.070 ppm, 8-hour secondary standard would provide substantially improved protection in some areas for vegetation from seasonal O<sub>3</sub> exposures of concern. The 2007 Staff Paper recognizes, however, that some areas meeting a 0.070 ppm 8-hour standard could continue to have elevated seasonal exposures, including forested park lands and other natural areas, and Class I areas which are federally mandated to preserve certain air quality related values. This is especially important in the high elevation forests in the Western U.S. where there are few O<sub>3</sub> monitors. This is because the air quality patterns in remote areas can result in relatively low 8-hour averages while still experiencing relatively high cumulative exposures.

To further characterize O<sub>3</sub> air quality in terms of various secondary standard forms, an analysis was performed in the 2007 Staff Paper to evaluate the extent to which county-level O<sub>3</sub> air quality measured in terms of various levels of the current 8-hour average form overlapped with that measured in terms of various levels of the 12-hour W126 cumulative, seasonal form. The 2007 Staff Paper presented this analysis using 2002–2004<sup>56</sup> county-level O<sub>3</sub> air quality

<sup>56</sup> This analysis was updated using 2003–2005 air quality as it became available, finding similar results.

data from AQS sites and the subset of CASTNET sites having the highest O<sub>3</sub> levels for the counties in which they are located. Since the current 8-hour average secondary form is a 3-year average, the analysis initially compared the 3-year averages of both the 8-hour and W126 forms. In addition, recognizing that some vegetation effects (e.g. crop yield loss and foliar injury) are driven solely by annual O<sub>3</sub> exposures and are typically evaluated with respect to exposures within the annual growing season, the 2007 Staff Paper also presented a comparison of the current 3-year average 8-hour form to the annual W126 form for the individual years, 2002 and 2004.

Results of the 3-year average comparisons showed that of the counties with air quality meeting the 3-year average form of a 0.084 ppm, 8-hour average standard, 7 counties showed 3-year average W126 values above the 21 ppm-hour level. At the lower W126 level of 13 ppm-hour, 135 counties with air quality meeting the 3-year average form of a 0.084 ppm, 8-hour average standard, would be above this W126 level. In addition, when the 3-year average of an 8-hour form was compared to annual W126 values, further variability in the degree of overlap between the 8-hour form and W126 form became apparent. For example, the relatively high 2002 O<sub>3</sub> air quality year showed a greater degree of overlap between those areas that would meet the levels analyzed for the current 8-hour and alternative levels of the W126 form than did the relatively low O<sub>3</sub> 2004 air quality year. This lack of a consistent degree of overlap between the two forms in different air quality years demonstrates that annual vegetation would be expected to receive widely differing degrees of protection from cumulative seasonal exposures in some areas from year to year, even when the 3-year average of the 8-hour form was consistently met.

It is clear that this analysis is limited by the lack of monitoring in rural areas where important vegetation and ecosystems are located, especially at higher elevation sites. This is because O<sub>3</sub> air quality distributions at high elevation sites often do not reflect the typical urban and near-urban pattern of low morning and evening O<sub>3</sub> concentrations with a high mid-day peak, but instead maintain relatively flat patterns with many concentrations in the mid-range (e.g., 0.05–0.09 ppm) for extended periods. These conditions can lead to relatively low daily maximum 8-hour averages concurrently with high cumulative values so that there is potentially less overlap between an 8-

hour average and a cumulative, seasonal form at these sites. The 2007 Staff Paper concluded that it is reasonable to anticipate that additional unmonitored rural high elevation areas important for vegetation may not be adequately protected even with a lower level of the 8-hour form.

The 2006 Criteria Document discusses policy relevant background (PRB) levels for high elevation sites and makes the following observations: (1) PRB concentrations of 0.04 to 0.05 ppm occur occasionally at high-elevation sites (e.g., > 1.5 km) in the spring due to the free-tropospheric influence, including some limited contribution from hemispheric pollution ( $O_3$  produced from anthropogenic emissions outside North America); and (2) while stratospheric intrusions might occasionally elevate  $O_3$  at high-altitude sites, these events are rare at surface sites. Therefore, the 2007 Staff Paper concluded that springtime PRB levels in the range identified above and rare stratospheric intrusions of  $O_3$  are unlikely to be a major influence on 3-month cumulative seasonal W126 values.

It further remains uncertain as to the extent to which air quality improvements designed to reduce 8-hour  $O_3$  average concentrations would reduce  $O_3$  exposures measured by a seasonal, cumulative W126 index. The 2007 Staff Paper indicated this to be an important consideration because: (1) The biological database stresses the importance of cumulative, seasonal exposures in determining plant response; (2) plants have not been specifically tested for the importance of daily maximum 8-hour  $O_3$  concentrations in relation to plant response; and (3) the effects of attainment of a 8-hour standard in upwind urban areas on rural air quality distributions cannot be characterized with confidence due to the lack of monitoring data in rural and remote areas. These factors are important considerations in determining whether the current 8-hour form can appropriately provide requisite protection for vegetation.

## 2. Assessment of Risks to Vegetation

The 2007 Staff Paper presents results from quantitative and qualitative risk assessments of  $O_3$  risks to vegetation (EPA, 2007). In the 1997 review, crop yield and seedling biomass loss OTC data provided the basis for staff analyses, conclusions, and recommendations (EPA, 1996b). Since then, several additional lines of evidence have progressed sufficiently to provide staff with a more complete and

coherent picture of the scope of  $O_3$ -related vegetation risks, especially those faced by seedling, sapling and mature tree species growing in field settings, and indirectly, forested ecosystems. Specifically, research published after the 1997 review reflects an increased emphasis on field-based exposure methods (e.g., free air exposure and ambient gradient), improved field survey biomonitoring techniques, and mechanistic tree process models. Findings from each of these research areas are discussed separately below. In conducting these assessments, the Staff Paper analyses relied on both measured and modeled air quality information. For some effects, like visible foliar injury and modeled mature tree growth response, only monitored air quality information was used. For other effects categories (e.g., crop yield and tree seedling growth), staff relied on interpolated  $O_3$  exposures.

### a. Visible Foliar Injury

As discussed above (section IV.A.2.c), systematic injury surveys have documented visible foliar injury symptoms diagnostic of phytotoxic  $O_3$  exposures on sensitive bioindicator plants. These surveys have produced more expansive evidence than that available at the time of the 1997 review that visible foliar injury is occurring in many areas of the U.S. under current ambient conditions. The 2007 Staff Paper presents an assessment combining recent U.S. Forest Service Forest Inventory and Analysis (FIA) biomonitoring site data with the county level air quality data for those counties containing the FIA biomonitoring sites. This assessment showed that incidence of visible foliar injury ranged from 21 to 39 percent during the four-year period (2001–2004) across all counties with air quality levels at or below that of a 0.084 ppm, 8-hour standard. Of the counties that met an 8-hour level of 0.070 ppm in those years, 11 to 30 percent still had incidence of visible foliar injury. The magnitude of these percentages suggests that phytotoxic exposures sufficient to induce visible foliar injury would still occur in many areas after meeting the level of a 0.084 ppm secondary standard or alternative 0.070 ppm 8-hour standard. Additionally, the data showed that visible foliar injury occurrence was geographically widespread and occurring on a variety of plant species in forested and other natural systems. Linking visible foliar injury to other plant effects is still problematic. However, its presence indicates that other  $O_3$ -related vegetation effects could also be present.

### b. Seedling and Mature Tree Biomass Loss

In the 1997 review, analyses of the effects of  $O_3$  on trees were limited to 11 tree species for which C–R functions for the seedling growth stage had been developed from OTC studies conducted by the NHEERL–WED. Important tree species such as quaking aspen, ponderosa pine, black cherry, and tulip poplar were found to be sensitive to cumulative seasonal  $O_3$  exposures. Work done since the 1997 review at the AspenFACE site in Wisconsin on quaking aspen (Karnosky *et al.*, 2005) and a gradient study performed in the New York City area (Gregg *et al.* 2003) has confirmed the detrimental effects of  $O_3$  exposure on tree growth in field studies without chambers and beyond the seedling stage (King *et al.* 2005). These field studies are discussed above in section IV.A.

To update the seedling biomass loss risk analysis, C–R functions for biomass loss for available seedling tree species taken from the 2006 Criteria Document and information on tree growing regions derived from the U.S. Department of Agriculture's Atlas of United States Trees were combined with projections of  $O_3$  air quality based on 2001 interpolated exposures, to produce estimated biomass loss for each of the seedling tree species individually. Maps of these biomass loss projections are presented in the 2007 Staff Paper. For example, quaking aspen had a wide range of  $O_3$  exposures across its growing range and therefore, showed significant variability in percentages of projected seedling biomass loss across its range. Quaking aspen seedling biomass loss was projected to be greater than 4 percent over much of its geographic range, though it can reach above 10 percent in areas of Ohio, Pennsylvania, New York, New Jersey and California. Biomass loss for black cherry was projected to be greater than 20 percent in approximately half its range. Greater than 30 percent biomass loss for black cherry was projected in North Carolina, Tennessee, Indiana, Ohio, Pennsylvania, Arizona, Michigan, New York, New Jersey, Maryland and Delaware. For ponderosa pine, an important tree species in the western U.S., biomass loss was projected to be above 10 percent in much of its range in California. Biomass loss still occurred in many tree species when  $O_3$  air quality was adjusted to meet the then current 8-hour standard of 0.084 ppm. For instance, black cherry, ponderosa pine, eastern white pine, and aspen had estimated median seedling biomass losses over portions of their growing

range as high as 24, 11, 6, and 6 percent, respectively, when O<sub>3</sub> air quality was rolled back to just meet a 0.084 ppm, 8-hour standard. The 2007 Staff Paper noted that these results are for tree seedlings and that mature trees of the same species may have more or less of a response to O<sub>3</sub> exposure. Due to the potential for compounding effects over multiple years, experts at a consensus workshop on O<sub>3</sub> vegetation effects and secondary standards, hereinafter referred to as the 1996 Consensus Workshop, reported in a subsequent 1997 Workshop Report, that a biomass loss greater than 2 percent annually can be significant (Heck and Cowling, 1997). Decreased seedling root growth and survivability could affect overall stand health and composition in the long term.

In addition to the estimation of O<sub>3</sub> effects on seedling growth, recent work available in the 2008 rulemaking has enhanced our understanding of risks beyond the seedling stage. In order to better characterize the potential O<sub>3</sub> effects on mature tree growth, a tree growth model (TREGRO) was used as a tool to evaluate the effect of changing O<sub>3</sub> air quality under just meet scenarios for selected alternative O<sub>3</sub> standards on the growth of mature trees. TREGRO is a process-based, individual tree growth simulation model (Weinstein et al., 1991). This model has been used to evaluate the effects of a variety of O<sub>3</sub> exposure scenarios on several species of trees by incorporating concurrent climate data in different regions of the U.S. to account for O<sub>3</sub> and climate/meteorology interactions (Tingey et al., 2001; Weinstein et al., 1991; Retzlaff et al., 2000; Laurence et al., 1993; Laurence et al., 2001; Weinstein et al., 2005). The model provides an analytical framework that accounts for the nonlinear relationship between O<sub>3</sub> exposure and response. The interactions between O<sub>3</sub> exposure, precipitation and temperature are integrated as they affect vegetation, thus providing an internal consistency for comparing effects in trees under different exposure scenarios and climatic conditions. An earlier assessment of the effectiveness of national ambient air quality standards in place since the early 1970s took advantage of 40 years of air quality and climate data for the Crestline site in the San Bernardino Mountains of California to simulate ponderosa pine growth over time with the improving air quality using TREGRO (Tingey et al., 2004).

The TREGRO model was used to assess growth of Ponderosa pine in the San Bernardino Mountains of California (Crestline) and the growth of yellow poplar and red maple in the

Appalachian mountains of Virginia and North Carolina, Shenandoah National Park (Big Meadows) and Linville Gorge Wilderness Area (Cranberry), respectively. Total tree growth associated with "as is" air quality, and air quality adjusted to just meet alternative O<sub>3</sub> standards was assessed. Ponderosa pine is one of the most widely distributed pines in western North America, a major source of timber, important as wildlife habitat, and valued for aesthetics (Burns and Honkala, 1990). Red maple is one of the most abundant species in the eastern U.S. and is important for its brilliant fall foliage and highly desirable wildlife browse food (Burns and Honkala, 1990). Yellow poplar is an abundant species in the southern Appalachian forest. It is 10 percent of the cove hardwood stands in southern Appalachians which are widely viewed as some of the country's most treasured forests because the protected, rich, moist set of conditions permit trees to grow the largest in the eastern U.S. The wood has high commercial value because of its versatility and as a substitute for increasingly scarce softwoods in furniture and framing construction. Yellow poplar is also valued as a honey tree, a source of wildlife food, and a shade tree for large areas (Burns and Honkala, 1990).

The 2007 Staff Paper analyses found that just meeting a 0.084 ppm standard would likely continue to allow O<sub>3</sub>-related reductions in annual net biomass gain in these species. This is based on model outputs that estimate that as O<sub>3</sub> levels are reduced below those of a 0.084 ppm standard, significant improvements in growth would occur. For instance, estimated growth in red maple increased by 4 and 3 percent at Big Meadows and Cranberry sites, respectively, when air quality was rolled back to just met a W126 value of 13 ppm-hour. Yellow poplar was projected to have a growth increase between 0.6 and 8 percent under the same scenario at the two eastern sites.

Though there is uncertainty associated with the above analyses, this information should be given careful consideration in light of several other pieces of evidence. Specifically, new evidence from experimental studies that go beyond the seedling growth stage continues to show decreased growth under elevated O<sub>3</sub> (King et al. 2005). Some mature trees such as red oak have shown an even greater sensitivity of photosynthesis to O<sub>3</sub> than seedlings of the same species (Hanson et al., 1994). As indicated above, smaller growth loss increments may be significant for perennial species. The potential for

cumulative "carry over" effects as well as compounding also must be considered. The accumulation of such "carry-over" effects over time may affect long-term survival and reproduction of individuals and ultimately the abundance of sensitive tree species in forest stands.

### c. Crops

As discussed in the 2007 Staff Paper, risk of O<sub>3</sub> exposure and associated monetized benefits were estimated for commodity crops, fruits and vegetables. Similar to the tree seedling analysis, this analysis combined C-R information on crops, crop growing regions and interpolated exposures during each crop growing season. NCLAN crop functions were used for commodity crops. According to USDA National Agricultural Statistical Survey (NASS) data, the 9 commodity crop species (e.g., cotton, field corn, grain sorghum, peanut, soybean, winter wheat, lettuce, kidney bean, potato) included in the 2007 Staff Paper analysis accounted for 69 percent of 2004 principal crop acreage planted in the U.S. in 2004.<sup>57</sup> The C-R functions for six fruit and vegetable species (tomatoes-processing, grapes, onions, rice, cantaloupes, Valencia oranges) were identified from the California fruit and vegetable analysis from the 1997 review (Abt Associates Inc, 1995). The 2007 Staff Paper noted that fruit and vegetable studies were not part of the NCLAN program and C-R functions were available only in terms of seasonal 7-hour or 12-hour mean index. This index form is considered less effective in predicting plant response for a given change in air quality than the cumulative form used with other crops. Therefore, the fruit and vegetable C-R functions were considered more uncertain than those for commodity crops.

Analyses in the 2007 Staff Paper showed that some of the most important commodity crops such as soybean, winter wheat and cotton had some projected losses under the 2001 base year air quality. Soybean yield losses were projected to be 2-4 percent in parts of Pennsylvania, New Jersey, Maryland and Texas. Winter wheat was projected to have yield losses of 2-6 percent in parts of California.

<sup>57</sup> Principal crops as defined by the USDA include corn, sorghum, oats, barley, winter wheat, rye, durum wheat, other spring wheat, rice, soybeans, peanuts, sunflower, cotton, dry edible beans, potatoes, sugar beets, canola, proso millet, hay, tobacco, and sugarcane. Acreage data for the principal crops were taken from the USDA NASS 2005 Acreage Report (<http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bba/acrg0605.pdf>).

Additionally, cotton was projected to have yield losses of above 6 percent in parts of California, Texas and North Carolina in 2001. The risk assessment estimated that just meeting the then current 0.084 ppm, 8-hour standard would still allow O<sub>3</sub>-related yield loss to occur in some commodity crop species and fruit and vegetable species currently grown in the U.S. For example, based on median C-R function response, in counties with the highest O<sub>3</sub> levels, potatoes and cotton had estimated yield losses of 9–15 percent and 5–10 percent, respectively, when O<sub>3</sub> air quality just met the level of a 0.084 ppm, 8-hour standard. Estimated yield improved in these counties when the alternative W126 standard levels were met. The very important soybean crop had generally small yield losses throughout the country under just meeting the then current standard (0–4 percent).

The 2007 Staff Paper also presented estimates of monetized benefits for crops associated with a 0.084 ppm, 8-hour and alternative standards. The Agriculture Simulation Model (AGSIM) (Taylor, 1994; Taylor, 1993) was used to calculate annual average changes in total undiscounted economic surplus for commodity crops and fruits and vegetables when the then current and alternative standard levels were met. Meeting the various alternative standards did show some significant benefits beyond a 0.084 ppm, 8-hour standard. However, the 2007 Staff Paper recognized that the AGSIM economic benefits estimates also incorporate several sources of uncertainty, including: (1) Estimates of economic benefits derived from use of the more uncertain C-R relationships for fruits and vegetables; (2) uncertain assumptions about the treatment and effect of government farm payment programs; and (3) uncertain assumptions about near-term changes in the agriculture sector due to the increased use of crops as biofuels. Although the AGSIM model results provided a relative comparison of agricultural benefits between alternative standards, these uncertainties limited the utility of the absolute numbers.

#### D. Reconsideration of Secondary Standard

As discussed above at the beginning of section IV, this reconsideration of the secondary O<sub>3</sub> standard set in the 2008 rulemaking focuses on reconsidering certain elements of the standard, the form, averaging times, and level. The general approach for setting a secondary O<sub>3</sub> standard used in the 2008 rulemaking, and in the previous 1997

rulemaking, was to consider two basic policy options: Setting a distinct secondary standard with a biologically relevant form and averaging times, or setting a secondary standard identical to the primary standard. In the 2007 proposed rule, both such options were evaluated, commented on by CASAC and the public, and proposed, as discussed below in sections IV.D.1 and IV.D.2, respectively. In the 2008 final rule, EPA decided to set the secondary standard identical to the revised 8-hour primary standard, as discussed below in section IV.D.3. Section IV.D.4 summarizes comments received from CASAC following the 2008 decision. The Administrator's proposed conclusions based on this reconsideration are presented in section IV.D.5.

#### 1. Considerations Regarding the 2007 Proposed Cumulative Seasonal Standard

##### a. Form

The 2006 Criteria Document and 2007 Staff Paper concluded that the recent vegetation effects literature evaluated in the 2008 rulemaking strengthened and reaffirmed conclusions made in the 1997 review that the use of a cumulative exposure index that differentially weights ambient concentrations is best able to relate ambient exposures to vegetation response at this time (EPA, 2006a, b; see also discussion in IV.B above). The 1997 review focused in particular on two of these cumulative forms, the SUM06 and W126. In the 2008 rulemaking, the 2007 Staff Paper again evaluated these two forms in light of two key pieces of then recent information: Estimates of PRB that were lower than in the 1997 review, and continued lack of evidence within the vegetation effects literature of a biological threshold for vegetation exposures of concern. On the basis of those policy and science-related considerations, the 2007 Staff Paper concluded that the W126 form was more appropriate in the context of the 2008 rulemaking. Specifically, the W126 form, by its incorporation of a sigmoidal weighting scheme, does not create an artificially imposed concentration threshold, gives proportionally more weight to the higher and typically more biologically potent concentrations, and is not significantly influenced by O<sub>3</sub> concentrations within the range of estimated PRB. The Staff Paper further concluded that "it is not appropriate to continue to use an 8-hour averaging time for the secondary standard" and that "the 8-hour average form should be replaced with a cumulative, seasonal,

concentration weighted form" (EPA, 2007b; pg. 8–25).

The CASAC, based on its assessment of the same vegetation effects science, agreed with the 2006 Criteria Document and 2007 Staff Paper and unanimously concluded that it is not appropriate to try to protect vegetation from the known or anticipated adverse effects of ambient O<sub>3</sub> by continuing to promulgate identical primary and secondary standards for O<sub>3</sub>. Moreover, the members of the CASAC and a substantial majority of the CASAC O<sub>3</sub> Panel agreed with 2007 Staff Paper conclusions and encouraged EPA to establish an alternative cumulative secondary standard for O<sub>3</sub> and related photochemical oxidants that is distinctly different in averaging time, form and level from the current or potentially revised 8-hour primary standard. The CASAC also stated that "the recommended metric for the secondary ozone standard is the (sigmoidally-weighted) W126 index" (Henderson, 2007).

The EPA agreed with the conclusions drawn in the 2006 Criteria Document, 2007 Staff Paper and by CASAC that the scientific evidence available in the 2008 rulemaking continued to demonstrate the cumulative nature of O<sub>3</sub>-induced plant effects and the need to give greater weight to higher concentrations. Thus, EPA concluded that a cumulative exposure index that differentially weights O<sub>3</sub> concentrations represents a reasonable policy choice for a seasonal secondary standard to protect against the effects of O<sub>3</sub> on vegetation. The EPA further agreed with both the 2007 Staff Paper and CASAC that the most appropriate cumulative, concentration-weighted form to consider in the 2008 rulemaking was the sigmoidally weighted W126 form, due to EPA's recognition that there is no evidence in the literature for an exposure threshold that would be appropriate across all O<sub>3</sub>-sensitive vegetation and that this form is unlikely to be significantly influenced by O<sub>3</sub> air quality within the range of PRB levels identified in this rulemaking. Thus, in 2007 EPA proposed as one option to replace the then current 0.084 ppm, 8-hour average secondary standard with a standard defined in terms of the cumulative, seasonal W126 form. The EPA also proposed the option of making the secondary identical to the proposed revised primary standard.

##### b. Averaging Times<sup>58</sup>

The 2007 Staff Paper, in addition to form, also considered what exposure

<sup>58</sup> While the term "averaging time" is used, for the cumulative, seasonal standard the seasonal and

periods or durations are most relevant for vegetation, which, unlike people, is exposed to ambient air continuously throughout its lifespan. For annual species, this lifespan encompasses a period of only one year or less; while for perennials, lifespans can range from a few years to decades or centuries. However, because O<sub>3</sub> levels are not continuously elevated and plants are not equally sensitive to O<sub>3</sub> over the course of a day, season or lifetime, it becomes necessary to identify periods of exposure that have the most relevance for plant response. The 2007 Staff Paper discussed exposure periods relevant for vegetation in terms of a seasonal window and a diurnal window, and it also discussed defining the standard in terms of an annual index value versus a 3-year average of annual index values. The numbered paragraphs below present the 2007 Staff Paper discussions on these exposure periods, and the annual versus 3-year average index value, followed by a discussion of CASAC views and EPA proposed conclusions.

(1) In considering an appropriate seasonal window, the 2007 Staff Paper recognized that, in general, many annual crops are grown for periods of a few months before being harvested. In contrast, other annual and perennial species may be photosynthetically active longer, and for some species and locations, throughout the entire year. In general, the period of maximum physiological activity and thus, maximum potential O<sub>3</sub> uptake for annual crops, herbaceous species, and deciduous trees and shrubs coincides with some or all of the intra-annual period defined as the O<sub>3</sub> season, which varies on a state-by-state basis. This is because the high temperature and high light conditions that promote the formation of tropospheric O<sub>3</sub> also promote physiological activity in vegetation.

The 2007 Staff Paper noted that the selection of any single seasonal exposure period for a national standard would represent a compromise, given the significant variability in growth patterns and lengths of growing seasons among the wide range of vegetation species occurring within the U.S. that may experience adverse effects associated with O<sub>3</sub> exposures. However, the 2007 Staff Paper further concluded that the consecutive 3-month period within the O<sub>3</sub> season with the highest W126 index value (e.g., maximum 3-month period) would, in most cases,

diurnal time periods at issue are those over which exposures during a specified period of time are cumulated, not averaged.

likely coincide with the period of greatest plant sensitivity on an annual basis. Therefore, the 2007 Staff Paper again concluded, as it did in the 1997 review, that the annual maximum consecutive 3-month period is a reasonable seasonal time period, when combined with a cumulative, concentration weighted form, for protection of sensitive vegetation.

(2) In considering an appropriate diurnal window, the Staff Paper recognized that over the course of the 24-hour diurnal period, plant stomatal conductance varies in response to changes in light level, soil moisture and other environmentally and genetically controlled factors. In general, stomata are most open during daylight hours in order to allow sufficient CO<sub>2</sub> uptake for use in carbohydrate production through the light-driven process of photosynthesis. At most locations, O<sub>3</sub> concentrations are also highest during the daytime, and thus, most likely to coincide with maximum stomatal uptake. It is also known however, that in some species, stomata may remain open sufficiently at night to allow for some nocturnal uptake to occur. In addition, at some rural, high elevation sites, the O<sub>3</sub> concentrations remain relatively flat over the course of the day, often at levels above estimated PRB. At these sites, nighttime W126 values can be of similar magnitude as daytime values, though the significance of these exposures is much less certain. This is because O<sub>3</sub> uptake during daylight hours is known to impair the light-driven process of photosynthesis, which can then lead to impacts on carbohydrate production, plant growth, reproduction (yield) and root function. It is less clear at this time to what extent and by what mechanisms O<sub>3</sub> uptake at night adversely impacts plant function. In addition, many species have not been shown to take up O<sub>3</sub> at night and/or do not occur in areas with elevated nighttime O<sub>3</sub> concentrations.

In reviewing the information on this topic that became available after the 1997 review, the 2007 Staff Paper considered the information compiled in a summary report by Musselman and Minnick (2000). This work reported that some species take up O<sub>3</sub> at night, but that the degree of nocturnal stomatal conductance varies widely between species and its relevance to overall O<sub>3</sub>-induced vegetation effects remain unclear. In considering this information, the 2007 Staff Paper concluded that for the vast majority of studied species, daytime exposures represent the majority of diurnal plant O<sub>3</sub> uptake and are responsible for inducing the plant response of most significance to the

health and productivity of the plant (e.g., reduced carbohydrate production). Until additional information is available about the extent to which co-occurrence of sensitive species and elevated nocturnal O<sub>3</sub> exposures exists, and what levels of nighttime uptake are adverse to affected species, the 2007 Staff Paper concluded that this information continues to be preliminary, and does not provide a basis for reaching a different conclusion regarding the diurnal window at this time. The 2007 Staff Paper further noted that additional research is needed to address the degree to which a 12-hour diurnal window may be under-protective in areas where elevated nighttime levels of O<sub>3</sub> co-occur with sensitive species with a high degree of nocturnal stomatal conductance. Thus, as in the 1997 review, the 2007 Staff Paper again concluded that based on the available science, the daytime 12-hour window (8 a.m. to 8 p.m.) is the most appropriate period over which to cumulate diurnal O<sub>3</sub> exposures, specifically those most relevant to plant growth and yield responses.

(3) In considering whether the standard should be defined in terms of an annual index value or a 3-year average of annual index values, the 2007 Staff Paper recognized that though most cumulative seasonal exposure levels of concern for vegetation have been expressed in terms of the annual timeframe, it may be appropriate to consider a 3-year average for purposes of standard stability. However, the 2007 Staff Paper noted that for certain welfare effects of concern (e.g., foliar injury, yield loss for annual crops, growth effects on other annual vegetation and potentially tree seedlings), an annual time frame may be a more appropriate period in which to assess what level would provide the requisite degree of protection, while for other welfare effects (e.g., mature tree biomass loss), a 3-year average may also be appropriate. Thus, the 2007 Staff Paper concluded that it is appropriate to consider both an annual and a 3-year average. Further, the 2007 Staff Paper concluded that should a 3-year average of the 12-hour W126 form be selected, a lower standard level should be considered to reduce the potential of adverse impacts to annual species from a single high O<sub>3</sub> year that could still occur while attaining a standard on average over 3 years.

The CASAC, in considering what seasonal, diurnal, and annual or multiyear time periods are most appropriate when combined with a cumulative, seasonal form to protect vegetation from exposures of concern, agreed that the 2007 Staff Paper

conclusion regarding the 3-month seasonal period and 12-hour daylight window was appropriate, with the distinction that both of these time periods likely represents the minimum time periods of importance. In particular, one O<sub>3</sub> Panel member commented that for some species, additional O<sub>3</sub> exposures of importance were occurring outside the 3-month seasonal and 12-hour diurnal windows. Further, the CASAC concluded that multi-year averaging to promote a "stable" secondary standard is less appropriate for a cumulative, seasonal secondary standard than for a primary standard based on daily maximum 8-hour concentrations. The CASAC further concluded that if multi-year averaging is employed to afford greater stability of the secondary standard, the level of the standard should be revised downward to assure that the desired degree of protection is not exceeded in individual years.

The EPA, in determining which seasonal and diurnal time periods are most appropriate to propose, took into account the 2007 Staff Paper and CASAC views. In being careful to consider what is needed to provide the requisite degree of protection, no more and no less, in 2007 EPA proposed that the 3-month seasonal period and 12-hour daylight period are appropriate. Based on the 2007 Staff Paper conclusions discussed above, EPA was mindful that there is the potential for under-protection with a 12-hour diurnal window in areas with sufficiently elevated nighttime levels of O<sub>3</sub> where sensitive species with a high degree of nocturnal stomatal conductance occur. On the other hand, EPA also recognized that a longer diurnal window (e.g., 24-hour) has the possibility of over-protecting vegetation in areas where nighttime O<sub>3</sub> levels remain relatively high but where no species having significant nocturnal uptake exist. In weighing these considerations, EPA agreed with the 2007 Staff Paper conclusion that until additional information is available about the extent to which this co-occurrence of sensitive species and elevated nocturnal O<sub>3</sub> exposures exists, and what levels of nighttime uptake are adverse to affected species, this information does not provide a basis for reaching a different conclusion at this time. The EPA also considered to what extent the 3-month period within the O<sub>3</sub> season was appropriate, recognizing that many species of vegetation have longer growing seasons. The EPA further proposed that the maximum 3-month period is sufficient and appropriate to

characterize O<sub>3</sub> exposure levels associated with known levels of plant response. Therefore, EPA proposed that the most appropriate exposure periods for a cumulative, seasonal form is the daytime 12-hour window (8 a.m. to 8 p.m.) during the consecutive 3-month period within the O<sub>3</sub> monitoring season with the maximum W126 index value.

The EPA also proposed an annual rather than a multi-year cumulative, seasonal standard. In proposing this option, EPA also believed that it was appropriate to consider the benefits to the public welfare that would accrue from establishing a 3-year average secondary standard, and solicited comment on this alternative. In so doing, EPA also agreed with 2007 Staff Paper and CASAC conclusions that should a 3-year standard be finalized, the level of the standard should be set so as to provide the requisite degree of protection for those vegetation effects judged to be adverse to the public welfare within a single annual period.

#### c. Level

The 2007 Staff Paper, in identifying a range of levels for a 3-month, 12-hour W126 annual form appropriate to protect the public welfare from adverse impacts to vegetation from O<sub>3</sub> exposures, considered what information from the array of vegetation effects evidence and exposure and risk assessment results was most useful. Regarding the vegetation effects evidence, the 2007 Staff Paper found stronger support than what was available at the time of the 1997 review for an increased level of protection for trees and ecosystems. Specifically, this expanded body of support includes: (1) Additional field based data from free air, gradient and biomonitoring surveys demonstrating adverse levels of O<sub>3</sub>-induced above and/or below-ground growth reductions on trees at the seedling, sapling and mature growth stages and incidence of visible foliar injury occurring at biomonitoring sites in the field at ambient levels of exposure; (2) qualitative support from free air (e.g., AspenFACE) and gradient studies on a limited number of tree species for the continued appropriateness of using OTC-derived C-R functions to predict tree seedling response in the field; (3) studies that continue to document below-ground effects on root growth and "carry-over" effects occurring in subsequent years from O<sub>3</sub> exposures; and (4) increased recognition and understanding of the structure and function of ecosystems and the complex linkages through which O<sub>3</sub>, and other stressors, acting at the organism and species level can

influence higher levels within the ecosystem hierarchy and disrupt essential ecological attributes critical to the maintenance of ecosystem goods and services important to the public welfare.

Based on the above observations and on the vegetation effects and the results of the exposure and impact assessment summarized above, the 2007 Staff Paper concluded that just meeting the then current standard would still allow adverse levels of tree seedling biomass loss in sensitive commercially and ecologically important tree species in many regions of the country. Seedling risk assessment results showed that some tree seedling species are extremely sensitive (e.g., cottonwood, black cherry and aspen), with annual biomass losses occurring in the field of the same or greater magnitude that that of annual crops. Such information from the tree seedling risk assessment suggests that O<sub>3</sub> levels would need to be substantially reduced to protect sensitive tree seedlings like black cherry from growth and foliar injury effects.

In addition to the currently quantifiable risks to trees from ambient exposures, the 2007 Staff Paper also considered the more subtle impacts of O<sub>3</sub> acting in synergy with other natural and man-made stressors to adversely affect individual plants, populations and whole systems. By disrupting the photosynthetic process, decreasing carbon storage in the roots, increasing early senescence of leaves and affecting water use efficiency in trees, O<sub>3</sub> exposures could potentially disrupt or change the nutrient and water flow of an entire system. Weakened trees can become more susceptible to other environmental stresses such as pest and pathogen outbreaks or harsh weather conditions. Though it is not possible to quantify all the ecological and societal benefits associated with varying levels of alternative secondary standards, the 2007 Staff Paper concluded that this information should be weighed in considering the extent to which a secondary standard should be set so as to provide potential protection against effects that are anticipated to occur.

In addition, the 2007 Staff Paper also recognized that in the 1997 review, EPA took into account the results of a 1996 Consensus Workshop. At this workshop, a group of independent scientists expressed their judgments on what standard form(s) and level(s) would provide vegetation with adequate protection from O<sub>3</sub>-related adverse effects. Consensus was reached with respect to selecting appropriate ranges of levels in terms of a cumulative, seasonal 3-month, 12-hr SUM06



standard for a number of vegetation effects endpoints. These ranges are identified below, with the estimated approximate equivalent W126 standard values shown in parentheses. For growth effects to tree seedlings in natural forest stands, a consensus was reached that a SUM06 range of 10 to 15 (W126 range of 7 to 13) ppm-hour would be protective. For growth effects to tree seedlings and saplings in plantations, the consensus SUM06 range was 12 to 16 (W126 range of 9 to 14) ppm-hour. For visible foliar injury to natural ecosystems, the consensus SUM06 range was 8 to 12 (W126 range of 5 to 9) ppm-hour.

Taking these consensus statements into account, EPA stated in the 1997 final rule (62 FR 38856) that "the report lends important support to the view that the current secondary standard is not adequately protective of vegetation \* \* \* [and] \* \* \* foreshadows the direction of future scientific research in this area, the results of which could be important in future reviews of the O<sub>3</sub> secondary standard" (62 FR 38856).

Given the importance EPA put on the consensus report in the 1997 review, the 2007 Staff Paper considered to what extent research published after 1997 provided empirical support for the ranges of levels identified by the experts as protective of different types of O<sub>3</sub>-induced effects. With regard to O<sub>3</sub>-induced biomass loss in sensitive tree seedlings/saplings growing in natural forest stands, the information discussed in the 2007 Staff Paper, including the evidence from free air and gradient studies, provides additional direct support for the conclusion that the 1996 Consensus Workshop approximate W126 range of 7–13 ppm-hour was an appropriate range to consider in selecting a protective level. With regard to visible foliar injury, the available evidence, including the 2007 Staff Paper analysis of incidence in counties with FIA monitoring sites and air quality data, showed significant levels of county-level visible foliar injury incidence at the W126 level of 13 ppm-hour. However, because this analysis did not address risks of this effect at lower levels of O<sub>3</sub> air quality, and because there is a significant uncertainty in predicting the degree of visible foliar injury symptoms expected for lower levels of O<sub>3</sub> air quality, the evidence provides less certain but qualitative directional support for the 1996 Consensus Workshop range of 5 to 9 ppm-hour to protect against this effect. With regard to O<sub>3</sub>-induced effects on plantation trees, there is far less direct information available. Though some forest plantation trees are O<sub>3</sub>-sensitive,

the monoculture nature of these stands makes uncertain the degree to which competition for resources might play a role and to what degree the variety of management practices applied would be expected to mitigate the O<sub>3</sub>-induced effects. Thus, it is difficult to distinguish a protective range of levels for plantation trees from a range of levels that would be protective of O<sub>3</sub>-sensitive tree seedlings and saplings in natural forest stands. Therefore, on the basis of the strength of the evidence available, the 2007 Staff Paper concluded that it was appropriate to consider a range for a 3-month, 12-hour, W126 standard that included the 1996 consensus recommendations for growth effects in tree seedlings in natural forest stands (*i.e.*, 7–13 ppm-hour in terms of a W126 form).

In considering the available information on O<sub>3</sub>-related effects on crops in the 2008 rulemaking, the 2007 Staff Paper observed the following regarding the strength of the underlying crop science: (1) Nothing in the recent literature points to a change in the relationship between O<sub>3</sub> exposure and crop response across the range of species and/or cultivars of commodity crops currently grown in the U.S. that could be construed to make less appropriate the use of commodity crop C–R functions developed in the NCLAN program; (2) new field-based studies (*e.g.*, SoyFACE) provide qualitative support in a few limited cases for the appropriateness of using OTC-derived C–R functions to predict crop response in the field; and (3) refinements in the exposure, risk and benefits assessments in this review reduce some of the uncertainties present in the 1997 review. On the basis of these observations, the 2007 Staff Paper concluded that nothing in the newly assessed information called into question the strength of the underlying science upon which EPA based its proposed decision in the 1997 review to select a level of a cumulative, seasonal form associated with protecting 50 percent of crop cases from no more than 10 percent yield loss as providing the requisite degree of protection for commodity crops.

The 2007 Staff Paper then considered whether any additional information is available to inform judgments as to the adversity of various O<sub>3</sub>-induced levels of crop yield loss to the public welfare. As noted above, the 2007 Staff Paper observed that agricultural systems are heavily managed, and that in addition to stress from O<sub>3</sub>, the annual productivity of agricultural systems is vulnerable to disruption from many other stressors (*e.g.*, weather, insects, disease), whose

impact in any given year can greatly outweigh the direct reduction in annual productivity resulting from elevated O<sub>3</sub> exposures. On the other hand, O<sub>3</sub> can also more subtly impact crop and forage nutritive quality and indirectly exacerbate the severity of the impact from other stressors. Though these latter effects currently cannot be quantified, they should be considered in judging to what extent a level of protection selected to protect commodity crops should be precautionary.

Based on the above considerations, the 2007 Staff Paper concluded that the level of protection (no more than 10% yield or biomass loss in 50% of studied cases) judged requisite in the 1997 review to protect the public welfare from adverse levels of O<sub>3</sub>-induced reductions in crop yields and tree seedling biomass loss, as provided by a W126 level of 21 ppm-hour, remains appropriate for consideration as an upper bound of a range of appropriate levels.

Thus, the 2007 Staff Paper concluded, based on all the above considerations, that an appropriate range of 3-month, 12-hour W126 levels was 7 to 21 ppm-hour, recognizing that the level selected is largely a policy judgment as to the requisite level of protection needed. In determining the requisite level of protection for crops and trees, and indirectly, ecosystems, the 2007 Staff Paper recognized that it is appropriate to weigh the importance of the predicted risks of these effects in the overall context of public welfare protection, along with a determination as to the appropriate weight to place on the associated uncertainties and limitations of this information.

The CASAC, in its final letter to the Administrator (Henderson, 2007), agreed with the 2007 Staff Paper recommendations that the lower bound of the range within which a seasonal W126 welfare-based (secondary) O<sub>3</sub> standard should be considered is approximately 7 ppm-hour; however, it did not agree with staff's recommendation that the upper bound of the range for consideration should be as high as 21 ppm-hour. Rather, CASAC recommended that the upper bound of the range considered should be no higher than 15 ppm-hour, which is just above the upper ends of the ranges identified in the 1996 Consensus Workshop as being protective of tree seedlings and saplings grown in natural forest stands and in plantations. The lower end of this range (7 ppm-hour) is the same as the lower end of the range identified in the 1996 Consensus Workshop as protective of tree seedlings

in natural forest stands from growth effects.

In the 2007 proposed rule, taking 2007 Staff Paper and CASAC views into account, EPA proposed a range of levels for a cumulative, seasonal secondary standard as expressed in terms of the maximum 3 month, 12-hour W126 form, in the range of 7 to 21 ppm-hour. This range encompasses the range of levels recommended by CASAC, and also includes a higher level as recommended for consideration in the 2007 Staff Paper. Given the uncertainty in determining the risk attributable to various levels of exposure to O<sub>3</sub>, EPA believed, as a public welfare policy judgment, that this was a reasonable range to propose.

## 2. Considerations Regarding the 2007 Proposed 8-Hour Standard

In the 1997 review, the 1996 Staff Paper included an analysis to compare the degree of overlap between areas that would be expected not to meet the range of alternative 8-hour standards being considered for the primary NAAQS and those expected not to meet the range of values (expressed in terms of the seasonal SUM06 index) of concern for vegetation. This result suggested that improvements in national air quality expected to result from attaining an 8-hour primary standard within the recommended range of levels would also be expected to reduce levels of concern for vegetation in those same areas. In the 1997 final rule, the decision was made, on the basis of both science and policy considerations, to make the secondary identical to the primary standard. It acknowledged, however, that uncertainties remained "as to the extent to which air quality improvements designed to reduce 8-hour average O<sub>3</sub> concentrations averaged over a 3-year period would reduce O<sub>3</sub> exposures measured by a seasonal SUM06 index" (62 FR 38876).

On the basis of that history, the 2007 Staff Paper analyzed the degree of overlap expected between alternative 8-hour and cumulative seasonal secondary standards (as discussed above in section IV.C.1) using then recent air quality. Based on the results, the 2007 Staff Paper concluded that the degree to which the then current 8-hour standard form and level would overlap with areas of concern for vegetation expressed in terms of the 12-hour W126 standard is inconsistent from year to year and would depend greatly on the level of the 12-hour W126 and 8-hour standards selected and the distribution of hourly O<sub>3</sub> concentrations within the annual and/or 3-year average period.

Thus, though the 2007 Staff Paper recognized again that meeting the current or alternative levels of the 8-hour average standard could result in air quality improvements that would potentially benefit vegetation in some areas, it urged caution be used in evaluating the likely vegetation impacts associated with a given level of air quality expressed in terms of the 8-hour average form in the absence of parallel W126 information. This caution was due to the concern that the analysis in the 2007 Staff Paper may not be an accurate reflection of the true situation in non-monitored, rural counties due to the lack of more complete monitor coverage in many rural areas. Further, of the counties that did not show overlap between the two standard forms, most were located in rural/remote high elevation areas which have O<sub>3</sub> air quality patterns that are typically different from those associated with urban and near urban sites at lower elevations. Because the majority of such areas are currently not monitored, it is believed there are likely to be additional areas that have similar air quality distributions that would lead to the same disconnect between forms. Thus, the 2007 Staff Paper concluded that it remained problematic to determine the appropriate level of protection for vegetation using an 8-hour average form.

The CASAC recognized that an important difference between the effects of acute exposures to O<sub>3</sub> on human health and the effects of O<sub>3</sub> exposures on welfare is that vegetation effects are more dependent on the cumulative exposure to, and uptake of, O<sub>3</sub> over the course of the entire growing season (Henderson, 2006c). The CASAC O<sub>3</sub> Panel members were unanimous in concluding the protection of natural terrestrial ecosystems and managed agricultural crops requires a secondary O<sub>3</sub> standard that is substantially different from the primary O<sub>3</sub> standard in averaging time, level, and form (Henderson, 2007).

In considering the appropriateness of proposing a revised secondary standard that would be identical to the proposed primary standard, EPA took into account the approach used by the Agency in the 1997 review, the conclusions of the 2007 Staff Paper, CASAC advice, and the views of public commenters. The EPA first considered the 2007 Staff Paper analysis of the projected degree of overlap between counties with air quality expected to meet various alternative levels of an 8-hour standard and alternative levels of a W126 standard based on monitored air quality data. This analysis showed significant overlap within the proposed

range of the primary 8-hour form and selected levels of the W126 standard form being considered, with the degree of overlap between these two forms depending greatly on the levels selected and the distribution of hourly O<sub>3</sub> concentrations within the annual and/or 3-year average period. On this basis, EPA concluded that a secondary standard set identical to the proposed primary standard would provide a significant degree of additional protection for vegetation as compared to that provided by the current secondary standard. The EPA also recognized that lack of rural monitoring data made uncertain the degree to which the proposed 8-hour or W126 alternatives would be protective, and that there would be the potential for not providing the appropriate degree of protection for vegetation in areas with air quality distributions that result in a high cumulative, seasonal exposure but do not result in high 8-hour average exposures. While this potential for under-protection using an 8-hour standard was clear, the number and size of areas at issue and the degree of risk was hard to determine. On the other hand, EPA also considered at that time that there was a potential risk of over-protection with a cumulative, seasonal standard given the inherent uncertainties associated with moving to a new form for the secondary standard, in particular those associated with predicting exposure and risk patterns based on a limited rural monitoring network.

The EPA also considered the views and recommendations of CASAC, and agreed that a cumulative, seasonal standard is the most biologically relevant way to relate exposure to plant growth response. However, as reflected in the public comments, EPA also recognized that there remained significant uncertainties in determining or quantifying the degree of risk attributable to varying levels of O<sub>3</sub> exposure, the degree of protection that any specific cumulative, seasonal standard would produce, and the associated potential for error in determining the standard that will provide a requisite degree of protection—*i.e.*, sufficient but not more than what is necessary. Given this uncertainty, EPA also believed it was appropriate to consider the degree of protection that would be afforded by a secondary standard that was identical to the then proposed primary standard. Based on its consideration of the full range of views as described above, and in the 2007 proposed rule, EPA proposed as a second option to revise

the secondary standard to be identical in every way to the then proposed primary standard.

### 3. Basis for 2008 Decision on the Secondary Standard

In the 2008 final rule, EPA noted that deciding on the appropriate secondary standard involved making a choice between two possible alternatives, each with their strengths and weaknesses. The 2008 final rule reported that within the Administration at that time there had been a robust discussion of the same strengths and weaknesses associated with each option that were identified earlier. The process by which EPA reached its final conclusion is described in the final rule (73 FR 16497). The rationale for the 2008 decision presented in the final rule (73 FR 16499–16500) is described below.

In considering the appropriateness of establishing a new standard defined in terms of a cumulative, seasonal form, or revising the then current secondary standard by making it identical to the revised primary standard, EPA took into account the approach used by the Agency in the 1997 review, the conclusions of the 2007 Staff Paper, CASAC advice, and the views of public commenters. In giving consideration to the approach taken in the 1997 review, EPA first considered the 2007 Staff Paper analysis of the projected degree of overlap between counties with air quality expected to meet the revised 8-hour primary standard, set at a level of 0.075 ppm, and alternative levels of a W126 standard based on currently monitored air quality data. This analysis showed significant overlap between the revised 8-hour primary standard and selected levels of the W126 standard form being considered, with the degree of overlap between these alternative standards depending greatly on the W126 level selected and the distribution of hourly O<sub>3</sub> concentrations within the annual and/or 3-year average period.<sup>59</sup> On this basis, as an initial matter, EPA concluded that a secondary standard set identical to the proposed primary standard would provide a significant degree of additional protection for vegetation as compared to that provided by the then current 0.084 ppm secondary standard. In further considering the significant uncertainties that remain in the available body of evidence of O<sub>3</sub>-related vegetation effects and in the exposure and risk analyses conducted for the 2008 rulemaking, and

the difficulty in determining at what point various types of vegetation effects become adverse for sensitive vegetation and ecosystems, EPA focused its consideration on a level for an alternative W126 standard at the upper end of the proposed range (*i.e.*, 21 ppm-hour). The 2007 Staff Paper analysis showed that at that W126 standard level, there would be essentially no counties with air quality that would be expected both to exceed such an alternative W126 standard and to meet the revised 8-hour primary standard—that is, based on this analysis of currently monitored counties, a W126 standard would be unlikely to provide additional protection in any monitored areas beyond that likely to be provided by the revised primary standard.

The EPA also recognized that the general lack of rural monitoring data made uncertain the degree to which the revised 8-hour standard or an alternative W126 standard would be protective in those areas, and that there would be the potential for not providing the appropriate degree of protection for vegetation in areas with air quality distributions that result in a high cumulative, seasonal exposure but do not result in high 8-hour average exposures. While this potential for under-protection using an 8-hour standard was clear, the number and size of areas at issue and the degree of risk was hard to determine. However, EPA concluded at that time that an 8-hour standard would also tend to avoid the potential for providing more protection than is necessary, a risk that EPA concluded would arise from moving to a new form for the secondary standard despite significant uncertainty in determining the degree of risk for any exposure level and the appropriate level of protection, as well as uncertainty in predicting exposure and risk patterns.

The EPA also considered the views and recommendations of CASAC, and agreed that a cumulative, seasonal standard was the most biologically relevant way to relate exposure to plant growth response. However, as reflected in some public comments, EPA also judged that there remained significant uncertainties in determining or quantifying the degree of risk attributable to varying levels of O<sub>3</sub> exposure, the degree of protection that any specific cumulative, seasonal standard would produce, and the associated potential for error in determining the standard that will provide a requisite degree of protection—*i.e.*, sufficient but not more than what is necessary. Given these significant uncertainties, EPA concluded at that time that establishing

a new secondary standard with a cumulative, seasonal form would result in uncertain benefits beyond those afforded by the revised primary standard and therefore may be more than necessary to provide the requisite degree of protection.

Based on its consideration of the views discussed above, EPA judged in the 2008 rulemaking that the appropriate balance to be drawn was to revise the secondary standard to be identical in every way to the revised primary standard. The EPA believed that such a standard would be sufficient to protect public welfare from known or anticipated adverse effects, and did not believe that an alternative cumulative, seasonal standard was needed to provide this degree of protection. The EPA believed that this judgment appropriately considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose.

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of the CASAC Panel, and the public comments to date, EPA decided to revise the existing 8-hour secondary standard. Specifically, EPA revised the then current 8-hour average 0.084 ppm secondary standard by making it identical to the revised 8-hour primary standard set at a level of 0.075 ppm.

### 4. CASAC Views Following 2008 Decision

Following the 2008 decision on the O<sub>3</sub> standards, serious questions were raised as to whether the standards met the requirements of the CAA. In April 2008, the members of the CASAC Ozone Review Panel sent a letter to EPA stating “In our most-recent letters to you on this subject—dated October 2006 and March 2007—\* \* \* the Committee recommended an alternative secondary standard of cumulative form that is substantially different from the primary Ozone NAAQS in averaging time, level and form—specifically, the W126 index within the range of 7 to 15 ppm-hour, accumulated over at least the 12 “daylight” hours and the three maximum ozone months of the summer growing season” (Henderson, 2008). The letter continued: “The CASAC now wishes to convey, by means of this letter, its additional, unsolicited advice with regard to the primary and secondary Ozone NAAQS. In doing so, the participating members of the CASAC Ozone Review Panel are unanimous in strongly urging you or your successor as EPA Administrator to

<sup>59</sup> Prior to publication of the 2008 final rule, EPA did further analysis of the degree of overlap to extend the 2007 Staff Paper analyses, and that analysis was available in the docket.

ensure that these recommendations be considered during the next review cycle for the Ozone NAAQS that will begin next year" (id.). The letter further stated the following views:

The CASAC was \* \* \* greatly disappointed that you failed to change the form of the secondary standard to make it different from the primary standard. As stated in the preamble to the Final Rule, even in the previous 1996 ozone review, "there was general agreement between the EPA staff, CASAC, and the Administrator, \* \* \* that a cumulative, seasonal form was more biologically relevant than the previous 1-hour and new 8-hour average forms (61 FR 65716)" for the secondary standard. Therefore, in both the previous review and in this review, the Agency staff and its advisors agreed that a change in the form of the secondary standard was scientifically well-justified.

\* \* \* \* \*

Unfortunately, this scientifically-sound approach of using a cumulative exposure index for welfare effects was not adopted, and the default position of using the primary standard for the secondary standard was once again instituted. Keeping the same form for the secondary Ozone NAAQS as for the primary standard is not supported by current scientific knowledge indicating that different indicator variables are needed to protect vegetation compared to public health. The CASAC was further disappointed that a secondary standard of the W126 form was not considered from within the Committee's previously-recommended range of 7 to 15 ppm-hour. The CASAC sincerely hopes that, in the next round of Ozone NAAQS review, the Agency will be able to support and establish a reasonable and scientifically-defensible cumulative form for the secondary standard. (Henderson, 2008)

#### 5. Administrator's Proposed Conclusions

For the reasons discussed below, the Administrator proposes to set a cumulative seasonal standard expressed as an annual index of the sum of weighted hourly concentrations (*i.e.*, the W126 form), cumulated over 12 hours per day (8 am to 8 pm) during the consecutive 3-month period within the O<sub>3</sub> season with the maximum index value, set at a level within the range of 7 to 15 ppm-hour. This proposed decision takes into account the information and assessments presented in the 2006 Criteria Document and the 2007 Staff Paper and related technical support documents, the advice and recommendations of CASAC both during and following the 2008 rulemaking, and public comments received in conjunction with review of drafts of these documents and on the 2007 proposed rule.

##### a. Form

As discussed above in section IV.B, the 2006 Criteria Document and 2007

Staff Paper concluded that the recent vegetation effects literature evaluated in the 2008 rulemaking strengthens and reaffirms conclusions made in the 1997 review that the use of a cumulative exposure index that differentially weights ambient concentrations is best able to relate ambient exposures to vegetation response. The 1997 review focused in particular on two of these cumulative forms, the SUM06 and W126 (EPA, 1996). Given that the data available at that time were unable to distinguish between these forms, the EPA, based on the policy consideration of not including O<sub>3</sub> concentrations considered to be within the PRB, estimated at that time to be between 0.03 and 0.05 ppm, concluded that the SUM06 form would be the more appropriate choice for a cumulative, exposure index for a secondary standard.

In the 2008 rulemaking, the 2007 Staff Paper evaluated the continued appropriateness of the SUM06 form in light of new estimates of PRB that were lower than in the 1997 review, and the continued lack of evidence within the vegetation effects literature of a biological threshold for vegetation exposures of concern. On the basis of these policy and science-related considerations, the 2007 Staff Paper concluded that the W126 form was the more appropriate cumulative, concentration-weighted form. Specifically, the W126, by its incorporation of a sigmoidal weighting scheme, does not create an artificially imposed concentration threshold, gives proportionally more weight to the higher and typically more biologically potent concentrations, and is not significantly influenced by O<sub>3</sub> concentrations within the range of estimated PRB.

As discussed above, the CASAC, based on its assessment of the same vegetation effects science, agreed with the 2006 Criteria Document and 2007 Staff Paper and unanimously concluded that protection of vegetation from the known or anticipated adverse effects of ambient O<sub>3</sub> "requires a secondary standard that is substantially different from the primary standard in averaging time, level, and form," *i.e.* not identical to the primary standard for O<sub>3</sub> (Henderson, 2007). Moreover, the members of CASAC and a substantial majority of the other CASAC Panel members agreed with 2007 Staff Paper conclusions and encouraged EPA to establish an alternative cumulative secondary standard for O<sub>3</sub> and related photochemical oxidants that is distinctly different in averaging time, form and level from the then current or

potentially revised 8-hour primary standard (Henderson, 2006c). The CASAC Panel also stated that "the recommended metric for the secondary ozone standard is the (sigmoidally weighted) W126 index" (Henderson, 2007).

In reconsidering the 2008 final rule, the Administrator agrees with the conclusions drawn in the 2006 Criteria Document, 2007 Staff Paper and by CASAC that the scientific evidence available in the 2008 rulemaking continues to demonstrate the cumulative nature of O<sub>3</sub>-induced plant effects and the need to give greater weight to higher concentrations. Thus, the Administrator concludes that a cumulative exposure index that differentially weights O<sub>3</sub> concentrations represents a reasonable policy choice for a secondary standard to protect against the effects of O<sub>3</sub> on vegetation. The Administrator further agrees with both the 2007 Staff Paper and CASAC that the most appropriate cumulative, concentration-weighted form to consider is the sigmoidally weighted W126 form.

The Administrator notes that in the 2007 proposed rule, EPA proposed a second option of revising the then current 8-hour average secondary standard by making it identical to the proposed 8-hour primary standard. The 2007 Staff Paper analyzed the degree of overlap expected between alternative 8-hour and cumulative seasonal secondary standards using recent air quality monitoring data. Based on the results, the 2007 Staff Paper concluded that the degree to which the current 8-hour standard form and level would overlap with areas of concern for vegetation expressed in terms of the 12-hour W126 standard is inconsistent from year to year and would depend greatly on the level of the 12-hour W126 and 8-hour standards selected and the distribution of hourly O<sub>3</sub> concentrations within the annual and/or 3-year average period. The 2007 Staff Paper also recognized that meeting the then current or alternative levels of the 8-hour average standard could result in air quality improvements that would potentially benefit vegetation in some areas, but urged caution be used in evaluating the likely vegetation impacts associated with a given level of air quality expressed in terms of the 8-hour average form in the absence of parallel W126 information. This caution was due to the concern that the analysis in the 2007 Staff Paper may not be an accurate reflection of the true situation in non-monitored, rural counties due to the lack of more complete monitor coverage in many rural areas. Further, of

the counties that did not show overlap between the two standard forms, most were located in rural/remote high elevation areas which have O<sub>3</sub> air quality patterns that are typically different from those associated with urban and near urban sites at lower elevations. Because the majority of such areas are currently not monitored, there are likely to be additional areas that have similar air quality distributions that would lead to the same disconnect between forms. Thus, the 2007 Staff Paper concluded that it remains problematic to determine the appropriate level of protection for vegetation using an 8-hour average form.

The Administrator also notes that CASAC recognized that an important difference between the effects of acute exposures to O<sub>3</sub> on human health and the effects of O<sub>3</sub> exposures on welfare is that vegetation effects are more dependent on the cumulative exposure to, and uptake of, O<sub>3</sub> over the course of the entire growing season (Henderson, 2006c). The CASAC O<sub>3</sub> Panel members were unanimous in concluding the protection of natural terrestrial ecosystems and managed agricultural crops requires a secondary O<sub>3</sub> standard that is substantially different from the primary O<sub>3</sub> standard in form, averaging time, and level (Henderson, 2007).

In reaching her proposed decision in this reconsideration of the 2008 final rule, the Administrator has considered the comments received on the 2007 proposed rule regarding revising the secondary standard either to reflect a new, cumulative form or by remaining equal to a revised primary standard. The commenters generally fell into two groups.

One group of commenters, including environmental organizations, strongly supported the proposed option of moving to a cumulative, seasonal standard, generally based on the reasoning explained in the 2007 proposal. Commenters in this group also expressed serious concerns with the other proposed option of setting a secondary O<sub>3</sub> standard in terms of the same form and averaging time (*i.e.*, daily maximum 8-hour average O<sub>3</sub> concentration) as the primary standard. These commenters expressed the view that such a standard would fail to protect public welfare because the maximum daily 8-hour average O<sub>3</sub> concentration failed to adequately characterize harmful O<sub>3</sub> exposures to vegetation. This view was generally based on the observation that there is no consistent relationship in areas across the U.S. between 8-hour peak O<sub>3</sub> concentrations and the longer-term cumulative exposures aggregated over a

growing season that are biologically relevant in characterizing O<sub>3</sub>-related effects on sensitive vegetation. Thus, as EPA noted in the 2007 proposed rule, there is a lack of a rational connection between the level of an 8-hour standard and the requisite degree of protection required for a secondary O<sub>3</sub> NAAQS.

Another group of commenters, including industry organizations, agreed that a cumulative form of the standard may better match the underlying data, but expressed the view that remaining uncertainties associated with the vegetation effects evidence and/or EPA's exposure, risk and benefits assessments were so great that the available information did not provide an adequate basis to adopt a standard with a level based on a cumulative, seasonal form. These commenters asserted that because of the substantial uncertainties remaining at the time of the 2008 rulemaking, the benefits of changing to a W126 form were too uncertain to warrant revising the form of the standard at that time.

The Administrator notes that in both the 1997 and the 2008 decisions, EPA recognized that the risk to vegetation from O<sub>3</sub> exposures comes from cumulative exposures over a season or seasons. The CASAC has fully endorsed this view based on the available scientific evidence and assessments, and there is no significant disagreement on this issue by commenters. Thus, it is clear that the purpose of the secondary O<sub>3</sub> NAAQS should be to provide an appropriate degree of protection against cumulative, seasonal exposures to O<sub>3</sub> that are known or anticipated to harm sensitive vegetation or ecosystems. In reconsidering the 2008 final rule, the Administrator recognizes that the issue before the Agency is what form of the standard is most appropriate to perform that function.

Within this framework, the Administrator recognizes that it is clear that a cumulative, seasonal form has a distinct advantage in protecting against cumulative, seasonal exposures. Such a form is specifically designed to measure directly the kind of O<sub>3</sub> exposures that can cause harm to vegetation. In contrast, an 8-hour standard does not measure cumulative, seasonal exposures directly, and can only indirectly afford some degree of protection against such exposures. To the extent that clear relationships exist between 8-hour daily peak O<sub>3</sub> concentrations and cumulative, seasonal exposures, the 8-hour form and averaging time would have the potential to be effective as an indirect surrogate. However, as discussed in the 2007 proposed rule and the 2008 final rule, the evidence shows that there are

known types of O<sub>3</sub> air quality patterns that can lead to high levels of cumulative, seasonal O<sub>3</sub> exposures without the occurrence of high daily 8-hour peak O<sub>3</sub> concentrations. An 8-hour form and averaging time is an indirect way to measure biologically relevant exposure patterns, is poorly correlated with such exposure patterns, and therefore is less likely to identify and protect against the kind of cumulative, seasonal exposure patterns that have been determined to be harmful.

Past arguments or reasons for not moving to a cumulative, seasonal form, with appropriate exposure periods, have not been based on disagreement over the biological relevance of the cumulative, seasonal form, or the recognized disadvantages of an 8-hour standard in measuring and identifying a specified cumulative, seasonal exposure pattern. The reasons for not moving to such a form have been based on concerns over whether EPA has an adequate basis to identify the nature and magnitude of cumulative, seasonal exposure patterns that the standard should be designed to protect against, given the various uncertainties in the evidence and the lack of rural O<sub>3</sub> monitoring data. This most directly translates into a concern over whether EPA has an adequate basis to determine an appropriate level for a cumulative, seasonal secondary standard.

The Administrator has also considered issues associated with selection of the W126 cumulative form, as reflected in the following assertions made by some commenters on the 2007 proposed rule: (1) The W126 form lacks a biological basis, since it is merely a mathematical expression of exposure that has been fit to specific responses in OTC studies, such that its relevance for real world biological responses is unclear; (2) a flux-based model would be a better choice than a cumulative metric because it is an improvement over the many limitations and simplifications associated with the cumulative form; however, there is insufficient data to apply such a model at present; (3) the European experience with cumulative O<sub>3</sub> metrics has been disappointing and now Europeans are working on their second level approach, which will be flux-based; and (4) a second index that reflects the accumulation of peaks at or above 0.10 ppm (called N100) should be added to a W126 index to achieve appropriate protection.

With regard to whether the W126 index lacks a biological basis, the Administrator finds no basis for reaching such a conclusion. As discussed above in section IV.B, the

vegetation effects science is clear that exposures of concern to plants are not based on one discrete 8-hour period but on the repeated occurrence of elevated O<sub>3</sub> levels throughout the plant's growing season. The cumulative nature of the W126 is supported by the basic biological understanding that plants in the U.S. are generally most biologically active during the warm season and are exposed to ambient O<sub>3</sub> throughout this biologically active period. In addition, it has been shown in the scientific literature that all else being equal, plants respond more to higher O<sub>3</sub> concentrations, with no evidence of an exposure threshold for vegetation effects. The W126 sigmoidal weighting function reflects both of these understandings, by not including a threshold below which concentrations are not included, and by differentially weighting concentrations to give greater weight to higher concentrations and less weight to lower ones.

With regard to whether a flux-based model would be a better choice, the 2007 Staff Paper acknowledged that flux models may produce a more accurate calculation of dose to a specific plant species in a specific area. However, dose-response relationships have not been developed for these flux calculations for plants growing in the U.S. Further, flux calculations require large amounts of data for the physiology of each plant species and the local conditions for the growing range of each plant species. These exercises may be useful for limited small-scale risk assessments, but do not provide an appropriate basis for a national standard at this time.

With regard to dissatisfaction with the performance of a particular cumulative index in use in Europe,<sup>60</sup> and growing interest in development of flux-based models, the 2007 Staff Paper (Appendix 7A) noted that "because of a lack of flux-response data, a cumulative, cutoff concentration based (e.g., AOT40) exposure index will remain in use in Europe for the near future for most crops and for forests and semi-natural herbaceous vegetation (Ashmore *et al.*, 2004a)." Further, like the SUM06 index, the AOT40 index incorporates a threshold below which concentrations are not considered. Though the AOT40 threshold is lower than the threshold value in SUM06, the 2007 Staff Paper concluded that the vegetation effects

<sup>60</sup> The AOT40 index used in Europe is a cumulative index that incorporates a threshold at 0.04 ppm (40 ppb). This index is calculated as the area over the threshold (AOT) by subtracting 40 ppb from the value of each hourly concentration above that threshold and then cumulating each hourly difference over a specified window.

information does not provide evidence of an effects threshold that applies to all species. Thus, the Administrator concludes neither of these forms is as biologically relevant as the W126 form.

With regard to consideration of coupling a W126 form with a separate N100 index, there was very little research on the N100 index or a coupled approach to be evaluated in the 2008 rulemaking. The CASAC, after reviewing all the information in the 2006 Criteria Document and the 2007 Staff Paper, did not recommend an additional N100 index for consideration. Therefore, there is no basis at this time to judge the extent to which such a coupled W126-N100 form would be a better choice than the proposed W126 form. Further, the W126 form incorporates a weighting scheme that places greater weight on increasing concentrations and gives every concentration of 0.10 ppm and above an equal weight of 1, which is the highest weight in this sigmoidal weighting function.

In summary, having considered the scientific information and assessment results available in the 2008 rulemaking as discussed above in this proposal notice, as well as the recommendations of the staff and CASAC, and having taken into consideration issues raised in public comments received as part of the 2008 rulemaking, and recognizing the determinations made below in section IV.D.5.c on level, the Administrator concludes that it is appropriate to set the secondary standard using a cumulative, seasonal form. The Administrator also concludes that the W126 form is best suited to reflect the biological impacts of O<sub>3</sub> exposure on vegetation, and that there is adequate certainty in the information available in the 2008 rulemaking to support such a change in form. Thus, the Administrator proposes to set the secondary standard using a cumulative, seasonal W126 form.

#### b. Averaging Times<sup>61</sup>

The Administrator, in addition to reconsidering what form of a secondary standard is most appropriate for protecting vegetation, is also reconsidering what exposure periods (e.g., seasonal window, diurnal window), and what standard index, in terms of an annual index value versus a 3-year average of annual index values, are most appropriate when used in conjunction with the W126 cumulative

<sup>61</sup> While the term "averaging time" is used, for the cumulative, seasonal standard the seasonal and diurnal time periods at issue are those over which exposures during a specified period of time are cumulated, not averaged.

seasonal form. Based on the information set forth in the 2007 Staff Paper, as well as CASAC views, as discussed above in section IV.D.1.b, the Administrator has reached conclusions regarding exposure periods, and the annual versus 3-year average index, that have the most biological relevance for plant response, as discussed below.

In considering an appropriate seasonal window, the Administrator notes that the 2007 Staff Paper concluded that the consecutive 3-month period within the O<sub>3</sub> season with the highest W126 index value (e.g., maximum 3-month period) was a reasonable seasonal time period to consider. The Administrator further notes that the 2007 Staff Paper acknowledged that the selection of any single seasonal exposure period for a national standard would necessarily represent a compromise, given the significant variability in growth patterns and lengths of growing seasons among the wide range of sensitive vegetation species occurring within the U.S. However, the Administrator also considered the Staff Paper conclusion that the period of maximum potential plant uptake of O<sub>3</sub> would also likely coincide with the period of highest O<sub>3</sub> occurring within the intra-annual period defined as the O<sub>3</sub> season, since the high temperature and light conditions conducive to O<sub>3</sub> formation are also conducive for plant activity. The Administrator also observes that the CASAC panel was supportive of the Staff Paper views, while recognizing that 3 months likely represented the minimum timeframe appropriate to consider. Therefore, the Administrator concludes, on these bases, that the consecutive 3-month period within the O<sub>3</sub> season with the highest W126 index value (e.g., maximum 3-month period) remains an appropriate seasonal window to propose for the protection of sensitive vegetation.

With regard to consideration of an appropriate diurnal window, the Administrator has taken into account the 2007 Staff Paper conclusion that for the vast majority of studied species, daytime exposures represent the majority of diurnal plant O<sub>3</sub> uptake and are responsible for inducing the plant response of most significance to the health and productivity of the plant (e.g., reduced carbohydrate production). The Administrator is also aware, based on discussions in the 2007 Staff Paper that there are some number of species that show non-negligible amounts of O<sub>3</sub> uptake at night due to incomplete stomatal closure. In reaching her conclusion that the 2007 Staff Paper recommendation of a 12-hour daytime

window (8 a.m. to 8 p.m.) remains the most appropriate period over which to cumulate diurnal O<sub>3</sub> exposures, specifically those most relevant to plant growth and yield responses, the Administrator places weight on the fact that the CASAC comments were also supportive of this diurnal window, recognizing again that it likely represents a minimum period over which plants can be vulnerable to O<sub>3</sub> uptake. Therefore, the Administrator is again proposing the 12-hour daytime window (8 a.m. to 8 p.m.) as an appropriate diurnal window to protect against O<sub>3</sub>-induced plant effects.

Lastly, in considering whether an annual or a 3-year average index is more appropriate, the Administrator notes that in addition to the available scientific evidence regarding plant effects that can be brought to bear, there are also other public welfare considerations that may be appropriate to consider. In taking this view, the Administrator notes that the 2007 Staff Paper recognized that though most cumulative seasonal exposure levels of concern for vegetation have been expressed in terms of the annual timeframe, it may be appropriate to consider a 3-year average for purposes of standard stability. The Administrator has considered that while the 2007 Staff Paper notes that for certain welfare effects of concern (e.g., foliar injury, yield loss for annual crops, growth effects on other annual vegetation and potentially tree seedlings), an annual time frame may be a more appropriate period in which to assess what level would provide the requisite degree of protection, for other welfare effects (e.g., mature tree biomass loss), it also points out that a 3-year average may also be appropriate. The Administrator further observes that in concluding that it was appropriate to consider both an annual and a 3-year average, the 2007 Staff Paper also concluded that should a 3-year average of the 3-month, 12-hour W126 form be selected, a potentially lower level should be considered to reduce the potential of adverse impacts to annual species from a single high O<sub>3</sub> year that could still occur while attaining a standard on average over 3-years. The Administrator also took note that the CASAC Panel, in addressing this issue of annual versus 3-year average concluded that multi-year averaging to promote a "stable" secondary standard is less appropriate for a cumulative, seasonal secondary standard than for a primary standard based on maximum 8-hour concentrations, and further concluded that if multi-year averaging is employed

to increase the stability of the secondary standard, the level of the standard should be revised downward to assure that the desired degree of protection is not exceeded in individual years. The Administrator, in considering the merits of both the annual and 3-year average, and taking into account both the 2007 Staff Paper and CASAC views, concludes that it is important to place more weight on the public welfare benefit in having a stable standard, and that appropriate protection for vegetation can be achieved using a 3-year average form. The Administrator is thus proposing a 3-year average. However, given the uncertain nature of the evidence and potential concerns with using a 3-year average form, the Administrator is proposing to take comment on the appropriateness of the specific seasonal and diurnal exposure periods proposed, as well as the use of a 3-year average, and, as discussed below, the impact that selection of these proposed seasonal and diurnal exposure periods would have, in conjunction with a 3-year average form, on the appropriateness of the proposed range of levels.

#### c. Level

##### i. Considerations Regarding 2007 Proposed Range of Levels

The 2007 Staff Paper, in identifying a range of levels for a 3-month, 12-hour (daytime) W126 standard appropriate for the Administrator to consider in protecting the public welfare from known or anticipated adverse effects to vegetation from O<sub>3</sub> exposures, considered what information from the array of vegetation effects evidence and exposure and risk assessment results was most useful. With respect to the vegetation effects evidence, the 2007 Staff Paper found stronger support than what was available at the time of the 1997 review for an increased level of protection for trees and forested ecosystems. Specifically, the expanded body of evidence included: (1) Additional field based data from free air, gradient and biomonitoring surveys demonstrating adverse levels of O<sub>3</sub>-induced growth reductions on trees at the seedling, sapling and mature growth stages and incidence of visible foliar injury occurring at biomonitoring sites in the field at ambient levels of exposure; (2) qualitative support from free air (e.g., AspenFACE) and gradient studies on a limited number of tree species for the continued appropriateness of using OTC-derived C-R functions to predict tree seedling response in the field; (3) studies that continued to document below-ground

effects on root growth and "carry-over" effects occurring in subsequent years from O<sub>3</sub> exposures; and (4) increased recognition and understanding of the structure and function of ecosystems and the complex linkages through which O<sub>3</sub>, and other stressors, acting at the organism and species level can influence higher levels within the ecosystem hierarchy and disrupt essential ecological attributes critical to the maintenance of ecosystem goods and services important to the public welfare.

Based on the above sources of vegetation effects information and the results of the exposure and risk assessments summarized above, the 2007 Staff Paper concluded that just meeting the then current 0.084 ppm, 8-hour average standard would continue to allow adverse levels of O<sub>3</sub>-induced effects to occur in sensitive commercially and ecologically important tree species in many regions of the country. The 2007 Staff Paper further concluded that air quality levels would need to be substantially reduced to protect sensitive tree seedlings, such as black cherry, aspen, and cottonwood, from these growth and foliar injury effects.

In addition to the currently quantifiable risks to trees from ambient exposures, the 2007 Staff Paper also considered the more subtle impacts of O<sub>3</sub> acting in synergy with other natural and man-made stressors to adversely affect individual plants, populations and whole systems. By disrupting the photosynthetic process, decreasing carbon storage in the roots, increasing early senescence of leaves and affecting water use efficiency in trees, O<sub>3</sub> exposures could potentially disrupt or change the nutrient and water flow of an entire system. Weakened trees can become more susceptible to other environmental stresses such as pest and pathogen outbreaks or harsh weather conditions. Though it is not possible to quantify all the ecological and societal benefits associated with varying levels of alternative secondary standards, the 2007 Staff Paper concluded that this information should be weighed in considering the extent to which a secondary standard should be set so as to provide potential protection against effects that are anticipated to occur.

The 2007 Staff Paper also recognized that in the 1997 review, EPA took into account the results of a 1996 Consensus Workshop. At this workshop, a group of independent scientists expressed their judgments on what standard form(s) and level(s) would provide vegetation with adequate protection from O<sub>3</sub>-related adverse effects. Consensus was reached

on protective ranges of levels in terms of a cumulative, seasonal 3-month, 12-hr SUM06 standard for a number of vegetation effects endpoints. These ranges are identified below, with the estimated approximate equivalent W126 standard levels shown in parentheses. For growth effects to tree seedlings in natural forest stands, a consensus was reached that a SUM06 range of 10 to 15 (W126 range of 7 to 13) ppm-hour would be protective. For growth effects to tree seedlings and saplings in plantations, the consensus SUM06 range was 12 to 16 (W126 range of 9 to 14) ppm-hour. For visible foliar injury to natural ecosystems, the consensus SUM06 range was 8 to 12 (W126 range of 5 to 9) ppm-hour.

The 2007 Staff Paper then considered to what extent recent research provided empirical support for the ranges of levels identified by the experts as protective of different types of O<sub>3</sub>-induced effects. As discussed above in section IV.D.1.c, the 2007 Staff Paper concluded on the basis of the available evidence that it was appropriate to consider a range for a 3-month, 12-hour, W126 standard level that included the 1996 Consensus Workshop recommendations regarding a range of levels protective against O<sub>3</sub>-induced growth effects in tree seedlings in natural forest stands (*i.e.*, 7–13 ppm-hour in terms of a W126 form).

In considering the newly available information on O<sub>3</sub>-related effects on crops in this review, the 2007 Staff Paper observed the following regarding the strength of the underlying crop science: (1) Nothing in the recent literature points to a change in the relationship between O<sub>3</sub> exposure and crop response across the range of species and/or cultivars of commodity crops currently grown in the U.S. that could be construed to make less appropriate the use of commodity crop C-R functions developed in the NCLAN program; (2) new field-based studies (*e.g.*, SoyFACE) provide qualitative support in a few limited cases for the appropriateness of using OTC-derived C-R functions to predict crop response in the field; and (3) refinements in the exposure, risk and benefits assessments in this review reduce some of the uncertainties present in 1996. On the basis of these observations, the 2007 Staff Paper concluded that nothing in the newly assessed information calls into question the strength of the underlying science upon which EPA based its proposed decision in the last review to select a level of a cumulative, seasonal form associated with protecting 50 percent of crop cases from no more than 10 percent yield loss as providing

the requisite degree of protection for commodity crops.

The 2007 Staff Paper then considered whether any additional information was available to inform judgments as to the adversity of various O<sub>3</sub>-induced levels of crop yield loss to the public welfare. As noted above, the 2007 Staff Paper observed that agricultural systems are heavily managed, and that in addition to stress from O<sub>3</sub>, the annual productivity of agricultural systems is vulnerable to disruption from many other stressors (*e.g.*, weather, insects, disease), whose impact in any given year can greatly outweigh the direct reduction in annual productivity resulting from elevated O<sub>3</sub> exposures. On the other hand, O<sub>3</sub> can also more subtly impact crop and forage nutritive quality and indirectly exacerbate the severity of the impact from other stressors. Since these latter effects could not be quantified at that time, they could only be considered qualitatively in reaching judgments about an appropriate degree of protection for commodity crops from O<sub>3</sub>-related effects.

Based on the above considerations, the 2007 Staff Paper concluded that the level of protection judged requisite in the 1997 review to protect the public welfare from adverse levels of O<sub>3</sub>-induced reductions in crop yields and tree seedling biomass loss, as approximately provided by a W126 level of 21 ppm-hour, remained appropriate for consideration as an upper bound of a range of appropriate levels. The 2007 Staff Paper also recognized that a standard set at this level would not protect the most sensitive species or individuals within a species from all potential effects related to O<sub>3</sub> exposures and further, that this level derives from the extensive and quantitative historic and recent crop effects database, as well as current staff exposure and risk analyses (EPA, 2007, pg. 8–22).

In identifying a lower bound for the range of alternative standard levels appropriate for consideration, staff concluded that several lines of evidence pointed to the need for greater protection for tree seedlings, mature trees, and associated forested ecosystems. Staff believed that tree growth was an important endpoint to consider because it is related to other aspects of societal welfare such as sustainable production of timber and related goods, recreation, and carbon (CO<sub>2</sub>) sequestration. Impacts on tree growth can also affect ecosystems through shifts in species composition and the loss of genetic diversity due to the loss of O<sub>3</sub> sensitive individuals or species. In selecting an appropriate level

of protection for trees, staff considered the results of the 1996 Consensus Workshop which identified the SUM06 range of 10 to 15 (W126 of 7 to 13) ppm-hour for growth effects to tree seedlings in natural forest stands.

Because staff believed that O<sub>3</sub>-related effects on forest tree species are important public welfare effects of concern, it therefore concluded, based on the above, that it was appropriate to include 7 ppm-hour as the lower bound of the recommended range, the lower end of the approximate range recommended by CASAC (Henderson, 2006c) and identified by the 1996 Consensus Workshop participants as protective of forest trees. At this lower end of the range, staff anticipated, based on its analyses of risks of tree seedling biomass loss and mature tree growth reductions and on the basis of the scientific effects literature, that adverse effects of O<sub>3</sub> on forested ecosystems would be substantially reduced. Further, staff anticipated that the lower end of this range would provide increased protection from the more subtle impacts of O<sub>3</sub> acting in synergy with other natural and man-made stressors to adversely affect individual plants, populations and whole systems. Staff also noted that by disrupting the photosynthetic process, decreasing carbon storage in the roots, increasing early senescence of leaves and affecting water use efficiency in trees, O<sub>3</sub> exposure could potentially disrupt or change the nutrient and water flow of an entire system. Such weakened trees can become more susceptible to other environmental stresses such as pest and pathogen outbreaks or harsh weather conditions. While recognizing that it is not possible to quantify all the ecological and societal benefits associated with varying levels of alternative secondary standards, staff believed that this information should be weighed in considering the extent to which a secondary standard should be precautionary in nature in protecting against effects that have not yet been adequately studied and evaluated.

Thus, the 2007 Staff Paper concluded, based on all the above considerations, that an appropriate range of levels, for an annual standard using a 3-month, 12-hour W126 form, for the Administrator to consider was 7 to 21 ppm-hour, recognizing that the level selected is largely a policy judgment as to the requisite level of protection needed. In determining the requisite level of protection for crops and trees, the 2007 Staff Paper recognized that it was appropriate to weigh the importance of the predicted risks of these effects in the overall context of



public welfare protection, along with a determination as to the appropriate weight to place on the associated uncertainties and limitations of this information.

ii. CASAC and Public Comments Prior to 2008 Decision

In considering the evidence described in both the 2006 Criteria Document and 2006 draft Staff Paper, CASAC, in its October 24, 2006 letter to the Administrator, expressed its view regarding the appropriate form and range of levels for the Administrator to consider. The CASAC preferred a seasonal 3-month W126 standard in a range that is the approximate equivalent of the SUM06 at 10 to 20 ppm-hour. Following the 2007 proposal, EPA received additional CASAC and public comments regarding an appropriate range of levels of a W126 form for the Administrator to consider in finalizing a revised secondary NAAQS for O<sub>3</sub>. The CASAC, in its final letter to the Administrator (Henderson, 2007), agreed with the 2007 Staff Paper recommendations that the lower bound of the range within which a seasonal W126 secondary O<sub>3</sub> standard should be considered is approximately 7 ppm-hour; however, it did not agree with staff's recommendation that the upper bound of the range should be as high as 21 ppm-hour. Rather, as discussed above in section IV.D.1.c, the CASAC Panel recommended that the upper bound of the range considered should be no higher than a W126 of 15 ppm-hour for an annual standard.

The comments received from the public fell into two groups. One group of commenters supported the CASAC recommended range of 7–15 ppm-hour for a W126 standard. Many of these same commenters further emphasized the lower end of the proposed range as necessary to provide adequate protection for sensitive species. These commenters based their recommendation primarily on four sources of information: (1) Field-based evidence of foliar injury occurring on sensitive species at air quality levels well below that of the current standard; (2) the 1996 Consensus Workshop recommendations for protective levels in terms of cumulative exposures for different vegetation types; (3) CASAC advice and recommendations; and (4) studies published after the close of the 2006 Criteria Document that potentially strengthen the link between species level impacts and ecosystem response.

The other group of commenters did not support revising the current secondary standard. These commenters primarily focused on uncertainties

regarding the sources of information relied upon by the first group of commenters as support for a level within the range of levels recommended by CASAC. These uncertainties included: (1) potential confounders, such as soil moisture, on visible foliar injury and the lack of a clear relationship between visible foliar injury symptoms and other vegetation effects; (2) lack of documentation of the basis for the recommendations from the 1996 Consensus Workshop in selecting a range of levels, indicating that these recommendations should be used with great caution; (3) failure of CASAC and EPA to take into account the monitor height measurement gradient when making their recommendations concerning the level of the secondary standard; and (4) inability to quantitatively estimate ecosystem effects of O<sub>3</sub> or to extrapolate meaningfully from effects on individual plants to ecosystem effects due to inadequate data.

iii. Conclusions on Level

The Administrator is proposing to set a cumulative, seasonal standard expressed in terms of the maximum 3-month, 12-hour W126 form, in the range of 7 to 15 ppm-hour. In reaching this proposed decision about an appropriate range of levels for the secondary standard, the Administrator has considered the following: the evidence described in the 2006 Criteria Document and the 2007 Staff Paper; the results of the vegetation exposure and risk assessments discussed above and in the 2007 Staff Paper, giving weight to the assessments as judged appropriate; the CASAC Panel's advice and recommendations in the CASAC's letters to the Administrator; EPA staff recommendations; and public comments received during the development of these documents, either in connection with CASAC meetings or separately. In considering what range of levels of a cumulative 3-month standard to propose, the Administrator notes that this choice requires judgment as to what standard will protect the public welfare from any known or anticipated adverse effects. This choice must be based on an interpretation of the evidence and other information, such as the exposure and risk assessments, that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn. In taking all of the above into consideration, the Administrator also notes that there is no bright line clearly directing the choice of level for any of the effects of concern, and the choice of what is appropriate is

clearly a public welfare policy judgment entrusted to the Administrator.

In particular, the Administrator has given careful consideration to the following: (1) The nature and degree of effects of O<sub>3</sub> to the public welfare, including what constitutes an adverse effect; (2) the strengths and limitations of the evidence that is available regarding known or anticipated adverse effects from cumulative, seasonal exposures, and its usefulness in informing selection of a proposed range; and (3) CASAC's views regarding the strength of the evidence and its adequacy to inform a range of levels. Each of these topics is discussed in turn below.

In determining the nature and degree of effects of O<sub>3</sub> on the public welfare, the Administrator recognizes that the significance to the public welfare of O<sub>3</sub>-induced effects on sensitive vegetation growing within the U.S. can vary, depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Any given O<sub>3</sub>-related effect on vegetation and ecosystems (e.g., biomass loss, foliar injury), therefore, may be judged to have a different degree of impact on the public depending, for example, on whether that effect occurs in a Class I area, a city park, or commercial cropland. In her judgment, it is appropriate that this variation in the significance of O<sub>3</sub>-related vegetation effects should be taken into consideration in judging the level of ambient O<sub>3</sub> that is requisite to protect the public welfare from any known or anticipated adverse effects. In this regard, the Administrator agrees with the definition of adversity as described above in section IV.A.3 and in the 2008 rulemaking. As a result, the Administrator concludes that of those known and anticipated O<sub>3</sub>-related vegetation and ecosystem effects identified and discussed in this reconsideration, the highest priority and significance should be given to those that occur on sensitive species that are known to or are likely to occur in federally protected areas such as Class I areas<sup>62</sup> or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public

<sup>62</sup> For example, the level of protection granted by Congress under the Wilderness Act of 1964 for designated "wilderness areas" requires that these areas "shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use as wilderness, and so as to provide for the protection of these areas, the preservation of their wilderness character" (The Wilderness Act, 1964).

welfare, for residents on those lands, as well as visitors to those areas.

Likewise, the Administrator also notes that the same known or anticipated O<sub>3</sub>-induced effects, occurring in other areas may call for less protection. For example, the maintenance of adequate agricultural crop yields is extremely important to the public welfare and is currently achieved through the application of intensive management practices, including in some cases, genetic engineering. These management practices, in conjunction with market forces and government programs, assure an appropriate balance is reached between costs of production and market availability. Thus, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O<sub>3</sub>-induced effects is considered less useful in informing judgments on what level(s) would be sufficient but not more than necessary to protect the public welfare. With respect to commercial production of commodities, the Administrator notes that judgments about the extent to which O<sub>3</sub>-related effects on commercially managed vegetation are adverse from a public welfare perspective are particularly difficult to reach, given that what is known about the relationship between O<sub>3</sub> exposures and agricultural crop yield response derives largely from data generated almost 20 years ago. The Administrator recognizes that there is substantial uncertainty at this time as to whether these data remain relevant to the majority of species and cultivars of crops being grown in the field today. In addition, the extensive management of such vegetation may to some degree mitigate potential O<sub>3</sub>-related effects. The management practices used on these lands are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. Thus, the Administrator concludes there is no need for such additional protection for agricultural crops through the NAAQS.

The Administrator also recognizes that O<sub>3</sub>-related effects on sensitive vegetation can occur in other areas that have not been afforded special Federal protections, ranging from effects on vegetation growing in residential or commercial settings, such as ornamentals used in urban/suburban landscaping, to vegetation grown in land use categories that are heavily managed for commercial production of commodities such as timber. For vegetation used for residential or commercial ornamental purposes, such

as urban/suburban landscaping, the Administrator believes that there is not adequate information at this time to establish a secondary standard based specifically on impairment of urban/suburban landscaping and other uses of ornamental vegetation, but notes that a secondary standard revised to provide protection for sensitive natural vegetation and ecosystems would likely also provide some degree of protection for such ornamental vegetation.

Based on the above, the Administrator finds that the types of information most useful in informing the selection of an appropriate range of protective levels is appropriately focused on information regarding exposures and responses of sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas.

With regard to the available evidence, the Administrator finds the coherence and strength of the weight of evidence from the large body of available literature compelling. This evidence addresses a broad array of O<sub>3</sub>-induced effects on a variety of tree species across a range of growth stages (*i.e.*, seedlings, saplings and mature trees) using diverse field-based (*e.g.* free air, gradient and ambient) and OTC exposure methods. It demonstrates that significant numbers of forest tree species are potentially experiencing O<sub>3</sub>-induced stress under levels of ambient air quality, both at and below the level of the 1997 standard.

In particular, the Administrator notes the evidence from recent field-based studies and a gradient study of eastern cottonwood saplings (Gregg *et al.*, 2003). She observes that this study found that cottonwood saplings grown in urban New York City grew faster than saplings grown in downwind rural areas where cumulative O<sub>3</sub> exposures were higher, and the difference in biomass production between the urban site with the lowest cumulative exposure and the rural site with the highest cumulative exposure is dramatic (Figure 7-17 in the 2007 Staff Paper). The Administrator further notes that cottonwood is one of the most sensitive tree species studied to date and it is also important both from an ecological and public welfare perspective, as discussed above in section IV.A.2.b and in the 2007 Staff Paper.

The Administrator also notes the evidence related to the O<sub>3</sub>-induced effect of visible foliar injury. The Administrator observes that the visible foliar injury database created from the

ambient field-based monitoring network managed by the United States Forest Service (USFS) Forest Inventory and Analysis (FIA) Program has continued to expand since the conclusion of the 1997 review. In utilizing this dataset, EPA staff collaborated with FIA staff to compare the incidence of visible foliar injury at different levels of air quality by county throughout the U.S. in counties with FIA monitoring sites. In considering the results of this analysis, depicted in Table 7-4 of the 2007 Staff Paper, the Administrator notes that for the 2001-2004 period, the percent of counties with documented foliar injury at a level approximately equivalent to the W126 of 21 ppm-hour, was 26 to 49 percent, while at the lower level approximately equivalent to a W126 of 13 ppm-hour, incidence values ranged from 12 to 35 percent. The Administrator believes it likely that some sensitive species occurring in specially protected areas would also exhibit visible foliar injury symptoms to a similar degree at these exposure levels. She further notes that while direct links between O<sub>3</sub> induced visible foliar injury symptoms and other adverse effects (*e.g.*, biomass loss) are not always found, visible foliar injury in itself is considered by the National Park Service (NPS) to affect adversely air quality related values (AQRV) in Class I areas.

The Administrator places significant weight on the judgments of CASAC. In so doing, the Administrator has carefully considered its stated views and the basis for the range of levels the CASAC O<sub>3</sub> Panel recommended. In its 2007 letter to the Administrator, the CASAC O<sub>3</sub> Panel agreed with EPA staff recommendations that the lower bound of the range within which a seasonal W126 O<sub>3</sub> standard should be considered is approximately 7 ppm-hour. However, "it does not agree with Staff's recommendations that the upper bound of the range should be as high as 21 ppm-hour. Rather, the Panel recommends that the upper bound of the range considered should be no higher than 15 ppm-hour, which the Panel estimates is approximately equivalent to a seasonal 12-hour SUM06 level of 20 ppm-hour" (Henderson, 2007). The Administrator notes that CASAC views concerning an appropriate range of levels for the Administrator to consider were presented after CASAC had considered the entire body of evidence presented in both the 2006 Criteria Document and 2007 Staff Paper, and are generally consistent with the 1996 Consensus Workshop recommendations.

In considering the issues raised by commenters on the 2007 proposed rule, the Administrator noted that many public commenters supported the range of levels recommended by CASAC. The Administrator also considered the views expressed by the NPS as to what range of levels it identified as useful in helping it achieve its mandate to protect AQRVs in national parks and wilderness areas and to provide a level of protection for its resources in keeping with the Congressional mandate set forth in The Wilderness Act of 1964. In so doing, the Administrator notes that the NPS supported the range recommended by CASAC, while emphasizing that the lower end of the range was more appropriate. The NPS notes that though some visible foliar injury would still be expected to occur above the lower end of the CASAC recommended range (*i.e.* 7 ppm-hour), the potential for growth impacts at that level would be very low. It further notes that most of these parks contain aspen, black cherry, or ponderosa pine, all sensitive species predicted to have significant growth effects at current W126 levels.

The Administrator also considered those comments that highlighted sources of uncertainty in the evidence and risk assessments (summarized above in section IV.D.5.c.ii) to inform her judgments on how much weight to place on these associated uncertainties, as discussed below.

With regard to the issue of possible confounders of foliar injury information, the Administrator recognizes that visible foliar injury, like other O<sub>3</sub>-induced plant effects, is moderated by environmental factors other than O<sub>3</sub> exposure. However, the Administrator also notes that the O<sub>3</sub>-related visible foliar injury effect persisted across a four year period (2001–2004), despite year-to-year variability in meteorology and other environmental factors (see Table 7–4 in the 2007 Staff Paper). She also notes that approximately 26 to 49 percent of counties had visible foliar injury incidence at the approximate W126 level of 21 ppm-hour, while at a W126 level of 13 ppm-hour, this range of percentages dropped to approximately 12 to 23 percent. In an area such as a national park, where visitors come in part for the aesthetic quality of the landscape, the Administrator recognizes that visible foliar injury incidence is an important welfare effect which should be considered in determining an appropriately protective standard level.

With regard to the issues of what weight to place on the recommendations from the 1996 Consensus Workshop in

selecting a range of levels, as the 1997 Workshop Report did not clearly document the basis for its recommendations, the Administrator recognizes that the absence of such documentation does call for care in placing weight on such recommendations. However, the Administrator notes that the workshop participants were asked to review both the 1996 O<sub>3</sub> Criteria Document and Staff Paper, representing the most up to date compilation of the state of the science available at that time, in order to ensure that their expert judgments made were also informed by the latest science. She also notes that another group of experts, the CASAC O<sub>3</sub> Panel, reached a similar consensus based upon an expanded body of scientific evidence. In addition, the 2007 Staff Paper evaluated the same recommendations in the context of subsequent empirical evidence, and reached similar views, with the exception of the upper end of the recommended range, which in the 2007 Staff Paper was based on effects on commercial crops that had been considered in the 1997 review. While it would always be more useful to have documentation of the reasoning and basis for an expert's advice, in this case the Administrator judges that the 1996 Consensus Workshop recommendations should be given substantial weight.

With regard to other issues raised by some commenters related to uncertainties in the technical evidence and analyses, the Administrator notes that such issues had been addressed in the 2007 Staff Paper that reflected CASAC's advice on such issues. For example, while the Administrator recognizes that uncertainty remains as to what level of annual tree seedling biomass loss when compounded over multiple years should be judged adverse to the public welfare, she believes that the potential for such anticipated effects should be considered in judging to what degree a standard should be precautionary.

In considering all of the issues discussed above, the Administrator has decided to propose a range of 7–15 ppm-hour. In selecting as an upper bound a level of 15 ppm-hour, the Administrator notes that this level was specifically supported by the CASAC O<sub>3</sub> Panel and is just above the range identified in the 1996 Consensus Workshop report as needed to provide adequate protection for trees growing in natural areas. In addition, the NPS, along with many public commenters, were in support of the CASAC range, including the upper bound of 15 ppm-hour, and indicated that lower values within this range would be more

protective for sensitive trees in protected areas from biomass loss and visible foliar injury symptoms.

While the upper end of this range is lower than the upper end of 21 ppm-hour recommended in the 2007 Staff Paper, this upper level of 21 ppm-hour was originally put forward in the 1997 review in terms of a SUM06 of 25 ppm-hour (W126 of 21 ppm-hour) and was justified on the basis that it was predicted to allow up to 10% biomass loss annually in 50% of studied commercial crops and tree seedling species. Recognizing the significant uncertainties that are associated with evaluating effects on commercial crops from a public welfare perspective, the Administrator now concludes that commercial crop data are no longer useful for setting the upper level of the range for proposal.

With regard to her selection of a proposed range, the Administrator has considered that the direction from Congress to provide a high degree of protection in Class I areas creates a clearer target for gauging what types and magnitudes of effects would be known or anticipated to affect the intended use of these and other similarly protected areas, that would thus be considered adverse to the public welfare. Such similar areas include lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas. The Administrator also believes that in order to preserve wilderness areas in an unimpaired state for future generations, she must consider a level that affords substantial protection from known adverse O<sub>3</sub>-related effects of biomass loss and foliar injury on sensitive tree species, as well as a level that takes into account potential "anticipated" adverse O<sub>3</sub>-related effects, including effects that result in continued impairment in the year following O<sub>3</sub> exposure (*i.e.*, carry-over effects), below ground impacts, ecosystem level impacts, and reduced CO<sub>2</sub> sequestration.

While the Administrator acknowledges that growth effects and visible foliar injury can still occur in sensitive species at levels below the upper bound of the proposed range, the Administrator also recognizes that some significant uncertainties remain regarding the risk of these effects, as discussed above. For example, the Administrator concludes that remaining uncertainties make it difficult to judge the point at which visible foliar injury becomes adverse to the public welfare in various types of specially protected areas. Uncertainties associated with monitoring ambient exposures must be

considered in evaluating the strength of predictions regarding the degree of tree seedling growth impairment estimated to occur at varying ambient exposures. These uncertainties add to the challenge of judging which exposure levels are expected to be associated with levels of tree seedling growth effects considered adverse to public welfare. The Administrator believes that it is important to consider these uncertainties, and the weight to place on such uncertainties, in selecting a range of standard levels to propose. Establishing 15 ppm-hour as the upper end of the proposed range reflects her judgment regarding the appropriate weight to place on these uncertainties in determining the degree of protection that is warranted for known and anticipated adverse effects.

With regard to her selection of a lower bound for the proposed range, the Administrator believes that if weight is placed on taking a more precautionary approach, recognizing that the real world impacts on trees and ecosystems could, in some cases, be greater than predicted, then the lower end of the range of 7 ppm-hour could be warranted. There is clear evidence that higher cumulative exposures can occur in rural areas downwind of urban areas and potentially in Class I areas. Unmonitored high elevation sites would also likely have higher cumulative exposures than lower elevation sites that are currently monitored. All of these considerations lead the Administrator to propose 7 ppm-hour as the low end of the proposed range.

As discussed above in section IV.D.5.a, the main opposition to changing to a secondary standard with a cumulative, seasonal form has been the view that EPA does not have an adequate basis to identify the kinds and types of cumulative, seasonal exposure patterns that the standard should be designed to protect against, given the various uncertainties in the evidence, and whether EPA has an adequate basis to determine an appropriate level for a cumulative, seasonal secondary standard. While EPA agreed with this position in the 1997 review, the Administrator believes that the evidence before her appropriately supports a secondary standard that is distinctly different in form and averaging time from the 8-hour primary standard, and that such a standard is necessary to provide sufficient protection from cumulative, seasonal exposures to O<sub>3</sub>.

While a different conclusion on this issue was reached in the 1997 review, the current conclusion that an exposure index that is cumulative and seasonal in nature, and therefore that setting a

standard based on such a form is necessary and appropriate, is based on information newly available in the 2008 rulemaking, which strengthens the information available in the 1997 review and reduces remaining uncertainties.

Such newly available information includes quantitative information for a broader array of vegetation effects (extending to sapling and mature tree growth stages) obtained using a more diverse set of field-based research study designs and improved analytical methods for assessing O<sub>3</sub>-related exposures and risks as discussed above in sections IV.A–C.

These newly available studies also provide important support to the quantitative estimates of impaired tree growth based on earlier studies available in the 1997 review and address one of the key data gaps cited in the 1997 review. Additional qualitative information is also available regarding improved understanding of linkages between stress-related effects of O<sub>3</sub> exposures at the species level and those at higher levels within ecosystems. Finally, this information includes the use of new analytical methods, including a new multi-pollutant, multi-scale air quality model used to characterize exposures of O<sub>3</sub>-sensitive tree and crop species further address uncertainties in the assessments done in the 1997 review. In total, this newly available information increases the Administrator's confidence in important aspects of this rulemaking.

The decision in 2008 to set the secondary O<sub>3</sub> standard identical to the 8-hour primary standard largely mirrored the decision in 1997, but failed to account for this significant increase in the body of knowledge available to support the 2008 rulemaking. This body of knowledge, while continuing to reflect significant uncertainties, provides an appropriate basis for determining a level of a cumulative, seasonal standard that, in the judgment of the Administrator, provides sufficient but not more than necessary protection from cumulative, seasonal exposures to O<sub>3</sub>. This is clearly so when compared to a standard that uses an indirect form that is not biologically relevant, an 8-hour average standard aimed at peak daily exposures. This judgment is fully consistent with the advice provided by CASAC.

After carefully taking the above considerations into account, and giving significant weight to the views of CASAC, the Administrator has decided to propose a range of levels of 7–15 ppm-hour for a cumulative, seasonal secondary O<sub>3</sub> standard expressed as an index of the annual sum of weighted

hourly concentrations (*i.e.*, the W126 form), cumulated over 12 hours per day during the consecutive 3-month period within the O<sub>3</sub> season with the maximum index value, averaged over three years. In the Administrator's judgment, based on the information available in the 2008 rulemaking, a standard could be set within this range that would be requisite to protect public welfare from known or anticipated adverse effects to O<sub>3</sub>-sensitive vegetation and ecosystems. In the Administrator's judgment, a standard set at a level below the lower end of the range is not now supported by the weight of evidence and would not give sufficient weight to the important uncertainties and limitations inherent in the available scientific evidence and in the quantitative assessments conducted for the 2008 rulemaking. A standard set at a level above the upper end of the range is also not now supported by the weight of evidence and would not give sufficient weight to the credible inferences that the Agency has drawn from the scientific evidence nor to the quantitative assessments conducted for the 2008 rulemaking. The Administrator judges that the appropriate balance to be drawn, based on the entire body of evidence and information available in the 2008 rulemaking, is a range between 7 and 15 ppm-hour. On balance, the Administrator believes that a standard could be set within this range that would be sufficient but not more than necessary to protect public welfare from known or anticipated adverse effects due to O<sub>3</sub>.

In reaching this proposed decision, as discussed above, the Administrator has focused on the nature of the benefits associated with setting a distinct secondary standard with a cumulative, seasonal form relative to a standard with a peak daily 8-hour average form, as well as on assessments that quantify the degree of protection likely to be afforded by such standards. In so doing, the Administrator has acknowledged limitations in quantifying the expected benefits associated with the proposed cumulative seasonal standard relative to the secondary standard set in 2008. Having considered the public comments received on the 2007 proposed rule in reaching this proposed decision, the Administrator is interested in again receiving public comment on the benefits to public welfare associated with the proposed cumulative seasonal standard set at specific levels within the proposed range relative to the standard set in 2008.

### *E. Proposed Decision on the Secondary O<sub>3</sub> Standard*

For the reasons discussed above, and taking into account information and assessments presented in the 2006 Criteria Document and 2007 Staff Paper, the advice and recommendations of CASAC, and the public comments received in conjunction with the 2008 rulemaking, the Administrator has decided to propose to set a few cumulative, seasonal secondary O<sub>3</sub> standard with a form expressed as an index of the annual sum of weighted hourly concentrations (*i.e.*, the W126 form), cumulated over 12 hours per day (8 a.m. to 8 p.m.) during the consecutive 3-month period within the O<sub>3</sub> season with the maximum index value, averaged over three years, set within a range of 7 to 15 ppm-hour. The Administrator solicits comment on the weight that is appropriately placed on the various types of evidence and analyses upon which this proposed standard is based, and on the appropriate weight to be placed on the uncertainties in this information, as well as on the benefits to public welfare associated with the proposed standard relative to the benefits associated with the standard set in 2008.

Data handling conventions for the proposed new secondary O<sub>3</sub> standard are specified in the proposed addition of a new section to 40 CFR 50 Appendix P, as discussed in section V below. Issues related to monitoring requirements for the proposed new secondary O<sub>3</sub> standard are discussed below in section VI.

### **V. Interpretation of the NAAQS for O<sub>3</sub> and Proposed Revisions to the Exceptional Events Rule**

Appendix P to 40 CFR part 50, Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone, addresses data completeness requirements, data reporting, handling, and rounding conventions, and example calculations. The current Appendix P explains the computations necessary for determining when the current identical primary and secondary standards are met. The EPA is proposing to revise Appendix P to reflect the proposed revisions to the primary and secondary O<sub>3</sub> NAAQS discussed above and to make other changes described below.

As discussed below, the proposed revisions to Appendix P include the following: The addition of data interpretation procedures applicable to the proposed cumulative, seasonal secondary NAAQS (see section V.B); clarification of certain language in the

current provisions applicable to the primary NAAQS to reduce potential confusion (section V.C); revisions to the provisions regarding the use of incomplete data sets for purposes of the primary NAAQS and the data completeness requirements across three years (sections V.D and V.E); the addition of a provision providing the Administrator discretion to use incomplete data as if it were complete, for the purpose of the primary NAAQS (section V.F); a change from truncation to rounding of multi-hour and multi-year average O<sub>3</sub> concentrations for the purposes of the primary standard (section V.G); and the addition of provisions addressing data to be used in making comparisons to the NAAQS (section V.H). The proposed revisions also include changes in organization for greater clarity and consistency with other data interpretation appendices to 40 CFR part 50, which are not further described in this preamble.

The EPA is also proposing changes to the O<sub>3</sub>-specific deadlines, in 40 CFR 50.14, by which states must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which states must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The O<sub>3</sub>-specific deadlines in the current 40 CFR 50.14 would not be appropriate given the anticipated schedule for the designations of areas under the proposed revised O<sub>3</sub> NAAQS.

#### *A. Background*

The purpose of a data interpretation appendix in general is to provide the practical details on how to make a comparison between multi-day and possibly multi-monitor ambient air concentration data and the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. Appendix P was promulgated in March 2008 along with the most recent revisions to the primary and secondary O<sub>3</sub> NAAQS. It is very similar to Appendix I, Interpretation of the 8-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone, which was adopted in 1997 when the O<sub>3</sub> NAAQS were first revised to have an 8-hour averaging period rather than the earlier 1-hour averaging period, along with other changes in form and level. The only substantive difference between Appendix I and the

current version of Appendix P is that Appendix P contains truncation procedures consistent with the additional decimal digit used to express the level of the 2008 NAAQS in parts per million (0.075 ppm) compared to the 1997 NAAQS (0.08 ppm). In July 2007, EPA had also proposed to include in Appendix P data interpretation procedures for the proposed cumulative, seasonal secondary O<sub>3</sub> NAAQS, but these procedures were not finalized given that the final secondary NAAQS was identical in all respects to the final primary NAAQS.

An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that are determined to have been affected by an exceptional event under the procedural steps and substantive criteria specified in section 50.14 may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS. The key procedural deadlines in section 50.14 are that a state must notify EPA that data have been affected by an event, *i.e.*, "flag" the data in the Air Quality Systems (AQS) database, and provide an initial description of the event by July 1 of the year after the data are collected, and that the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data, for example a designation action, is anticipated, the schedule is shortened and all information must be submitted to EPA no later than a year before the decision is to be made. This generic schedule presents problems when a NAAQS has been recently revised, as discussed in section V.I below. On May 15, 2009, EPA finalized a set of O<sub>3</sub>-specific deadlines that corrected these problems at the time with respect to the 2008 NAAQS revisions (74 FR 23307). However, because of the anticipated effect of the current reconsideration on the schedule for O<sub>3</sub> designations, the schedule problems will resurface unless the deadlines are adjusted again.

#### *B. Interpretation of the Secondary O<sub>3</sub> Standard*

The EPA is proposing data interpretation procedures for the proposed secondary O<sub>3</sub> NAAQS, which is defined in terms of a specific cumulative, seasonal form, commonly

referred to as the W126 form, as described above in section IV. The proposed new section 4 of Appendix P on data interpretation for the secondary standard contains the following main features.

The "design value" for the secondary standard, the statistic for a monitoring site which would be compared to the level of the secondary standard to determine if the site meets the standard, would be the average of the annual maximum values of the three-month index value from three calendar years.

The new section would provide clear directions and examples for the calculation of the daily index value, the monthly cumulative index value, the annual maximum index value for a year, and the design value itself.

Only the data from the required O<sub>3</sub> monitoring season would be examined to determine the annual maximum index value; any additional period of monitoring undertaken voluntarily by a state would not be considered. The EPA believes that because of the recently proposed extension of the required monitoring seasons in many states (74 FR 34525, July 16, 2009), as discussed below in section VI, such a period of voluntary monitoring would be unlikely to have such high index values as to affect the annual maximum index value. Moreover, the proposed required monitoring season may encompass the most active growing season in many areas. The EPA invites comment on whether instead the entire actual O<sub>3</sub> monitoring period should be considered, to eliminate any possibility that the highest cumulative index value that can be determined with available data might be missed.

For each month in a three-month period, O<sub>3</sub> data would have to be available for at least 75 percent of daylight hours (defined for this purpose as 8 a.m.–7:59 p.m. LST). If data are available for at least 75 percent but fewer than 100 percent of these daylight hours in a month, the cumulative index value calculated from the available daylight hours in the month would be increased to compensate for the missing hours, based on an assumption that the missing hours would have the same distribution of O<sub>3</sub> concentrations as the available hours. A substitution test is also proposed, by which months in which fewer than 75 percent of daylight hours have O<sub>3</sub> concentration data might also be useable for calculating a valid cumulative index value. Such months would be used if the available O<sub>3</sub> concentrations are so high that even substituting low concentration values for enough missing data to meet the 75 percent requirement would result in a

design value greater than the level of the standard. The low value that would be substituted would be the lowest 1-hour O<sub>3</sub> concentration observed at the monitoring site during daylight hours during the required O<sub>3</sub> monitoring season, in that calendar year, or one-half the method detection limit (MDL) of the ozone instrument, whichever is higher.<sup>63</sup>

The EPA notes that while this proposed approach to identifying the substitution value for the secondary standard is technically appropriate, it would necessitate data processing efforts during implementation that might be avoidable via some other approach that is also technically reasonable. We therefore invite comment on such alternative approaches, and we may adopt another approach in the final rule. For example, for simplicity the substituted 1-hour O<sub>3</sub> concentration value could instead simply always be zero or one-half the MDL of the O<sub>3</sub> instrument, noting that because of the sigmoidal weighting factor the exact magnitude of the low substitution value may typically make very little difference to the annual index value. Also, using the previous calendar year as the source of the substitution value instead of the current calendar year would have the advantage of allowing all parties to know early in each year what the substitution value will be.

The EPA is proposing that all decimal digits be retained in intermediate steps of the calculation of the cumulative index, with the result rounded to have no decimal digits when expressed in ppm-hours before comparison the level of the secondary NAAQS.

EPA expects that the three months over which the cumulative weighted index value is highest will generally occur in the middle of each year. Therefore, the proposed new section 4 of Appendix P presumes this, and does not address a situation in which the three months of maximum cumulative index spans two calendar years, for example December to February. The EPA invites comment on whether a provision addressing such a remote possibility is needed and what its terms

<sup>63</sup> Because only enough missing 1-hour ozone values would be substituted as needed to meet the 75 percent completeness requirement, to avoid unreasonable underestimation of the true W126 index, tying the selection of the substitution value to the hour of the missing value, as is proposed for data substitution for the purpose of the primary standard (see section V.D), would introduce considerable complexity by requiring an algorithm for determining which specific missing values would be substituted. Therefore, EPA is proposing this simpler substitution approach for the secondary standard.

should be. For example, the process of checking each three month period in a calendar year to determine which gives the highest index value could include the combinations of December/January/February and November/December/January within one calendar year.

#### C. Clarifications Related to the Primary Standard

The EPA is proposing two clarifying changes to Appendix P to make unambiguous two aspects of data interpretation for the primary 8-hour standard. The first change clarifies that the standard data completeness requirement that valid daily maximum 8-hour values exist for 75 percent of all days refers to days within the required O<sub>3</sub> monitoring season only. The current wording of Appendix P is somewhat open to a reading that the requirement applies to all days in the actual monitoring record for the site in question, which could be longer than the required season if a state voluntarily monitors on additional days, or shorter than the required season if a monitor has started or ceased operation sometime during the required season. The O<sub>3</sub> data completeness requirement is intended to avoid a determination that an area has met the NAAQS when in fact more than a reasonable number of days with high O<sub>3</sub> potential were not successfully monitored. This purpose can be served if the data within the required O<sub>3</sub> monitoring season only are reasonably complete, because as mentioned above EPA has proposed to revise the required O<sub>3</sub> seasons so that they encompass all days with potential for an exceedance of even the lowest proposed level for the primary standard. Unsuccessful monitoring outside the required season should not be an obstacle to a finding of attainment. However, if an O<sub>3</sub> monitor has missed more than 25 percent of the required O<sub>3</sub> monitoring season, for example because it started or stopped operation mid-season, this should prevent a finding of attainment based on a three-year period that includes that season. The proposed clarifying language reflects EPA's actual intention and our past practice in applying Appendix P for regulatory purposes, and Appendix I as well.<sup>64</sup>

<sup>64</sup> At present, EPA's Air Quality System (AQS) for storing and reporting air quality data provides a completeness report that is based on yet a third approach, in which the period for reporting data completeness is the required monitoring season plus any extension needed to encompass any exceedances that may have occurred outside the required season. However, EPA's practice for regulatory purposes has been to consider completeness only over the required ozone monitoring season.

The second proposed clarifying change would make it clear that when determining the fourth-highest daily maximum 8-hour O<sub>3</sub> concentration for a year, all days with monitoring data are to be considered, not just days within the required O<sub>3</sub> monitoring season. This proposed clarifying language also reflects EPA's actual intention and our past practice in applying Appendix P, and Appendix I as well. While EPA believes it to be quite unlikely that an exceedance will occur outside the proposed revised required O<sub>3</sub> monitoring seasons and have a high enough concentration to affect the selection of the fourth-highest concentration for the year, when and if such an occurrence does happen, the data should not be ignored.

#### *D. Revision to Exceptions From Standard Data Completeness Requirements for the Primary Standard*

The EPA is proposing to revise portions of Appendix P that describe certain exceptions to the standard data completeness requirements, under which a monitoring site can in some cases be determined to be meeting or violating the primary NAAQS despite not meeting the standard data completeness requirements. These changes would make Appendix P more logical in certain types of cases with incomplete data. While the particular types of cases whose outcome would be different with these changes have been rare historically, there may be more such affected cases in the future in conjunction with a primary O<sub>3</sub> standard revised to a level within the range of levels proposed in this action.

The standard data completeness requirements in Appendix P for the primary O<sub>3</sub> NAAQS apply a 75 percent requirement at each of three stages of data completeness testing. As discussed below, for each stage, there is an existing exception to the 75 percent requirement.

In the first stage, an 8-hour period can be considered to have a valid 8-hour average O<sub>3</sub> concentration only if at least 75 percent of the hours, *i.e.*, 6 or more hours, have a valid hourly O<sub>3</sub> value. The provided exception is that if there are 5 or fewer hours but if substituting a very low value (specifically, one-half the MDL of the O<sub>3</sub> instrument) for all the missing hours results in a hypothetical 8-hour average that is above the level of the primary standard, the 8-hour period is considered valid and is assigned the hypothetical level resulting from the data substitution.<sup>65</sup> For example, if the

O<sub>3</sub> concentration was 0.125 ppm for 5 hours, substituting a typical MDL/2 value of 0.0025 ppm for three missing hours would result in an 8-hour average of 0.079 ppm, which is an exceedance of the current primary standard, so the valid 8-hour average for the period would be taken to be 0.079 ppm. If this value is higher than one or more of the highest four daily maximum 8-hour concentrations otherwise calculated for the year, considering it to be valid affects the value identified as the fourth-highest for the year and thus also affects the final design value. The logical problem with this approach is that it is possible for a hypothetical 8-hour average with such substitution to be below the level of the NAAQS, thus not meeting the current condition for the exception, but for it to still make a critical difference in making the three-year design value be above the level of the NAAQS, because a three-year design value can include (and be sensitive to the exact value of) an annual fourth-highest daily maximum that is not above the level of the NAAQS. This could be the case if the hypothetical 8-hour average with substitution is the maximum concentration 8-hour period for its day, and the day is one of the highest four O<sub>3</sub> days of the year. Whether it actually is the case would further depend on the value of the 8-hour average itself, the values of the next highest daily maximum 8-hour average concentration in the year, and the values of the annual fourth-highest daily maximum 8-hour concentration from the other two years. If the substituted 8-hour average would make a critical difference, it should be treated as valid and used in the calculation of the three-year design value, even if it is not itself above the level of the standard. Another problem is that one-half of the MDL, which typically is about 0.0025 ppm, is very likely to be considerably lower than the actual O<sub>3</sub> concentrations that were not successfully measured. Thus, while the one-half-MDL-substituted value is prevented from being an overestimate of the actual 8-hour average concentration, it is an unreasonably low estimate of that concentration which may have the effect of allowing a site with actual O<sub>3</sub> levels above the standard to be found to meet the standard. The condition in the exception requiring a one-half-MDL-substituted "8-hour" average to be above

<sup>65</sup> from the data substitution is to be taken as the "8-hour" average, rather than the average of the available 5 or fewer hours of data, which would be higher. The text is not entirely clear on this point.

the level of the NAAQS is therefore inappropriate.

In the second stage of data completeness testing, 75 percent of the 24 possible 8-hour time blocks, which is 18 or more, must have valid 8-hour average concentrations values. The intent of this requirement is to make sure that most of the day was actually monitored, such that the highest concentration 8-hour period was likely to be captured in the data. When this is not the case, the day is not considered in selecting the annual fourth-highest daily maximum 8-hour concentration and no credit for the day's monitoring is given towards the third stage of data interpretation (see below). The provided exception in the current Appendix P is that a day is considered valid if at least one 8-hour period has an average concentration above the level of the standard. However, as in the first stage, it is possible for an 8-hour period with an average concentration at or below the level of the NAAQS to play a critical role in whether the three-year design value meets the standard. Invalidating the day could have the effect of causing a lower value to be selected as the annual fourth-highest daily maximum 8-hour concentration, leading to a three-year design value that does not exceed the NAAQS while it would have exceeded if the day and the 8-hour average value had been treated as valid. The condition in the exception requiring at least one 8-hour average during the day to be above the level of the NAAQS is therefore inappropriate.

In the third stage of data completeness testing, a completeness criterion is applied for the number of days in the required O<sub>3</sub> season that have a valid maximum 8-hour average, *i.e.*, days that have met the completeness conditions in the first two stages or have met the condition for an exception. Specifically, for each of the three years being used in the design value calculation, the number of valid days within the required O<sub>3</sub> monitoring season (with no credit for extra days outside the season) must be at least 75 percent of the days in the required O<sub>3</sub> season, and the number of valid days across all three years must be 90 percent of the days in the three seasons.<sup>66</sup> The provided exception to the 75/90 percent requirement is that data from a year with less than 75 percent of seasonal days can nevertheless be used if during the year at least one day's maximum 8-hour average O<sub>3</sub> concentration was

<sup>66</sup> EPA also is proposing eliminate this 90 percent requirement, see section V.E. The point made in this paragraph applies with or without the 90 percent requirement in place.

<sup>65</sup> Actually, it is an interpretation of the text of Appendix P, section 2.1, that the average resulting

above, the level of the standard and if the three-year design value is also above the standard.<sup>67</sup> The problem with this exception, similar to the problems with the exceptions in the first and second stages of data completeness testing, is that a daily maximum 8-hour concentration that is at or below the level of the NAAQS can nevertheless make a critical difference in making the three-year design value be above the level of the NAAQS. When it does, an incorrect final result will be reached if the year of data is not granted an exception to the 75/90 percent requirement. Specifically, there would be no valid three-year design value and no conclusion would be reached as to attainment or nonattainment, despite it being clear that the actual situation is nonattainment, in the sense that successful collection of additional hours and days of monitoring data could not possibly have resulted in a passing three-year design value. Moreover, since the three-year design value is the average of the fourth-highest daily maximum 8-hour concentration from each year, there is no logical connection between the design value and the existence of a single daily maximum concentration greater than the level of the standard, which is the current condition for the exception for this stage of testing for data incompleteness.

EPA proposes to remedy this situation by replacing the three separate statements of the exceptions to the three standard completeness requirements with a new data substitution step that addresses the root cause of the data incompleteness situation: missing hourly concentrations which make it doubtful whether actual maximum daily 8-hour concentrations were measured on a reasonably large percentage of the days during the required O<sub>3</sub> monitoring season of each year. In the event that only 1, 2, 3, 4, or 5 hourly averages are available for an 8-hour period, a partially substituted 8-hour average would be computed by substituting for all the hours without hourly averages a low hourly average value selected as follows, and then using 8 as the divisor.<sup>68</sup> For days within the required O<sub>3</sub> monitoring season, the substitution

value would be the lowest hourly average O<sub>3</sub> concentration observed for that hour of the day (local standard time) on any day during the required O<sub>3</sub> monitoring season of that year, or one-half the MDL, whichever is higher. Using this value makes it highly unlikely that the resulting partially substituted 8-hour average concentration is higher than the actual concentration. Therefore, using the partially substituted 8-hour average in the design value calculation procedure is highly unlikely to result in an incorrect finding that a site does not meet the standard, but it may lead to a correct finding that a site does not meet the standard in some cases in which there would be no finding possible or an incorrect finding under the current version of Appendix P. However, the use of the higher of the lowest observed same-hour concentration or one-half the MDL could be problematic if a robust set of hourly measurements is not available for the year, for example if a monitor began operation late in an ozone season. In such a case, the lowest observed same-hour concentration might not be low enough to eliminate all possibility that the value used for substitution is higher than the missing concentration value. To reduce this likelihood to essentially zero, we are proposing that if the number of same-hour concentration values available for the required O<sub>3</sub> monitoring season for the year is less than 50 percent of the number of days during the required O<sub>3</sub> monitoring season, one-half the MDL of the O<sub>3</sub> instrument would be used in the substitution instead of the lowest observed concentration. We invite comment on whether another percentage should be used for this purpose instead of 50 percent.

The EPA notes that while this proposed approach to identifying the substitution value for the primary standard is technically appropriate, it would necessitate new data processing efforts during implementation that might be avoidable via some other approach that is also technically reasonable. There may also be approaches which are more technically appropriate. We therefore invite comment on such alternative approaches, and we may adopt another approach in the final rule. Examples of simpler approaches would be to identify in the final rule a fixed substitution value other than one-half the MDL, to accept as valid 8-hour periods with only five measured hourly concentrations, to interpret between two hourly concentrations to obtain a substitute for a single missing hourly concentration,

or to use the previous calendar year as the source of the substitution value instead of the current calendar year (thereby allowing all parties to know early in each year what the substitution value will be). Examples of more complex approaches that might be more technically appropriate include selecting a low percentile of the available same-hour concentration data rather than the lowest value to be the substitution value, or selecting the lowest same-hour value from the same calendar quarter or month (of the current year or the most recent year) rather than from the entire required ozone monitoring season. We also invite comment on whether the proposed approach to substitution should be used at all and if not what other approach should be used to address the potential problem just described.

We propose that for simplicity and to further reduce any risk of a false finding that a site does not meet the standard, for days outside the required O<sub>3</sub> monitoring season, the substitution value would always be one-half the MDL of the O<sub>3</sub> instrument. We similarly invite comment on this aspect.

There would be no condition that a partially substituted 8-hour average exceed the level of the standard for it be used in calculating the design value, unlike is now the case. An 8-hour period with no available hourly averages at all would not have a valid 8-hour average, as is now the case.

In addition, to complete the solution to the problems described above, we are proposing that a design value that is greater than the level of the primary standard would be valid provided that in each year there were at least four days with at least one valid 8-hour concentration.<sup>69</sup> One or more of these 8-hour average concentrations could be the partially substituted 8-hour average concentration resulting from the above described substitution procedure. In such a case, there is essentially no possibility that more complete monitoring data would have shown the site to be meeting the NAAQS. It is appropriate to include all 8-hour averages including those involving substitution when testing for an exceedance of the standard, because those averages are extremely unlike to

<sup>67</sup> EPA notes that in the current versions of Appendix J and P, it is not explicit that this provided exception also applies in the case of three years which each have 75 percent or more of days with valid data but less than 90 percent across three years. Because EPA is proposing to remove the 90 percent requirement (see section V.E) this ambiguity does not need correction.

<sup>68</sup> Appendix P now provides that in the event that only 6 or 7 hourly averages are available, the valid 8-hour average shall be computed on the basis of the hours available, using 6 or 7 as the divisor. We are not proposing to change this provision.

<sup>69</sup> The requirement that there be at least four days with at least one hourly measurement is actually redundant and is stated only for ease of understanding, since there would be no annual fourth-highest daily maximum 8-hour concentration unless there are at least four days with monitoring data, and a single hourly data point is necessary and sufficient (with the proposed substitution step) to generate a daily maximum 8-hour concentration.



be overestimates of actual concentrations.

Finally, a design value equal to or less than the level of the standard would be valid only if at least 75 percent of the days in the required O<sub>3</sub> monitoring season of each year have daily maximum 8-hour concentrations that are based on at least 18 periods with at least 6 hourly concentrations. This ensures that a site will be found to meet the standard only when a reasonably high percentage of the days in the required O<sub>3</sub> monitoring season have reasonably complete hourly data. In this situation, it would be inappropriate to count the 8-hour periods with five or fewer actual hourly measurement values towards the 75 percent requirement when testing for whether a site meets the standard, because those 8-hour averages will be based on substitution of low values and therefore will be underestimates of actual concentrations. The only way to be reasonably certain that no 8-hour period had a high enough concentration so as to contribute to a design value over the level of the standard is to have at least 18 periods in which substitution for missing O<sub>3</sub> values was not needed. This provision has the same effect as several elements of the current Appendix P considered together, and thus is not a substantive change.

#### *E. Elimination of the Requirement for 90 Percent Completeness of Daily Data Across Three Years*

As stated above in section VI.D, Appendix P currently requires that in order for a design value equal to or less than the standard to be valid, at least 75 percent of days in each of three years must have a valid daily maximum 8-hour average concentration value, *i.e.*, that many days must have at least 18 8-hour periods with at least 6 reported hourly concentrations each. Appendix P also requires that the average of the percentages from three consecutive years be at least 90 percent. The EPA is proposing to eliminate this 90 percent requirement for the average of three years and to retain only the requirement that each individual year have a percentage of at least 75 percent.

The 90 percent requirement was incorporated into Appendix I (the data interpretation appendix for the 0.08 ppm O<sub>3</sub> NAAQS) in 1997 with an explanation that EPA had observed that 90 percent of O<sub>3</sub> monitoring sites routinely achieved 90 percent data capture. The EPA now notes, however, that while the majority of monitoring sites do achieve 90 percent or better data capture in any given year, there are exceptions every year. The 90 percent

requirement applied to the average percentage over three years is quite unforgiving if there has been one year with relatively low data completeness. For example, if one year just met the 75 percent requirement, the remaining two years would have to achieve a 97.5 percent data capture rate in order for the three years to meet the 90 percent requirement. This would allow only 4 missed hours of measurements per week, which would be challenging. The consequences for states could be important, under the current requirement. One possible result could be that an area actually in nonattainment with the NAAQS might have to be designated unclassifiable, although the substitution procedure proposed for cases of incomplete data, as described above in section VI.D, provides a path to an appropriate nonattainment finding in at least some cases. Another possible result is that a nonattainment area which had actually come into attainment could be unable to receive an attainment determination until three more years of sufficiently complete data are collected. This might, for example, result in an area which has achieved needed emissions reductions by its attainment deadline nevertheless being bumped up to a higher classification.

The 90 percent requirement over three years has the potential to treat two areas disparately, for no obvious logical reason. Consider two areas with identical air quality. Suppose the first area has annual completeness percentages of 75, 95, and 95 percent (averaging to 85 percent and thus failing the 90 percent requirement) and the second area has annual completeness percentages of 75, 98, and 98 percent (averaging to 90 percent). Suppose that the three-year design values in both areas are below the level of the NAAQS. Practically speaking, the most important uncertainty about whether each area actually meets the NAAQS is the low data capture rate in the first year. There is no obvious logic why the fact that the second area achieves marginally better data capture in the second and third year should permit it to receive an attainment finding despite this uncertainty, while the first area may not.

The EPA also notes that for the other gaseous criteria pollutants—sulfur dioxide, carbon monoxide and nitrogen dioxide—the completeness requirement is for 75 percent completeness of hourly measurements in an individual year.<sup>70</sup>

<sup>70</sup> EPA has recently proposed to amend the completeness requirements for sulfur dioxide and nitrogen dioxide to add quarterly 75 percent

For these reasons, EPA proposes to eliminate the 90 percent requirement across three years of data but to retain the 75 percent requirement for individual years. The EPA notes that as a practical matter, the current 90 percent requirement in effect requires a minimum data capture rate somewhat above 75 percent in each year, because if data capture in any one year were as low as 75 percent the required data capture in the other years would be very hard to achieve. The minimum annual data capture rate is effectively somewhere in the range of 80 percent (implying a requirement to achieve 95 percent data capture in the two remaining years in order to meet the 90 percent requirement across three years) and 85 percent (implying a requirement to achieve 92.5 percent data capture in the two remaining years). The EPA invites comment on whether instead of retaining the 75 percent completeness requirement in each individual year, the requirement should be 80 percent or 85 percent.

#### *F. Administrator Discretion To Use Incomplete Data*

The EPA is proposing that the Administrator have general discretion to use incomplete data to calculate design values that would be treated as valid for comparison to the NAAQS despite the incompleteness, either at the request of a state or at her own initiative. Similar provisions exist already for the PM<sub>2.5</sub> and lead NAAQS, and EPA has recently proposed such provisions to accompany the proposed 1-hour NO<sub>2</sub> and SO<sub>2</sub> primary NAAQS. The Administrator would consider monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

#### *G. Truncation Versus Rounding*

Almost all State agencies now report hourly O<sub>3</sub> concentrations in parts per million to three decimal places, since the typical incremental sensitivity of currently used O<sub>3</sub> monitors is 0.001 ppm. In the current Appendix P approach, in calculating 8-hour average O<sub>3</sub> concentrations from such hourly data any calculated digits past the third decimal place are truncated rather than retained or rounded back to three decimal places. Also, in calculating 3-year averages of the fourth-highest daily maximum 8-hour average concentrations, Appendix P currently requires the result to be reported to the

completeness requirements in connection with proposals to establish 1-hour primary NAAQS for these pollutants, still with no requirement for 90 percent completeness across three years.

third decimal place with digits to the right of the third decimal place truncated. In this regard, Appendix P follows the precedent of Appendix I, except that Appendix P is based on a NAAQS level specified to three decimal places (0.075 ppm) while Appendix I addressed the case of a NAAQS level specified to only two decimal places (0.08 ppm). In the rulemaking that concluded in 2008 by establishing the 0.075 ppm level, EPA noted that the 2007 Staff Paper demonstrated that taking into account the precision and bias in 1-hour O<sub>3</sub> measurements, the 8-hour design value had an uncertainty of approximately 0.001 ppm. Thus, EPA considered any value less than 0.001 ppm to be highly uncertain and, therefore, proposed and adopted truncation to the third decimal place for reporting 1-hour O<sub>3</sub> concentrations and for both the individual 8-hour averages used to determine the annual fourth maximum and the 3-year average of the fourth maxima.

The effect of this repeated truncation is that there is a consistent downward bias in the calculation of the three-year design value. The size of this bias can be notable. For example, seven hours with O<sub>3</sub> concentrations of 0.076 ppm plus one hour of 0.075 ppm results in an 8-hour average of 0.075 ppm after truncation, nearly a full 0.001 ppm below the actual 8-hour average of 0.075875 ppm. Seven hours with O<sub>3</sub> concentrations of 0.077 ppm plus one hour of 0.076 ppm results in an 8-hour average of 0.076 ppm after truncation. One year with the first pattern plus two years with the second pattern would give a three-year design value of 0.075 ppm, meeting the NAAQS, even though 23 of the 24 individual 1-hour concentrations involved in the calculation of the design value were above 0.075 ppm.

The EPA has decided to reconsider this aspect of O<sub>3</sub> data interpretation. Specifically, we are proposing that (1) 1-hour concentrations continue to be reported to only three decimal places, the same as is now specified in Appendix P, *i.e.*, that the current practice of truncation of the 1-hour data to the nearest 0.001 ppm be retained; (2) all digits resulting from the calculation of 8-hour averages be retained; and (3) the three-year average of annual fourth-highest daily maximum 8-hour concentrations be rounded to three decimal places before comparison to the NAAQS. The EPA continues to believe that given the uncertainty in individual 1-hour O<sub>3</sub> concentration measurements it is appropriate to truncate those measurements at three decimal places (many O<sub>3</sub> instruments are programmed

to only report three digits anyway). However, the calculations of 8-hour averages and three-year averages are mathematical steps, not a measurement process subject to uncertainties, and EPA perceives no logic in having a consistent downward bias by truncating the results of these mathematical steps. The EPA notes that the O<sub>3</sub> NAAQS is the only NAAQS for which multi-hour, multi-day, or multi-year averages of concentrations are truncated rather than rounded. The proposed change will make this aspect of O<sub>3</sub> data interpretation consistent with data interpretation procedures for the other criteria pollutants.

#### H. Data Selection

The current version of Appendix P does not explicitly address the issue of what ambient monitoring data for O<sub>3</sub> can and must be compared to the O<sub>3</sub> NAAQS. The EPA proposes to add to Appendix P language addressing this issue. This language is similar to provisions recently proposed to be included in new data interpretation appendices for nitrogen dioxide and sulfur dioxide. The new section of Appendix P would clarify that all quality assured data collected with approved monitoring methods and known to EPA shall be compared to the NAAQS, even if not submitted to EPA's Air Quality System. The section also addresses the question of what O<sub>3</sub> data should be used when two or more O<sub>3</sub> monitors have been operating and have reported data for the same period at one monitoring site.

#### I. Exceptional Events Information Submission Schedule

States are responsible for identifying air quality data that they believe warrant special consideration, including data affected by exceptional events. States identify such data by flagging (making a notation in a designated field in the electronic data record) specific values in the Air Quality System (AQS) database. States must flag the data and submit a justification that the data are affected by exceptional events if they wish EPA to consider excluding the data in determining whether or not an area is attaining the new O<sub>3</sub> NAAQS.

All states that include areas that could exceed the O<sub>3</sub> NAAQS and could therefore be designated as nonattainment for the O<sub>3</sub> NAAQS have the potential to be affected by this rulemaking. Therefore, this action applies to all states; to local air quality agencies to which a state has delegated relevant responsibilities for air quality management including air quality monitoring and data analysis; and to

Tribal air quality agencies where appropriate. The Exceptional Events Rule preamble describes in greater detail to whom the rule applies (72 FR 13562–13563, March 22, 2007).

The CAA Section 319(b)(2) authorizes EPA to promulgate regulations that govern the review and handling of air quality monitoring data influenced by exceptional events. Under this authority, EPA promulgated the Exceptional Events Rule (Treatment of Data Influenced by Exceptional Events (72 FR 13560, March 22, 2007) which sets a schedule for states to flag monitored data affected by exceptional events in AQS and for them to submit documentation to demonstrate that the flagged data values were caused by an exceptional event. Under this schedule, a state must initially notify EPA that data have been affected by an exceptional event by July 1 of the year after the data are collected; this is accomplished by flagging the data in AQS. The state must also include an initial description of the event when flagging the data. In addition, the state is required to submit a full demonstration to justify exclusion of such data within three years after the quarter in which the data were collected, or if a regulatory decision based on the data (such as a designation action) is anticipated, the demonstration must be submitted to EPA no later than one year before the decision is to be made.

The rule also authorizes EPA to revise data flagging and documentation schedules for data used in the initial designation of areas under a new NAAQS. The generic schedule, while appropriate for the period after initial designations have been made under a NAAQS, may need adjustment when a new NAAQS is promulgated because until the level and form of the NAAQS have been promulgated, a state would not have complete knowledge of the criteria for excluding data. In these cases, the generic schedule may preclude states from submitting timely flags and associated documentation for otherwise approvable exceptional events. This could, if not modified, result in some areas receiving a nonattainment designation when the NAAQS violations were legitimately due to exceptional events.

As a result of the Administrator's decision to reconsider the 2008 O<sub>3</sub> NAAQS, EPA is proposing to revise the exceptional events flagging and documentation schedule to correspond to the designations schedules that EPA is considering for the proposed revisions to the primary and secondary O<sub>3</sub> NAAQS. The designation schedules

under consideration are discussed in greater detail below in section VII.A and summarized here. The CAA requires EPA to promulgate the initial designations for all areas no later than 2 years from the promulgation of a new NAAQS. Such period may be extended for up to one year if EPA has insufficient information. (See CAA section 107(d).) For a new primary O<sub>3</sub> standard, EPA intends to issue designations on an accelerated schedule. For a new seasonal secondary O<sub>3</sub> standard, EPA is considering two alternative schedules for initial area designations.

**Primary Standard:** If, as a result of the reconsideration, EPA promulgates a new primary O<sub>3</sub> standard on August 31, 2010, EPA is proposing that state Governors would need to submit their initial designation recommendations to EPA by January 7, 2011. EPA would promulgate the final designations in July 2011 to allow sufficient time for the designations to be published and effective by August 31, 2011. EPA expects to base the final designations for the primary O<sub>3</sub> standard on three consecutive years of certified air quality monitoring data from the years 2007–2009 or 2008–2010, if available. EPA is proposing that for exceptional event claims made for data years 2007–2009, states must flag and provide an initial description and detailed documentation by November 1, 2010. For data collected during data year 2010, EPA is proposing that exceptional event data that states want EPA to exclude from consideration in the designations process must be

flagged with an initial description and fully documented by March 1, 2011 or 60 days after the end of the quarter when the event occurred, whichever date is first. To meet this proposed 60-day deadline, a state would also have to submit the O<sub>3</sub> concentration data to AQS sooner than the normal deadline for such submission, which is 90 days after the end of the calendar quarter. EPA believes this is a reasonable expectation given that most states currently submit O<sub>3</sub> data earlier than the 90-day deadline.

**Secondary Standard:** If, as a result of the reconsideration, EPA promulgates a new seasonal secondary O<sub>3</sub> standard by August 31, 2010, EPA is taking comment on two alternative designations schedules. Under the first alternative, EPA would designate areas for the secondary standard on the same accelerated schedule discussed above for the primary standard. Under the second alternative, EPA would designate areas for the secondary standard on the maximum 2-year schedule provided under the CAA. **Accelerated Schedule:** Under the accelerated schedule for a seasonal secondary O<sub>3</sub> NAAQS, EPA is proposing that for exceptional event claims made for data years 2007–2009, states must flag and provide an initial description and detailed documentation by November 1, 2010. For data collected during data year 2010, EPA is proposing that exceptional event data that states want EPA to exclude from consideration in the designations process must be flagged with an initial description and

fully documented by March 1, 2011 or 60 days after the end of the quarter when the event occurred, whichever date is first.

**2-year Schedule:** Under the 2-year schedule, states would have 1 year, or by August 2011, to submit their designations recommendations and EPA would finalize designations under the new secondary standard by August 2012. EPA expects to base final designations for a new seasonal secondary standard on the most recent three years of certified air quality monitoring data, which would typically be from the years 2009–2011 in this case. Exceptional event data claims used from years 2008–2010 must be flagged with an initial description included in AQS and submitted with complete documentation supporting such claims by July 1, 2011. Exceptional event data claims from data year 2011 must be flagged with an initial description and submitted with complete documentation supporting such claims 60 days after the end of the calendar quarter when the event occurred or March 1, 2012, whichever occurs first.

Therefore, using the authority provided in CAA section 319(b)(2) and in the Exceptional Events Rule at 40 CFR 50.14(c)(2)(vi), EPA is proposing to modify the schedule for data flagging and submission of demonstrations for exceptional events data considered for initial designations under the proposed reconsidered O<sub>3</sub> primary and secondary NAAQS, as follows:

TABLE 1—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW NAAQS

NAAQS Pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
Primary Ozone/8-Hr Standard (Level TBD)/promulgated by August 31, 2010.	2007–2009	November 1, 2010 <sup>b</sup> .....	November 1, 2010. <sup>b</sup>
	2010	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>
Secondary Ozone/(Level TBD) Alternative 2-year Schedule—to be promulgated by August 31, 2010.	2008	July 1, 2011 <sup>b</sup> .....	July 1, 2011. <sup>a</sup>
	2009–2010 2011	July 1, 2011 <sup>b</sup> .....	July 1, 2011. <sup>b</sup> 60 Days after the end of the calendar quarter in which the event occurred or March 1, 2012, whichever occurs first. <sup>b</sup>
Secondary Ozone/(Level TBD)—Alternative Accelerated Schedule—to be promulgated by August 31, 2010.	2007–2009	November 1, 2010 <sup>b</sup> .....	November 1, 2010. <sup>b</sup>
	2010	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>

<sup>a</sup> These dates are unchanged from those published in the original rulemaking.

<sup>b</sup> Indicates change from general schedule in 40 CFR 50.14.

**Note:** EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

## VI. Ambient Monitoring Related to Proposed O<sub>3</sub> Standards

Presently, States (including the District of Columbia, Puerto Rico, and the Virgin Islands, and including local agencies when so delegated by the State) are required to operate minimum numbers of EPA-approved O<sub>3</sub> monitors based on the population of each of their Metropolitan Statistical Areas (MSA) and the most recently measured O<sub>3</sub> levels in each area. Each State (or in some cases portions of a State) also has a required O<sub>3</sub> monitoring season based on historical experience on when O<sub>3</sub> levels are high enough to be of regulatory or public health concern. These requirements are contained in 40 CFR part 58 Appendix D, Network Design Criteria for Ambient Air Quality Monitoring. See section 4.1, especially Tables D-2 and D-3. These requirements were last revised on October 17, 2006 as part of a comprehensive review of ambient monitoring requirements for all criteria pollutants (71 FR 61236).

### A. Background

In the 2007 proposed rule for the O<sub>3</sub> NAAQS (72 FR 37818), EPA did not propose specific changes to monitoring requirements to support the proposed NAAQS revisions, but instead solicited comment on several key matters that were expected to be important issues affecting the potential redesign of monitoring networks if revisions to the NAAQS were finalized. These matters included O<sub>3</sub> monitoring requirements in urban areas, the potential need for monitoring to support multiple objectives important to characterization in non-urban areas including the support of the secondary O<sub>3</sub> NAAQS, and the length of the required O<sub>3</sub> monitoring seasons. Comments on these monitoring issues were received during the ensuing public comment period, and these comments were summarized in the 2008 final rule for the O<sub>3</sub> NAAQS (73 FR 16501). As noted in that action, EPA stated its intention to propose, in a separate rulemaking, the specific changes to O<sub>3</sub> monitoring requirements that were deemed necessary to support the revised 2008 O<sub>3</sub> NAAQS which set the level of the primary 8-hour O<sub>3</sub> standard to 0.075 ppm and set the secondary standard identical in all respects to the primary standard. EPA published these proposed changes to O<sub>3</sub> monitoring requirements in a proposal dated July 16, 2009, Ambient Ozone

Monitoring Regulations: Revisions to Network Design Requirements (74 FR 34525). The EPA currently plans to finalize these changes in a final O<sub>3</sub> monitoring rule in 2010, either before or in conjunction with the final rule on the O<sub>3</sub> NAAQS.

In the following sections, the specific provisions of the 2009 O<sub>3</sub> monitoring proposal are briefly reviewed, and then discussed in the context of the proposed revisions of the 2008 O<sub>3</sub> NAAQS that have been discussed earlier in this notice.

### B. Urban Monitoring Requirements

As noted earlier, current O<sub>3</sub> monitoring requirements for urban areas are based on two factors: MSA population and the most recent 3-year design value concentrations within each MSA. There are higher minimum monitoring requirements for areas that have most recent design values greater than or equal to 85 percent of the NAAQS (*i.e.*, design value concentrations that are greater than or equal to 85 percent of the level of the NAAQS), and lower requirements for areas that have design values less than 85 percent of the NAAQS. These minimum monitoring requirements for O<sub>3</sub> were revised during the 2006 monitoring rulemaking to ensure that additional monitors would be required in areas with higher design values and to also ensure that these requirements would remain applicable through future NAAQS reviews and potential revisions of the standards. Accordingly, these requirements do not need to be updated with the revisions of the O<sub>3</sub> NAAQS proposed in this action since the 85 percent threshold will be applied to the standard levels that are finalized for the primary and secondary standards.<sup>71</sup> For example, given the range of levels of the primary standard being proposed, the level of the 85 percent threshold that requires greater minimum monitoring requirements ranges from 0.051 ppm (85 percent of 0.060 ppm) to 0.060 ppm (85 percent of 0.070 ppm).

EPA did propose one change to urban monitoring requirements in the 2009 O<sub>3</sub>

<sup>71</sup> The requirements specified in Table D-2 of Appendix D to part 58, as noted in the third footnote of Table D-2, are applicable to the levels of the O<sub>3</sub> NAAQS as defined in 40 CFR part 50. Accordingly, the 85 percent threshold for requiring higher minimum monitoring requirements within MSAs would apply to the proposed levels for the cumulative, seasonal secondary standard as well as to the proposed levels of the 8-hour primary standard.

monitoring proposal. Specifically, EPA proposed to modify the minimum O<sub>3</sub> monitoring requirements to require one monitor to be placed in MSAs of populations ranging from 50,000 to less than 350,000 in situations where there is no current monitor and no history of O<sub>3</sub> monitoring within the previous 5 years indicating a design value of less than 85 percent of the revised NAAQS.<sup>72</sup> Since this proposed change to minimum requirements is also subject to the 85 percent threshold, EPA believes that the proposed change remains appropriate to support the revisions to the primary and secondary O<sub>3</sub> NAAQS proposed in this action.

### C. Non-Urban Monitoring Requirements

In the 2007 proposed rule for the O<sub>3</sub> NAAQS, EPA solicited comment on the status of monitoring requirements for non-urban areas, specifically whether non-urban areas with sensitive vegetation that are only currently sparsely monitored for O<sub>3</sub> could experience undetected violations of the secondary NAAQS as a result of transport from urban areas with high precursor emissions and/or O<sub>3</sub> concentrations or from formation of additional O<sub>3</sub> from precursors emitted from sources outside urban areas.

Comments that were received in response to the 2009 O<sub>3</sub> NAAQS monitoring proposal noted the voluntary nature of most non-urban O<sub>3</sub> monitoring and the resulting relative lack of non-urban O<sub>3</sub> monitors in some areas. These commenters stated that EPA should consider adding monitoring requirements to support the secondary NAAQS by requiring O<sub>3</sub> monitors in locations that contain O<sub>3</sub>-sensitive plants or ecosystems. These commenters also noted that the placement of current O<sub>3</sub> monitors may not be appropriate for evaluating issues such as vegetation exposure since many of these monitors were likely located to meet other objectives.

Based on these comments as well as analyses of O<sub>3</sub> concentrations from discretionary non-urban monitors located across the U.S., EPA included new proposed non-urban O<sub>3</sub> monitoring requirements in the 2009 O<sub>3</sub> monitoring proposal. These proposed requirements are intended to satisfy several important objectives including: (1) Better characterization of O<sub>3</sub> concentrations to which O<sub>3</sub>-sensitive vegetation and

<sup>72</sup> These MSAs are not currently required to monitor for O<sub>3</sub>.

ecosystems are exposed in rural/remote areas to ensure that potential secondary NAAQS violations are measured; (2) assessment of O<sub>3</sub> concentrations in smaller communities located outside of the larger urban MSAs covered by urban monitoring requirements; and (3) the assessment of the location and severity of maximum O<sub>3</sub> concentrations that occur in non-urban areas and may be attributable to upwind urban sources. For reasons noted below, EPA believes that these proposed O<sub>3</sub> monitoring requirements are sufficient to support the revisions to the O<sub>3</sub> NAAQS proposed in this action.

With regard to the first objective, we note uncertainties will remain about the O<sub>3</sub> concentrations to which sensitive natural vegetation and ecosystems are exposed until additional monitors are sited in National Parks, State and/or tribal areas, wilderness areas, and other similar locations with sensitive ecosystems that are set aside to provide similar public welfare benefits. These monitors would support evaluation of the secondary NAAQS with a more robust data set than is now available. As noted in the 2009 O<sub>3</sub> monitoring proposal, EPA proposed that States operate at least one monitor to be located in areas such as some Federal, State, Tribal, or private lands, including wilderness areas that have O<sub>3</sub>-sensitive natural vegetation and/or ecosystems. If EPA finalizes a cumulative, seasonal secondary standard at the lower end of the proposed range, then it is plausible that additional O<sub>3</sub> monitors, above the number required by the monitoring proposal, may be needed in such areas to provide adequate coverage of locations likely to experience violations of the revised secondary NAAQS. These additional monitors could be established through discretionary State initiatives to supplement minimum monitoring requirements, negotiated agreements between States and EPA Regional Administrators, or through a future rulemaking that addresses potential increased O<sub>3</sub> monitoring requirements to specifically address the need for additional monitoring to ensure detection of secondary standard violations.

With regard to the second objective of characterizing elevated ambient O<sub>3</sub> levels to which people are exposed in smaller communities located outside of the larger urban MSAs, the likelihood of measuring concentrations that approach or exceed the levels of the NAAQS due to the transport of O<sub>3</sub> from upwind areas and/or the formation of O<sub>3</sub> due to precursor emissions from industrial sources outside of urban areas is clearly increased due to the revised NAAQS

proposed in this action. Given that the analyses described in the 2009 O<sub>3</sub> monitoring proposal demonstrated that 50 percent of existing monitors located in such Micropolitan Statistical Areas<sup>73</sup> exceeded the current NAAQS and nearly all monitors recorded design values greater than or equal to 85 percent of the current NAAQS, the potential for violations in such areas can only be increased with the NAAQS revisions proposed in this action. As noted for the first non-urban monitoring objective, it is plausible that additional O<sub>3</sub> monitors, above the number required by the 2009 monitoring proposal may be needed in Micropolitan Statistical Areas to provide adequate coverage of locations likely to experience violations of the proposed lower primary NAAQS levels. These additional monitors could be established through discretionary State initiatives to supplement minimum monitoring requirements, negotiated requirements between States and EPA Regional Administrators, or through a future rulemaking that addresses potential increased O<sub>3</sub> monitoring requirements to specifically address the need for additional monitoring to ensure detection of primary standard violations in smaller communities.

The third proposed non-urban monitoring objective, requiring O<sub>3</sub> monitors to be located in the area of expected maximum O<sub>3</sub> concentration outside of any MSA, potentially including the far downwind transport zones of currently well-monitored urban areas, is not directly related to the level of the O<sub>3</sub> NAAQS. It is instead intended to ensure that all parts of a State meet the NAAQS and that all necessary emission control strategies have been included in State Implementation Plans. Accordingly, this proposed monitoring objective remains applicable independent of revisions to the O<sub>3</sub> NAAQS proposed in this action.

#### *D. Revisions to the Length of the Required O<sub>3</sub> Monitoring Seasons*

Ozone monitoring is only required during the seasons of the year that are conducive to O<sub>3</sub> formation. These seasons vary in length as the conditions that determine the likely O<sub>3</sub> formation (*i.e.*, seasonally-dependent factors such as ambient temperature, strength of solar insolation, and length of day) differ by location. In some locations, conditions conducive to O<sub>3</sub> formation are limited to a few summer months of the year while in other locations these

conditions occur year-round. As a result, the length of currently required O<sub>3</sub> monitoring seasons can vary from a length of 4 months in colder climates to a length of 12 months in warmer climates.

The 2009 O<sub>3</sub> monitoring proposal also addressed the issue of whether in some areas the required O<sub>3</sub> monitoring season should be made longer. The proposal also addressed the status of any currently effective Regional Administrator-granted waiver approvals to O<sub>3</sub> monitoring seasons, and the impact of proposed changes to monitoring requirements on such waiver approvals.

The EPA performed several analyses in support of proposed changes to the required O<sub>3</sub> monitoring seasons. The first analysis determined the number of observed exceedances of the 0.075 ppm level of the current 8-hour NAAQS in the months falling outside the currently required local O<sub>3</sub> monitoring season using monitors in areas that collected O<sub>3</sub> data year-round in 2004–2006. The second analysis examined observed occurrences of daily maximum 8-hour O<sub>3</sub> averages of at least 0.060 ppm. This threshold was chosen because it represented 80 percent of the current 0.075 ppm NAAQS level and provides an indicator of ambient conditions that may be conducive to the formation of O<sub>3</sub> concentrations that approach or exceed the NAAQS. While proposals for revising each State's required monitoring season were based on observed data in and surrounding each State, statistically predicted exceedances were also used to validate conclusions for each State.

The aforementioned analyses provided several results. The analysis of observed exceedances of the 0.075 ppm level of the current O<sub>3</sub> NAAQS indicated occurrences in eight States during months outside of the current required monitoring season. The eight States were Maine, Massachusetts, New Hampshire, New Jersey, New York, South Carolina, Vermont, and Wyoming. With the exception of Wyoming, these exceedances occurred in a very limited manner and timeframe, just before the beginning of these States' required O<sub>3</sub> monitoring season (beginning in these States on April 1). The frequency of observed occurrences of maximum 8-hour average O<sub>3</sub> levels of at least 0.060 ppm was quite high across the country in months outside of the current required monitoring season. A total of 32 States experienced such occurrences; 22 States had such levels only before the required monitoring season; 9 States had such levels both before and after the required monitoring

<sup>73</sup> Defined as areas having at least one urban cluster of at least 10,000 but less than a population of 50,000.

season; and 1 State had such levels only after the required monitoring season. In a number of cases, the frequency of such ambient concentrations was high, with some States experiencing between 31 to 46 out-of-season days during 2004 to 2006 at a high percentage of all operating year-round O<sub>3</sub> monitors.

Based on these analyses, EPA proposed a lengthening of the O<sub>3</sub> monitoring season requirements in many areas. The 2009 proposed changes were based not only on the goal of monitoring out-of-season O<sub>3</sub> NAAQS violations but also on the goal of ensuring monitoring when ambient O<sub>3</sub> levels reach 80 percent of the NAAQS so that persons unusually sensitive to O<sub>3</sub> would be alerted to potential NAAQS exceedances.

The EPA believes that the factors used to support the 2009 proposed changes to O<sub>3</sub> monitoring seasons are appropriate to support the revisions of the O<sub>3</sub> NAAQS proposed in this action. With regard to the primary standard, we note that the lower end of the range being proposed is an 8-hour level of 0.060 ppm, which is identical to the ambient O<sub>3</sub> level that was utilized in one of the analyses discussed above. Although that level was chosen to provide an indicator of ambient levels that were below but approaching the level of the NAAQS and hence to serve as an alert to potential exceedances, we note that EPA's traditional practice had been to base the length of required O<sub>3</sub> monitoring seasons on the likelihood of measuring exceedances of the level of the NAAQS. Therefore, if EPA finalizes the level of the primary standard at the lower end of the proposed range, the O<sub>3</sub> monitoring seasons that have been proposed as part of the 2009 O<sub>3</sub> monitoring proposal would provide sufficient monitoring coverage to ensure the goal of measuring potential violations of the primary standard.

One O<sub>3</sub> monitoring season issue that was not considered in the 2009 O<sub>3</sub> monitoring proposal was the question of whether analyses of ambient data based on 8-hour average statistics would also indicate whether the resulting proposed monitoring seasons would capture the cumulative maximum consecutive 3-month O<sub>3</sub> levels necessary to compute design values based on the secondary NAAQS proposed in this action, which is defined in terms of a W126 cumulative peak-weighted index, as discussed above in section IV. If areas experienced high cumulative index values during months outside of the required O<sub>3</sub> monitoring seasons (based on 8-hour statistics), then further revisions to the required monitoring seasons might be necessary to ensure

monitoring during all months important to the calculation of design values for the revised form proposed for the secondary NAAQS. A related issue is whether such high cumulative O<sub>3</sub> values also occurred during time periods that are biologically relevant for O<sub>3</sub>-sensitive vegetation.

The EPA is not proposing additional revisions to O<sub>3</sub> monitoring seasons at this time. Additional analyses of the distribution of elevated cumulative W126 index values will be conducted, and the biologically relevant seasonal issue will be further reviewed. Based on the results of these analyses, EPA may consider proposing further revisions to the O<sub>3</sub> monitoring season as related to the secondary O<sub>3</sub> NAAQS.

## VII. Implementation of Proposed O<sub>3</sub> Standards

### A. Designations

After EPA establishes or revises a NAAQS, the CAA directs EPA and the states to take steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. This step is known as the initial area designations.

The CAA provides that, "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall \* \* \* submit to the Administrator a list of all areas (or portions thereof) in the state" that designates those areas as nonattainment, attainment, or unclassifiable. The CAA specifies that, "The Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard." The CAA defines an area as nonattainment if it is violating the NAAQS or if it is contributing to a violation in a nearby area. (See CAA section 107(d)(1).)

The CAA further provides, "Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) \* \* \* as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations." EPA is required to notify states of any intended modifications to their recommendations that EPA may

deem necessary no later than 120 days prior to promulgating designations. States then have an opportunity to demonstrate why any such proposed modification is inappropriate. Whether or not a state provides a recommendation, EPA must promulgate the designation that the Agency deems appropriate. (See CAA section 107(d)(1)(B).)

On September 16, 2009, when the Administrator announced her decision to reconsider the 2008 O<sub>3</sub> NAAQS, she also indicated that the Agency would work with states to accelerate implementation of the standards adopted after reconsideration, including the initial area designations process. Acceleration of designations for the primary standard would help limit any delays in health protections associated with the reconsideration of the standards. If a secondary standard different from the primary standard is adopted, this would be the first time different primary and secondary standards would be in place for the O<sub>3</sub> standards. While welfare protection is also important, for the reasons provided below, we are providing alternative schedules for designating areas for the secondary standard.

If, as a result of the reconsideration, EPA determines that the record supports a primary standard different from that promulgated in 2008 and promulgates such different primary O<sub>3</sub> NAAQS in 2010, EPA intends to promulgate final designations on an accelerated schedule to allow the designations to be effective in 1 year. In order to meet such a schedule, EPA is proposing that the deadline for states to submit their designations recommendations for the revised 2010 primary standard be 129 days after promulgation of that primary standard. EPA recognizes that the proposed deadline would be an ambitious schedule. Therefore, EPA intends to provide technical information and guidance for states as early as possible to facilitate the development of their recommendations. Many of the areas that would be violating the proposed primary ozone standard are also violating the 2008 ozone standards. State Governors have provided recommendations on these areas pursuant to the 2008 standards and recommendations may not need much further evaluation.

Based on this proposed schedule, if EPA promulgates a new primary standard on August 31, 2010, state Governors would need to submit their initial designation recommendations to EPA by January 7, 2011. If the Administrator intends to modify any state recommendation, EPA would

notify the Governor no later than March 2011, 120 days prior to promulgating the final designations. States would then have an opportunity to comment on EPA's intended designations before EPA promulgates the final designations. EPA would promulgate the final designations in July 2011 to allow sufficient time for the designations to be published and effective by August 31, 2011. EPA expects to base the final designations for the primary O<sub>3</sub> standard on three consecutive years of certified air quality monitoring data from the years 2007–2009 or from 2008–2010, if available.

If, as a result of the reconsideration, EPA promulgates a distinct secondary standard that differs from that promulgated in 2008 and also differs from the 2010 primary standard, as proposed above, EPA is proposing two alternative deadlines for states to submit their designations recommendations. Under the first alternative, EPA would designate areas for the secondary standard on the same accelerated schedule discussed above for the primary standard. In order to meet that schedule, EPA is proposing that states submit their recommendations for the revised 2010 secondary standard 129 days after promulgation of that secondary standard. Accordingly, if EPA promulgates the new secondary standard on August 31, 2010, state Governors would need to submit their initial designation recommendations to EPA by January 7, 2011.

Weighing in favor of designating areas for the secondary standard at the same time as designations for the primary standard is that planning for both standards would occur on the same schedule. Our examination of current air quality data from the existing monitoring network indicates that for levels of the primary and secondary standards proposed in this action, it is likely that the vast majority of areas violating the secondary standard would overlap with areas violating the primary standard. In this case, implementing requirements for the primary and secondary standards on different schedules could present resource challenges to state and local agencies by requiring duplication of effort and hindering consideration of all factors when deciding which control strategies to adopt for each standard. For example, if designations for the secondary standard were delayed by a certain period (e.g., a year) beyond the designations for the primary standard, then EPA would likely delay submission of attainment SIPs for the secondary standard for a similar period beyond the proposed date for

submission of the attainment SIPs for the primary standard. In this case, the initial transportation conformity determination for the secondary standard would be required later than the initial determination for the primary standard by the difference in time between the effective dates of the two designations.

Under the second alternative, EPA would designate areas for the secondary standard on the maximum 2-year schedule provided under the CAA. To meet that 2-year schedule, EPA is proposing that states submit their recommendations for the revised secondary standard no later than 1 year after promulgation of the 2010 secondary standard. Accordingly, if EPA promulgates a secondary standard on August 31, 2010, that differs from the primary standard, as proposed, under the alternative 2-year designations schedule, state Governors would need to submit their initial designation recommendations to EPA by August 31, 2011. If the Administrator intends to modify any state recommendation, EPA would notify the Governor no later than May 2012, 120 days prior to the 2-year deadline for promulgating the final designations. States would then have an opportunity to comment on EPA's intended designations before EPA promulgates the final designations. EPA would promulgate the final designations for the secondary standard by August 31, 2012. EPA expects to base the final designations in August 2012 for a different secondary standard on the most recent three consecutive years of certified air quality monitoring data, which would be from the years 2009–2011.

In the past, EPA has always set the secondary O<sub>3</sub> standard to be identical to the primary O<sub>3</sub> standard and the standards have embodied relatively short-term average concentrations (e.g., 1-hour or 8-hour). In this action, EPA is proposing a cumulative, seasonal secondary standard that differs from the proposed primary standard. EPA has not previously set a seasonal secondary standard for O<sub>3</sub>. Therefore, EPA and states do not have experience in implementing this type of secondary O<sub>3</sub> standard or in determining what area boundaries would be appropriate. As we further explore implementation considerations for the secondary standard, we may encounter unanticipated issues that may require additional time to address. Thus, EPA is considering whether an accelerated schedule for a seasonal secondary standard would provide adequate time for resolving issues that we cannot now anticipate. If EPA designates areas for

the secondary standard on a 2-year schedule, we note that we expect that accelerated implementation of the health-based primary standard would also result in accelerated welfare benefits. EPA requests comment on factors affecting the efficient and effective implementation of a secondary standard that differs from the primary standard in the context of establishing designations schedules.

EPA notes, as discussed in greater detail above in section VI, that it has proposed a monitoring rule that would increase the density of monitoring in National Parks and other non-urban and lesser populated areas (July 16, 2009; 74 FR 34525). The proposed requirements are intended to satisfy several important objectives, including better characterization of O<sub>3</sub> exposures to O<sub>3</sub>-sensitive vegetation and ecosystems in rural/remote areas to ensure that potential secondary NAAQS violations are measured. As proposed, the new monitors would not be deployed until 2012 or 2013. Therefore, data from these monitors would not be available for use within the statutory timeframe for EPA to complete designations for a 2010 secondary standard regardless of which schedule EPA follows.

While CAA section 107 specifically addresses states, EPA intends to follow the same process for tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority, and the Tribal Authority Rule (63 FR 7254; February 12, 1998).

In a separate notice elsewhere in today's *Federal Register*, EPA is announcing that it is using its authority under the CAA to extend by 1 year the deadline for promulgating initial area designations for the O<sub>3</sub> NAAQS that were promulgated in March 2008. The new deadline is March 12, 2011. That notice explains the basis for the deadline extension. As mentioned above, on September 16, 2009, EPA notified the Court of its decision to initiate a rulemaking to reconsider the primary and secondary O<sub>3</sub> NAAQS set in March 2008 to ensure they satisfy the requirements of the CAA. In its notice to the Court, EPA stated that the final rule would be signed by August 31, 2010. Extending the deadline for promulgating designations for the 2008 O<sub>3</sub> NAAQS until March 12, 2011 will allow EPA to complete the reconsideration rulemaking for the 2008 O<sub>3</sub> NAAQS before determining whether it is necessary to finalize designations for those NAAQS or, instead, whether it is necessary to begin the designation process for different NAAQS promulgated pursuant to the reconsideration.

### B. State Implementation Plans

The CAA section 110 provides the general requirements for SIPs. Within 3 years after the promulgation of new or revised NAAQS (or such shorter period as the Administrator may prescribe) each State must adopt and submit "infrastructure" SIPs to EPA to address the requirements of section 110(a)(1). Thus, States should submit these SIPs no later than August 21, 2013, three years after promulgation of the reconsidered ozone standard in 2010. These "infrastructure SIPs" provide assurances of State resources and authorities, and establish the basic State programs, to implement, maintain, and enforce new or revised standards.

In addition to the infrastructure SIPs, which apply to all States, CAA title I, part D outlines the State requirements for achieving clean air in designated nonattainment areas. These requirements include timelines for when designated nonattainment areas must attain the standards, deadlines for developing SIPs that demonstrate how the State will ensure attainment of the standards, and specific emissions control requirements. EPA plans to address how these requirements, such as attainment demonstrations and attainment dates, reasonable further progress, new source review, conformity, and other implementation requirements, apply to the O<sub>3</sub> NAAQS promulgated pursuant to the reconsideration in a subsequent rulemaking. Also in that rulemaking EPA will establish deadlines for submission of nonattainment area SIPs but anticipates that the deadlines will be no later than the end of December 2013, or 28 months after final designations.

### C. Trans-Boundary Emissions

Cross border O<sub>3</sub> contributions from within North America (Canada and Mexico) entering the U.S. are generally thought to be small. Section 179B of the Clean Air Act allows designated nonattainment areas to petition EPA to consider whether such a locality might have met a clean air standard "but for" cross border contributions. To date, few areas have petitioned EPA under this authority. The impact of foreign emissions on domestic air quality in the United States is a challenging and complex problem to assess. EPA is engaged in a number of activities to improve our understanding of international transport. As work progresses on these activities, EPA will be able to better address the uncertainties associated with trans-

boundary flows of air pollution and their impacts.

## VIII. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), the O<sub>3</sub> NAAQS action is an "economically significant regulatory action" because it is likely to have an annual effect on the economy of \$100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared this regulatory impact analysis (RIA) of the potential costs and benefits associated with this action. This analysis is contained in the Regulatory Impact Analysis for the Ozone NAAQS Reconsideration, October 2009 (henceforth, "RIA"). A copy of the analysis is available in the RIA docket (EPA-HQ-OAR-2007-0225) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining five alternative O<sub>3</sub> NAAQS nationwide. Specifically, the RIA examines the alternatives of 0.079 ppm, 0.075 ppm, 0.070 ppm, 0.065 ppm, and 0.060 ppm. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve these alternative O<sub>3</sub> NAAQS. However, the Clean Air Act (CAA) and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this proposed rule.

### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* There are no information collection requirements directly associated with the establishment of a NAAQS under section 109 of the CAA.

Burden means the total time, effort, or financial resources expended by persons

to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

### C. Regulatory Flexibility Act

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

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

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of O<sub>3</sub> in ambient air as required by section 109 of the CAA. See also *American Trucking Associations v. EPA*, 175 F. 3d at 1044-45 (NAAQS do not have significant impacts upon small



entities because NAAQS themselves impose no regulations upon small entities). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts

#### *D. Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The proposed rule imposes no new expenditure or enforceable duty on any State, local or Tribal governments or the private sector, and EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments.

Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. See also *American Trucking Associations v. EPA*, 175 F. 3d at 1043 (noting that because EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this proposed decision. The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA will address, as appropriate, unfunded mandates if and when it proposes any revisions to 40 CFR parts 51 or 58.

#### *E. Executive Order 13132: Federalism*

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this

proposed rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

However, as also noted in section D (above) on UMRA, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This rule concerns the establishment of O<sub>3</sub> NAAQS. The Tribal Authority Rule gives Tribes the opportunity to develop and implement CAA programs such as the O<sub>3</sub> NAAQS, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt.

This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, EPA contacted tribal environmental professionals during the development of the March 2008 rule. The EPA staff participated in the regularly scheduled Tribal Air call sponsored by the National Tribal Air Association during the spring of 2007 as the proposal was under development. EPA specifically solicits additional comment on this proposed rule from Tribal officials.

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

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action may have a disproportionate effect on children. The proposed rule will establish uniform national ambient air quality standards for O<sub>3</sub>; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because children, especially children with asthma, along with other sensitive population subgroups such as all people with lung disease and people active outdoors, are potentially susceptible to health effects resulting from O<sub>3</sub> exposure. Because children are considered a potentially susceptible population, we have carefully evaluated the environmental health effects of exposure to O<sub>3</sub> pollution among children. Discussions of the results of the evaluation of the scientific evidence, policy considerations, and the exposure and risk assessments pertaining to children are contained in sections II.B and II.C of this preamble. A listing of the documents that contain the evaluation of scientific evidence, policy considerations, and exposure and risk assessments that pertain to children is found in the section on Children's Environmental Health in the Supplementary Information section of this preamble, and a copy of all documents have been placed in the public docket for this action. The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to O<sub>3</sub>.

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

This proposed rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because in the Agency's judgment it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for O<sub>3</sub>. The rule does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects and does not constitute a significant energy action as defined in Executive Order 13211.

*I. National Technology Transfer and Advancement Act*

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

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high

and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States:

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The proposed rule will establish uniform national standards for O<sub>3</sub> air pollution.

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**List of Subjects in 40 CFR Parts 50 and 58**

Environmental protection, Air pollution control, Carbon monoxide,

Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: January 6, 2010.

**Lisa P. Jackson,**  
Administrator.

For the reasons set forth in the preamble, parts 50 and 58 of chapter 1 of title 40 of the code of Federal regulations are proposed to be amended as follows:

**PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS**

1. The authority citation for part 50 continues to read as follows:

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

2. Section 50.15 is revised to read as follows:

**§ 50.15 National primary and secondary ambient air quality standards for ozone.**

(a) The level of the national 8-hour primary ambient air quality standard for O<sub>3</sub> is (0.060–0.070) parts per million (ppm), daily maximum 8-hour average, measured by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(b) The 8-hour primary O<sub>3</sub> ambient air quality standard is met at an ambient air quality monitoring site when the average of the annual fourth-highest daily maximum 8-hour average O<sub>3</sub> concentration is less than or equal to

(0.060–0.070) ppm, as determined in accordance with appendix P to this part.

(c) The level of the national secondary ambient air quality standard for O<sub>3</sub> is a cumulative index value of (7–15) ppm-hours, measured by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(d) The secondary O<sub>3</sub> ambient air quality standard is a seasonal standard expressed as a sum of weighted hourly concentrations, cumulated over the 12 hour daylight period from 8 a.m. to 8 p.m. local standard time, during the consecutive 3-month period within the O<sub>3</sub> monitoring season with the maximum index value. The secondary O<sub>3</sub> standard is met at an ambient air quality monitoring site when the annual maximum consecutive 3-month cumulative index value (W126) is less than or equal to (7–15) ppm-hours, as determined in accordance with appendix P to this part.

3. Section 50.14 is amended by adding entries for primary and secondary ozone standards to the end of Table 1 in paragraph (c)(2)(vi) to read as follows:

**§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.**

- \* \* \* \* \*
- (c) \* \* \*
- (2) \* \* \*
- (vi) \* \* \*

**TABLE 1—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW NAAQS**

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
Primary Ozone/8-Hr Standard (Level TBD)/promulgated by August 31, 2010.	2007–2009	November 1, 2010 <sup>b</sup>	November 1, 2010. <sup>b</sup>
	2010	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>
Secondary Ozone/(Level TBD) Alternative 2-year Schedule—to be Promulgated by August 31, 2010.	2008	July 1, 2011 <sup>b</sup>	July 1, 2011. <sup>a</sup>
	2009–2010	July 1, 2011 <sup>b</sup>	July 1, 2011. <sup>b</sup>
	2011	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2012, whichever occurs first. <sup>b</sup>	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2012, whichever occurs first. <sup>b</sup>
Secondary Ozone/(Level TBD)—Alternative Accelerated Schedule—to be promulgated by August 31, 2010.	2007–2009	November 1, 2010 <sup>b</sup>	November 1, 2010. <sup>b</sup>
	2010	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>	60 Days after the end of the calendar quarter in which the event occurred or March 1, 2011, whichever date occurs first. <sup>b</sup>

TABLE 1—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW NAAQS—Continued

NAAQS pollutant/ standard/(level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description- deadline	Detailed documentation submission deadline
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<sup>a</sup> These dates are unchanged from those published in the original rulemaking.

<sup>b</sup> Indicates change from general schedule in 40 CFR 50.14.

**Note:** EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

4. Appendix P to part 50 is revised to read as follows:

**Appendix P to Part 50—Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone**

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining whether the 8-hour primary and secondary national ambient air quality standards for ozone specified in § 50.15 are met at an ambient ozone air quality monitoring site. Ozone is measured in the ambient air by a reference method based on Appendix D of this part, as applicable, and designated in accordance with part 53 of this chapter, or by an equivalent method designated in accordance with part 53 of this chapter. Data reporting, data handling, and computation procedures to be used in making comparisons between reported ozone concentrations and the levels of the ozone standards are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including stratospheric ozone intrusion and other natural events, is determined by the requirements under §§ 50.1, 50.14 and 51.930.

(c) The terms used in this appendix are defined as follows:

*8-hour average* is the rolling average of eight hourly ozone concentrations as explained in section 3 of this appendix.

*Annual fourth-highest daily maximum* refers to the fourth-highest value measured at a monitoring site during a particular year.

*Annual Cumulative W126 Index* is the maximum sum over three consecutive calendar months of the monthly W126 index in a year, as explained in section 4 of this appendix.

*Daily maximum 8-hour average concentration* refers to the maximum calculated 8-hour average for a particular day as explained in section 3 of this appendix.

*Daily W126 Index* is the sum of the sigmoidally weighted hourly ozone concentrations during the 12-hour daylight period, 8 a.m. to 7:59 p.m. local standard time (LST).

*Design values* are the metrics (i.e., statistics) that are compared to the primary and secondary NAAQS levels to determine compliance, calculated as shown in sections 3 and 4 of this appendix.

*Monthly W126 Index* is the sum of the daily W126 index over one calendar month

during the required ozone monitoring season, adjusted for incomplete data if appropriate, as explained in section 4 of this appendix.

*Required ozone monitoring season* refers to the span of time within a calendar year when individual States are required to measure ambient ozone concentrations as listed in part 58 Appendix D to this chapter.

*Year* refers to calendar year.

2. Requirements for Data Used for Comparisons With the Ozone NAAQS

(a) All valid FRM/FEM ozone data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations.

(b) When two or more ozone monitors are operated at a site, the state may in advance designate one of them as the primary monitor. If the state has not made this designation, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid primary or secondary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the state has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly average concentrations shall be reported in parts per million (ppm) to the third decimal place, with additional digits to the right of the third decimal place truncated. The start of each hour shall be identified in local standard time (LST).

3. Comparison to the Primary Standard for Ozone

(a) Computing 8-Hour Averages

Running 8-hour averages shall be computed from the hourly ozone concentration data for each hour of the year and shall be stored in the first, or start, hour of the 8-hour period. In the event that only 6 or 7 hourly averages are available, the valid 8-hour average shall be computed on the basis of the hours available, using 6 or 7 as the divisor. In the event that only 1, 2, 3, 4, or 5 hourly averages are available, the 8-hour average shall be computed on the basis of substituting for all the hours without hourly averages a low hourly average value selected as follows, using 8 as the divisor. For days within the required ozone monitoring season, the substitution value shall be the lowest hourly average ozone concentration observed during the same hour (local standard time) of any day in the required ozone monitoring season of that year, or one-half of the method detection limit of the ozone instrument, whichever is higher. However, if the number of same-hour concentration values available for the required ozone monitoring season for the year, from which the lowest observed hourly concentration would be identified for purposes of this substitution, is less than 50% of the number of days during the required ozone monitoring season, one-half the method detection limit of the ozone instrument shall be used in the substitution. For days outside the required ozone monitoring season, the substitution value shall be one-half the method detection limit of the ozone instrument. An 8-hour period with no available hourly averages does not have a valid 8-hour average. The computed 8-hour average ozone concentrations are not rounded or truncated.

(b) Daily Maximum 8-Hour Average Concentrations

There are 24 8-hour periods in each calendar day. Some of these may not have valid 8-hour averages, under section 3(a). The daily maximum 8-hour concentration for a given calendar day is the highest of the valid 8-hour average concentrations computed for that day. This process is repeated, yielding a daily maximum 8-hour average ozone concentration for each day with ambient ozone monitoring data, including days outside the required ozone monitoring season if data are available. The daily maximum 8-hour concentrations from two consecutive days may have some hourly concentrations in common. Generally, overlapping daily maximum 8-hour averages are not likely,

except in those non-urban monitoring locations with less pronounced diurnal variation in hourly concentrations. In these cases, the maximum 8-hour average concentration from each day is used, even if the two averages have some hours in common.

(c) Primary Standard Design Value  
The primary standard design value is the annual fourth-highest daily maximum 8-hour ozone concentration considering all days with monitoring data including any days outside the required ozone monitoring season, expressed in parts per million, averaged over three years. The 3-year average shall be computed using the three most recent, consecutive years of monitoring data that can yield a valid design value. For a design value to be valid for comparison to the standard, the monitoring data set on which it is based must meet the data completeness requirements described in section 3(d). The computed 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations shall be rounded to three decimal places. Values equal to or greater than 0.0005 ppm shall round up.

(d) Data Completeness Requirements for a Valid Design Value

(i) A design value greater than the standard is valid if in each of the three years there are

at least four days with a daily maximum 8-hour average concentration. Under sections 3(a) and 3(b), there will be a daily maximum 8-hour average concentration on any day with at least one hourly concentration. One or more of these four days may be outside the required ozone monitoring season.

(ii) A design value less than or equal to the standard is valid if for at least 75% of the days in the required ozone monitoring season in each of the three years there are at least 18 8-hour averages in the day that are based on at least 6 measured hourly average concentrations.

(iii) When computing whether the minimum data completeness requirement in section 3(d)(ii) has been met for the purpose of showing that a design value equal to or less than the standard is valid, meteorological or ambient data may be sufficient to demonstrate that ozone levels on days with missing data would not have affected the design value. At the request of the state, the Regional Administrator may consider demonstrations that meteorological conditions on one or more days in the required ozone monitoring season which do not have at least 18 8-hour averages in the day that are based on at least 6 measured hourly average concentrations could not have caused a daily maximum 8-hour concentration high enough to have been one

of the four highest daily maximum 8-hour concentrations for the year. At the request of the state, days so demonstrated may be counted towards the 75% requirement for the purpose of validating the design value, subject to the approval of the Regional Administrator.

(vi) Years that do not meet the completeness criteria stated in 3(d)(ii) may nevertheless be used to calculate a design value that will be deemed valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) Comparison With the Primary Ozone Standard

(i) The primary ozone ambient air quality standard is met at an ambient air quality monitoring site when the design value is less than or equal to [0.075] ppm.

(ii) Comparison with the primary ozone standard is demonstrated by examples 1 and 2 as follows:

*Example 1.* Ambient monitoring site attaining the primary ozone standard.

Year	Percent valid days (within the required monitoring season)	1st Highest daily max 8-hour conc. (ppm)	2nd Highest daily max 8-hour conc. (ppm)	3rd Highest daily max 8-hour conc. (ppm)	4th Highest daily max 8-hour conc. (ppm)	5th Highest daily max 8-hour conc. (ppm)
2006	80	0.092500	0.090375	0.085125	0.078375	0.078125
2007	96	0.084750	0.083500	0.075375	0.071875	0.070625
2008	98	0.080875	0.079750	0.077625	0.075500	0.060375
Average					0.075250	
Rounded					0.075	

As shown in Example 1, this monitoring site meets the primary ozone standard because the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations (*i.e.*, 0.075256 ppm, rounded to 0.075 ppm) is less than or

equal to [0.075] ppm. The data completeness requirement is also met because no single year has less than 75% data completeness. In Example 1, the individual 8-hour averages and the 3-year average are shown with six decimal digits. In actual calculations, all

digits supported by the calculator or calculation software must be retained.

*Example 2.* Ambient monitoring site failing to meet the primary ozone standard.

Year	Percent valid days (within the required monitoring season) (percent)	1st Highest daily max 8-hour conc. (ppm)	2nd Highest daily max 8-hour conc. (ppm)	3rd Highest daily max 8-hour conc. (ppm)	4th Highest daily max 8-hour conc. (ppm)	5th Highest daily max 8-hour conc. (ppm)
2006	96	0.105125	0.103500	0.101125	0.078625	0.072375
2007	74	0.104250	0.103625	0.093000	0.080250	0.069500
2008	98	0.103125	0.101875	0.101750	0.075375	0.074625
Average					0.078083	
Rounded					0.078	

As shown in Example 2, the data capture in 2007 is less than 75%. The primary ozone standard is not met for this monitoring site because the 3-year average of the fourth-

highest daily maximum 8-hour average ozone concentrations (*i.e.*, 0.078083 ppm, rounded to 0.078 ppm) is greater than [0.075] ppm and is therefore valid despite this

incompleteness. In Example 2, the individual 8-hour averages and the 3-year average are shown with six decimal digits. In actual calculations, all digits supported by the

calculator or calculation software must be retained.

4. Secondary Ambient Air Quality Standard for Ozone

(a) *Computing the daily W126 index value.*

The secondary ozone ambient air quality standard is a seasonal standard expressed as a sum of weighted hourly concentrations, cumulated over the 12 hour daylight period from 8 a.m. to 8 p.m. local standard time, during the consecutive 3-month period within the ozone monitoring season with the maximum index value. The first step in determining whether the standard is met at

a monitoring site is to compute the daily W126 index value for each day by applying the sigmoidal weighting function in Equation 1 to each reported measurement of hourly average concentration.

Equation 1

$$daily\ W126 = \sum_{i=8am}^{i=8pm} w_{ci} C_i$$

Where:

$C_i$  = hourly  $O_3$  at hour  $i$ , and

$$w_c = \frac{1}{1 + 4403e^{-126C}}$$

The computed value of the sigmoidally weighted hourly concentration is not rounded or truncated. The daily W126 index is formed by summing the twelve computed hourly values, retaining all decimal places. An illustration of computing a daily W126 index value is below:

*Example 3.* Daily W126 index value calculation for an ambient ozone monitoring site.

Start of hour	Concentration (ppm)	Weighted concentration (ppm)
8:00 a.m.	0.045	0.002781
9:00 a.m.	0.060	0.018218
10:00 a.m.	0.075	0.055701
11:00 a.m.	0.080	0.067537
12:00 p.m.	0.079	0.065327
1:00 p.m.	0.082	0.071715
2:00 p.m.	0.085	0.077394
3:00 p.m.	0.088	0.082448
4:00 p.m.	0.083	0.073683
5:00 p.m.	0.081	0.069667
6:00 p.m.	0.065	0.029260
7:00 p.m.	0.056	0.011676
Sum=Daily W126 index value		* 0.625406

\* ppm-hours.

In Example 3, the individual weighted concentrations and their sum are shown with six decimal digits. In actual calculations, all digits supported by the calculator or calculation software must be retained. There are no data completeness requirements for the daily index. If fewer than 12 hourly values are available, only the available hours are weighted and summed. However, there are data completeness requirements for the monthly W126 index values and a required adjustment for incomplete data, as describe in the next section.

(b) *Computing the Monthly W126 Index*

As described in section 4(a), the daily index value is computed at each monitoring site for each calendar day in each month during the required ozone monitoring season with no rounding or truncation. The monthly W126 index is the sum of the daily index values over one calendar month. At an individual monitoring site, a monthly W126 index is valid if hourly average ozone concentrations are available for at least 75% of the possible daylight hours in the month. For months with more than 75% but less than 100% data completeness, the monthly W126 value shall be adjusted for incomplete data by multiplying the unadjusted monthly W126 index value by the ratio of the number of possible reporting hours to the number of hours with reported ambient hourly concentrations using Equation 2 in this appendix:

Equation 2

$$M.I. = \left[ \sum_{j=1}^n (D.I.) \right] * (n * 12) / v$$

where

M.I. = the adjusted monthly W126 index,  
 D.I. = daily W126 index (i.e., the daily sum of the sigmoidally weighted daylight hourly concentrations),  
 n = the number of days in the calendar month,  
 v = the number of daylight reporting hours (8 a.m.–7:59 p.m. LST) in the month with reported valid hourly ozone concentrations.

The resulting adjusted value of the monthly W126 index shall not be rounded or truncated.

(c) *Secondary Standard Design Value*

The secondary standard design value is the 3-year average of the annual maximum consecutive 3-month sum of adjusted monthly W126 index values expressed in ppm-hours. Specifically, the annual W126 index value is computed on a calendar year basis using the three highest, consecutive adjusted monthly W126 index values. The 3-year average shall be computed using the most recent, consecutive three calendar years of monitoring data meeting the data completeness requirements described in section 4(c). The computed 3-year average of the annual maximum consecutive 3-month sum of adjusted monthly W126 index values in ppm-hours shall be rounded to a whole

number with decimal values equal to or greater than 0.500 rounding up.

(c) *Data Completeness Requirement*

(i) The annual W126 index is valid for purposes of calculating a 3-year design value if each full calendar month in the required ozone monitoring season has at least 75% data completeness for daylight hours.

(ii) If one or more months during the ozone monitoring seasons of three successive years has less than 75% data completeness, the three years shall nevertheless be used in the computation of a valid design value for the site if substituting the lowest hourly ozone concentration observed during daylight hours in the required ozone monitoring season of each year, or one-half of the method detection limit of the ozone instrument, whichever is higher, for enough of the missing hourly concentrations within each incomplete month to make the month 75% complete, and then adjusting for the remaining missing data using Equation 2, above results in a design value greater than the level of the standard.

(d) *Comparisons With the Secondary Ozone Standard*

(i) The secondary ambient ozone air quality standard is met at an ambient air quality monitoring site when the design value is less than or equal to [15] ppm-hours.

(ii) Comparison with the secondary ozone standard is demonstrated by example 4 as follows:

*Example 4.* Ambient Monitoring Site Failing to Meet the Secondary Ozone Standard

	April	May	June	July	August	September	October	Overall
<b>2006</b>								
Adjusted monthly W126 index .....	4.442	9.124	12.983	16.153	13.555	4.364	1.302	.....
3-Month sum .....	na	na	26.549	38.260	42.691	34.072	19.221	.....
2006 Maximum .....	.....	.....	.....	.....	42.691	.....	.....	42.691
<b>2007</b>								
Adjusted monthly W126 index .....	3.114	7.214	8.214	8.111	7.455	7.331	5.115	.....
3-Month sum .....	na	na	18.542	23.539	23.780	22.897	19.901	.....
2007 Maximum .....	.....	.....	.....	.....	23.780	.....	.....	23.780
<b>2008</b>								
Adjusted monthly W126 index .....	4.574	5.978	6.786	8.214	5.579	4.331	2.115	.....
3-Month sum .....	na	na	17.338	20.978	20.579	18.124	12.025	.....
2008 Maximum .....	.....	.....	.....	20.978	.....	.....	.....	20.978
3-Year average W126 index .....	.....	.....	.....	.....	.....	.....	.....	29.149666
Rounded .....	.....	.....	.....	.....	.....	.....	.....	29

As shown in example 4, the secondary ozone standard is not met for this monitoring site because the 3-year average of the annual W126 index value for this site is greater than [15] ppm-hours:

$$3\text{-year average W126 index} = (42.691 + 23.780 + 20.978) / 3 = 29.149666, \text{ which rounds to } 29 \text{ ppm-hours.}$$

In Example 4, the adjusted monthly W126 index values and the 3-month sums of the adjusted monthly W126 index values are shown with three decimal digits. In actual calculations, all digits supported by the calculator or calculation software must be retained.

**PART 58—AMBIENT AIR QUALITY SURVEILLANCE**

5. The authority citation for part 58 continues to read as follows:

**Authority:** 42 U.S.C. 7410 7403, 7410, 7601(a), 7611, and 7619.

6. Section 58.50 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

**§ 58.50 Index reporting.**

\* \* \* \* \*

(c) The population of a metropolitan statistical area for purposes of index reporting is the latest available U.S. census population.

(d) For O<sub>3</sub>, reporting is required in metropolitan and micropolitan statistical areas wherever monitoring is required under Appendix D to Part 58—SLAMS Minimum O<sub>3</sub> Monitoring Requirements.

7. Appendix G of Part 58 is amended by revising section 3. to read as follows:

**Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting**

\* \* \* \* \*

**3. Must I Report the AQI?**

You must report the AQI daily if yours is a metropolitan statistical area (MSA) with a population over 350,000. For O<sub>3</sub>, reporting is required in metropolitan and micropolitan statistical areas wherever monitoring is required under Appendix D to Part 58—SLAMS Minimum O<sub>3</sub> Monitoring Requirements.

\* \* \* \* \*

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# Federal Register

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Tuesday,  
January 19, 2010

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**Part III**

## **Department of Labor**

**Employee Benefits Security  
Administration**

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**Application Numbers and Proposed  
Exemptions; Notice**

## DEPARTMENT OF LABOR

## Employee Benefits Security Administration

[D-11502, D-11518, D-11521, D-11425, D-11448, D-11495]

## Application Numbers and Proposed Exemptions

**AGENCY:** Employee Benefits Security Administration, Labor.

**ACTION:** Notice of Proposed Exemptions.

[Application Nos. and Proposed Exemptions; Putnam Fiduciary Trust Company (PFTC), The PNC Financial Services Group, Inc.; Deutsche Asset Management (UK) Limited (the Applicant); UBS Financial Services Inc. and Its Affiliates; Deutsche Bank AG and Its Affiliates (together, Deutsche Bank of the Applicant); Morgan Stanley & Co. Inc. and its current and future affiliates and subsidiaries (Morgan Stanley) and Union bank, N.A. and its affiliates (Union Bank), et al.]

**SUMMARY:** This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code).

## Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

**ADDRESSES:** All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N-5700, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. \_\_\_\_\_, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via e-mail or Fax. Any such comments or requests should be

sent either by e-mail to: "moffitt.betty@dol.gov", or by Fax to (202) 219-0204 by the end of the scheduled comment period. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N-1513, 200 Constitution Avenue, NW., Washington, DC 20210.

**Warning:** If you submit written comments or hearing requests, do not include any personally-identifiable or confidential business information that you do not want to be publicly-disclosed. All comments and hearing requests are posted on the Internet exactly as they are received, and they can be retrieved by most Internet search engines. The Department will make no deletions, modifications or redactions to the comments or hearing requests received, as they are public records.

## Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

**SUPPLEMENTARY INFORMATION:** The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Putnam Fiduciary Trust Company (PFTC), Located in Boston, Massachusetts, [Application No. D-11425].

## Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

## Section I—Proposed Exemption

Effective as of January 19, 2010, the restrictions of section 406(a) and (b) of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to either (a) the purchase or sale by a Collective Fund (as defined in Section III(b) below) of shares of a Mutual Fund (as defined in Section III(d) below) where Putnam Fiduciary Trust Company ("PFTC" or the "Applicant") or its affiliate (PFTC and its affiliates are referred to herein as "Putnam") is the investment advisor of the Mutual Fund as well as a fiduciary with respect to the Collective Fund (or an affiliate of such fiduciary) or (b) the receipt of fees by Putnam from a Mutual Fund for acting as an investment advisor for the Mutual Fund and/or for providing other services to the Mutual Fund which are Secondary Services (as defined in Section III(g) below) in connection with the investment by the Collective Fund in shares of the Mutual Fund, provided that the following conditions and the general conditions of Section II are met: (a) Each Collective Fund satisfies either (but not both) of the following:

(1) The Collective Fund receives a cash credit equal to such Collective Fund's proportionate share of all fees charged to the Mutual Fund by Putnam for investment advisory services. Such credit shall be paid to the Collective Fund no later than the same day on which such investment advisory fees are paid to Putnam. The crediting of all such fees to the Collective Funds by Putnam is audited by an independent accounting firm on at least an annual basis to verify the proper crediting of the fees to each Collective Fund. The audit report shall be completed not later than six months after the period to which it relates; or

(2) No management fees, investment advisory fees, or similar fees are paid to Putnam with respect to any of the assets of such Collective Fund that are invested in shares of the Mutual Fund. This condition does not preclude the payment of investment advisory or similar fees by the Mutual Fund to Putnam under the terms of an investment management agreement adopted in accordance with section 15



of the Investment Company Act of 1940 (the 1940 Act), nor does it preclude the payment of fees for Secondary Services to Putnam pursuant to a duly adopted agreement between Putnam and the Mutual Fund if the conditions of this proposed exemption are otherwise met.

(b) The price paid or received by a Collective Fund for shares in the Mutual Fund is the net asset value (NAV) per share (as defined in Section III (h)) and is the same price that would have been paid or received for the shares by any other investor in the Mutual Fund at that time, and all other dealings between the Collective Funds and the Mutual Fund will be on a basis no less favorable to the Collective Fund than such dealings will be with the other shareholders of the Mutual Fund.

(c) Putnam, including any officer or director of Putnam, does not purchase or sell shares of the Mutual Fund from or to any Collective Fund; provided that this condition shall not preclude the purchase or redemption of such shares between a Collective Fund and an affiliate of PFTC acting solely in its capacity as underwriter for the Mutual Fund, if such affiliate acts as a riskless principal, the purchase or redemption is at NAV at the time of the transaction, and the affiliate does not receive any direct or indirect compensation, spread or other consideration in connection with such purchase or redemption.

(d) No sales commissions, redemption fees, or other similar fees are paid by the Collective Funds in connection with the purchase or sale of shares of the Mutual Fund.

(e) For each Collective Fund, the combined total of all fees received by Putnam for the provision of services to the Collective Fund, and in connection with the provision of services to the Mutual Fund in which the Collective Fund may invest, are not in excess of "reasonable compensation" within the meaning of section 408(b)(2) of the Act.

(f) Putnam does not receive any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with the transactions covered by this proposed exemption.

(g) The Second Fiduciary (as defined in Section III (f) below) with respect to each plan having an interest in a Collective Fund (a "Client Plan") receives in writing, in advance of any investment by the Collective Fund in the Mutual Fund, full and detailed disclosure of information concerning the Mutual Fund, including but not limited to: (1) A current prospectus issued by the Mutual Fund; (2) a statement describing the fees for investment advisory or similar services, any Secondary Services and all other

fees to be charged to or paid by (or with respect to) the Collective Fund and by the Mutual Fund, including the nature and extent of any differential between the rates of such fees; (3) the reasons why PFTC may consider such investment to be appropriate for the Collective Fund; (4) a statement describing whether there are any limitations applicable to PFTC with respect to which Collective Fund assets may be invested in shares of the Mutual Fund and, if so, the nature of such limitations; and (5) upon request of the Second Fiduciary, a copy of both the notice of proposed exemption and a copy of the final exemption once it is published in the **Federal Register**, and any other reasonably available information regarding the transactions covered by this proposed exemption.

(h) On the basis of the information described in paragraph (g) above, the Second Fiduciary authorizes in writing the investment of assets of the Collective Fund in the Mutual Fund and the fees to be paid by the Mutual Fund to Putnam.

(i) On an annual basis, Putnam will provide to the Second Fiduciary of each Client Plan having an interest in the Collective Fund: (1) A current prospectus issued by the Mutual Fund in which the Collective Fund invests, and, upon the Second Fiduciary's request, a copy of the Statement of Additional Information for such Mutual Fund that contains a description of all fees paid by the Mutual Fund to Putnam; (2) a copy of the annual financial disclosure report prepared by Putnam that includes information about the Mutual Fund portfolios, as well as audit findings of an independent auditor, within 60 days of the preparation of the report; (3) oral or written responses to inquiries of the Second Fiduciary as they arise; (4) a statement (i) of the approximate percentage (which may be in the form of a range) of the assets of the Collective Fund that were invested in the Mutual Fund during the year and (ii) that, if the Second Fiduciary objects to the continued investment by the Collective Fund in the Mutual Fund, the Client Plan should withdraw from the Collective Fund; and (5) a form (Termination Form) expressly providing an election to withdraw from the Collective Fund, together with instructions on the use of such form. The instructions will inform the Second Fiduciary that: (i) The prior written authorization is terminable at will by the Plan, without penalty to the Plan, upon receipt by Putnam of written notice from the Second Fiduciary, and, (ii) failure to return the form will result

in continued authorization of Putnam to engage in the transactions described above on behalf of the Plan.

However, if the Termination Form has been provided to the Second Fiduciary pursuant to Section I(j), the Termination Form need not be provided again for an annual reauthorization pursuant to this Section I(i) unless at least six months has elapsed since the form was previously provided.

(j) Except as provided in Section I(j)(E), paragraph (h) of this Section I does not apply if:

(A) The purchase, holding and sale of Mutual Fund shares by the Collective Fund is performed subject to the prior and continuing authorization, in the manner described in this paragraph (j), of a Second Fiduciary with respect to each Client Plan whose assets are invested in the Collective Fund.

(B)(1) For each Collective Fund using the fee structure described in paragraph (a)(2) above with respect to investments in the Mutual Fund, in the event of an increase in the rate of fees paid by the Mutual Fund to Putnam regarding any investment management services, investment advisory services, or similar services that Putnam provides to the Mutual Fund over an existing rate for such services that had been authorized by a Second Fiduciary in accordance with paragraph (h) above or this paragraph (j); or

(2) For each Collective Fund under this exemption (regardless of whether the fee structure described in paragraph (a)(1) or (a)(2) is used), in the event an additional Secondary Service is provided by Putnam to the Mutual Fund for which a fee is charged, or an increase in the rate of any fee paid by the Mutual Fund to Putnam for any Secondary Service that results either from an increase in the rate of such fee or from a decrease in the number or kind of services performed by Putnam for such fee over an existing rate for such Secondary Service that had been authorized by a Second Fiduciary in accordance with paragraph (h) above or this paragraph (j):

Putnam will, at least 30 days in advance of the implementation of such additional service for which a fee is charged or for which there is a fee increase, provide a written notice (which may take the form of a letter or similar communication that is separate from the prospectus of the Fund and that explains the nature and amount of the additional service for which a fee is charged or of the increase in the rate of fee) to the Second Fiduciary of each Client Plan having an interest in the Collective Fund. Such written notice will include a Termination Form

expressly providing an election to withdraw from the Collective Fund, together with instructions on the use of such form.

(C) In the event a Second Fiduciary submits a notice in writing to PFTC objecting to the initial investment by the Collective Fund in the Mutual Fund or the implementation of such additional service for which a fee is charged or such rate of fee increase, whichever is applicable, the Client Plan on whose behalf the objection was intended is given the opportunity to terminate its investment in the Collective Fund, without penalty to such Client Plan, within such time as may be necessary to effect the withdrawal in an orderly manner that is equitable to all withdrawing Client Plans and to the non-withdrawing Client Plans. In the case of a Client Plan that elects to withdraw under this subparagraph (C), the withdrawal shall be effected prior to the initial investment by the Collective Fund in the Mutual Fund or the implementation of such additional service for which a fee is charged or such rate of fee increase, whichever is applicable.

(D) Notwithstanding the foregoing subparagraphs (B) and (C), Putnam may commence providing an additional Secondary Service for a fee or implement any increase in the rate of fee paid by the Mutual Fund to Putnam prior to providing the notice referred to in subparagraph (B) above or prior to the withdrawal of an objecting Client Plan, whichever is applicable, provided that, in either such event, the Collective Fund receives a cash credit equal to the Collective Fund's proportionate share of the fee for the additional Secondary Service or such fee increase charged to the Mutual Fund by Putnam, whichever is applicable, for the period from the date of such commencement or implementation to the later of the date that is 30 days after the notice referred to in subparagraph (B) above has been provided or, if applicable, the date on which any Client Plan that objects to the provision of such additional Secondary Service or to such fee increase has withdrawn from the Collective Fund pursuant to subparagraph (C) above. Any such cash credits shall be paid to the Collective Fund, with interest thereon at the prevailing Federal funds rate plus two percent (2%), no later than the fifth business day following the receipt of the increased fee by Putnam.<sup>1</sup> The crediting of all such fees to the

Collective Fund by Putnam will be audited by an independent accounting firm on at least an annual basis to verify the proper crediting of the fees and interest to the Collective Fund. The audit report shall be completed not later than six months after the period to which it relates.

(E) In the case of a Client Plan whose assets are proposed to be invested in the Collective Fund subsequent to the implementation of the arrangement and that has not authorized the investment of assets of the Collective Fund in the Mutual Fund, the Client Plan's investment in the Collective Fund is subject to: (1) The receipt by a Second Fiduciary of the full and detailed disclosures concerning the Mutual Fund pursuant to Section I(g), above, and (2) the prior written authorization of a Second Fiduciary pursuant to Section I(h), above (*i.e.*, the authorization must be provided by such new Client Plan investor in advance of the initial investment).

(k) For each Collective Fund using the fee structure described in paragraph (a)(1) above with respect to investments in the Mutual Fund, the Second Fiduciary of the Client Plan receives full written disclosure in a Fund prospectus or otherwise of any increases in the rates of fees charged by Putnam to the Mutual Fund for investment advisory services, or of a decrease in the number or kind of services performed by Putnam.

#### Section II—General Conditions

(a) PFTC maintains for a period of six years the records necessary to enable the persons described in paragraph (b) below to determine whether the conditions of this exemption have been met, except that:

(1) A separate prohibited transaction will not be considered to have occurred if, solely because of circumstances beyond the control of PFTC, the records are lost or destroyed prior to the end of the six-year period; and

(2) No party in interest other than Putnam shall be subject to the civil penalty that may be assessed under Section 502(i) of the Act or to the taxes imposed by Section 4975(a) and (b) of the Code, if the records are not maintained or are not available for examination as required by paragraph (b) below.

(b)(1) Except as provided in paragraph (b)(2) below and notwithstanding any provisions of Section 504(a)(2) of the Act, the records referred to in paragraph (a) above are unconditionally available at their customary location for examination during normal business hours by:

(i) Any duly authorized employee or representative of the Department, the Internal Revenue Service, or the Securities & Exchange Commission,

(ii) Any fiduciary of a Client Plan who has authority to acquire or dispose of the interest in the Collective Fund owned by such Client Plan, or any duly authorized employee or representative of such fiduciary, and

(iii) Any participant or beneficiary of a Client Plan having an interest in the Collective Fund or duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described in paragraph (b)(1)(ii) or (iii) above shall be authorized to examine trade secrets of Putnam, or commercial or financial information that is privileged or confidential.

#### Section III—Definitions

(a) An "affiliate" of a person includes:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(b) The term "Collective Fund" means any common or collective trust fund maintained by PFTC.

(c) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term "Mutual Fund" means the Putnam Prime Money Market Fund and any other money market fund that is a diversified open-end investment company registered under the 1940 Act and operated in accordance with Rule 2a-7 under the 1940 Act as to which Putnam serves as an investment adviser. Putnam may also serve as a custodian, dividend disbursing agent, shareholder servicing agent, transfer agent, fund accountant, or provider of some other "Secondary Service" (as defined below in paragraph (g) below).

(e) The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or a "member of the family") as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or a sister.

(f) The term "Second Fiduciary" means a fiduciary of a Client Plan who is independent of, and unrelated to, Putnam. For purposes of this exemption, the Second Fiduciary will

<sup>1</sup> Putnam will pay interest on any such amounts from the date it receives such incremental amounts to the date it makes the rebate payment to the Collective Fund.

not be deemed to be independent of an unrelated to Putnam if:

(1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with Putnam;

(2) Such fiduciary, or any officer, director, partner, employee, or relative of the fiduciary is an officer, director, partner or employee of Putnam (or is a relative of such persons); or

(3) Such fiduciary directly or indirectly receives any compensation or other consideration for his or her own personal account in connection with any transaction described in this exemption.

If an officer, director, partner or employee of Putnam (or a relative of such a person), is a director of such Second Fiduciary, and if he or she abstains from participation in (i) the decision of the Client Plan to invest in, and remain invested in, the Collective Fund and (ii) the granting of any authorization contemplated by Section I(h) or any deemed authorization contemplated by Section I(i) and (j) with respect to the Collective Fund, then paragraph (f)(2) above shall not apply.

(g) The term "Secondary Service" means a service other than an investment management, investment advisory, or similar service, which is provided by Putnam to the Mutual Fund, including but not limited to custodial, accounting, administrative, or any other service.

(h) The term "net asset value (*i.e.*, NAV)" means the amount for purposes of pricing all purchases and sales, calculated by dividing the value of all securities, determined by a method as set forth in a Fund's prospectus and statement of additional information, and other assets belonging to the Fund or portfolio of the Fund, less the liabilities charged to each such portfolio or Fund; by the number of outstanding shares.

#### Summary of Facts and Representations

1. The applicant is Putnam Fiduciary Trust Company (PFTC), a Massachusetts trust company subject to supervision by the Massachusetts Division of Banks. PFTC is a wholly-owned subsidiary of Putnam, LLC (together with PFTC and its other wholly-owned subsidiaries, collectively referred to herein as "Putnam"). Putnam is a majority-owned subsidiary of Great-West Lifeco U.S. Inc. Putnam is a global financial services firm primarily involved in the investment management business including the management of registered, open-end investment companies ("mutual funds"), other collective investment vehicles and single-client separate accounts. As of May 31, 2009,

Putnam's total assets under management were approximately \$102 billion.

2. PFTC manages assets held in both collective investment vehicles (other than mutual funds) and single-client separate accounts. As of May 31, 2009, 2006, PFTC managed approximately \$9 billion in assets.

3. In particular, PFTC maintains a number of collective investment funds, the assets of which are managed by PFTC on a discretionary basis (the "Collective Funds"). The Collective Funds are common or collective trust funds of a bank within the meaning of DOL Regulation 2510.3-101(h)(1)(ii) and, as such, the assets of the Collective Funds are "plan assets" subject to Title I of the Act to the extent of the interests of ERISA Plans therein.

4. Each of the Collective Funds generally has some level of cash balances and/or other assets to be invested in short-term, money market instruments. In the past, PFTC has typically invested such amounts in the short-term investment fund (the "STIF") made available by the custodian of the particular Collective Fund's assets or some other similar money market instrument or vehicle unrelated to Putnam.

5. Putnam acts as the advisor of the Putnam Prime Money Market Fund (the "Mutual Fund"), a money market mutual fund designed to serve as a short-term investment vehicle. The Mutual Fund is registered under the Investment Company Act of 1940 and is operated in accordance with the Securities & Exchange Commission (SEC) rules relating to money market funds (see, Rule 2a-7 under the Investment Company Act of 1940, as amended). The Applicant represents that since January 2006, the yield generated by the Mutual Fund has generally been superior to the yield generated by the STIF.

Accordingly, PFTC believes it would be desirable for the Collective Funds to have the flexibility to invest in the Mutual Fund when such investment is prudent and in the best interest of the Collective Funds.<sup>2</sup> Putnam further believes that it would be desirable to have the same flexibility to invest the assets of the Collective Funds in other money market mutual funds managed by Putnam when it is in the interest of the Collective Funds to do so.<sup>3</sup>

<sup>2</sup> In order to achieve the benefits of this higher yield as soon as practicable, PFTC requests that the exemption, if granted, be retroactive to the date the proposed exemption is published in the Federal Register.

<sup>3</sup> References to the Mutual Fund in this Summary of Facts and Representations should be read to include such other money market mutual funds where the context so requires.

6. Given that an affiliate of PFTC receives investment management or advisory fees from the Mutual Fund, a decision by PFTC to cause assets of a Collective Fund to be invested in the Mutual Fund could constitute a self-dealing prohibited transaction under Section 406(b)(1) of ERISA, absent an available exemption. Putnam may also receive fees from the Mutual Fund for services provided to the Mutual Fund other than investment management, investment advisory or similar services ("Secondary Services") in which event any increase in such fees as a result of PFTC's decision to invest assets of the Collective Funds in the Mutual Fund or the engagement of Putnam to perform an additional Secondary Service for which a fee is charged could constitute prohibited self-dealing, absent an exemption. Prohibited Transaction Exemption 77-4 (PTE 77-4, 42 FR 18732, April 8, 1977) is designed to provide exemptive relief in such situations. However, one of the conditions of PTE 77-4 is that an independent plan fiduciary approve in writing the investment of plan assets in the affiliated mutual fund.

7. In the case at hand, PFTC has not sought, and the relevant independent fiduciaries of existing ERISA Plan investors in the Collective Funds have not provided, any such written approval. Since the Collective Funds generally have numerous ERISA Plan investors (in many cases, a very large number of ERISA Plan investors), PFTC does not believe it is feasible, as a practical matter, to obtain the affirmative written approval of the relevant independent fiduciary of each and every ERISA Plan investor in the Collective Funds. Without such unanimous written approval, the exemption provided by PTE 77-4 will not be available and the Collective Funds will be precluded from investing in the Mutual Fund.

8. Similarly, in the event that Putnam is engaged to render an additional Secondary Service or any of the fees paid by the Mutual Fund is changed, PTE 77-4 would require PFTC to obtain the affirmative written approval of the relevant independent fiduciary of each ERISA Plan having an interest in the Collective Funds at the time of such engagement or change. Again, given the large number of ERISA Plans involved and the practical difficulty of obtaining an affirmative written approval from each and every one of them, it is unlikely that the requirements of PTE 77-4 would be able to be satisfied in the context of such an engagement or change.

9. No sales commissions are charged in connection with the purchase of any shares of the Mutual Fund. In addition, no 12b-1 fees are charged by the Mutual Fund with respect to any class of shares of the Mutual Fund to be purchased by the Collective Funds pursuant to the exemption transactions, nor will any redemption fees be charged in connection with any sale of shares of the Mutual Fund by the Collective Funds. Putnam, including any officer or director of Putnam, will not purchase or sell shares of the Mutual Fund from or to any Collective Fund. However, there may be purchases or redemptions of such shares between a Collective Fund and an affiliate of PFTC acting solely in its capacity as underwriter for the Mutual Fund, if the sale is at NAV, and such affiliate acts as a riskless principal and does not receive any compensation, spread or other consideration in connection with such purchase or redemption.

10. The Applicant represents that Putnam will not be providing any brokerage services for the acquisition or sale of securities by any Mutual Fund involved in this proposed exemption.

11. Prior to investing the assets of any Collective Fund in shares of the Mutual Fund, PFTC will provide advance notice to the relevant independent fiduciary of each ERISA Plan then having an interest in such Collective Fund. Such notice will include a current prospectus for the Fund and a written statement giving full disclosure of the fee structure under which either Putnam's investment advisory fees will be credited back to the Collective Fund or the investment management fees applicable to the Collective Fund with respect to the assets invested in the Mutual Fund will be waived. The notice will also describe why PFTC believes the investment of the Collective Fund's assets in the Mutual Fund may be appropriate. In the case of a Client Plan whose assets are proposed to be invested in the Collective Fund subsequent to the implementation of the arrangement and that has not authorized the investment of assets of the Collective Fund in the Mutual Fund, the Client Plan's investment in the Collective Fund is subject to the prior written authorization of a Second Fiduciary.

12. In the event the fee credit approach is utilized, the credit will not include any fees received by Putnam for Secondary Services rendered to the Mutual Fund because any such Secondary Services will not be duplicative of any services being provided by PFTC to the Collective Funds.

13. PFTC represents that, for each ERISA Plan having an interest in a Collective Fund that engages in transactions described in this proposed exemption, the combined total of all fees that Putnam will receive, directly or indirectly, with respect to such ERISA Plan's interest in the Collective Fund for the provision of services to the Collective Fund and/or to the Mutual Fund will not be in excess of "reasonable compensation" within the meaning of Section 408(b)(2) of the Act.

14. Prior to either the addition of any Secondary Service that will result in the payment of a fee by the Mutual Fund to Putnam or any increase in the rate of any fee paid to Putnam by the Mutual Fund, PFTC will provide advance notice to the relevant independent fiduciary of each ERISA Plan then having an interest in a Collective Fund as to which the utilization of the Mutual Fund has been approved. Such notice will include a description, as applicable, of the (i) additional Secondary Service to be provided by Putnam and the resultant fee payable to Putnam or (ii) increase in the rate of any such fee payable to Putnam by the Mutual Fund or from a decrease in the number or kind of services performed by Putnam. Such written notice will also include a form (the Termination Form) expressly providing an election to withdraw from the Collective Fund, together with instructions on the use of such form.

The advance notice described in this representation 13 need not be furnished 30 days in advance of the effective date for a fee increase provided an amount equal to the Collective Fund's proportionate share of the fee for such additional Secondary Service or the fee increase, whichever is applicable, for the period from the date of commencement of the additional Secondary Service or implementation of the fee increase, whichever is applicable, to the date that is 30 days after the delivery of the required notice or the date of the withdrawal of any objecting Client Plan, whichever is later, is credited to the Collective Fund with interest thereon at the prevailing Federal funds rate plus two percent (2%) ("the Applicable Interest Rate").<sup>4</sup>

<sup>4</sup> As an example, assume the Mutual Fund fee increase becomes effective on June 1, Putnam provides notice of the fee increase on May 16 and one (and only one) participating Plan objects to the fee increase on June 10, and the sole objecting Plan withdraws from the Collective Fund on June 20. In this case, Putnam will pay a rebate to the Collective Fund equal to the allocable portion of the fee increase for the period from June 1 (*i.e.*, the effective date of the fee increase) to June 20 (*i.e.*, the date that one objecting Plan withdrew, (with interest at the Applicable Interest Rate) because that

15. PFTC will maintain a system of internal accounting controls for the crediting or waiving of all relevant fees. In addition, PFTC proposes to retain Ernst & Young or another independent accounting firm to audit annually the crediting of such fees. Such audits will provide independent verification of the proper crediting of such fees. In the event an error is identified, it will be promptly corrected. If the correction requires a payment by PFTC, such payment shall include interest at the money market rate earned by the Mutual Fund. An independent accounting firm will also audit the crediting of fees and interest at the Applicable Interest Rate for the scenario described in paragraph 13, above.

16. The information described above (including (a) the information to be provided prior to the initial utilization of the Mutual Fund and (b) the information to be provided in connection with any additional Secondary Service or any increase in the rate of any fee payable by the Mutual Fund to Putnam (unless an amount equal to the Collective Fund's proportionate share of the fee for such additional Secondary Service or fee increase, whichever is applicable, is credited to the Collective Fund with interest at the Applicable Interest Rate thereon)), will be furnished to the relevant independent fiduciary of each ERISA Plan then investing in the Collective Fund not less than 30 days prior to the initiation of investment in the Mutual Fund by such Collective Fund or the implementation of the additional Secondary Service or the increase in the rate of any such fee payable to Putnam.<sup>5</sup>

17. In the event any such independent fiduciary submits a notice in writing to PFTC objecting to the initial utilization, additional Secondary Service or increased rate of fee, including a decrease in the number or kind of services performed by Putnam (unless an amount equal to the Collective Fund's share of the fee for such additional service or fee increase, whichever is applicable, is credited to the Collective Fund with interest at the Applicable Interest Rate thereon), the

date is later than the expiration of the 30-day notice period).

<sup>5</sup> The requested exemption would not apply to any plans maintained by Putnam or any of its affiliates for their own employees. The Applicant represents that to the extent any such plans have an interest in a Collective Fund, the investment of such Collective Fund's assets attributable to such plans in the Mutual Fund would be covered by Prohibited Transaction Exemption 77-3 (42 FR 18734, April 8, 1977). The Department expresses no opinion herein on whether such transactions would qualify for exemptive relief under PTE 77-3.

ERISA Plan on whose behalf the objection was tendered will be given the opportunity to withdraw its investment in the Collective Fund, without penalty to such ERISA Plan, within such time as may be necessary to effect such withdrawal in an orderly manner that is equitable to all withdrawing ERISA Plans and all non-withdrawing ERISA Plans. In the case of an ERISA Plan that elects to withdraw pursuant to the preceding sentence, such withdrawal shall be effected prior to (a) the initial utilization of the Mutual Fund, or (b) the implementation of the additional Secondary Service or the increase in the rate of fee (unless an amount equal to the fee for such additional Secondary Service or fee increase, whichever is applicable, for the period from the date of such implementation to the date on which the objecting Client Plan has withdrawn from the Collective Fund is credited to the Collective Fund with interest at the Applicable Interest Rate thereon); provided, however, that the Collective Fund's existing investment in the Mutual Fund need not be discontinued by reason of an ERISA Plan electing to withdraw. Putnam confirms that it will not receive any "float" with respect to its receipt of incremental fees for Secondary Services that become effective before the requisite negative consent has been obtained and that, as a result, must be credited to the Collective Fund. This is because Putnam will credit interest on any such amounts from the date it receives such incremental amounts to the date they are actually credited to the Collective Fund. Putnam emphasizes that the amount credited to the Collective Fund would not be limited to the portion of the fee increase that is allocable to the objecting Client Plan(s), but rather will be equal to the portion of the fee increase that is allocable to the Collective Fund's entire position in the Mutual Fund. Putnam represents that any such cash credits will be paid to the Collective Fund, with interest thereon at the Applicable Interest Rate, no later than the fifth business day following the receipt of the increased fee by Putnam.<sup>6</sup>

<sup>6</sup> As an example, assume the mutual fund fee increase is effective on June 1. Putnam provides notice of the fee increase to the participating Plans on May 31, one (and only one) participating Plan objects to the fee increase on June 25, and the sole objecting Plan withdraws from the Collective Fund on July 10. In this case, the aggregate rebate amount would be equal to the allocable portion of the fee increase for the period from June 1 (i.e., the effective date of the fee increase) to July 10 (i.e., the date that the sole objecting Plan withdraws, given that it is later than the expiration of the 30-day notice period). Further, assuming that Putnam receives payments of the increased fee from the Mutual Fund on the fifth day of each month, Putnam would receive a payment that includes the

Putnam further confirms that if a Client Plan objects to a Mutual Fund fee increase at a time when, due to extraordinary circumstances, withdrawals from the Collective Fund are suspended, then Putnam would continue to credit the allocable amount of the fee increase to the Collective Fund, with interest, until the objecting Client Plan is able to withdraw. To summarize, if Putnam were to implement an additional Secondary Service or increase the rate of fee for any Secondary Service before the expiration of the 30-day period after notice has been given to Plans, and a Plan objects and wishes to withdraw from the Collective Fund, Putnam will pay a rebate to the Collective Fund, with interest at the Applicable Interest Rate thereon, from the effective date of the fee increase to the later of the expiration of the 30-day period or the date on which the objecting Plan withdraws from the Collective Fund. Such rebate will be paid by Putnam within five business days of the date that Putnam actually receives the increased fee from the Mutual Fund.

18. On an annual basis, Putnam will provide notice to the relevant independent fiduciary of each ERISA Plan having an interest in the Collective Fund, which notice will include: (a) The approximate percentage (which may be in the form of a range) of the Collective Fund's assets that were invested in the Mutual Fund during the year; and (b) a statement that, if the fiduciary objects to the continued investment by the Collective Fund in the Mutual Fund, the ERISA Plan should withdraw from the Collective Fund, and (c) a Termination Form<sup>7</sup> expressly providing an election to withdraw from the Collective Fund, together with instructions on the use of such form. Specifically, the instructions will explain that the Client Plan has the opportunity to withdraw from the Collective Fund by submitting the completed Termination Form to PFTC.

fee increase for the month of June on July 5 and would rebate the entire allocable portion of that fee increase to the Collective Fund within 5 business days of July 5, with interest at the Applicable Interest Rate. Moreover, on August 5, Putnam would receive another payment from the Mutual Fund that includes the fee increase for the month of July. The allocable portion of the fee increase for the period from July 1 to July 10 (i.e., the date that the sole objecting Plan withdrew) would be rebated to the Collective Fund within 5 business days of August 5, with interest at the Applicable Interest Rate.

<sup>7</sup> However, if the Termination Form has been provided to the Second Fiduciary pursuant to Section 1(j), the Termination Form need not be provided again for an annual reauthorization pursuant to this Section 1(i) unless at least six months has elapsed since the form was previously provided.

Further, the instructions will provide the PFTC address to which the form must be submitted. The form will further provide that upon receipt thereof, the Client Plan's interest in the Collective Fund that is the subject of such withdrawal election will be redeemed as of the next regularly scheduled withdrawal date of the Collective Fund, following whatever advance notice period is applicable to the particular Collective Fund (assuming, of course, that such Collective Fund is not subject to a suspension of withdrawals due to extraordinary events). PFTC represents that, consistent with standard practice in the industry with respect to collective funds, the governing documents of Putnam's Collective Funds contain provisions that allow for the suspension of withdrawals in extraordinary and unusual circumstances, such as market shutdowns, etc.

19. All other dealings between the Collective Funds and the Mutual Fund will be on a basis no less favorable to the Collective Fund than such dealings will be with the other shareholders of the Mutual Fund.

20. In summary, PFTC represents that the exemption transactions described herein will satisfy the statutory criteria of Section 408(a) of the Act because (a) the ability to invest in the Mutual Fund will provide the Collective Funds the opportunity to enhance the yield on their cash balances and other short-term investments; (b) PFTC will require annual audits by an independent accounting firm to verify the proper crediting of the relevant fees and interest due, if applicable; (c) PFTC will provide written notice to the relevant independent fiduciary of each affected ERISA Plan in advance of (i) the initial utilization by the Collective Fund of the Mutual Fund, (ii) the commencement of an additional Secondary Service by Putnam (unless an amount equal to the Collective Fund's proportionate share of the fee for such additional Secondary Service is credited to the Collective Fund with interest at the Applicable Interest Rate thereon) or (iii) the effective date of any increase in the rate of any fee payable to Putnam by the Mutual Fund (unless an amount equal to the Collective Fund's proportionate share of the fee increase is credited to the Collective Fund with interest at the Applicable Interest Rate thereon); (d) prior to any such initial utilization, commencement or increase, such independent fiduciary will have an opportunity to express an objection and to cause the Client Plan to withdraw from the Collective Fund, provided that Putnam may commence providing an

additional Secondary Service for a fee or implement an increase in the rate of fee paid by the Mutual Fund to Putnam prior to the withdrawal of the objecting Client Plan as long as the amount described in (c) above is credited to the Collective Fund; (e) no commissions or redemption fees will be paid by an ERISA Plan in connection with either the purchase or sale of shares of the Mutual Fund; (f) Putnam will not receive any 12b-1 fees as a result of the Collective Fund's purchase or holding of shares of the Mutual Fund; and (g) all dealings between the Collective Funds and the Mutual Fund will be on a basis that is at least as favorable to the ERISA Plans as such dealings are with other shareholders of the Mutual Fund.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gary H. Lefkowitz of the Department, telephone (202) 693-8546. (This is not a toll-free number.)

The PNC Financial Services Group, Inc., Located in Pittsburgh, Pennsylvania, [Application No. D-11448].

### Proposed Exemption

#### *Section I—Exemption for In-Kind Redemption of Assets*

The Department is considering granting an exemption under the authority of section 408(a) of the Act and 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570 Subpart B (55 FR 32836, 32847, August 10, 1990). If the proposed exemption is granted, the restrictions in sections 406(a)(1)(A) through (D) and 406(b)(1) and (b)(2) of the Act, and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply<sup>8</sup> to certain in-kind redemptions (the Redemption(s)) by The Employees' Thrift Plan of Mercantile Bankshares Corporation and Participating Affiliates (the Mercantile Plan) that occurred overnight on October 31, 2007, of shares (the Shares) of proprietary mutual funds (the Funds) for which The PNC Financial Services Group, Inc. (PNC) or an affiliate thereof provides investment advisory and other services, provided that the following conditions were satisfied:

(A) No sales commissions, redemption fees, or other similar fees were paid in connection with the Redemptions (other than customary transfer charges paid to parties other than PNC and any affiliates of PNC (PNC Affiliates));

<sup>8</sup> For purposes of this proposed exemption, references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

(B) The assets transferred to the Mercantile Plan pursuant to the Redemptions consisted entirely of cash and Transferable Securities, as such term is defined in Section II, below;

(C) In each Redemption, the Mercantile Plan received its pro rata portion of the securities with respect to the Capital Opportunities Fund, and certain securities, selected pursuant to a verifiable methodology, that were approved by an independent fiduciary (Independent Fiduciary, as such term is defined in Section II) with respect to the other four Funds covered by this proposed exemption, such that the securities received were equal in value to that of the number of Shares redeemed, as determined in a single valuation (using sources independent of PNC and PNC Affiliates) performed in the same manner and as of the close of business on the same day, in accordance with Rule 2a-4 under the Investment Company Act of 1940, as amended (the 1940 Act) and the then-existing procedures adopted by the Board of Directors of PNC Funds, Inc., which were in compliance with all applicable securities laws;

(D) Neither PNC nor any PNC Affiliate received any direct or indirect compensation or any fees, including any fees payable pursuant to Rule 12b-1 under the 1940 Act, in connection with any Redemption of the Shares;

(E) Prior to a Redemption, the Independent Fiduciary received a full written disclosure of information regarding the Redemption;

(F) Prior to a Redemption, the Independent Fiduciary communicated its approval for such Redemption to PNC;

(G) Prior to a Redemption, based on the disclosures provided to the Independent Fiduciary, the Independent Fiduciary determined that the terms of the Redemption were fair to the Mercantile Plan, and comparable to and no less favorable than terms obtainable at arm's length between unaffiliated parties, and that the Redemption was in the best interests of the Mercantile Plan and its participants and beneficiaries;

(H) Not later than thirty (30) business days after the completion of a Redemption, the Independent Fiduciary received a written confirmation regarding such Redemption containing:

(i) The number of Shares held by the Mercantile Plan immediately before the Redemption (and the related per Share net asset value and the total dollar value of the Shares held) for each Fund;

(ii) The identity (and related aggregate dollar value) of each security provided to the Mercantile Plan pursuant to the Redemption, including each security

valued in accordance with Rule 2a-4 under the 1940 Act and procedures adopted by the Board of Directors of PNC Funds, Inc. (using sources independent of PNC and PNC Affiliates);

(iii) The current market price of each security received by the Mercantile Plan pursuant to the Redemption; and

(iv) If applicable, the identity of each pricing service or market maker consulted in determining the value of such securities;

(I) The value of the securities received by the Mercantile Plan for each redeemed Share equaled the net asset value of such Share at the time of the transaction, and such value equaled the value that would have been received by any other investor for shares of the same class of the Fund at that time;

(J) Subsequent to a Redemption, the Independent Fiduciary performed a post-transaction review that included, among other things, a random sampling of the pricing information it received;

(K) Each of the Mercantile Plan's dealings with the Funds, the investment advisors to the Funds, the principal underwriter for the Funds, or any affiliated person thereof, were on a basis no less favorable to the Mercantile Plan than dealings between the Funds and other shareholders holding shares of the same class as the Shares;

(L) Within sixty (60) days of the date of publication of this notice of proposed exemption, PNC reimburses The PNC Financial Services Group, Inc. Incentive Savings Plan (the PNC Plan), into which the Mercantile Plan was merged on November 1, 2007, for all brokerage costs incurred by the Mercantile Plan on November 1, 2007 to liquidate the securities that the Mercantile Plan received in kind pursuant to a Redemption;

(M) PNC maintains, or causes to be maintained, for a period of six years from the date of any covered transaction such records as are necessary to enable the persons described in paragraph (N) below to determine whether the conditions of this exemption have been met, except that (i) a separate prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of PNC, the records are lost or destroyed prior to the end of the six-year period and (ii) no party in interest with respect to the Mercantile Plan other than PNC shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975(a) and (b) of the Code if such records are not maintained or are not available for examination as required by paragraph (N) below;

(N)(1) Except as provided in subparagraph (2) of this paragraph (N), and notwithstanding any provisions of section 504(a)(2) and (b) of the Act, the records referred to in paragraph (M) above are unconditionally available at their customary locations for examination during normal business hours by (i) any duly authorized employee or representative of the Department, the Internal Revenue Service, or the Securities and Exchange Commission (SEC), (ii) any fiduciary of the PNC Plan as the successor to the Mercantile Plan or any duly authorized representative of such fiduciary, (iii) any participant or beneficiary of the PNC Plan as the successor to the Mercantile Plan or duly authorized representative of such participant or beneficiary, and (iv) any employer whose employees are covered by the PNC Plan as the successor to the Mercantile Plan and any employee organization whose members are covered by such plan;

(2) None of the persons described in paragraphs (N)(1)(ii), (iii) and (iv) shall be authorized to examine trade secrets of PNC or the Funds, or commercial or financial information which is privileged or confidential;

(3) Should PNC or the Funds refuse to disclose information on the basis that such information is exempt from disclosure pursuant to paragraph (N)(2) above, PNC or the Funds shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

#### Section II—Definitions

For purposes of this exemption—

(A) The term “affiliate” means:

(1) Any person (including corporation or partnership) directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(B) The term “control” means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(C) The term “net asset value” means the amount for purposes of pricing all purchases and sales calculated by dividing the value of all securities, determined by a method as set forth in the Fund’s prospectus and statement of

additional information, and other assets belonging to the Fund, less the liabilities charged to each such Fund, by the number of outstanding shares.

(D) The term “Independent Fiduciary” means a fiduciary who is: (i) Independent of and unrelated to PNC and its affiliates, and (ii) appointed to act on behalf of the Mercantile Plan with respect to the in-kind transfer of assets from one or more Funds to, or for the benefit of, the Mercantile Plan. For purposes of this exemption, a fiduciary will not be deemed to be independent of and unrelated to PNC if: (i) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with, PNC; (ii) such fiduciary directly or indirectly receives any compensation or other consideration in connection with any transaction described in this exemption (except that an independent fiduciary may receive compensation from PNC in connection with the transactions contemplated herein if the amount or payment of such compensation is not contingent upon, or in any way affected by, the independent fiduciary’s decision); and (iii) an amount equal to more than one percent (1%) of such fiduciary’s gross income (for federal income tax purposes, in its prior tax year), is paid by PNC and its affiliates to the fiduciary in 2007, the tax year at issue.

(E) The term “Transferable Securities” means securities (1) for which market quotations are readily available (as determined under Rule 2a-4 of the 1940 Act) from persons independent of PNC and (2) which are not:

(i) Securities that, if publicly offered or sold, would require registration under the Securities Act of 1933;

(ii) Securities issued by entities in countries which (a) restrict or prohibit the holding of securities by non-nationals other than through qualified investment vehicles, such as the Funds, or (b) permit transfers of ownership of securities to be effected only by transactions conducted on a local stock exchange;

(iii) Certain portfolio positions (such as forward foreign currency contracts, futures and options contracts, swap transactions, certificates of deposit, and repurchase agreements) that, although liquid and marketable, involve the assumption of contractual obligations, require special trading facilities, or can only be traded with the counter-party to the transaction to effect a change in beneficial ownership;

(iv) Cash equivalents (such as certificates of deposit, commercial paper, and repurchase agreements);

(v) Other assets that are not readily distributable (including receivables and

prepaid expenses), net of all liabilities (including accounts payable); and

(vi) Securities subject to “stop transfer” instructions or similar contractual restrictions on transfer.

(F) The term “relative” means a “relative” as that term is defined in section 3(15) of the Act (or a “member of the family” as that term is defined in section 4975(e)(6) of the Code), or a brother, sister, or a spouse of a brother or a sister.

*Effective Date:* The exemption, if granted, will be effective as of October 31, 2007.<sup>9</sup>

#### Summary of Facts and Representations

1. The PNC Financial Services Group, Inc. (PNC) is a bank holding company that owns or controls two principal banks, (i) PNC Bank, National Association (PNC Bank, N.A.) and (ii) PNC Bank, Delaware, as well as a number of non-bank subsidiaries. In addition, on March 2, 2007, PNC acquired Mercantile Bankshares Corporation (Mercantile), the parent company of eleven subsidiary banks. PNC merged the Mercantile subsidiary banks with, and into, PNC Bank, N.A. on September 14, 2007, pursuant to an application filed with, and approved by, the Office of the Comptroller of the Currency. Immediately after consummation of that merger, PNC Bank, N.A. transferred to PNC Bank, Delaware nine Delaware branches previously held by two of the Mercantile subsidiary banks, pursuant to a Bank Merger Act application filed

<sup>9</sup> As a general matter, it is the Department’s view that the model practice to effect an in-kind redemption by a mutual fund to a shareholder pension plan, subject to Title I of ERISA, is through a pro rata distribution because the adoption of such a method ensures that the individual stocks selected for the in-kind redemption are objectively determined. The Department recognizes that the in-kind redemption described in this notice of proposed exemption involves unique circumstances because, among other things, it facilitated the transfer of plan assets and the merger of The Employees’ Thrift Plan of Mercantile Bankshares Corporation and Participating Affiliates (the Mercantile Plan) with The PNC Financial Services Group, Inc. Incentive Savings Plan (the PNC Plan). See also Facts and Representations #12, which summarizes the basis for satisfying the section 408(a) statutory criteria for providing exemptive relief. In this regard, an important condition contained in this notice of proposed exemption is that PNC will pay all brokerage commissions associated with the Mercantile Plan’s sale of the securities received in the Redemptions. Further, the Department encourages applicants, their advisers and counsel to confer, in advance, with EBSA’s Office of Exemption Determinations as to whether a contemplated non-pro rata in-kind redemption involving plan assets may qualify for prohibited transaction exemptive relief. Although the applicant requested both retroactive and prospective exemptive relief, the Department is proposing only retroactive exemptive relief relating to the October 31, 2007 Redemptions.

with, and approved by, the Federal Reserve Bank of Cleveland.

PNC provides, through its subsidiaries, a wide variety of trust and banking services to individuals, corporations, and institutions. Through its banking subsidiaries, PNC provides investment management, fiduciary, and trustee services to employee benefit plans and charitable and endowment assets, as well as non-discretionary services and investment options for defined contribution plans. PNC also provides a range of tailored investment, trust, and private banking products to affluent individuals and families.

PNC, through its affiliates, also provides various types of administrative services to mutual funds, including acting as transfer and disbursing agent and providing custodial and accounting services.

2. In connection with PNC's acquisition of Mercantile, PNC assumed sponsorship of The Employees' Thrift Plan of Mercantile Bankshares Corporation and Participating Affiliates (the Mercantile Plan), a qualified defined contribution retirement plan, and PNC Bank, N.A. became the Mercantile Plan's trustee. PNC Bank, N.A. is also the trustee of The PNC Financial Services Group, Inc. Incentive Savings Plan (the PNC Plan), a qualified defined contribution plan sponsored by PNC.

The applicant represents that the Administrative Committee of PNC (the Committee), the named fiduciary for plan investments for the PNC Plan, acting in its fiduciary capacity, initiated a study of how best to integrate the investment options under the two Plans, which had different investment platforms. The Mercantile Plan used eight proprietary mutual funds, each of which is a series of PNC Funds, Inc.<sup>10</sup> (*i.e.*, the Funds),<sup>11</sup> while the PNC Plan used an "open" platform that includes non-proprietary funds.<sup>12</sup>

<sup>10</sup> Prior to October 1, 2007, the name of the Fund family was "Mercantile Funds, Inc."

<sup>11</sup> It is represented that the Mercantile Plan's assets were invested in the Funds in accordance with Prohibited Transaction Exemption (PTE) 77-3. PTE 77-3 (42 FR 18734, April 8, 1977) is a class exemption that permits, under certain conditions, the acquisition or sale of shares of a registered, open-end investment company by an employee benefit plan covering only employees of such investment company, employees of the investment adviser or principal underwriter for such investment company, or employees of any affiliated person (as defined therein) of such investment adviser or principal underwriter. The Department expresses no opinion herein as to whether the terms and conditions of PTE 77-3 were satisfied.

<sup>12</sup> The applicant has disclosed that several of these third-party mutual funds included among the PNC Plan investment options are advised by BlackRock, Inc., in which PNC has a significant minority interest (approximately 34%).

The Committee was advised by its investment consultant Wilshire Associates (Wilshire), who is also the Independent Fiduciary for the Mercantile Plan in the subject Redemptions, to transition the Mercantile Plan participants to the PNC Plan investment platform as soon as it would be prudent to do so. Wilshire's recommendation considered, among other things, the additional costs to the PNC Plan to maintain two separate investment platforms, the appropriateness of the funds on the PNC Plan investment platform, and the upcoming administrative costs associated with the transition of Mercantile employees to the PNC payroll. On this basis, the Committee determined that it would be prudent, and in the best interests of the Mercantile Plan participants and beneficiaries, to transfer out of such plan's investment options as soon as possible.

Effective November 1, 2007, the Mercantile Plan was merged into the PNC Plan. In connection therewith, Mercantile Plan assets invested in shares of the Funds (the Shares) were redeemed in order to acquire shares of mutual funds available as investment options under the PNC Plan.

3. According to the applicant, each of the eight Funds is a registered investment company subject to the 1940 Act and constitutes a distinct investment vehicle, which has a joint prospectus with the other Funds. The overall management of the Funds, including the negotiation of investment advisory contracts, rests with the Board of Directors of the Funds (the Fund Board); the Fund Board is elected by the shareholders of the Funds and includes a majority of individuals who are not "interested persons" (as defined in the 1940 Act) of the Funds and are represented to be independent directors.

PNC, through its affiliate PNC Capital Advisors, Inc. (PCA),<sup>13</sup> serves as the investment adviser, within the meaning of section 2(20) of the 1940 Act, to each Fund. In certain instances, the investment adviser may pay fees to sub-advisers, which may also be PNC affiliates.

PCA also serves as administrator for the Funds. As administrator, PCA maintains the Fund's offices, coordinates preparation of reports to shareholders, prepares filings with state securities commissions, and coordinates federal and state tax returns, among other administrative functions.

<sup>13</sup> Prior to September 17, 2007, PCA was named "Mercantile Capital Advisors, Inc."

The other service providers to the Funds, including the additional sub-advisers, the distributor, the fund accountant, the transfer agent, and the custodian, are all independent of, and unaffiliated with, PNC.

The Funds charge a Rule 12b-1 distribution fee that is between 0.50% and 1.00% with respect to their Class A and Class C shares. However, Institutional Shares, the class offered to plan investors, are not subject to 12b-1 fees.

4. In accordance with the procedures of the Funds, the Fund Board, including a majority of the directors who are represented to be unaffiliated and independent of PNC and Mercantile, determined that the redemption of Shares by the Mercantile Plan with respect to five of the eight Funds should be effected in kind and in cash. The Funds elected to be governed by the provisions of Rule 18f-1 under the 1940 Act. This election committed each Fund, during any ninety-day period for any one shareholder, to redeem its shares solely in cash up to the lesser of \$250,000 or 1% of the Fund's net asset value at the beginning of such period. Accordingly, the redemption with respect to each Fund included a cash redemption of \$250,000.

The applicant notes that PTE 77-3 provides exemptive relief for the sale of shares of a mutual fund by an employee benefit plan covering employees of the investment adviser for the mutual fund and its affiliates, subject to certain conditions. However, in previous published exemptions involving the in-kind redemption of shares by plans sponsored by the investment advisers of mutual funds, the notices describe PTE 77-3 as being available for a redemption of shares for cash, implying that PTE 77-3 would not be available for an in-kind redemption. See, *e.g.*, PTE 2003-01 (68 FR 6194, February 6, 2003) granted to the Northern Trust Company and Affiliates; PTE 2002-20 (67 FR 4986, March 28, 2002) granted to the Union Bank of California; and PTE 2001-46 (66 FR 64280, December 12, 2001) granted to Bank of America Corporation.<sup>14</sup>

The Redemptions commenced after the close of the financial markets on October 31, 2007. In its application dated November 1, 2007, PNC requests retroactive exemptive relief for the in-kind Redemption of the Mercantile Plan's investments in the Funds. PNC asserts that it meets the standards for a retroactive exemption set forth in ERISA

<sup>14</sup> The most recent examples are PTE 2008-4 (73 FR 13585, March 13, 2008) granted to GE Asset Management Incorporated and 2007-04 (72 FR 13126, March 20, 2007) granted to Mellon Financial Corporation.



Technical Release 85-1 because it acted in good faith, *i.e.*, PNC identified the potential prohibited transactions, sought legal counsel prior to the execution of the Redemptions, and structured the Redemption transactions in a manner to ensure that the necessary safeguards

were in place, including review and approval by a qualified, independent fiduciary (as described further in Item 10, below).

The five of the eight Funds involved in the in-kind Redemption transactions were: the Growth & Income Fund, the

Equity Growth Fund, the Equity Income Fund, the Capital Opportunities Fund, and the International Equity Fund. It is represented that, as of October 30, 2007, the Mercantile Plan's approximate percentages of ownership for each of these Funds were as follows.

Fund	Estimated mercantile plan assets	Approximate percentage of fund held by mercantile plan
Growth & Income Fund .....	\$87,622,519.81	21.22
Equity Growth Fund .....	12,285,590.58	23.43
Equity Income Fund .....	11,246,725.44	12.52
Capital Opportunities Fund .....	11,154,446.73	5.39
International Equity Fund .....	29,540,576.94	3.58

5. *Fund Redemption Procedures.* The applicant represents that neither the Mercantile Plan nor the Committee had any control over the manner in which the Redemptions were consummated. The Fund Board had the authority, pursuant to the Funds' procedures, to decide the manner in which the Redemptions were effected, and the counsel to the Funds has represented that the Redemptions were effected in compliance with federal securities laws.

Because the Mercantile Plan's investment in some of the Funds exceeded 5% of Fund assets, the Fund's pre-established redemption procedures required a determination by the Fund Board whether the redemption should be made in kind rather than in cash. The Funds' "Procedures for Redemptions In Kind to Affiliated Shareholders" (adopted by the Fund Board on May 19, 2006) were designed to comply with the 1940 Act rules governing transactions with affiliated entities and, in particular, with the SEC no-action letter issued to *Signature Financial Group, Inc.* (the *Signature* letter).<sup>15</sup> These

<sup>15</sup> According to the applicant, the *Signature* letter (Dec. 28, 1999) permits in-kind redemptions by an affiliated shareholder under certain conditions set forth in the letter. Those conditions are designed to address the fact that, in many instances, the affiliate may have the ability and pecuniary incentive to influence the actions of the mutual fund, which presents the affiliate with an opportunity to inappropriately influence the mutual fund. To this end, the *Signature* letter requires a mutual fund's Board of Directors to adopt procedures designed to ensure that the affiliated shareholder does not influence the selection of the securities to be redeemed in kind. The SEC staff made clear its view that a pro rata security selection process essentially eliminated the affiliated shareholder's ability to influence or control the security selection process and, therefore, the SEC staff would not recommend enforcement action under the 1940 Act with respect to a pro rata in-kind redemption to an affiliate. However, also according to the applicant, the SEC staff also made clear that a mutual fund's Board of Directors could use any other method for selecting the securities to be redeemed in kind, provided that such selection process addressed the affiliate's

redemption procedures require the Fund Board to consider the following factors:

(b) The percentage of the Fund's shares that are being redeemed and over what time period the transactions will occur;

(c) The tax impact to remaining shareholders;

(d) Portfolio transaction costs, including associated commission and transfer fees, and potential market impact;

(e) Other direct expenses, including custody transaction charges and fund accounting charges; and

e. Effect on the Fund's investment policies. For example, would the Fund temporarily be out of compliance with stated investment objectives due to the need to increase cash holdings, and if so for what period of time?

Further, the pre-established redemption procedures require that the Fund Board, including a majority of its members who are not "interested persons" (as defined in the 1940 Act), determine that (1) the redemption will not favor the redeeming shareholder to the detriment of any other shareholder; and (2) the redemption will be in the best interests of the Fund. If the distribution of securities from the Fund in the redemption is *pro rata* - *i.e.*, of each security in the Fund's portfolio in proportion to the redeeming shareholder's interest in the overall Fund—prior approval of the Fund Board is not required; however, if the distribution is not *pro rata*, then the Fund Board must approve the redemption in advance of the redemption date, in conformity with the conditions of the *Signature* letter.

In late July 2007, the Fund Board, including a majority of its independent Directors, determined, in accordance

ability to influence or control the security selection process.

with the Fund procedures, not only that the Redemptions should be effected in kind for five of the eight Funds but also that the distribution of securities from four of those five Funds (all except the Capital Opportunities Fund) would be made on a non-*pro rata* basis, and approved conducting the Redemptions in this manner. The distribution of securities from the Capital Opportunities Fund would be made on a *pro rata* basis, except for those not meeting the definition of "Transferable Securities" as defined in Section II(E) of this notice. The Fund Board's determinations regarding the Redemptions were based upon the conclusions reached by the Chief Compliance Officer (CCO) of the Funds.

6. *Non-pro rata Exemptions.* The applicant acknowledges that similar individual exemptions involving in-kind redemptions previously granted by the Department contained a condition requiring that the distribution of securities be *pro rata*. The applicant distinguishes the instant exemption request—involving the in-kind Redemption of shares from five Funds, four on a non-*pro rata* basis—by noting that the prior cases involved an in-kind transfer of the distributed securities to another proprietary fund of the fiduciary or an affiliate or to a separate account managed by the fiduciary or an affiliate, with a similar portfolio of investments. The applicant points out that, as a general matter, the Mercantile Plan had no intention of holding the securities received. Thus, the focus was on the ability of the Mercantile Plan to immediately sell the securities received rather than to continue to manage those securities, based upon Wilshire's advice for the Mercantile Plan to replace its investment platform. The Redemptions in the instant case were immediately followed by liquidation of the vast majority of the distributed securities

and reinvestment of the sale proceeds in third-party mutual funds available under the PNC Plan.<sup>16</sup> The Committee, in consultation with Wilshire, determined that it was in the Mercantile Plan's best interests to receive a smaller number of highly liquid securities in larger blocks in order to facilitate an easier and less costly liquidation, a goal that could be achieved only by means of a non-*pro rata* redemption. For example, in the case of the International Equity Fund, the implementation of a *pro rata* redemption would have resulted in the receipt of over 480 different securities.

7. *Security Selection Criteria.* The applicant represents that the selection of the particular securities to be distributed was made in accordance with the established procedures of the Funds, pursuant to the methodology described below, and was reviewed and approved in advance by the CCO, who is represented by the applicant to be "independent" of, and not affiliated with, PNC. The CCO reviewed the securities selected for the Redemptions and the method of selection. The CCO concluded in his report of October 29, 2007 to the Fund Board that the selection of the securities was made so as not to harm either the Mercantile Plan or the shareholders remaining in the Funds.

When the Committee learned that the Funds planned to make several of the distributions in kind, it communicated to the Funds the Mercantile Plan's preference for large blocks of highly liquid securities. It is represented that the Funds took the Mercantile Plan's preferences into consideration in determining the security selection criteria used for the Redemptions.

Ultimately, following review of the proposed selection methodology by the Funds' CCO, the Funds used three criteria for the selection of the securities to be distributed in the Redemptions. As memorialized in an October 29, 2007 memorandum by the CCO, who was required to review the methodology to assure that Fund procedures were satisfied and that there was no overreaching in favor of either the redeeming shareholder or the non-redeeming shareholder, those criteria were:

- A minimum detriment to the remaining shareholders in the fund (*i.e.* tax and other expenses).

<sup>16</sup> According to the applicant, the only securities not liquidated were those accepted in kind by two of the third-party receiving funds; those securities were immediately transferred to the new funds within one business day from the date of the Mercantile Plan's receipt.

- A minimum number of securities transferred and, therefore, a minimum in associated transaction costs [*i.e.*, for the Mercantile Plan as the redeeming shareholder receiving the securities].

- A preference for liquid securities.

*Large Cap Domestic Funds.* For the three domestic equity Funds involved in the non-*pro rata* Redemptions—the Equity Income Fund, the Equity Growth Fund and the Growth and Income Fund—liquidity was not an issue, as all of their security holdings were liquid. It was decided that the other two criteria could best be met by delivering those tax lots in each fund that represented the greatest percentage appreciation over their cost, because that would minimize the tax impact on the remaining shareholders while reducing the number of securities distributed to the redeeming shareholder. The CCO noted in his report that the Funds' investment adviser, and Citi Fund Services, Inc., the Funds' sub-administrator and an independent party, both verified that the selection methodology properly identified the tax lots with the greatest increases and ranked the tax lots accordingly.

The applicant represents that the Funds would have used the same approach of allocating by tax lot even in conducting an in-kind redemption with a taxable shareholder because the redeeming shareholder is indifferent to the tax basis of the received securities. According to the applicant, the reason is that the shareholder, if subject to tax, recognizes gain or loss equal to the difference between the fair market value of the assets distributed and the shareholder's adjusted tax basis in its fund shares—the tax basis of the distributed assets is not a factor. At the same time, a mutual fund that qualifies as a regulated investment company (a RIC) under the Code does not recognize gain on the distribution of securities to a redeeming shareholder.

*International Equity Fund.* For the International Equity Fund, the Fund's independent sub-adviser, Morgan Stanley,<sup>17</sup> consistent with the criteria described in the CCO's memorandum, followed the objective of selecting as small a number of securities as possible and limiting the selections to tradable issues in tradable volumes, as preferred by the Committee, while also avoiding an adverse effect on the remaining shareholders. The Fund Board had concerns about the transferability of

<sup>17</sup> Morgan Stanley was one of two sub-advisers for the International Equity Fund, managing approximately 80% of the Fund's assets. The Mercantile Plan's proportionate interest in the portfolio of the other sub-adviser was distributed in cash.

many of the securities in the International Equity Fund and, if transferable, the associated transfer costs, as some foreign jurisdictions require that their domestic securities be held under special custody arrangements within the respective jurisdiction. On this basis, it recommended redeeming out the securities of ten large companies whose highly liquid securities were freely traded on European stock exchanges. In addition to avoiding the issue of custody costs and delays on transfer noted above, this also avoided the problem of trying to allocate multiple small positions, as the Fund held approximately 482 different investment securities at the time.

While the CCO was concerned that this approach would not encompass the tax lots with the most profit, as under the equity fund methodology, he found that 72 of the 91 most profitable tax lots would be included. Because of changes in the Fund's portfolio and market values during the period between the initial selection date (in August or September 2007) and the Redemption date, Morgan Stanley determined that the Redemption amount could be satisfied using only eight of the ten securities on the list. The applicant represents that many of the International Equity Fund's other freely transferable foreign securities were relatively less liquid, and including those securities in the Redemption would have taken a longer time to sell them.

8. According to the applicant, the procedures utilized in the valuation of securities in the in-kind Redemptions were protective of the rights of the Mercantile Plan and its participants and beneficiaries. The Redemptions were accomplished by transferring, in exchange for Shares of the Funds held by the Mercantile Plan, a selection of the securities held by each Fund as determined by the Funds in accordance with the Funds' redemption policies. The Fund assets transferred to the Mercantile Plan consisted entirely of cash and securities for which market quotations were readily available. Securities not meeting the definition of "Transferable Securities" as defined in Section II(E) of this notice were excluded, *i.e.*, (i) Securities that, if publicly offered or sold, would require registration under the Securities Act of 1933; (ii) Securities issued by entities in countries which (a) restrict or prohibit the holding of securities by non-nationals other than through qualified investment vehicles, such as the Funds, or (b) permit transfers of ownership of securities to be effected only by

transactions conducted on a local stock exchange; (iii) Certain portfolio positions (such as forward foreign currency contracts, futures and options contracts, swap transactions, certificates of deposit, and repurchase agreements) that, although liquid and marketable, involve the assumption of contractual obligations, require special trading facilities, or can only be traded with the counter-party to the transaction to effect a change in beneficial ownership; (iv) Cash equivalents (such as certificates of deposit, commercial paper, and repurchase agreements); (v) Other assets that are not readily distributable (including receivables and prepaid expenses), net of all liabilities (including accounts payable); and (vi) Securities subject to "stop transfer" instructions or similar contractual restrictions on transfer.

In addition, the Redemptions did not include securities that were odd lots, fractional shares, and accruals on such securities. The applicant also represents that no Rule 144A securities were involved in the Redemptions.

For purposes of the in-kind Redemptions, the value of the securities in the Funds generally were determined based on their market value as of the close of business on the Redemption date (using sources independent of PNC and PNC Affiliates), in accordance with the requirements of the 1940 Act and the procedures adopted by the Fund Board, in conformity with the *Signature* letter.<sup>18</sup> The pricing methodology to be applied with respect to an in-kind redemption under these procedures complies with Rule 2a-4 under the 1940 Act, the general rule that governs the

valuation process for purposes of determining the current price of mutual fund shares. The value for the types of securities held by the Funds was determined as follows.

(i) Securities primarily traded on a domestic securities exchange are valued at the last price on that exchange or, if there were no sales during the day, at the current quoted bid price. Securities traded through the National Association of Securities Dealers Automated Quotations (NASDAQ) National Market System are valued at the NASDAQ Official Closing Price;

(ii) Securities primarily traded on foreign exchanges are valued at the closing values of such securities on their respective exchanges, provided that if such securities are not traded on the valuation date, they will be valued at the preceding closing values;

(iii) Over-the-counter domestic securities and securities listed or traded on foreign exchanges with operations similar to the U.S. over-the-counter market are valued at the closing price of the primary exchange for which the security is traded; or

(iv) With respect to the International Equity Fund, the Fund Board determined that movements in relevant indices or other appropriate market indicators, after the close of the foreign securities exchanges, may demonstrate that market quotations no longer represent the fair value of the foreign securities held by the International Equity Fund and may require fair value pricing. Therefore, the Fund Board adopted written policies and procedures requiring that, when there is a market movement greater than 50 basis points in the Russell 1000 Index from the open and close of the U.S. market, the securities in the International Equity Fund are priced utilizing a fair value determined by an independent pricing service, Investment Technology Group, Inc. (ITG).<sup>19</sup>

9. The Redemptions occurred after the close of the markets on Wednesday, October 31, 2007, at which time the five Funds distributed to the Mercantile Plan a combination of securities and a small amount of cash.<sup>20</sup> The securities

previously identified as acceptable by two of the receiving funds in the PNC Plan were transferred to those funds in kind, and the remaining securities that were received pursuant to the Redemptions were liquidated to cash on November 1, 2007.

The Committee had arranged for the liquidation of the securities with two brokers (the Liquidation Arrangements)—one for the domestic securities and one for the foreign securities. To help minimize the time during which the Mercantile Plan participants' accounts would remain uninvested, the Liquidation Arrangements provided for the brokers to accept the securities at the close of the markets on October 31, 2007 at their closing prices so that the brokers assumed the market risk involved in liquidating the securities. In the view of the Committee, a factor in the brokers' willingness to accept this risk was the limited number of securities involved, because it would be more difficult for the brokers to arrange buyers for a significantly larger number of positions. According to the applicant, it is unlikely the Committee could have secured such a commitment if the larger number of securities resulting from a *pro rata* Redemption of all five Funds had been involved. The Committee further entered into agreements with the receiving funds to accept the new investments on the next business day, November 1, 2007, with an extended settlement date (up to three days later in most instances) to cover the possibility of a delay in payment of the liquidation proceeds, at no additional cost to the Mercantile Plan so that the Mercantile Plan participants would not lose the benefit of being fully invested in their chosen investment options (through the respective successor options on the PNC Plan platform) for more than one day.<sup>21</sup>

10. No brokerage commissions or other fees or expenses (other than customary transfer charges paid to parties other than PNC's affiliates) were charged to the Mercantile Plan as part of the Redemptions. Third-party brokerage costs, however, were incurred in connection with the liquidation of the securities that the Mercantile Plan received in kind pursuant to the Redemptions. The liquidation of all such securities was completed on

<sup>21</sup> According to the applicant, this arrangement created an additional benefit for the Mercantile Plan participants. Because there was a market decline on November 1, 2007, the participants were able to receive the higher October 31, 2007 closing prices on the liquidation of the distributed securities, and were able to reinvest those proceeds at the lower November 1, 2007 share prices of the receiving funds. The overall benefit to the participants was approximately \$3 million.

<sup>18</sup> In the *Signature* letter, the Division of Investment Management of the SEC states that it will not recommend enforcement action pursuant to section 17(a) of the 1940 Act for certain in-kind distributions of portfolio securities to an affiliate of a mutual fund. Funds seeking to use this "safe harbor" must value the securities to be distributed to an affiliate in an in-kind distribution "in the same manner as they are valued for purposes of computing the distributing fund's net asset value." As explained in Item 5, "Fund Redemption Procedures," the Funds had pre-established procedures for conducting affiliated transactions in accordance with the *Signature* letter.

The *Signature* letter does not address the marketability of the securities distributed in kind. The range of securities distributed pursuant to this "safe harbor" may therefore be broader than the range of securities covered by SEC Rule 17a-7, 17 CFR 270.17a-7. In granting past exemptive relief with respect to in-kind transactions involving mutual funds, the Department has required that the securities being distributed in-kind fall within Rule 17a-7. One of the requirements of Rule 17a-7 is that the securities are those for which "market quotations are readily available." SEC Rule 17a-7(a). Under this exemption request, exemptive relief also would be limited to in-kind distribution of securities for which market quotations are readily available.

<sup>19</sup> Securities of non-U.S. issuers may be traded on U.S. exchanges or NASDAQ, directly or in the form of ADRs, or may be acquired on foreign exchanges or foreign over-the-counter markets. In the latter case, valuation is in accordance with (iv).

<sup>20</sup> In accordance with the provisions of Rule 18F-1 under the 1940 Act, the Funds were obligated to redeem in cash the lesser of \$250,000 or 1% of their net asset value. Consequently, each of the non-*pro rata* Funds distributed \$250,000 in cash, and the *pro rata* distribution from the Capital Opportunities Fund included a *pro rata* portion of the Fund's cash holdings and the cash value of any non-transferable securities, in an amount that exceeded \$250,000.

November 1, 2007, and those brokerage costs were paid from the PNC Plan's forfeiture account, which held forfeitures accumulated from prior plan mergers. As a condition of this proposed exemption, PNC will reimburse the PNC Plan, into which the Mercantile Plan was merged on November 1, 2007, for all brokerage costs that the Mercantile Plan incurred on November 1, 2007.

During the process leading up to the Redemption date, the Funds provided the Mercantile Plan trustee with lists of the securities that were likely to be included in the Redemptions, to permit the Mercantile Plan fiduciaries to determine in advance how best to dispose of the securities. The Mercantile Plan trustee passed those lists along to the funds on the PNC Plan investment platform that were to receive the proceeds of the respective Redemptions. Two of the receiving funds—a Vanguard fund and a Harbor Capital fund (neither affiliated with PNC)—informed the Mercantile Plan trustee that they would be willing to accept certain securities from the lists in kind. As a result, on the Redemption date, those securities were not liquidated, but rather were transferred in kind to the receiving funds.

Because the Committee was not able to lock in the October 31, 2007 values of the securities that were transferred in kind to the new funds, the shares acquired with those securities on November 1st were less in value than the value of the distributed securities the previous day. The applicant represents that the Plan participants were in the same financial position that they would have been in had they remained invested in the Funds, because their investments in the Funds would have suffered a corresponding decrease. Nevertheless, the Committee decided that it would be appropriate under the unique circumstances of the Redemptions to insulate the participants' accounts from the impact of this brief period of negative investment performance, by making up the difference from the PNC Plan's forfeiture account.<sup>22</sup>

11. As previously noted in Item 2, the applicant appointed Wilshire, also located in Pittsburgh, Pennsylvania, to serve as the Independent Fiduciary on behalf of the Mercantile Plan in regard to the subject Redemptions. It is represented that, as of the end of 2007, all fees paid by PNC to Wilshire equaled less than 1% of Wilshire's annual gross income.

<sup>22</sup> The Department is not opining herein as to whether this use of the forfeiture account is permitted under Title I of ERISA.

Prior to the Redemptions, Wilshire received a full written disclosure of information regarding the Redemptions and communicated in writing its approval of the Mercantile Plan's participation in such Redemptions. In a letter dated November 1, 2007, Wilshire opined,

Based on our review of the proposed procedure and methodology for the in-kind redemption, and discussions with members of The Administrative Committee, PNC staff, and legal counsel for the [Mercantile] Plan, it is Wilshire's opinion that an in-kind redemption of Mercantile Plan participants' assets in certain funds is in their best interests. As you know, a redemption of fund interests is necessary to transition participant assets from the funds currently available in the Mercantile Plan into the funds available in the PNC Incentive Savings Plan. \* \* \* Based on the process set forth, participants in funds for which redemption is completed in kind are not exposed to greater market risk, security specific risk, investment management or other costs, than they would be in any other arms-length transaction between unaffiliated parties.

No later than thirty (30) business days after the completion of the Redemptions, Wilshire received a written confirmation regarding such Redemptions containing: (i) The number of Shares held by the Mercantile Plan immediately before the Redemption (and the related per Share net asset value and the total dollar value of the Shares held); (ii) The identity (and related aggregate dollar value) of each security provided to the Mercantile Plan pursuant to the Redemption, including each security valued in accordance with Rule 2a-4 under the 1940 Act and procedures adopted by the Board of Directors of PNC Funds, Inc. (using sources independent of PNC and PNC Affiliates); (iii) The current market price of each security received by the Mercantile Plan pursuant to the Redemption; and (iv) The identity of each pricing service or market maker consulted in determining the value of such securities.

Subsequent to the Redemptions, Wilshire performed a post-transaction review, which is summarized in its letter dated December 21, 2007, to determine whether or not the Redemptions were effected at a fair market price. In the letter, Wilshire confirmed that the Redemptions were conducted in accordance with the conditions of this proposed exemption as described in PNC's exemption application of November 1, 2007.<sup>23</sup> Wilshire downloaded the "Committee on Uniform Security Identification

<sup>23</sup> It is noted that the condition in Section I(L) of this notice was not contained therein.

Procedures" of each individual security from the Funds (totaling nearly 300 equity securities) into Atlas, Wilshire's proprietary security database to independently review the prices for securities received by the Mercantile Plan from the Funds. Wilshire wrote:

The prices received by Mercantile Plan participants for their investments in these funds were equal to the closing market price as of October 31, 2007, with the exception of the investments in the International Equity Fund. According to the policies utilized by the Board of Directors of PNC Funds, a fair value pricing methodology is employed if, subsequent to the closing of foreign securities exchanges, the U.S. equity market, as measured by the Russell 1000 stock index, closes at a value that differs from its opening value by more than 0.5%. On October 31, 2007, the Russell 1000 Index increased by 1.22% from its opening price. This increase was large enough to trigger the fair value pricing policy employed by the Funds. Investors in the International Equity Fund received prices through the in-kind redemption that were higher than the closing prices of these securities on their local exchanges. The use of prices that were greater than the closing prices on the local exchanges indicates that the fair value adjustment was made in the International Equity Fund.

At the Department's request, Wilshire provided a supplemental letter dated August 28, 2009, which addressed the methodologies for selecting the securities to be distributed on a non-pro rata basis and the securities liquidation process.

First, Wilshire noted:

Because the [Mercantile] Plan did not intend to continue to hold the securities it received in the redemptions, but rather immediately to reinvest the proceeds of their sale in other mutual funds, \* \* \* it was in the Mercantile Plan's best interest to receive a limited number of investment positions that were highly liquid, to facilitate an easier and less costly sale and liquidation to cash.

Wilshire also stated, "[W]e reviewed the securities selected for the redemptions, based on lists provided in advance of the redemption date, to confirm that they were highly liquid." Regarding the International Equity Fund, Wilshire stated:

By contrast, a pro rata redemption from this fund would have caused the [Mercantile] Plan to receive a much larger number of smaller investment positions (the fund held over 480 different securities at the time), which would have required a more difficult, costly and time consuming liquidation process—particularly for those foreign jurisdictions that would have required the [Mercantile] Plan to set up special custody arrangements to hold the securities pending their disposition.

Finally, Wilshire noted:

The [Mercantile] Plan entered into arrangements for brokers to acquire the distributed securities from the [Mercantile] Plan at their closing prices on October 31, 2007, and to assume the risk of future price changes. In addition, the [Mercantile] Plan arranged for the receiving funds to accept the proceeds from the sale of the securities on November 1.<sup>24</sup> These arrangements were in the best interests of the [Mercantile] Plan because they (1) locked in the values at which the securities were distributed to the [Mercantile] Plan and (2) reduced the time during which the [Mercantile] Plan participants were out of the market to one day. In our view, a positive factor in the brokers' willingness to accept the risk of selling the securities was the limited number of securities involved, because it would be more difficult for the brokers to arrange buyers for a significantly larger number of positions.

12. In summary, the applicant represents that the Redemptions satisfied the statutory criteria for an exemption under section 408(a) of the Act for the following reasons: (i) The Mercantile Plan received its pro rata portion of the securities with respect to the Capital Opportunities Fund; (ii) the absence of a pro rata distribution for four of the other Funds benefited the Mercantile Plan by permitting the distribution of securities that could be more easily and quickly liquidated to cash, consistent with the Mercantile Plan's objective to reinvest the proceeds as soon as possible in the PNC Plan's "open" investment platform that included non-proprietary funds; (iii) the security selection criteria used were determined by parties independent of PNC, namely, the Fund Board, the Fund CCO and (in the case of the International Equity Fund) an unaffiliated sub-adviser; (iv) the transaction was overseen by an Independent Fiduciary and written authorization was provided by the Independent Fiduciary based on its determination, following full and detailed disclosure of information regarding the transaction, that the terms of the Redemptions were fair and reasonable to the Mercantile Plan, and comparable to and no less favorable than terms obtainable at arm's length between unaffiliated parties, and that the Redemptions were in the best interests of the Mercantile Plan and its participants and beneficiaries; and (v) the Independent Fiduciary conducted a post-transaction analysis of the securities selected for the Redemptions based upon the lists provided in

<sup>24</sup> In the interests of clarity, Wilshire is referring here to the Mercantile Plan's broker agreements regarding the distributed securities that were liquidated; however, as previously noted in Item 9, the receiving funds agreed to accept a small percentage of the distributed securities in kind.

advance of the Redemption date and confirmed that the in-kind Redemptions were effected at a fair market value price. It is also noted that condition I(L) requires PNC to reimburse the PNC Plan for all brokerage costs incurred to liquidate the securities that the Mercantile Plan received in kind pursuant to the Redemptions so that, in combination with the methodology used in the selection of stocks for the non-pro rata Redemptions, the distribution of such stocks was economically equivalent to a cash Redemption.

#### Notice to Interested Persons

The applicant represents that notice to interested persons shall be furnished to the Independent Fiduciary, inactive participants and beneficiaries of the Mercantile Plan by first-class mail, and by e-mail to Mercantile Plan participants who are actively employed (provided that such active participants have effective access to electronic documents at work—otherwise, the active participants must receive such notice by first-class mail), within 30 days of the date of publication of this notice of pendency in the **Federal Register**. The notice shall inform interested persons of their right to comment and/or request a hearing with respect to the proposed exemption. Comments and requests for a hearing are due within 30 days following completion of notice to interested persons.

**FOR FURTHER INFORMATION CONTACT:** Ms. Karin Weng of the Department, telephone (202) 693-8557. (This is not a toll-free number.)

Deutsche Asset Management (UK) Limited (the Applicant), Located in London, England, a Wholly-Owned Subsidiary of Deutsche Bank AG, Located in Frankfurt, Germany, and Throughout the World, [Exemption Application Number D-11495].

#### Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

#### Section I—Covered Transactions

If the proposed exemption is granted, the restrictions of sections 406(a)(1)(A), 406(a)(1)(B), 406(a)(1)(D), 406(b)(1), and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of sections 4975(c)(1)(A), (B), (D), and (E) of the Code, shall not apply to certain foreign exchange hedging transactions that

occurred between November 30, 2007 and May 30, 2008, inclusive, between the DB Torus Japan Master Portfolio (the Master Fund), in which the assets of certain client employee benefit plans (the Client Plans) were invested, and Deutsche Asset Management (UK) Ltd. or its affiliates (collectively, Deutsche Bank), a party in interest with respect to the Client Plans, provided that the conditions contained herein are satisfied.

#### Section II—General Conditions

(a) The foreign exchange transactions were executed solely in connection with the Master Fund's hedging of the Japanese yen currency risk for its share classes denominated in U.S. dollars (USD);

(b) At the time that the foreign exchange transactions were entered into, the terms of the foreign exchange transactions were not less favorable to the Fund than the terms generally available in comparable arm's length foreign exchange transactions between unrelated parties;

(c) Any foreign exchange transactions authorized or executed by Deutsche Bank or its affiliates were not part of any agreement, arrangement, or understanding, written or otherwise, designed to benefit Deutsche Bank, its affiliates, or any other party in interest;

(d) Prior to investing in the Master Fund, the fiduciary of each Client Plan received the offering memorandum for the DB Torus Japan Fund Ltd., the feeder fund (Feeder Fund) through which investments in the Master Fund are effected;

(e) The exchange rate used for a particular foreign exchange transaction did not deviate by more than three percent (above or below) the interbank bid and ask rate for such currency at the time of the foreign exchange transaction, as displayed on an independent, nationally-recognized service that reports rates of exchange in the foreign currency market for such currency;

(f) Prior to the granting of an exemption concerning the subject foreign exchange transactions, Deutsche Bank shall reimburse each such Client Plan for its pro-rata share of: (1) The spread on each foreign exchange transaction subject to this proposed exemption; and (2) Any fees charged by financial institutions for executing the subject foreign exchange transaction(s), plus interest at the applicable Internal Revenue Service underpayment penalty rate, up to the date of reimbursement;

(g) Within 30 days of taking the corrective action described in Section II(f) above, Deutsche Bank provides the independent fiduciaries of each Client

Plan whose assets were involved in the foreign exchange transactions with: (1) Written information, formulas, and/or other documentation sufficient to enable such fiduciaries to independently verify that the Plans have been reimbursed in accordance with the requirements of Section II(f) above; and (2) a copy of this notice of proposed exemption (the Notice);

(h) Within 30 days of taking the corrective action described in Section II(f) above, Deutsche Bank provides the Department with written documentation demonstrating that the foregoing reimbursements to each Client Plan were correctly computed and paid;

(i) Effective May 31, 2008, Deutsche Bank, in conjunction with the administrator of both the Master Fund and the Feeder Fund (together, the Funds), continuously monitors the percentage of total assets invested by benefit plan investors in the Funds so that, as of each acquisition or redemption of equity interests, Deutsche Bank and the administrator of the Funds are able to verify whether equity participation in the Funds by benefit plan investors is not significant pursuant to section 3(42) of the Act and 29 CFR 2510.3-101;

(j) Deutsche Bank maintains, or causes to be maintained, for a period of six years from the date of the transactions that are the subject of this proposed exemption, the following records, as well as any other records necessary to enable the persons described in Section II(l) of this exemption, to determine whether the conditions of this exemption have been met:

(1) The account name;

(2) The trade and settlement dates of the subject foreign exchange hedging transactions;

(3) The USD/Japanese yen currency exchange rates on the trade and settlement dates;

(4) The high and low currency prices on Bloomberg or similar independent service on the dates of the subject transactions;

(5) The identification of the type of currency trade undertaken (whether spot or forward);

(6) The amount of Japanese yen sold or purchased in the hedging transactions; and

(7) The amount of U.S. dollars exchanged for Japanese yen in the hedging transactions.

(k) The following are exceptions to the requirements of Section II(j):

(1) A separate prohibited transaction shall not be considered to have occurred solely because, due to circumstances beyond the control of Deutsche Bank or its affiliates, the records necessary to

enable the persons described in Section II(l) to determine whether the conditions of the exemption have been met or lost or destroyed prior to the end of the six-year period; and

(2) No party in interest, other than Deutsche Bank and its affiliates, shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the excise taxes imposed by section 4975(a) and (b) of the Code if the records are not maintained for examination as required by Section II(l) below.

(l)(1) Except as provided in paragraph (2) of this Section II(l) and notwithstanding the provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in Section II(j) are unconditionally available for examination during normal business hours at their customary location to the following persons or an authorized representative thereof:

(i) Any duly authorized employee or representative of the Department or of the Internal Revenue Service (the Service);

(ii) The independent fiduciary of each Client Plan (or a duly authorized employee or representative of such fiduciary), or

(iii) Any participant or beneficiary of such Client Plans or any duly authorized employee or representative of a participant or beneficiary in such Client Plans.

(2) None of the persons described above in paragraphs (ii) and (iii) of Section II(l)(1) shall be authorized to examine trade secrets of Deutsche Bank or its affiliates, or any commercial or financial information, which is privileged or confidential.

### Section III—Definitions

For purposes of this proposed exemption:

(a) An "affiliate" of the Applicant means: (1) Any person or entity directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such person or entity; (2) Any officer, director, partner, employee, or relative (as defined in section 3(15) of the Act) of such other person or entity; and (3) Any corporation or partnership of which such other person or entity is an officer, director, partner, or employee.

(b) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(c) The term "client plan" means an employee benefit plan, other than a plan sponsored by the Applicant and its affiliates, as described in section 3(3) of

the Act or section 4975(e)(1) of the Code that invested in the Master Fund and the Feeder Fund, and for which the Applicant or its affiliate served as an investment advisor.

(d) The term "foreign exchange transaction" means the exchange of the currency of one nation for the currency of another nation.

(e) The term "hedging" means a strategy used to offset the investment risk of future gains or losses resulting from anticipated fluctuations in the value of currency, such as an investor's decision to exchange foreign currency in anticipation of upward or downward movement in the value of that currency.

### Summary of Facts and Representations

1. Deutsche Asset Management (UK) Limited (DeAM UK) is a wholly-owned subsidiary of Deutsche Bank AG. DeAM UK (the Applicant) is an investment adviser domiciled in the United Kingdom with approximately \$2.2 billion in assets under management, and is registered in the United States under the Investment Advisers Act of 1940. The Applicant also represents that it is regulated by the Financial Services Authority (FSA), an independent non-governmental body, which was granted statutory powers by the United Kingdom Financial Services and Markets Act 2000.

The Applicant is a sub-advisor to both the DB Torus Japan Master Portfolio (the Master Fund), a Cayman Islands exempted company, and the DB Torus Japan Master Portfolio Ltd. (the Feeder Fund), also a Cayman Islands exempted company. The adviser to both the Master Fund and the Feeder Fund is Deutsche Bank Trust Company Americas (DBTCA), a New York banking corporation, which also is wholly-owned by Deutsche Bank AG.

2. Deutsche Bank AG (together with its affiliates, Deutsche Bank), a German banking corporation and a leading commercial bank, provides a wide range of global banking, fiduciary, record keeping, custodial, brokerage, and investment services to corporations, institutions, employee benefit plans, and private investors. Through its numerous affiliates, subsidiaries, and branches, Deutsche Bank has a worldwide physical presence. As of December 31, 2007, Deutsche Bank had approximately \$1.19 trillion in assets under management and had approximately \$54.09 billion in shareholder equity.

The Applicant represents that Deutsche Bank is subject to a comprehensive system of regulatory oversight and a mandatory insurance program. The Applicant also represents

that Deutsche Bank, its branches, and its subsidiary banks worldwide are subject to regulatory requirements and protections that are, qualitatively, at least equal to those imposed on U.S.-domiciled banks.<sup>25</sup> Within the United States, the Applicant represents that both the New York branch of Deutsche Bank and DBTCA are regulated and supervised by the New York State Banking Department. In addition, the Applicant represents that certain activities of Deutsche Bank's New York branch and DBTCA are regulated and supervised by the Federal Reserve Bank of New York.

3. The Applicant represents that the Master Fund invests in Japanese equity and equity-related securities. Client investment is effected through the Feeder Fund. The Feeder Fund, in turn, has invested all of its assets in the Master Fund, with the exception of cash reserves maintained, for example, for the payment of fees and expenses. The "base" currency in which both the Master Fund and the Feeder Fund maintain their books, records, and financial statements (and in which they charge applicable fees) is the Japanese yen. The Feeder Fund offers distinct share classes denominated in U.S. dollars (USD) for the convenience of investors wishing to invest with USD (USD Investors). Among the investors in the USD share class of the Feeder Fund are client employee benefit plans (the Client Plans).

4. As disclosed in the Feeder Fund's offering memorandum, which is distributed to all potential investors (including potential Client Plan investors) prior to investment, the managing member of the Master Fund is charged with maintaining a continuous dollar/yen hedge with respect to investments in its USD share class in order to disaggregate the impact of currency fluctuations on the performance of a USD Investor's investment. The currency hedge offers USD Investors exposure to the portfolio of the Master Fund while reducing exposure to fluctuations in relative value of yen to the USD. Thus, the Applicant represents that an investor investing in the USD share class of the Feeder Fund necessarily expects that its investments will, as fully as possible, hedge the USD against the yen. The Applicant represents that it has investment discretion over the assets

involved in the exemption transactions described herein. In addition, the Applicant represents that it is affiliated with the counterparty to those transactions.

The Applicant represents that the currency hedging activity was fully disclosed to Client Plans and other investors in the Feeder Fund's offering memorandum, and it would have occurred regardless of the identity of the counterparty. The Applicant further represents that, by investing in the USD share class of the Feeder Fund, the independent fiduciaries of the investing employee benefit plans consented to the hedging transactions. The Applicant also states that, in investing in the Feeder Fund, each Client Plan's independent fiduciary necessarily approved the execution of currency trades through DeAM UK as principal.

5. The foregoing hedge is effected each month through the following transactions: (1) A foreign exchange "forward trade"<sup>26</sup> that settles on the last business day of the month; (2) A foreign exchange spot trade<sup>27</sup> that settles on the last business day of the month (which closes out the forward trade); and (3) Another foreign exchange forward trade. The Applicant represents that this currency hedging activity is largely automatic and ministerial in nature. Since the inception of the Master Fund, the Applicant represents, hedging transactions have been consistently effected each month at particular times and in mechanically determined amounts, which are specified in the operating procedures of the Master Fund. The Applicant further represents that, since all gains and losses resulting from the currency hedging activity are "reversed out" from the performance of the USD share classes prior to calculation of the performance fee and the "high water mark"<sup>28</sup>, the hedging transactions are canceled out for

purposes of the performance fees paid to the investment manager.

6. From their inception, both the Master Fund and the Feeder Fund were intended to operate as "non-plan asset" vehicles. In particular, the Applicant represents that the Master Fund intended to limit the aggregate investment by benefit plan investors in each class of its equity to less than 25%, so that the quantity of assets in each class would not be deemed to constitute significant equity participation by benefit plan investors within the meaning of the Department's "plan asset regulation" at 29 CFR 2510.3-101.<sup>29</sup>

7. Effective May 1, 2006, the Master Fund and the Feeder Fund (together, the Funds) entered into an administrative services agreement with International Fund Services (Ireland) Limited (hereinafter IFS or the Administrator). The Applicant represents that IFS is not related to or affiliated with Deutsche Bank, and provides fund accounting, fund administration, and risk services to asset management groups with trading operations throughout the world. Under the agreement, IFS was responsible for, among other things, monitoring the percentage investment by benefit plan investors in each share class of the Funds and reporting such percentage on a monthly basis to the Funds. The agreement also required IFS to report the percentage of investment by benefit plan investors "on such other dates as [a] Fund accepts subscriptions and/or effects redemptions and delivering such

<sup>29</sup> This regulation generally defines what constitutes assets of a plan with respect to a plan's investment in another entity for purposes of Subtitle A, and Parts 1 and 4 of Subtitle B, of Title I of the Act and section 4975 of the Code. Generally, the plan asset regulation states that when a plan invests in another entity, the plan's assets include its investment, but do not, solely by reason of such investment, include any of the underlying assets of the entity. However, in the case of a plan's investment in an equity interest that is neither a publicly-offered security nor a security issued by an investment company registered under the Investment Company Act of 1940, its assets include both the equity interest and an undivided interest in each of the underlying assets of the entity, unless it is established that, among other things, equity participation in the entity by benefit plan investors is not significant.

According to 29 CFR 2510.3-101(f)(1), "[e]quity participation in an entity by benefit plan investors is 'significant' on any date if, immediately after the most recent acquisition of any equity interest in the entity, 25 percent or more of the value of any class of equity interests in the entity is held by benefit plan investors." A "benefit plan investor" is defined in section 3(42) of the Act as "an employee benefit plan subject to part 4 [of the Act], any plan to which section 4975 of the [Code] applies, and any entity whose underlying assets include plan assets by reason of a plan's investment in such entity." For a discussion of the general scope and construction of the term "acquisition" as referenced in 29 CFR 2510.3-101(f)(1), including a benefit plan investor's redemption of an equity interest in an investment entity, see Advisory Opinion 89-05 (Apr. 6, 1989).

<sup>25</sup> The Applicant represents that the U.S. Department of the Treasury has accorded national treatment to German bank branches, and the German Ministry of Finance has granted relief to branches of U.S. banks in Germany, in particular with respect to "dotation" or endowment capital requirements and capital adequacy standards.

<sup>26</sup> A foreign exchange "forward" is an agreement to purchase or sell a fixed amount of foreign currency at a fixed price and on a predetermined future date (or within a predetermined range of dates).

<sup>27</sup> A foreign exchange "spot" trade is a purchase of one currency with a different currency for immediate delivery. These trades typically settle within two days from the date of execution. See also the Notice of Proposed Exemption preceding the final grant of PTE 94-20 at 56 FR 11757, 11759, n.3 (March 20, 1991).

<sup>28</sup> "High water mark" is a reference point by which a hedge fund manager's performance compensation is calculated. When a high water mark formula applies, the manager receives performance compensation only if the value of the fund is greater than its previous greatest value (i.e., the high water mark). If the value of the fund falls below the high water mark, the manager receives no performance fees until the value rises above the high water mark.

calculation to the Fund or to the Fund's counsel for approval." The agreement also states that, "[f]or the avoidance of doubt, each Fund shall instruct IFS [as to] the method of determining class of shares for the purpose of the calculation of percentages contemplated in this clause."

The Applicant represents that in December of 2007, IFS, through an error in its recordkeeping, failed to notify DeAM UK that the percentage of plan assets in one of the USD-denominated share classes may have exceeded 25% of the assets maintained in that corporate class. The Applicant has specifically identified the U.S. dollar-denominated nominal share class with respect to which the subject hedging transaction occurred (and in which redemptions may have caused benefit plan investor participation to equal or exceed the 25% limitation) as Class A of the Feeder Fund.<sup>30</sup> For a period of time after the redemptions, the Applicant represents, the Master Fund continued to execute hedging transactions with its DeAM UK-affiliated counterparty, the London branch of Deutsche Bank AG. The Applicant further represents that DeAM UK was not aware that redemptions associated with the foregoing currency hedging transactions caused a breach of the 25% limitation until approximately April 15, 2008. In this connection, the Applicant initiated communication with the Department with respect to the foregoing hedging transactions shortly after DeAM UK became aware of the problem, and has met with representatives from the Department concerning this matter.

8. The Applicant additionally represents that Bloomberg screen prints of the currency prices at the time of the subject currency hedging transactions demonstrate that the trades did not deviate by more than three percent (above or below) the interbank bid and ask rate for such currencies at the time of the foreign exchange transaction. In this connection, the Applicant represents that Bloomberg is an independent, nationally-recognized quotation service that reports rates of exchange in the foreign currency market for widely-traded currencies, including the Japanese yen. The Applicant further represents that, because it knows both the precise rate at which the Master Fund executed each of the subject currency hedging transactions and the best rate available on these trades based

on the aforementioned Bloomberg screen prints, it will calculate the difference between these rates and give any positive difference to the Client Plan, based on its ownership percentage in the Feeder Fund.

The Applicant also represents that, with respect to the assessment of fees, commissions, and related transactional expenses, any Client Plan whose assets were involved in the foreign exchange transactions that are the subject of this proposed exemption were treated the same as all other investors with assets invested in the Master Fund and the Feeder Fund that engaged in the subject hedging transactions.

9. The Applicant represents that, after discovering the foreign exchange hedging transactions that gave rise to the current exemption application, it revised its compliance procedures in May of 2008 to minimize the risk that such a situation may recur. These updated procedures include, among other things, the following elements: (i) On a monthly basis, the Deutsche Bank sales team will notify the Deutsche Bank shareholder services team of any prospective Client Plan who will be making an investment in the Master Fund or the Feeder Fund in the coming month(s); (ii) All Client Plan investments must be approved by the Office of the Chief Operating Officer (COO) of the DB Advisors Hedge Fund Group before the investment is accepted; (iii) The Administrator of the Master Fund and the Feeder Fund will provide the Deutsche Bank shareholder services team a copy of all subscription agreements for those flagged investments upon receipt for review. The Administrator also will provide to the Deutsche Bank shareholder services team copies of the subscription documents of all incoming U.S. tax-exempt investors, to perform a duplicate check to ensure that none are in fact plan assets (for example, to identify any incorrectly completed documents); (iv) The Administrator of the Master Fund and the Feeder Fund will add to its monthly "ERISA Executive Summary" (a report of the current plan asset totals in each Deutsche Bank Advisors Hedge Fund through the most recent dealing date for subscriptions and redemptions) a column which calculates the month-to-month change in plan asset percentages for both the Master Fund and the Feeder Fund; and (v) When the total plan assets percentage of either the Master Fund or the Feeder Fund reaches 10%, it is placed on a "watch list." Investments by benefit plan investors into any funds on the watch list require additional approval by the office of the COO before they can be accepted. The

office of the COO may decide to close a Fund to any future investments by a benefit plan investor when the Fund's total plan assets percentage exceeds 10%.

According to the offering memorandum of the Feeder Fund, an investor generally may redeem all or a portion of its shares in the Fund at the close of business on the last business day of any calendar month by submitting to the administrator of the Fund a redemption request at least thirty days prior to the end of such month. An investor redeeming all or a portion of its shares will receive an amount equal to the net asset value per share for the relevant series of shares at the close of business on the redemption date. The Fund also may, upon five days notice, cause the involuntary redemption of any or all of an investor's shares at the end of any calendar month.

In addition, the offering memorandum of the Feeder Fund states that, in general, the directors of the Fund intend to restrict, through utilization of a "test" that is "ongoing", the aggregate investment by benefit plan investors to under 25% of the total capital of each class of shares in order to achieve compliance with the requirements of section 3(42) of the Act and 29 CFR § 2510.3-101. As a consequence of this ongoing test, not only may additional investments by benefit plan investors be restricted, but existing benefit plan investors may be required by the directors of the Fund to redeem their shares from the Fund in the event that other investors redeem.

10. The Applicant represents that the requested exemption is administratively feasible because correction of the prohibited transaction would occur pursuant to an objective, independently verifiable pricing mechanism (namely, the Bloomberg currency exchange data for the time period described in this proposed exemption). The Applicant also represents that the exemption would be in the interest of the participants and beneficiaries of each of the affected Plans because the correction will place each affected Plan in a better position than it would have been in had the currency hedging been executed through an unrelated third party in the first instance. The Applicant further represents that the exemption would be protective of the rights of participants and beneficiaries of the affected Plans because: (i) The correction will negate any benefit received by the Applicant (or its affiliate) in connection with the subject transactions; and (ii) The proposed conditions for exemptive relief are consistent with the safeguards generally required by the Department

<sup>30</sup>In its exemption application, the Applicant represents that the Master Fund may have held plan assets during the period between November 30, 2007 and May 30, 2008, inclusive, as a consequence of net redemptions involving Class A of the Feeder Fund.



for foreign exchange transactions of this nature.

11. In summary, the past transactions for which exemptive relief is sought meet the statutory criteria of section 408(a) of the Act because: (a) The foreign exchange transactions were executed solely in connection with the Master Fund's hedging of the Japanese yen currency risk for its share classes denominated in U.S. dollars (USD); (b) At the time that the foreign exchange transactions were entered into, the terms of the foreign exchange transactions were not less favorable to the Fund than the terms generally available in comparable arm's length foreign exchange transactions between unrelated parties; (c) Any foreign exchange transactions authorized or executed by Deutsche Bank or its affiliates were not part of any agreement, arrangement, or understanding, written or otherwise, designed to benefit Deutsche Bank, its affiliates, or any other party in interest; (d) Prior to investing in the Master Fund, the fiduciary of each Client Plan received the offering memorandum for the DB Torus Japan Fund Ltd., the feeder fund (Feeder Fund) through which investments in the Master Fund are effected; (e) The exchange rate used for a particular foreign exchange transaction did not deviate by more than three percent (above or below) the interbank bid and ask rate for such currency at the time of the foreign exchange transaction, as displayed on an independent, nationally-recognized service that reports rates of exchange in the foreign currency market for such currency; (f) Prior to the granting of an exemption concerning the subject foreign exchange transactions, Deutsche Bank shall reimburse each such Client Plan for its pro-rata share of: (1) The spread on each foreign exchange transaction subject to this proposed exemption; and (2) Any fees charged by financial institutions for executing the subject foreign exchange transaction(s), plus interest at the applicable Internal Revenue Service underpayment penalty rate; (g) Within 30 days of taking the corrective action described in Section II(f) above, Deutsche Bank provides the independent fiduciaries of each Client Plan whose assets were involved in the foreign exchange transactions with: (1) Written information, formulas, and/or other documentation sufficient to enable such fiduciaries to independently verify that the Plans have been reimbursed in accordance with the requirements of Section II(f) above; and (2) a copy of this notice of proposed exemption (the Notice); (h) Within 30 days of taking the

corrective action described in Section II(f) above, Deutsche Bank provides the Department with written documentation demonstrating that the foregoing reimbursements to each Client Plan were correctly computed and paid; (i) Effective May 31, 2008, Deutsche Bank, in conjunction with the administrator of both the Master Fund and the Feeder Fund (together, the Funds), continuously monitors the percentage of total assets invested by benefit plan investors in the Funds so that, as of each acquisition or redemption of equity interests, Deutsche Bank and the administrator of the Funds are able to verify whether equity participation in the Funds by benefit plan investors is not significant pursuant to section 3(42) of the Act and 29 CFR 2510.3-101; and (j) Deutsche Bank generally maintains records that are sufficient for regulatory authorities and independent third parties to determine whether the conditions of this exemption have been met.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mark Judge of the Department, telephone (202) 693-8550. (This is not a toll-free number.)

UBS Financial Services Inc. and Its Affiliates (UBS), Located in Weehawken, New Jersey, [Application No. D-11502].

#### Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act (or ERISA), and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).<sup>31</sup>

#### Section I. Transactions Involving Plans Described in Both Title I and Title II of ERISA

If the proposed exemption is granted, the restrictions of sections 406(a)(1)(A) through (D) and section 406(b) of the Act, and the taxes imposed by sections 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in Section III have been met:

- (a) The sale or exchange of an Auction Rate Security (as defined in Section IV(b)) by a Plan (as defined in Section IV(h)) to the Sponsor (as defined in Section IV(g)) of such Plan; or
- (b) A lending of money or other extension of credit to a Plan in

connection with the holding of an Auction Rate Security by the Plan, from: (1) UBS; (2) an Introducing Broker (as defined in Section IV(f)); or (3) a Clearing Broker (as defined in Section IV(d)); where the loan is: (i) repaid in accordance with its terms; and (ii) guaranteed by the Sponsor.

#### Section II. Transactions Involving Plans Described in Title II of ERISA Only

If the proposed exemption is granted, the sanctions resulting from the application of sections 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in Section III have been met:

- (a) The sale or exchange of an Auction Rate Security by a Title II Only Plan (as defined in Section IV(i)) to the Beneficial Owner (as defined in Section IV(c)) of such Plan; or
- (b) A lending of money or other extension of credit to a Title II Only Plan in connection with the holding of an Auction Rate Security by the Title II Only Plan, from: (1) UBS; (2) an Introducing Broker; or (3) a Clearing Broker; where the loan is: (i) repaid in accordance with its terms and; (ii) guaranteed by the Beneficial Owner.

#### Section III. Conditions

- (a) UBS acted as a broker or dealer, non-bank custodian, or fiduciary in connection with the acquisition or holding of the Auction Rate Security that is the subject of the transaction;
- (b) For transactions involving a Plan (including a Title II Only Plan) not sponsored by UBS for its own employees, the decision to enter into the transaction is made by a Plan fiduciary who is independent (as defined in Section IV(e)). For transactions involving a Plan sponsored by UBS for its own employees, UBS may direct such Plan to engage in a transaction described in Section I if all of the other conditions of this Section III have been met. Notwithstanding the foregoing, an employee of UBS who is the Beneficial Owner of a Title II Only Plan may direct such Plan to engage in a transaction described in Section II, if all of the other conditions of this Section III have been met;
- (c) The last auction for the Auction Rate Security was unsuccessful;
- (d) The Plan does not waive any rights or claims in connection with the loan or sale as a condition of engaging in the above-described transaction;
- (e) The Plan does not pay any fees or commissions in connection with the transaction;

<sup>31</sup> For purposes of this proposed exemption, references to section 406 of the Act should be read to refer as well to the corresponding provisions of section 4975 of the Code.

(f) The transaction is not part of an arrangement, agreement or understanding designed to benefit a party in interest;

(g) With respect to any sale described in Section I(a) or Section II(a):

(1) The sale is for no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(2) For purposes of the sale, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;<sup>32</sup>

(h) With respect to an in-kind exchange described in Section I(a) or Section II(a), the exchange involves the transfer by a Plan of an Auction Rate Security in return for a Delivered Security, as such term is defined in Section IV(j), where:

(1) The exchange is unconditional;

(2) For purposes of the exchange, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;

(3) The Delivered Security is valued at fair market value, as determined at the time of the in-kind exchange by a third party pricing service or other objective source;

(4) The Delivered Security is appropriate for the Plan and is a security that the Plan is otherwise permitted to hold under applicable law;<sup>33</sup> and

(5) The total value of the Auction Rate Security (i.e., par plus any accrued but unpaid interest) is equal to the fair market value of the Delivered Security;

(i) With respect to a loan described in Sections I(b) or II(b):

(1) The loan is documented in a written agreement that contains all of the material terms of the loan, including the consequences of default;

(2) The Plan does not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan:

(A) The coupon rate for the Auction Rate Security;

(B) The Federal Funds Rate; or

(C) The Prime Rate;

(3) The loan is unsecured; and

(4) The amount of the loan is not more than the total par value of the Auction Rate Securities held by the Plan.

#### Section IV. Definitions

(a) The term "affiliate" means: any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term "Auction Rate Security" or "ARS" means a security:

(1) That is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and

(2) With an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(c) The term "Beneficial Owner" means: the individual for whose benefit the Title II Only Plan is established and includes a relative or family trust with respect to such individual;

(d) The term "Clearing Broker" means: a member of a securities exchange that acts as a liaison between an investor and a clearing corporation and that helps to ensure that a trade is settled appropriately, that the transaction is successfully completed and that is responsible for maintaining the paper work associated with the clearing and executing of a transaction;

(e) The term "independent" means a person who is: (1) Not UBS or an affiliate; and (2) not a relative (as defined in section 3(15) of the Act) of the party engaging in the transaction;

(f) The term "Introducing Broker" means: a registered broker that is able to perform all the functions of a broker except for the ability to accept money, securities, or property from a customer;

(g) The term "Sponsor" means: a plan sponsor as described in section 3(16)(B) of the Act and any affiliates;

(h) The term "Plan" means: any plan described in section 3(3) of the Act and/or section 4975(e)(1) of the Code;

(i) The term "Title II Only Plan" means: any plan described in section 4975(e)(1) of the Code which is not an employee benefit plan covered by Title I of the Act;

(j) The term "Delivered Security" means a security that is: (1) Listed on a

national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); (2) a US Treasury obligation; (3) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (e.g., a highly rated municipal bond or a highly rated corporate bond); or (4) a certificate of deposit insured by the Federal Deposit Insurance Corporation. Notwithstanding the above, the term "Delivered Security" shall not include any Auction Rate Security, or any related Auction Rate Security, including derivatives or securities materially comprised of Auction Rate Securities or any illiquid securities.

*Effective Date:* If granted, this proposed exemption will be effective as of February 1, 2008.

#### Summary of Facts and Representations

1. The Applicant is UBS Financial Services Inc. and its affiliates (hereinafter, either "UBS" or the "Applicant"). UBS is a financial institution whose businesses provide a wide range of financial services to both consumer and corporate customers around the world. As of December 31, 2007, UBS Wealth Management US and its subsidiaries had total consolidated assets of approximately \$741 billion. UBS has approximately 8,220 financial advisors, located in approximately 484 offices across the United States, who serve approximately 2 million client relationships. In the ordinary course of its business, UBS provides a range of financial services to Title II Only Plans and pension, profit sharing, and 401(k) plans qualified under section 401(a) of the Code under which some or all of the participants are employees described in section 401(c) of the Code. Among other things, UBS acts as a broker and dealer with respect to the purchase and sale of securities, including Auction Rate Securities. The Applicant describes Auction Rate Securities and the arrangement by which ARS are bought and sold as follows. Auction Rate Securities are securities (issued as debt or preferred stock) with an interest rate or dividend that is reset at periodic intervals pursuant to a process called a Dutch Auction. Investors submit orders to buy, hold, or sell a specific ARS to a broker-dealer selected by the entity that issued the ARS. The broker-dealers, in turn, submit all of these orders to an auction agent. The auction agent's functions include collecting orders from all participating broker-dealers by the auction deadline, determining the amount of securities available for sale,

<sup>32</sup> This proposed exemption does not address tax issues. The Department has been informed by the Internal Revenue Service (the Service) and the Department of the Treasury that they are considering providing limited relief from the requirements of sections 72(t)(4), 401(a)(9), and 4974 of the Code with respect to retirement plans that hold Auction Rate Securities. The Department has also been informed by the Service that if Auction Rate Securities are purchased from a Plan in a transaction described in Sections I and II at a price that exceeds the fair market value of those securities, then the excess value would be treated as a contribution for purposes of applying applicable contribution and deduction limits under sections 219, 404, 408, and 415 of the Code.

<sup>33</sup> The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 of the Act requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a Plan fiduciary must act prudently with respect to, among other things: (1) The decision to exchange an Auction Rate Security for a Delivered Security; and (2) the negotiation of the terms of such exchange (or a cash sale or loan described above), including the pricing of such securities. The Department further emphasizes that it expects Plan fiduciaries, prior to entering into any of the proposed transactions, to fully understand the risks associated with these types of transactions following disclosure by UBS of all relevant information.

and organizing the bids to determine the winning bid. If there are any buy orders placed into the auction at a specific rate, the auction agent accepts bids with the lowest rate above any applicable minimum rate and then successively higher rates up to the maximum applicable rate, until all sell orders and orders that are treated as sell orders are filled. Bids below any applicable minimum rate or above the applicable maximum rate are rejected. After determining the clearing rate for all of the securities at auction, the auction agent allocates the ARS available for sale to the participating broker-dealers based on the orders they submitted. If there are multiple bids at the clearing rate, the auction agent will allocate securities among the bidders at such rate on a pro-rata basis.

2. The Applicant states that UBS is permitted, but not obligated, to submit orders in auctions for its own account either as a bidder or a seller and routinely does so in the auction rate securities market in its sole discretion. UBS may routinely place one or more bids in an auction for its own account to acquire ARS for its inventory, to prevent: (a) A failed auction (*i.e.*, an event where there are insufficient clearing bids which would result in the auction rate being set at a specified rate); or (b) an auction from clearing at a rate that UBS believes does not reflect the market for the particular ARS being auctioned.

3. The Applicant states that for many ARS, UBS has been appointed by the issuer of the securities to serve as a dealer in the auction and is paid by the issuer for its services. UBS is typically appointed to serve as a dealer in the auctions pursuant to an agreement between the issuer and UBS. That agreement provides that UBS will receive from the issuer auction dealer fees based on the principal amount of the securities placed through UBS.

4. The Applicant states further that UBS may share a portion of the auction rate dealer fees it receives from the issuer with other broker-dealers that submit orders through UBS, for those orders that UBS successfully places in the auctions. Similarly, with respect to ARS for which broker-dealers other than UBS act as dealer, such other broker-dealers may share auction dealer fees with UBS for orders submitted by UBS.

5. According to the Applicant, since February 2008, a minority of auctions have cleared, particularly involving municipalities. As a result, Plans holding Auction Rate Securities may not have sufficient liquidity to make benefit payments, mandatory payments and

withdrawals and expense payments when due.<sup>34</sup>

6. The Applicant represents that, in certain instances, UBS may have previously advised or otherwise caused a Plan to acquire and hold an Auction Rate Security and thus may be considered a fiduciary to the Plan so that a loan to the Plan by UBS may violate sections 406(a) and (b) of the Act; in addition, a sale between a Plan and its sponsor or a Title II Only Plan and its Beneficial Owner violates section 406 of the Act and/or section 4975(c)(1) of the Code.<sup>35</sup> The Applicant is therefore requesting relief for the following transactions, involving all Plans, effective February 1, 2008: (a) The sale or exchange of an Auction Rate Security from a Plan to the Plan's Sponsor; and (b) a lending of money or other extension of credit to a Plan in connection with the holding of an Auction Rate Security from: UBS, an Introducing Broker, or a Clearing Broker, where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Sponsor.

7. The Applicant is requesting similar relief for Title II Only Plans, also effective February 1, 2008. In this regard, the Applicant is requesting relief for: (a) The sale or exchange of an Auction Rate Security from a Title II Only Plan to the Beneficial Owner of such Plan; and (b) a lending of money or other extension of credit to a Title II Only Plan in connection with the holding of an Auction Rate Security from: UBS; an Introducing Broker; or a Clearing Broker; where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Beneficial Owner.

8. The Applicant represents that the transactions have been or will be in the interests of the Plans. In this regard, the Applicant states that the exemption, if granted, will provide Plan fiduciaries with liquidity notwithstanding changes that occurred in the Auction Rate Securities markets. The Applicant also notes that, other than for Plans sponsored by the Applicant, the

decision to enter into a transaction described herein has been made or will be made by a Plan fiduciary which is independent of UBS.

9. The proposed exemption contains a number of safeguards designed to protect the interests of each Plan. With respect to the sale of an Auction Rate Security by a Plan, the Plan must receive cash equal to the par value of the Security, plus any accrued interest. The sale must also be unconditional, other than being for payment against prompt delivery. For in-kind exchanges covered by the proposed exemption, the security delivered to the Plan (*i.e.*, the Delivered Security) must be: (a) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); (b) a US Treasury obligation; (c) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (d) a certificate of deposit insured by the Federal Deposit Insurance Corporation. The Delivered Security must also be appropriate for the Plan, and a security that the Plan is permitted to hold under applicable law. The proposed exemption further requires that the Delivered Security be valued at its fair market value, as determined at the time of the exchange from a third party pricing service or other objective source, and must equal the total value of the Auction Rate Security being exchanged (*i.e.*, par value, plus any accrued interest).

10. With respect to a loan to a Plan holding an Auction Rate Security, such loan must be documented in a written agreement containing all of the material terms of the loan, including the consequences of default. Further, the Plan may not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan: The coupon rate for the Auction Rate Security; the Federal Funds Rate; or the Prime Rate. Additionally, such loan must be unsecured and for an amount that is no more than the total par value of Auction Rate Securities held by the affected Plan.

11. Additional conditions apply to each transaction covered by the exemption, if granted. Among other things, the Plan may not pay any fees or commissions in connection with the transaction and the transaction may not be part of an arrangement, agreement, or understanding designed to benefit a party in interest. The exemption expressly prohibits any waiver of rights

<sup>34</sup> The Department notes that Prohibited Transaction Exemption 80-26 (45 FR 28545 (April 29, 1980), as amended at 71 FR 17917 (April 7, 2006)) permits interest-free loans or other extensions of credit from a party in interest to a Plan if, among other things, the proceeds of the loan or extension of credit are used only: (1) For the payment of ordinary operating expenses of the Plan, including the payment of benefits in accordance with the terms of the Plan and periodic premiums under an insurance or annuity contract, or (2) for a purpose incidental to the ordinary operation of the Plan.

<sup>35</sup> The relief contained in this proposed exemption does not extend to the fiduciary provisions of section 404 of the Act.

or claims by a Plan in connection with the sale or exchange of an Auction Rate Security by such Plan, or a lending of money or other extension of credit to a Plan holding an Auction Rate Security.

12. In summary, the Applicant represents that the transactions described herein have satisfied or will satisfy the statutory criteria for an exemption set forth in section 408(a) of the Act and section 4975(c)(2) of the Code because:

- (a) Any sale has been or will be:
  - (1) For no consideration other than cash payment against prompt delivery of the Auction Rate Security; and
  - (2) At par, plus any accrued but unpaid interest;
  - (b) Any in-kind exchange has been or will be unconditional, other than being for payment against prompt delivery, and has involved or will involve Delivered Securities that are:
    - (1) Appropriate for the Plan;
    - (2) Listed on a national securities exchange (but not OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); U.S. Treasury obligations; fixed income securities; or certificates of deposit; and
    - (3) Securities that the Plan is permitted to hold under applicable law; and,
    - (c) Any loan has been or will be:
      - (1) Documented in a written agreement containing all of the material terms of the loan, including the consequences of default;
      - (2) At an interest rate not in excess of: The coupon rate for the Auction Rate Security, the Federal Funds Rate, or the Prime Rate;
      - (3) Unsecured; and
      - (4) For an amount that is not more than the total par value of Auction Rate Securities held by the affected Plan.

#### Notice to Interested Persons

The Applicant represents that the potentially interested participants and beneficiaries cannot all be identified, and, therefore, the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 30 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

#### FOR FURTHER INFORMATION CONTACT:

Brian Shiker of the Department, telephone (202) 693-8552. (This is not a toll-free number.)

Deutsche Bank AG and Its Affiliates (together, Deutsche Bank or the Applicant), Located in New York, New York, [Application Number D-11518].

#### Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act (or ERISA) and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).<sup>36</sup>

#### Section I. Sales of Auction Rate Securities From Plan to Deutsche Bank: Unrelated to a Settlement Agreement

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) and (D) and section 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), (D), and (E) of the Code, shall not apply, effective February 1, 2008, to the sale by a Plan (as defined in Section V(e)) of an Auction Rate Security (as defined in Section V(c)) to Deutsche Bank, where such sale (an Unrelated Sale) is unrelated to, and not made in connection with, a Settlement Agreement (as defined in Section V(f)), provided that the conditions set forth in Section II have been met.

#### Section II. Conditions Applicable to Transactions Described in Section I

- (a) The Plan acquired the Auction Rate Security in connection with brokerage or advisory services provided by Deutsche Bank;
- (b) The last auction for the Auction Rate Security was unsuccessful;
- (c) Except in the case of a Plan sponsored by Deutsche Bank for its own employees (a Deutsche Bank Plan), the Unrelated Sale is made pursuant to a written offer by Deutsche Bank (the Offer) containing all of the material terms of the Unrelated Sale, including, but not limited to the most recent rate information for the Auction Rate Security (if reliable information is available). Either the Offer or other materials available to the Plan provide the identity and par value of the Auction Rate Security. Notwithstanding the foregoing, in the case of a pooled fund maintained or advised by Deutsche Bank, this condition shall be deemed met to the extent each Plan invested in the pooled fund (other than a Deutsche Bank Plan) receives written notice regarding the Unrelated Sale, where such notice contains the material terms of the Unrelated Sale (including, but not limited to, the material terms described in the preceding sentence);

<sup>36</sup> For purposes of this proposed exemption, references to section 406 of ERISA should be read, unless otherwise specified, to refer to the corresponding provisions of section 4975 of the Code.

(d) The Unrelated Sale is for no consideration other than cash payment against prompt delivery of the Auction Rate Security;

(e) The sales price for the Auction Rate Security is equal to the par value of the Auction Rate Security, plus any accrued but unpaid interest or dividends;

(f) The Plan does not waive any rights or claims in connection with the Unrelated Sale;

(g) The decision to accept the Offer or retain the Auction Rate Security is made by a Plan fiduciary or Plan participant or IRA owner who is independent (as defined in Section V(d)) of Deutsche Bank. Notwithstanding the foregoing: (1) In the case of an individual retirement account (an IRA, as described in Section V(e) below) which is beneficially owned by an employee, officer, director or partner of Deutsche Bank, the decision to accept the Offer or retain the Auction Rate Security may be made by such employee, officer, director or partner; or (2) in the case of a Deutsche Bank Plan or a pooled fund maintained or advised by Deutsche Bank, the decision to accept the Offer may be made by Deutsche Bank after Deutsche Bank has determined that such purchase is in the best interest of the Deutsche Bank Plan or pooled fund;<sup>37</sup>

(h) Except in the case of a Deutsche Bank Plan or a pooled fund maintained or advised by Deutsche Bank, neither Deutsche Bank nor any affiliate exercises investment discretion or renders investment advice within the meaning of 29 CFR 2510.3-21(c) with respect to the decision to accept the Offer or retain the Auction Rate Security;

(i) The Plan does not pay any commissions or transaction costs with respect to the Unrelated Sale;

(j) The Unrelated Sale is not part of an arrangement, agreement or understanding designed to benefit a party in interest to the Plan;

(k) Deutsche Bank and its affiliates, as applicable, maintain, or cause to be

<sup>37</sup> The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things, the decision to sell the Auction Rate Security to Deutsche Bank for the par value of the Auction Rate Security, plus any accrued but unpaid interest or dividends. The Department further emphasizes that it expects Plan fiduciaries, prior to entering into any of the proposed transactions, to fully understand the risks associated with this type of transaction following disclosure by Deutsche Bank of all relevant information.

maintained, for a period of six (6) years from the date of the Unrelated Sale, such records as are necessary to enable the persons described below in paragraph (l)(1), to determine whether the conditions of this exemption, if granted, have been met, except that—

(1) No party in interest with respect to a Plan which engages in an Unrelated Sale, other than Deutsche Bank and its affiliates, as applicable, shall be subject to a civil penalty under section 502(i) of the Act or the taxes imposed by section 4975(a) and (b) of the Code, if such records are not maintained, or not available for examination, as required, below, by paragraph (l)(1); and

(2) A separate prohibited transaction shall not be considered to have occurred solely because, due to circumstances beyond the control of Deutsche Bank or its affiliates, as applicable, such records are lost or destroyed prior to the end of the six-year period;

(l)(1) Except as provided below in paragraph (l)(2), and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in paragraph (k) are unconditionally available at their customary location for examination during normal business hours by—

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service, or the U.S. Securities and Exchange Commission; or

(B) Any fiduciary of any Plan, including any IRA owner, that engages in a Sale, or any duly authorized employee or representative of such fiduciary; or

(C) Any employer of participants and beneficiaries and any employee organization whose members are covered by a Plan that engages in the Unrelated Sale, or any authorized employee or representative of these entities;

(2) None of the persons described above in paragraph (l)(1)(B)–(C) shall be authorized to examine trade secrets of Deutsche Bank, or commercial or financial information which is privileged or confidential; and

(3) Should Deutsche Bank refuse to disclose information on the basis that such information is exempt from disclosure, Deutsche Bank shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

### *Section III. Sales of Auction Rate Securities From Plans to Deutsche Bank: Related to a Settlement Agreement*

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) and (D) and section 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), (D), and (E) of the Code, shall not apply, effective February 1, 2008, to the sale by a Plan of an Auction Rate Security to Deutsche Bank, where such sale (a Settlement Sale) is related to, and made in connection with, a Settlement Agreement, provided that the conditions set forth in Section IV have been met.

### *Section IV. Conditions Applicable to Transactions Described in Section III*

(a) The terms and delivery of the Offer are consistent with the requirements set forth in the Settlement Agreement;

(b) The Offer or other documents available to the Plan specifically describe, among other things:

(1) How a Plan may determine: The Auction Rate Securities held by the Plan with Deutsche Bank, the purchase dates for the Auction Rate Securities, and (if reliable information is available) the most recent rate information for the Auction Rate Securities;

(2) The number of shares and par value of the Auction Rate Securities available for purchase under the Offer;

(3) The background of the Offer;

(4) That participating in the Offer will not result in or constitute a waiver of any claim of the tendering Plan;

(5) The methods and timing by which Plans may accept the Offer;

(6) The purchase dates, or the manner of determining the purchase dates, for Auction Rate Securities tendered pursuant to the Offer;

(7) The timing for acceptance by Deutsche Bank of tendered Auction Rate Securities;

(8) The timing of payment for Auction Rate Securities accepted by Deutsche Bank for payment;

(9) The methods and timing by which a Plan may elect to withdraw tendered Auction Rate Securities from the Offer;

(10) The expiration date of the Offer;

(11) The fact that Deutsche Bank may make purchases of Auction Rate Securities outside of the Offer and may otherwise buy, sell, hold or seek to restructure, redeem or otherwise dispose of the Auction Rate Securities;

(12) A description of the risk factors relating to the Offer as Deutsche Bank deems appropriate;

(13) How to obtain additional information concerning the Offer; and

(14) The manner in which information concerning material

amendments or changes to the Offer will be communicated to affected Plans.

(c) The terms of the Settlement Sale are consistent with the requirements set forth in the Settlement Agreement; and

(d) All of the conditions in Section II have been met.

### *Section V. Definitions*

For purposes of this proposed exemption:

(a) The term “affiliate” means: Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term “control” means: The power to exercise a controlling influence over the management or policies of a person other than an individual;

(c) The term “Auction Rate Security” means a security that:

(1) Is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and  
(2) Has an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(d) A person is “independent” of Deutsche Bank if the person is: (1) Not Deutsche Bank or an affiliate; and (2) not a relative (as defined in ERISA section 3(15)) of the party engaging in the transaction;

(e) The term “Plan” means: An individual retirement account or similar account described in section 4975(e)(1)(B) through (F) of the Code (an IRA); an employee benefit plan as defined in section 3(3) of ERISA; or an entity holding plan assets within the meaning of 29 CFR 2510.3–101, as modified by ERISA section 3(42); and

(f) The term “Settlement Agreement” means: A legal settlement involving Deutsche Bank and a U.S. state or federal authority that provides for the purchase of an Auction Rate Security by Deutsche Bank from a Plan.

*Effective Date:* If granted, this proposed exemption will be effective as of February 1, 2008.

### **Summary of Facts and Representations**

1. Deutsche Bank AG is a German banking corporation and commercial bank that provides a wide range of services to various types of entities worldwide. Deutsche Bank AG's clients include a number of employee benefit plans. As of June 30, 2008, Deutsche Bank AG had 1.991 trillion euros (\$2.95 trillion) in assets and 31.9 billion euros (\$17.3 billion) in stockholder's equity.

Deutsche Bank AG is subject to a comprehensive system of regulatory oversight and a mandatory insurance program. With respect to regulatory and

supervisory requirements, Deutsche Bank AG, its branches, and its subsidiary banks worldwide are subject to regulatory requirements and protections that are, qualitatively, at least equal to those imposed on U.S.-domiciled banks. Within the United States, the New York branch of Deutsche Bank AG and Deutsche Bank Trust Company Americas are regulated and supervised by the New York State Banking Department. In addition, certain activities of Deutsche Bank AG's New York branch and Deutsche Bank Trust Company Americas (the trustee of ERISA-covered bank collective trusts) are regulated and supervised by the Federal Reserve Bank of New York. With respect to Deutsche Bank AG itself, globally, the bank is regulated and supervised by the BaFin, in cooperation with the Bundesbank. The BaFin is a federal institution with ultimate responsibility to the German Ministry of Finance. The Bundesbank, in turn, is the central bank of the Federal Republic of Germany and a part of the European System of Central Banks. The applicant notes that the U.S. Department of Treasury has accorded national treatment to German bank branches, and the German Ministry of finance has granted relief to branches of U.S. banks in Germany, in particular with respect to "dotation" or endowment capital requirements and capital adequacy standards.

2. The Applicant describes Auction Rate Securities (ARS) and the arrangement by which ARS are bought and sold as follows. ARS are securities (issued as debt or preferred stock) with an interest rate or dividend that is reset at periodic intervals pursuant to a process called a Dutch Auction. Investors submit orders to buy, hold, or sell a specific ARS to a broker-dealer selected by the entity that issued the ARS. The broker-dealers, in turn, submit all of these orders to an auction agent. The auction agent's functions include collecting orders from all participating broker-dealers by the auction deadline, determining the amount of securities available for sale, and organizing the bids to determine the winning bid. If there are any buy orders placed into the auction at a specific rate, the auction agent accepts bids with the lowest rate above any applicable minimum rate and then successively higher rates up to the maximum applicable rate, until all sell orders and orders that are treated as sell orders are filled. Bids below any applicable minimum rate or above the applicable maximum rate are rejected. After determining the clearing rate for all of the securities at auction, the

auction agent allocates the ARS available for sale to the participating broker-dealers based on the orders they submitted. If there are multiple bids at the clearing rate, the auction agent will allocate securities among the bidders at such rate on a pro-rata basis.

3. The Applicant states that, under a typical Dutch Auction process, Deutsche Bank AG is permitted, but not obligated, to submit orders in auctions for its own account either as a bidder or a seller and routinely does so in the auction rate securities market in its sole discretion. Deutsche Bank AG may place one or more bids in an auction for its own account to acquire ARS for its inventory, to prevent: (a) A failed auction (i.e., an event where there are insufficient clearing bids which would result in the auction rate being set at a specified rate, resulting in no ARS being sold through the auction process); or (b) an auction from clearing at a rate that Deutsche Bank AG believes does not reflect the market for the particular ARS being auctioned.

4. The Applicant states that for many ARS, Deutsche Bank AG has been appointed by the issuer of the securities to serve as a dealer in the auction and is paid by the issuer for its services. Deutsche Bank AG is typically appointed to serve as a dealer in the auctions pursuant to an agreement between the issuer and Deutsche Bank AG. That agreement provides that Deutsche Bank AG will receive from the issuer auction dealer fees based on the principal amount of the securities placed through Deutsche Bank AG.

5. The Applicant states further that Deutsche Bank AG may share a portion of the auction rate dealer fees it receives from the issuer with other broker-dealers that submit orders through Deutsche Bank AG, for those orders that Deutsche Bank AG successfully places in the auctions. Similarly, with respect to ARS for which broker-dealers other than Deutsche Bank AG act as dealer, such other broker-dealers may share auction dealer fees with Deutsche Bank AG for orders submitted by Deutsche Bank AG.

6. Since February 2008, the Applicant knows of no auctions that have been successful. According to the Applicant, the current state of the ARS market is virtually nonexistent. As a result, Plans holding ARS may not have sufficient liquidity to make benefit payments, mandatory payments and withdrawals and expense payments when due.<sup>38</sup>

<sup>38</sup> The Department notes that Prohibited Transaction Exemption 80-26 (45 FR 28545 (April 29, 1980), as amended at 71 FR 17917 (April 7, 2006)) permits interest-free loans or other

7. The Applicant represents that, in certain instances, Deutsche Bank AG may have previously advised or otherwise caused a Plan to acquire and hold an ARS.<sup>39</sup> In connection with Deutsche Bank AG's role in the acquisition and holding of ARS by various Deutsche Bank AG clients, including the Plans, Deutsche Bank AG entered into Settlement Agreements with certain U.S. states and federal authorities. Pursuant to these Settlement Agreements, among other things, Deutsche Bank AG was required to send a written offer to certain Plans that held ARS in connection with the advice and/or brokerage services provided by Deutsche Bank AG. As described in further detail below, eligible Plans that accepted the Offer were permitted to sell the ARS to Deutsche Bank AG for cash equal to the par value of such securities, plus any accrued interest and/or dividends. According to the Applicant, as of Monday, October 26, 2009, in connection with Offers issued by Deutsche Bank AG pursuant to the Settlement Agreement, Deutsche Bank AG has purchased approximately \$4,750,000 dollars in ARS from IRAs and \$725,000 in ARS from Plans subject to Title I of ERISA. The Applicant states that, prospectively, additional shares of ARS may be tendered by Plans to Deutsche Bank AG pursuant to an Offer issued by Deutsche Bank AG pursuant to a Settlement Agreement.

Accordingly, the Applicant is requesting retroactive and prospective relief for the Settlement Sales. With respect to Unrelated Sales, the Applicant states that to the best of its knowledge, as of June 30, 2009, no Unrelated Sale has occurred. However, the Applicant is requesting retroactive relief (and prospective relief) for Unrelated Sales in the event that a sale of ARS by a Plan to Deutsche Bank AG has occurred outside the Settlement process. If granted, the exemption would be effective as of February 1, 2008.

8. Specifically, the Applicant is requesting exemptive relief for the sale of ARS under two different circumstances: (a) Where Deutsche Bank AG initiates the sale by sending to a Plan a written Offer to acquire the ARS,

extensions of credit from a party in interest to a plan if, among other things, the proceeds of the loan or extension of credit are used only: (1) For the payment of ordinary operating expenses of the plan, including the payment of benefits in accordance with the terms of the plan and periodic premiums under an insurance or annuity contract, or (2) for a purpose incidental to the ordinary operation of the plan.

<sup>39</sup> The relief contained in this proposed exemption does not extend to the fiduciary provisions of section 404 of the Act.

notwithstanding that such Offer is not required under a Settlement Agreement (*i.e.*, an Unrelated Sale); and (b) where Deutsche Bank AG is required under a Settlement Agreement to send to Plans a written Offer to acquire the ARS (*i.e.*, a Settlement Sale). The Applicant states that the Unrelated Sales and Settlement Sales (hereinafter, either, a Covered Sale) are in the interests of Plans. In this regard, the Applicant states that the Covered Sales would permit Plans to normalize Plan investments. The Applicant represents that each Covered Sale will be for no consideration other than cash payment against prompt delivery of the ARS, and such cash will equal the par value of the ARS, plus any accrued but unpaid interest or dividends. The Applicant represents further that Plans will not pay any commissions or transaction costs with respect to any Covered Sale.

9. The Applicant represents that the proposed exemption is protective of the Plans. The Applicant states that, except in the case of a Plan sponsored by Deutsche Bank AG for its own employees (a Deutsche Bank AG Plan): Each Covered Sale will be made pursuant to a written Offer; and the decision to accept the Offer or retain the ARS will be made by a Plan fiduciary or Plan participant or IRA owner who is independent of Deutsche Bank AG.

Additionally, each Offer will be delivered in a manner designed to alert a Plan fiduciary that Deutsche Bank AG intends to purchase ARS from the Plan. In connection with an Unrelated Sale, the Offer will describe the material terms of the Unrelated Sale, including the most recent rate information for the ARS (if reliable information is available). Either the Offer or other materials available to the Plan will provide the identity and par value of the ARS. Offers made in connection with a Settlement Agreement will specifically include, among other things: the background of the Offer; the method and timing by which a Plan may accept the Offer; the expiration date of the Offer; a description of certain risk factors relating to the Offer; how to obtain additional information concerning the Offer; and the manner in which information concerning material amendments or changes to the Offer will be communicated to affected Plans. The Applicant states that, except in the case of a Deutsche Bank AG Plan or a pooled fund maintained or advised by Deutsche Bank AG, neither Deutsche Bank AG nor any affiliate will exercise investment discretion or render investment advice with respect to a Plan's decision to

accept the Offer or retain the ARS.<sup>40</sup> In the case of a Deutsche Bank AG Plan or a pooled fund maintained or advised by Deutsche Bank AG, the decision to engage in a Covered Sale may be made by Deutsche Bank AG after Deutsche Bank AG has determined that such purchase is in the best interest of the Deutsche Bank AG Plan or pooled fund. The Applicant represents further that Plans will not waive any rights or claims in connection with any Covered Sale.

10. The Applicant represents that the proposed exemption, if granted, would be administratively feasible. In this regard, the Applicant notes that each Covered Sale will occur at the par value of the affected ARS, plus any accrued but unpaid interest or dividends, and such value is readily ascertainable. The Applicant represents further that Deutsche Bank AG will maintain the records necessary to enable the Department and Plan fiduciaries, among others, to determine whether the conditions of this exemption, if granted, have been met.

11. In summary, the Applicant represents that the transactions described herein satisfy the statutory criteria of section 408(a) of the Act because, among other things:

- (a) Except in the case of a Deutsche Bank AG Plan, each Covered Sale shall be made pursuant to a written Offer;
- (b) Each Covered Sale shall be for no consideration other than cash payment against prompt delivery of the ARS;
- (c) The amount of each Covered Sale shall equal the par value of the ARS, plus any accrued but unpaid interest or dividends;
- (d) Plans will not waive any rights or claims in connection with any Covered Sale;
- (e) Except in the case of a Deutsche Bank AG Plan or a pooled fund maintained or advised by Deutsche Bank AG:
  - (1) The decision to accept an Offer or retain the ARS shall be made by a Plan fiduciary or Plan participant or IRA owner who is independent of Deutsche Bank AG; and
  - (2) Neither Deutsche Bank AG nor any affiliate shall exercise investment discretion or render investment advice within the meaning of 29 CFR 2510.3-21(c) with respect to the decision to accept the Offer or retain the ARS;
- (f) Plans shall not pay any commissions or transaction costs with respect to any Covered Sale;

<sup>40</sup> The Applicant states that while there may be communication between a Plan and Deutsche Bank subsequent to an Offer, such communication will not involve advice regarding whether the Plan should accept the Offer.

(g) A Covered Sale shall not be part of an arrangement, agreement or understanding designed to benefit a party in interest to the affected Plan;

(h) With respect to any Settlement Sale, the terms and delivery of the Offer, and the terms of Settlement Sale, shall be consistent with the requirements set forth in the Settlement Agreement;

(i) Deutsche Bank AG shall make available in connection with an Unrelated Sale the material terms of the Unrelated Sale, including the most recent rate information for the ARS (if reliable information is available), and the identity and par value of the ARS;

(j) Each Offer made in connection with a Settlement Agreement shall describe the material terms of the Settlement Sale, including the following:

- (1) Information regarding how the Plan can determine: The ARS held by the Plan with Deutsche Bank AG, the number of shares and par value of the ARS, purchase dates for such ARS, and (if reliable information is available) the most recent rate information for the ARS;
- (2) The background of the Offer;
- (3) That participating in the Offer will not result in or constitute a waiver of any claim of the tendering Plan;
- (4) The methods and timing by which the Plan may accept the Offer;
- (5) The purchase dates, or the manner of determining the purchase dates, for ARS pursuant to the Offer;
- (6) The timing for acceptance by Deutsche Bank AG of tendered ARS;
- (7) The timing of payment for ARS accepted by Deutsche Bank AG for payment;
- (8) The methods and timing by which a Plan may elect to withdraw tendered ARS from the Offer;
- (9) The expiration date of the Offer;
- (10) The fact that Deutsche Bank AG may make purchases of ARS outside of the Offer and may otherwise buy, sell, hold or seek to restructure, redeem or otherwise dispose of the ARS;
- (11) A description of the risk factors relating to the Offer as Deutsche Bank AG deems appropriate;
- (12) How to obtain additional information concerning the Offer; and
- (13) The manner in which information concerning material amendments or changes to the Offer will be communicated to affected Plans.

#### Notice to Interested Persons

The Applicant represents that the potentially interested participants and beneficiaries cannot all be identified and therefore the only practical means of notifying such participants and beneficiaries of this proposed

exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 30 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Warren Blinder of the Department, telephone (202) 693-8553. (This is not a toll-free number.)

Morgan Stanley & Co. Inc. and its current and future affiliates and subsidiaries (Morgan Stanley) and Union Bank, N.A. and its affiliates (Union Bank), located in New York, NY and San Francisco, CA., [Application No. D-11521].

### Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).

#### Section I—Transactions

If the exemption is granted, effective October 1, 2008, the restrictions of section 406(a)(1)(A) through (D) and 406(b)(1) and (2) of the Act, and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to:

(a) The lending of securities to:

(1) Morgan Stanley & Co.

Incorporated, and its successors (MS&Co.) and Union Bank, N.A., and its successors (UB);

(2) Any current or future affiliate of MS&Co. or UB,<sup>41</sup> that is a bank, as defined in section 202(a)(2) of the Investment Advisers Act of 1940, that is supervised by the U.S. or a state, any broker-dealer registered under the Securities Exchange Act of 1934 (the "1934 Act"), or any foreign affiliate that is a bank or broker-dealer that is supervised by (i) the Securities and Futures Authority ("SFA") in the United Kingdom; (ii) the Bundesanstalt für Finanzdienstleistungsaufsicht (the "BAFin") in Germany; (iii) the Ministry of Finance ("MOF") and/or the Tokyo Stock Exchange in Japan; (iv) the Ontario Securities Commission, the Investment Dealers Association and/or the Office of Superintendent of Financial Institutions in Canada; (v) the Swiss Federal Banking Commission in Switzerland; (vi) the Reserve Bank of Australia or the Australian Securities and Investments Commission and/or Australian Stock Exchange Limited in

Australia; (vii) the Commission Bancaire ("CB"), the Comité des Établissements de Crédit et des Entreprises d'Investissement (CECEI) and the Autorité des Marchés Financiers ("AMF") in France; and (viii) the Swedish Financial Supervisory Authority ("SFSA") in Sweden (the branches and/or affiliates in the enumerated foreign countries hereinafter referred to as the "Foreign Affiliates") and together with their U.S. branches or U.S. affiliates (individually, "Affiliated Borrower" and collectively, "Affiliated Borrowers"), by employee benefit plans, including commingled investment funds holding plan assets (the Client Plans or Plans),<sup>42</sup> for which MS&Co., UB or an affiliate of either acts as securities lending agent or subagent (the "Lending Agent"),<sup>43</sup> and also may serve as directed trustee or custodian of securities being lent, or for which a subagent is appointed by the Lending Agent, which subagent is either (I) a bank, as defined in section 202(a)(2) of the Investment Advisers Act of 1940 or a broker-dealer registered under the 1934 Act, (i) which has, as of the last day of its most recent fiscal year, equity capital in excess of \$100 million and (ii) which annually exercises discretionary authority to lend securities on behalf of clients equal to at least \$1 billion; or (II) an investment adviser registered under the Investment Advisers Act of 1940, (i) which has, as of the last day of its most recent fiscal year, equity capital in excess of \$1 million and (ii) which annually exercises discretionary authority to lend securities on behalf of clients equal to at least \$1 billion (each, a "Lending Subagent"); and

(b) The receipt of compensation by the Lending Agent and the Lending

<sup>42</sup> The common and collective trust funds for which MS&Co., UB or an affiliate act as directed trustee or custodian, and in which Client Plans invest, are referred to herein as "Commingled Funds." The Client Plan separate accounts for which MS&Co., UB or an affiliate act as directed trustee or custodian are referred to herein as "Separate Accounts." Commingled Funds and Separate Accounts are collectively referred to herein as "Lender" or "Lenders."

<sup>43</sup> MS&Co., UB or an affiliate may be retained by primary securities lending agents to provide securities lending services in a sub-agent capacity with respect to portfolio securities of clients of such primary securities lending agents. As a securities lending sub-agent, MS&Co.'s or UB's role parallels that under the lending transactions for which MS&Co., UB or an affiliate acts as a primary securities lending agent on behalf of its clients. References to MS&Co.'s or UB's performance of services as securities lending agent should be deemed to include its parallel performance as a securities lending sub-agent and references to the Client Plans should be deemed to include those plans for which the Lending Agent is acting as a sub-agent with respect to securities lending, unless otherwise specifically indicated or by the context of the reference.

Subagent in connection with these transactions.

#### Section II—Conditions

Section I of this exemption applies only if the conditions of Section II are satisfied. For purposes of this exemption, any requirement that the approving fiduciary be independent of MS&Co., UB, and their affiliates shall not apply in the case of an employee benefit plan sponsored and maintained by the Lending Agent and/or an affiliate for its own employees (an Affiliated Plan) invested in a Commingled Fund, provided that at all times the holdings of all Affiliated Plans in the aggregate comprise less than 10% of the assets of the Commingled Fund.

(a) For each Client Plan, neither MS&Co., UB, nor any of their affiliates has or exercises discretionary authority or control with respect to the investment of the assets of Client Plans involved in the transaction or renders investment advice (within the meaning of 29 CFR 2510.3-21(c)) with respect to such assets, including decisions concerning a Client Plan's acquisition or disposition of securities available for loan.

(b) Any arrangement for the Lending Agent to lend securities is approved in advance by a Plan fiduciary who is independent of MS&Co., UB, and their affiliates (the Independent Fiduciary). Notwithstanding the foregoing, section II(b) shall be deemed satisfied with respect to loans of securities by Client Plans to MS&Co. or a U.S. affiliate (Morgan Stanley Affiliated Borrower) by UB as Lending Agent or Lending Subagent that were outstanding as of October 1, 2008 (the Existing Loans), provided (i) no later than April 1, 2009, UB provided to Client Plans with Existing Loans a description of the general terms of the securities loan agreements between such Client Plans and the Morgan Stanley Affiliated Borrowers, and (ii) at the time of providing such information, UB notified each such Client Plan that if the Client Plan did not approve the continued lending of securities to Morgan Stanley by May 11, 2009, UB would terminate the loans and cease to make any new securities loans on behalf of that Client Plan to Morgan Stanley.

(c) The specific terms of the securities loan agreement (the Loan Agreement) are negotiated by the Lending Agent which acts as a liaison between the Lender and the Affiliated Borrower to facilitate the securities lending transaction. In the case of a Separate Account, the Independent Fiduciary of a Client Plan approves the general terms of the Loan Agreement between the

<sup>41</sup> Any reference to MS&Co. or UB shall be deemed to include any successors thereto.



Client Plan and the Affiliated Borrower as well as any material change in such Loan Agreement. In the case of a Commingled Fund, approval is pursuant to the procedure described in paragraph (i), below.

(d) The terms of each loan of securities by a Lender to an Affiliated Borrower are at least as favorable to such Separate Account or Commingled Fund as those of a comparable arm's-length transaction between unrelated parties.

(e) A Client Plan, in the case of a Separate Account, may terminate the lending agency or sub-agency arrangement at any time, without penalty, on five business days notice. A Client Plan in the case of a Commingled Fund may terminate its participation in the lending arrangement by terminating its investment in the Commingled Fund no later than 35 days after the notice of termination of participation is received, without penalty to the Plan, in accordance with the terms of the Commingled Fund. Upon termination, the Affiliated Borrowers will transfer securities identical to the borrowed securities (or the equivalent thereof in the event of reorganization, recapitalization or merger of the issuer of the borrowed securities) to the Separate Account or, if the Plan's withdrawal necessitates a return of securities, to the Commingled Fund within:

(1) The customary delivery period for such securities;

(2) Five business days; or

(3) The time negotiated for such delivery by the Client Plan, in a Separate Account, or by the Lending Agent, as lending agent to a Commingled Fund, and the Affiliated Borrowers, whichever is least.

(f) The Separate Account, Commingled Fund or another custodian designated to act on behalf of the Client Plan, receives from each Affiliated Borrower (either by physical delivery, book entry in a securities depository located in the United States, wire transfer or similar means) by the close of business on or before the day the loaned securities are delivered to the Affiliated Borrower, collateral consisting of U.S. currency, securities issued or guaranteed by the United States Government or its agencies or instrumentalities, irrevocable bank letters of credit issued by a U.S. bank, other than Morgan Stanley or Union Bank (or any subsequent parent corporation of the Lending Agent) or an affiliate thereof, or any combination thereof, or other collateral permitted under Prohibited Transaction Exemption (PTE) 2006-16 (71 FR 63786,

October 31, 2006) (as it may be amended or superseded) (collectively, the Collateral).<sup>44</sup> The Collateral will be held on behalf of a Client Plan in a depository account separate from the Affiliated Borrower.

(g) The market value (or in the case of a letter of credit, a stated amount) of the Collateral on the close of business on the day preceding the day of the loan is initially equal at least to the percentage required by PTE 2006-16 (as amended or superseded) but in no case less than 102 percent of the market value of the loaned securities. The applicable Loan Agreement gives the Separate Account or the Commingled Fund in which the Client Plan has invested a continuing security interest in, and a lien on or title to, the Collateral. The level of the Collateral is monitored daily by the Lending Agent. If the market value of the Collateral, on the close of trading on a business day, is less than 100 percent of the market value of the loaned securities at the close of business on that day, the Affiliated Borrower is required to deliver, by the close of business on the next day, sufficient additional Collateral such that the market value of the Collateral will again equal 102 percent or the percentage otherwise required by PTE 2006-16 (as amended or superseded).

(h)(1) For a Lender that is a Separate Account, prior to entering into a Loan Agreement, the applicable Affiliated Borrower furnishes its most recently available audited and unaudited financial statements to the Lending Agent which will, in turn, provide such statements to the Client Plan before the Client Plan approves the terms of the Loan Agreement. The Loan Agreement contains a requirement that the applicable Affiliated Borrower must give prompt notice at the time of a loan of any material adverse changes in its financial condition since the date of the most recently furnished financial statements. If any such changes have taken place, the Lending Agent will not make any further loans to the Affiliated Borrower unless an Independent Fiduciary of the Client Plan in a

Separate Account is provided notice of any material change and approves the continuation of the lending arrangement in view of the changed financial condition.

Notwithstanding the foregoing, section II(h)(1) shall be deemed satisfied with respect to the Existing Loans provided (i) UB provided to such Client Plans no later than April 1, 2009, the most recently available audited and unaudited financial statements of the Morgan Stanley Affiliated Borrower and notice of any material adverse change in financial condition since the date of the most recent financial statement being furnished to the Client Plans, and (ii) at the time of providing such information, UB notified each Client Plan that if the Client Plan did not approve the continued lending of securities to Morgan Stanley by May 11, 2009, UB would terminate the loans and cease to make any new securities loans on behalf of that Client Plan to Morgan Stanley.

(h)(2) For a Lender that is a Commingled Fund, the Lending Agent will furnish upon reasonable request to an Independent Fiduciary of each Client Plan invested in the Commingled Fund the most recently available audited and unaudited financial statements of the applicable Affiliated Borrower prior to authorization of lending, and annually thereafter.

(i) In the case of Commingled Funds, the information described in paragraph (c) (including any information with respect to any material change in the arrangement) shall be furnished by the Lending Agent as lending fiduciary to the Independent Fiduciary of each Client Plan whose assets are invested in the Commingled Fund, not less than 30 days prior to implementation of the arrangement or material change to the lending arrangement as previously described to the Client Plan, and thereafter, upon the reasonable request of the Client Plan's Independent Fiduciary. In the event of a material adverse change in the financial condition of an Affiliated Borrower, the Lending Agent will make a decision, using the same standards of credit analysis the Lending Agent would use in evaluating unrelated borrowers, whether to terminate existing loans and whether to continue making additional loans to the Affiliated Borrower.

In the event any such Independent Fiduciary submits a notice in writing within the 30-day period provided in the preceding paragraph to the Lending Agent, as lending fiduciary, objecting to the implementation of, material change in, or continuation of the arrangement, the Plan on whose behalf the objection was tendered is given the opportunity to

<sup>44</sup> PTE 2006-16 permits the use of certain types of foreign collateral if the lending fiduciary is a U.S. Bank or U.S. Broker-Dealer (as defined in the exemption) and such fiduciary indemnifies the plan with respect to the difference, if any, between the replacement cost of the borrowed securities and the market value of the collateral on the date of a borrower default plus interest and any transaction costs which a plan may incur or suffer directly arising out of a borrower default. See PTE 2006-16, Section V(f)(5). The Department notes that the requirements of Section V(f)(5) of PTE 2006-16 must be satisfied in order for those types of collateral to be used in connection with this proposed exemption, if granted.

terminate its investment in the Commingled Fund, without penalty to the Plan, no later than 35 days after the notice of withdrawal is received. In the case of a Plan that elects to withdraw pursuant to the foregoing, such withdrawal shall be effected prior to the implementation of, or material change in, the arrangement; but an existing arrangement need not be discontinued by reason of a Plan electing to withdraw. In the case of a Plan whose assets are proposed to be invested in the Commingled Fund subsequent to the implementation of the arrangement, the Plan's investment in the Commingled Fund shall be authorized in the manner described in paragraph (c).

(j) In return for lending securities, the Lender either—(1) Receives a reasonable fee, which is related to the value of the borrowed securities and the duration of the loan; or

(2) Has the opportunity to derive compensation through the investment of cash Collateral. (Under such circumstances, the Lender may pay a loan rebate or similar fee to the Affiliated Borrowers, if such fee is not greater than the fee the Lender would pay in a comparable arm's-length transaction with an unrelated party.)

(k) Except as otherwise expressly provided herein, all procedures regarding the securities lending activities will, at a minimum, conform to the applicable provisions of PTE 2006-16, as amended or superseded, as well as to applicable securities laws of the United States, the United Kingdom, Canada, Australia, Switzerland, Japan, France, Sweden and Germany.

(l) If any event of default occurs, to the extent that (i) liquidation of the pledged Collateral or (ii) additional cash received from the Affiliated Borrower does not provide sufficient funds on a timely basis, the Client Plan will have the right to purchase securities identical to the borrowed securities (or their equivalent as discussed in paragraph (e) above) and apply the Collateral to the payment of the purchase price. If the Collateral is insufficient to accomplish such purchase, the Affiliated Borrower will indemnify the Client Plan invested in a Separate Account or Commingled Fund in the United States with respect to the difference between the replacement cost of the borrowed securities and the market value of the Collateral on the date the loan is declared in default, together with expenses incurred by the Client Plan plus applicable interest at a reasonable rate, including reasonable attorney's fees incurred by the Client Plan for legal action arising out of default on the loans, or failure by the Affiliated

Borrower to properly indemnify the Client Plan. The Affiliated Borrower's indemnification will enable the Client Plan to collect on any indemnification from a U.S.-domiciled affiliate of the Affiliated Borrower.

(m) The Lender receives the equivalent of all distributions made to holders of the borrowed securities during the term of the loan, including but not limited to all interest and dividends on the loaned securities, shares of stock as a result of stock splits and rights to purchase additional securities, or other distributions.

(n) Prior to any Client Plan's approval of the lending of its securities to any Affiliated Borrower, a copy of the final exemption (if granted) and this notice of proposed exemption is provided to the Client Plan.

Notwithstanding the foregoing, effective October 1, 2008, through the publication date of the grant of this exemption in the **Federal Register**, section II(n) shall be deemed satisfied with respect to the Existing Loans, provided (i) UB provides to such Client Plans that have consented to securities lending prior to such publication date, a copy of the requested exemption and (ii) UB advises each such Client Plan that unless the Client Plan notifies UB to the contrary within 30 days, its consent to make loans to Morgan Stanley will be presumed.

(o) The Independent Fiduciary of each Client Plan that is invested in a Separate Account is provided with (including by electronic means) quarterly reports with respect to the securities lending transactions, including, but not limited to, the information described in Representation 40 of the Summary of Facts and Representations, so that the Independent Fiduciary may monitor such transactions with the Affiliated Borrower. The Independent Fiduciary invested in a Commingled Fund is provided with (including by electronic means) quarterly reports with respect to the securities lending transactions, including, but not limited to, the information described in Representation 40 of the Summary of Facts and Representations, so that the Independent Fiduciary may monitor such transactions with the Affiliated Borrower. The Lending Agent may, in lieu of providing the quarterly reports described in this paragraph (o) to each Independent Fiduciary of a Client Plan invested in a Commingled Fund, provide such Independent Fiduciary with the certification of an auditor selected by the Lending Agent who is independent of MS&Co, UB and their affiliates (but who may or may not be independent of the Client Plan) that the

loans appear no less favorable to the Lender than the pricing established in the schedule described in the paragraph 29 of the Summary of Facts and Representations. Where the Independent Fiduciary of a Client Plan invested in a Commingled Fund is provided the certification of an auditor, such Independent Fiduciary shall be entitled to receive the quarterly reports upon request.

Notwithstanding the foregoing, section II(o) shall be deemed satisfied with respect to the Existing Loans provided UB provides to such Client Plans no later than July 31, 2009, the material described in section II(o) with respect to the period from October 1, 2008, through June 30, 2009.

(p) Only Client Plans with total assets having an aggregate market value of at least \$50 million are permitted to lend securities to the Affiliated Borrowers; provided, however, that—

(1) In the case of two or more Client Plans which are maintained by the same employer, controlled group of corporations or employee organization, whose assets are commingled for investment purposes in a single master trust or any other entity the assets of which are "plan assets" under 29 CFR 2510.3-101 (the Plan Asset Regulation), which entity is engaged in securities lending arrangement with the Lending Agent, the foregoing \$50 million requirement shall be deemed satisfied if such trust or other entity has aggregate assets which are in excess of \$50 million; provided that if the fiduciary responsible for making the investment decision on behalf of such master trust or other entity is not the employer or an affiliate of the employer, such fiduciary has total assets under its management and control, exclusive of the \$50 million threshold amount attributable to plan investment in the commingled entity, which are in excess of \$100 million.

(2) In the case of two or more Client Plans which are not maintained by the same employer, controlled group of corporations or employee organization, whose assets are commingled for investment purposes in a group trust or any other form of entity the assets of which are "plan assets" under the Plan Asset Regulation, which entity is engaged in securities lending arrangements with the Lending Agent, the foregoing \$50 million requirement is satisfied if such trust or other entity has aggregate assets which are in excess of \$50 million (excluding the assets of any Client Plan with respect to which the fiduciary responsible for making the investment decision on behalf of such group trust or other entity or any member of the controlled group of

corporations including such fiduciary is the employer maintaining such Plan or an employee organization whose members are covered by such Plan). However, the fiduciary responsible for making the investment decision on behalf of such group trust or other entity—

(A) Has full investment responsibility with respect to plan assets invested therein; and

(B) Has total assets under its management and control, exclusive of the \$50 million threshold amount attributable to plan investment in the commingled entity, which are in excess of \$100 million.

In addition, none of the entities described above are formed for the sole purpose of making loans of securities.

(q) With respect to any calendar quarter, at least 50 percent or more of the outstanding dollar value of securities loans negotiated on behalf of Lenders will be to borrowers unrelated to MS&Co., UB and their affiliates.

(r) In addition to the above, all loans involving foreign Affiliated Borrowers have the following requirements:

(1) The foreign Affiliated Borrower is a bank, supervised either by a state or the United States, a broker-dealer registered under the Securities Exchange Act of 1934 or a bank or broker-dealer that is supervised by (i) the SFA in the United Kingdom; (ii) the BAFin in Germany; (iii) the MOF and/or the Tokyo Stock Exchange in Japan; (iv) the Ontario Securities Commission, the Investment Dealers Association and/or the Office of Superintendent of Financial Institutions in Canada; (v) the Swiss Federal Banking Commission in Switzerland; and (vi) the Reserve Bank of Australia or the Australian Securities and Investments Commission and/or Australian Stock Exchange Limited in Australia; (vii) the CB, the CECEI, and the AMF in France; and (viii) the SFSA in Sweden;

(2) The foreign Affiliated Borrower is in compliance with all applicable provisions of Rule 15a-6 under the Securities Exchange Act of 1934 (17 CFR 240.15a-6) (Rule 15a-6) which provides foreign broker-dealers a limited exemption from United States registration requirements;

(3) All Collateral is maintained in United States dollars or U.S. dollar-denominated securities or letters of credit (unless an applicable exemption provides otherwise);

(4) All Collateral is held in the United States and the situs of the securities lending agreements is maintained in the United States under an arrangement that complies with the indicia of ownership requirements under section 404(b) of the

Act and the regulations promulgated under 29 CFR 2550.404(b)-1 related to the lending of securities; and

(5) Prior to a transaction involving a foreign Affiliated Borrower, the foreign Affiliated Borrower—

(A) Agrees to submit to the jurisdiction of the United States;

(B) Agrees to appoint an agent for service of process in the United States, which may be an affiliate (the Process Agent);

(C) Consents to service of process on the Process Agent; and

(D) Agrees that enforcement by a Client Plan of the indemnity provided by the Affiliated Borrower will, at the option of the Client Plan, occur exclusively in the United States courts.

(s) The Lending Agent maintains, or causes to be maintained, within the United States for a period of six years from the date of such transaction, in a manner that is convenient and accessible for audit and examination, such records as are necessary to enable the persons described in paragraph (t)(1) to determine whether the conditions of the exemption have been met, except that—(1) A prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of the Lending Agent and/or its affiliates, the records are lost or destroyed prior to the end of the six-year period; and (2) No party in interest other than the Lending Agent or its affiliates shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975(a) and (b) of the Code, if the records are not maintained, or are not available for examination as required below by paragraph (t)(1).

(t)(1) Except as provided in subparagraph (t)(2) of this paragraph and notwithstanding any provisions of sections (a)(2) and (b) of section 504 of the Act, the records referred to in paragraph (s) are unconditionally available at their customary location for examination during normal business hours by:

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service or the Securities and Exchange Commission;

(B) Any fiduciary of a participating Client Plan or any duly authorized representative of such fiduciary;

(C) Any contributing employer to any participating Client Plan or any duly authorized employee or representative of such employer; and

(D) Any participant or beneficiary of any participating Client Plan, or any duly authorized representative of such participant or beneficiary.

(t)(2) None of the persons described above in paragraphs (t)(1)(B)–(t)(1)(D) are authorized to examine the trade secrets of the Lending Agent or its affiliates or commercial or financial information which is privileged or confidential.

(t)(3) Should the Lending Agent refuse to disclose information on the basis that such information is exempt from disclosure, the Lender shall, by the close of the thirtieth (30th) day following the request, provide written notice advising that person of the reason for the refusal and that the Department may request such information.

#### *Summary of Facts and Representations*

1. Morgan Stanley is a global financial services firm headquartered in New York. Its corporate parent is a bank holding company, Morgan Stanley, with its affiliates, serves a large and diversified group of clients and customers, including corporations, governments, financial institutions and individuals around the world. Morgan Stanley offers investment-related services, including securities research, brokerage, execution, asset allocation, financial planning, investment advice, discretionary asset management services, sweep and trust/custody services. In its Institutional Securities business segment, Morgan Stanley provides financial advisory and capital-raising services to a diverse group of institutional clients globally, primarily through wholly owned subsidiaries that include Morgan Stanley & Co. Incorporated (MS&Co.), Morgan Stanley & Co. International plc, Morgan Stanley Japan Securities Co., Ltd. and Morgan Stanley Asia Limited. These and other subsidiaries also conduct sales and trading activities worldwide, as principal and agent, and provide related financing services on behalf of institutional investors. MS&Co. is both a registered investment adviser subject to the Investment Advisers Act of 1940 and an SEC-registered broker dealer subject to the supervision of various governmental and self-regulatory bodies. As of November 30, 2007, Morgan Stanley employed over 48,000 employees in over 600 offices operating in 33 countries. In the ordinary course of its business, Morgan Stanley provides a range of financial services to IRAs and pension, profit sharing and 401(k) plans qualified under section 401(a) of the Code under which some or all of the participants are employees described in section 401(c) of the Code.

2. Mitsubishi UFJ Financial Group, Inc. ("MUFG"), Japan's largest financial group and the world's second largest bank holding company with \$1.1 trillion

in bank deposits, on October 13, 2008, made a \$9 billion equity investment in Morgan Stanley that gives MUFG approximately a 21 percent ownership interest in Morgan Stanley on a fully diluted basis. The investment is part of a previously announced global strategic alliance. Under the terms of the transaction, MUFG has acquired \$7.8 billion of perpetual non-cumulative convertible preferred stock with a 10 percent dividend and a conversion price of \$25.25 per share, and \$1.2 billion of perpetual non-cumulative non-convertible preferred stock with a 10 percent dividend. Half of the convertible preferred stock automatically converts after one year into common stock when Morgan Stanley's stock trades above 150 percent of the conversion price for a certain period and the other half converts on the same basis after year two. The non-convertible preferred stock is callable after year three at 110 percent of the purchase price. MUFG is entitled to nominate one member of Morgan Stanley's twelve-member board of directors and to have an additional "observer" present at meetings of Morgan Stanley's board.

3. UnionBanCal Corporation, headquartered in San Francisco, CA, is a financial holding company with assets of \$70.1 billion as of December 31, 2008. Its primary subsidiary, Union Bank, N.A. (UB), is a full-service commercial bank providing an array of financial services to individuals, small businesses, middle-market companies and major corporations. UB is California's fifth largest bank by deposits. The bank has 335 banking offices in California, Oregon and Washington, and two international offices. Effective November 4, 2008, UnionBanCal Corp. became a wholly owned subsidiary of The Bank of Tokyo-Mitsubishi UFJ, Ltd., which is a subsidiary of MUFG.

4. To the best of Morgan Stanley's knowledge and belief, the current status of the investment in Morgan Stanley by Union Bank's indirect, ultimate corporate parent, MUFG, does not make, as of the date of the application, Union Bank and Morgan Stanley affiliates of each other under the definition of affiliate in 29 CFR 2510.3-21(e) for purposes of ERISA.<sup>45</sup> However, Morgan

<sup>45</sup> An affiliate is defined in 29 CFR 2510.3-21(e) as including: "(i) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such person; (ii) Any officer, director, partner, employee or relative (as defined in section 3(15) of the Act) of such person; and (iii) Any corporation or partnership of which such person is an officer, director or partner." The term control is defined

Stanley filed this exemption request because (a) Union Bank might be viewed currently as having an interest in Morgan Stanley that could affect each entity's judgment as lending agent for Client Plans by reason of Union Bank's indirect parent's ownership interest in Morgan Stanley and (b) Morgan Stanley and Union Bank both believe that, at some future date, the status of MUFG's investment and future joint business initiatives may ultimately deem Union Bank and Morgan Stanley to be "affiliates" for purposes of 29 CFR 2510.3-21(e).

5. Morgan Stanley seeks an exemption to permit a securities lending agent affiliated with MS&Co. or UB (the Lending Agent) to lend securities of an account covered by ERISA or the Code to a broker-dealer or bank affiliated with MS&Co. or UB, including foreign broker-dealers and banks in Canada, Germany, Japan, the United Kingdom, Switzerland, France, Sweden and Australia (each, an Affiliated Borrower). The exemption would amend and supersede PTE 98-40, granted to MS&Co. and Morgan Stanley Trust Company, and EXPRO 99-01E, granted to MS&Co.

6. As of the closing of the MUFG/Morgan Stanley transaction, eight Client Plans for which UB served as securities lending agent or sub agent had loans outstanding to MS&Co. or a U.S. affiliate (the Existing Loans). As of March 9, 2009, the total amount of the Existing Loans from these Plans totaled \$8,196,460.29, compared to the amount outstanding to all borrowers from these funds which exceeded \$1.005 billion. Thus the total Existing Loans to Morgan Stanley affiliates were approximately 1% of the total loans for these Plans. The range of percentages for the eight plans was between .5% and 3.7% of plan assets. The Applicant requests that the exemption, if granted, apply retroactively to the Existing Loans. The Applicant has proposed certain conditions applicable to the Existing Loans, as described herein.

7. The Applicant represents that, for each Client Plan, neither MS&Co., UB, nor any affiliate will have or exercise discretionary authority or control with respect to the investment of the assets of Client Plans involved in the transaction, or render investment advice (within the meaning of 29 CFR 2510.3-21(c)) with respect to such assets, including decisions concerning a Client Plan's acquisitions or dispositions of securities available for loan.

therein as "the power to exercise a controlling influence over the management or policies of a person other than an individual."

8. Any arrangement for the Lending Agent to lend securities will be approved in advance by a Client Plan fiduciary who is independent of MS&Co., UB, and their affiliates (other than in the case of a Plan sponsored by MS&Co., UB, or any of their affiliates (Affiliated Plan) invested in a commingled fund, provided that at all times holdings of all Affiliated Plans in the aggregate comprise less than 10% of the assets of the commingled fund). Notwithstanding the foregoing, this condition will be deemed satisfied with respect to the Existing Loans provided (i) UB provided to Client Plans with Existing Loans no later than April 1, 2009, a description of the general terms of the securities loan agreements between such Client Plans and borrowers, including any conditions with respect to MS that differ from other borrowers, and (ii) at the time of providing such information, UB notified each such Client Plan that if the Client Plan did not approve the continued lending of securities to Morgan Stanley by May 11, 2009, UB would terminate the loans and cease to make any new securities loans on behalf of the Client Plan to Morgan Stanley.

9. When acting as a securities lending agent, the Lending Agent, pursuant to approval by the independent Plan fiduciary, will negotiate the terms of loans to Affiliated Borrowers and otherwise act as a liaison between the Lender and the Affiliated Borrower. The Lending Agent will have the responsibility for monitoring receipt of all collateral required under the exemption, marking such collateral to market daily to ensure adequate levels of collateral can be maintained, monitoring and evaluating the performance and creditworthiness of borrowers, and, if authorized by a lending plan, holding and investing cash collateral pursuant to given investment guidelines. The Lending Agent may also act as directed trustee or custodian for the Client Plan.

10. The Lending Agent, as securities lending agent for the Lenders, will negotiate a master securities borrowing agreement with a schedule of modifications attached thereto ("Loan Agreement") with the Affiliated Borrowers, as is the case with all borrowers. The Loan Agreement will specify, among other things, the right of the Lender to terminate a loan at any time and the Lender's rights in the event of any default by the Affiliated Borrowers. The Loan Agreement will set forth the basis for compensation to the Lender for lending securities to the Affiliated Borrowers under each category of collateral. The Loan

Agreement will also contain a requirement that the Affiliated Borrowers must pay all transfer fees and transfer taxes related to the securities loans.

11. With respect to Lenders that are Separate Accounts, as direct lending agent, the Lending Agent will, prior to lending the Client Plan's securities, enter into an agreement ("Client Agreement") with the Client Plan, signed by a fiduciary of the Client Plan who is independent of MS&Co., UB, and their affiliates (other than in the case of an Affiliated Plan, as discussed above in paragraph 8). The Client Agreement will, among other things, describe the operation of the lending program, disclose the form of the securities loan agreement to be entered into on behalf of the Client Plan with borrowers, identify generally the securities which are available to be lent, and identify the required collateral guidelines and the required daily marking-to-market of the loaned securities. The Client Agreement will also set forth the basis and rate of the Lending Agent's compensation for the performance of securities lending and cash collateral investment services. The Client Plan may terminate the Client Agreement with respect to any or all Affiliated Borrowers at any time, without penalty, on no more than five business days notice.

12. The Client Agreement will contain provisions to the effect that if any Affiliated Borrower is designated by the Client Plan as an approved borrower, the Client Plan will acknowledge the relationship between the Affiliated Borrower and the Lending Agent. The Lending Agent will represent to the Client Plan that each and every loan made to the Affiliated Borrower on behalf of the Client Plan will be effected at arm's-length terms, and such terms will be in no case less favorable to the Client Plan than the pricing established according to the schedule described in paragraph 29.

13. When the Lending Agent is lending agent with respect to a Commingled Fund, the Lending Agent will, prior to the investment of a Client Plan's assets in such Commingled Fund or prior to the first use of this exemption, obtain from the Client Plan approval to lend any securities held by the Commingled Fund to brokers and other approved borrowers, including the Affiliated Borrowers. Prior to obtaining such approval, the Lending Agent will provide a written description of the operation of the lending program (including the basis and rate of the Lending Agent's compensation for the performance of securities lending and cash collateral investment services),

disclose the form of the securities loan agreement to be entered into on behalf of the Commingled Fund with the borrowers, generally identify the securities which are available to be lent, and identify the required collateral and the required daily marking-to-market of loaned securities.<sup>46</sup> If the Client Plan is already invested in the Commingled Fund and objects to the arrangement, it will be permitted to withdraw from the Commingled Fund, without penalty, no later than 35 days after the notice of withdrawal is received in accordance with the terms of the Commingled Fund.

14. In addition, the Client Plan will be advised of the relationship between the Lending Agent and the Affiliated Borrowers, and the Lending Agent will represent that each and every loan made to the Affiliated Borrowers by the Commingled Fund will be effected at arm's-length terms, and such terms will be in no case less favorable to the Client Plan than the pricing established according to the schedule described in paragraph 29.

15. When the Lending Agent is lending securities under a sub-agency arrangement, before the Client Plan participates in the securities lending program, the primary lending agent will enter into a securities lending agency agreement (Primary Lending Agreement) with a fiduciary of the Client Plan who is independent of such primary lending agent, MS&Co., UB and their affiliates (other than in the case of an Affiliated Plan, as described in paragraph 8). The primary lending agent also will be unrelated to MS&Co., UB, and their affiliates. The Primary Lending Agreement will contain provisions substantially similar to those in the Client Agreement relating to: The description of the lending program, use of an approved form of securities loan agreement, specification of the securities to be lent, specification of the required collateral margin and the requirement of daily marking-to-market, and provision of a list of approved borrowers (which will include one or more of the Affiliated Borrowers). The Primary Lending Agreement will specifically authorize the primary lending agent to appoint sub-agents (including the Lending Agent) to facilitate performance of securities lending agency functions. The Primary Lending Agreement will expressly

<sup>46</sup> The Lending Agent may make transmittals required by the exemption to Client Plan fiduciaries via authorized recordkeepers. The Lending Agent represents that all decisions reserved to Client Plan fiduciaries under the terms of the exemption will be made by such fiduciaries and not by the recordkeeper on behalf of the Client Plan fiduciary.

disclose that the Lending Agent is to act in a sub-agency capacity. The Primary Lending Agreement will also set forth the basis and rate for the primary lending agent's compensation from the Client Plan for the performance of securities lending services and/or cash collateral investment services and will authorize the primary lending agent to pay a portion of its fee, as the primary lending agent determines in its sole discretion, to any sub-agent(s) it retains (including the Lending Agent) pursuant to the authority granted under such agreement.

16. Pursuant to its authority to appoint sub-agents, the primary lending agent will enter into a securities lending sub-agency agreement (Sub-Agency Agreement) with the Lending Agent under which the primary lending agent will retain and authorize the Lending Agent, as sub-agent, to lend securities of the primary lending agent's Client Plans, subject to the same terms and conditions specified in the Primary Lending Agreement. The Lending Agent represents that the Sub-Agency Agreement will contain provisions that are in substance comparable to those described above in connection with a Client Agreement in situations where the Lending Agent is the primary lending agent. The Lending Agent will make in the Sub-Agency Agreement the same representations described above in paragraph 12 with respect to arm's-length dealing with the Affiliated Borrowers. The Sub-Agency Agreement will also set forth the basis and rate for the Lending Agent's compensation to be paid by the primary lending agent.

17. In all cases, the Lending Agent will maintain transactional and market records sufficient to assure compliance with its representation that all loans to the Affiliated Borrowers are effected at arm's-length terms, and in no case less favorable to the Client Plan than the pricing established according to the schedule described in paragraph 29. Such records will be made available upon reasonable request and without charge to the Client Plan fiduciary, who (other than in the case of an Affiliated Plan as described in paragraph 8) is independent of MS&Co., UB, and their affiliates, in the manner and format agreed to by the Client Plan fiduciary and the Lending Agent.

18. A Lender, in the case of a Separate Account, will be permitted to terminate the lending agency or sub-agency arrangement with respect to any or all Affiliated Borrowers at any time without penalty, on five business days notice. A Client Plan in the case of a Commingled Fund will be permitted to terminate its participation in the lending arrangement

by terminating its investment in the Commingled Fund no later than 35 days after the notice of termination of participation is received, without penalty to the Plan, in accordance with the terms of the Commingled Fund. Upon a termination, the Affiliated Borrower will be contractually obligated to return securities identical to the borrowed securities (or the equivalent thereof in the event of reorganization, recapitalization or merger of the issuer of the borrowed securities) to the Lender within one of the following time periods, whichever is least: the customary delivery period for such securities, five business days of written notification of termination, or the time negotiated for such delivery by the Client Plan, in a Separate Account, or by the Lending Agent, as lending agent to a Commingled Fund, and the Affiliated Borrowers.

19. The Lender, or another custodian designated to act on its behalf, will receive collateral from each Affiliated Borrower by physical delivery, book entry in a U.S. securities depository, wire transfer or similar means by the close of business on or before the day the loaned securities are delivered to the Affiliated Borrower. All collateral will be received by the Lender or other custodian in the United States. The collateral will consist of U.S. currency, securities issued or guaranteed by the U.S. Government or its agencies or instrumentalities, irrevocable bank letters of credit issued by a U.S. bank other than Morgan Stanley, Union Bank (or any subsequent parent corporation of the Lending Agent) or an affiliate thereof, or any combination thereof, or other collateral permitted under PTE 2006-16 (as amended or superseded). The collateral will be held on behalf of a Client Plan in a depository account or other investment account or vehicle separate from the Affiliated Borrower.

20. The market value (or, in the case of a letter of credit, a stated amount) of the posted collateral on the close of business on the day preceding the day of the loan will be at least 102 percent of the market value of the loaned securities unless required to be at a higher level under PTE 2006-16. The Loan Agreement will give the Lender a continuing security interest in and a lien on or title to the collateral. The Lending Agent will monitor the level of the collateral daily. If the market value of the collateral, on the close of trading on a business day, is less than 100 percent (or such greater percentage as agreed to by the parties) of the market value of the loaned securities at the close of business on that day, the Lending Agent will require the

Affiliated Borrowers to deliver by the close of business on the next day sufficient additional collateral to bring the level back to at least 102 percent or such higher percentage as is required under PTE 2006-16.

21. Prior to making any loans under the Loan Agreement from Separate Accounts, the Affiliated Borrowers will furnish their most recent available audited and unaudited financial statements to the Lending Agent, which will provide such statements to the Client Plan invested in such Separate Account before the authorizing fiduciary of the Client Plan is asked to approve the proposed lending to the Affiliated Borrowers. The terms of the Loan Agreement will contain a requirement that the Affiliated Borrowers must give prompt notice to the Lending Agent at the time of any loan, of any material adverse change in their financial condition since the date of the most recently furnished financial statements. If any such material adverse change has taken place, the Lending Agent will request that the independent fiduciary of the Client Plan, if invested in a Separate Account, approve continuation of the lending arrangement in view of the changed financial conditions.

22. Notwithstanding the foregoing, this condition will be satisfied with respect to the Existing Loans provided (i) UB provided to such Client Plans no later than April 1, 2009, the most recently available audited and unaudited financial statements of the Affiliated Borrower and notice of any material adverse change in financial condition since the date of the most recent financial statement being furnished to the Client Plan, and (ii) at the time of providing such information, UB notified each Client Plan that if the Client Plan did not approve the continued lending of securities to Morgan Stanley by May 11, 2009, UB would terminate the loan and cease to make any new securities loans on behalf of that Client Plan to Morgan Stanley.

23. In addition, upon request, the Lending Agent will provide the audited financial statements of the applicable Affiliated Borrowers to Client Plans invested in Commingled Funds on an annual basis.

24. In the case of Client Plans currently invested in Commingled Funds, approval of lending to the Affiliated Borrowers will be accomplished by the following special procedure for Commingled Funds. The information described in paragraph 13 will be furnished by the Lending Agent as lending fiduciary to an independent fiduciary of each Client Plan invested in

Commingled Funds not less than 30 days prior to implementation of the lending arrangement, and thereafter, upon the reasonable request of the authorizing fiduciary. In the event any such authorizing fiduciary submits a notice in writing within the 30-day period to the Lending Agent, in its capacity as the lending fiduciary, objecting to the implementation of or continuation of the lending arrangement with the Affiliated Borrowers, the Plan on whose behalf the objection was tendered will be given the opportunity to terminate its investment in the Commingled Fund, without penalty to the Plan, no later than 35 days after the notice of withdrawal is received in accordance with the terms of the Commingled Fund. In the case of a Plan that elects to withdraw pursuant to the foregoing, such withdrawal shall be effected prior to the implementation of the arrangement; but an existing arrangement need not be discontinued by reason of a Plan electing to withdraw. In the case of a Plan whose assets are proposed to be invested in a Commingled Fund subsequent to the implementation of the arrangement, the Plan's investment in the Commingled Fund shall be authorized in the manner described in paragraph 13.

25. In the case of loans made by Commingled Funds, upon notice by the Affiliated Borrower to the Lending Agent of a material adverse change in its financial conditions, the Lending Agent will make a decision whether to terminate existing loans and whether to continue making additional loans to the Affiliated Borrower, using the same standards of credit analysis the Lending Agent would use in evaluating unrelated borrowers. In the event the Plan invested in a Commingled Fund has any objection to the continuation of lending to an Affiliated Borrower, it may withdraw from the fund as described above.

26. With respect to material changes in the lending arrangement with the Affiliated Borrowers after approval by Client Plans, the Lending Agent will obtain approval from Client Plans (whether in Separate Accounts or Commingled Funds) prior to implementation of any such change. For those Client Plans invested in Commingled Funds, approval of the proposed material change will be by the procedure described in paragraph 24.

27. In return for lending securities, the Lender either will receive a reasonable fee which is related to the value of the borrowed securities and the duration of the loan, or will have the opportunity to derive compensation through the investment of cash

collateral or a combination of both. In the case of a Lender investing the cash collateral, the Lender may pay a loan rebate or similar fee to the Affiliated Borrowers, if such fee is not greater than the fee the Lender would pay in a comparable arm's-length transaction with an unrelated party.

28. In this regard, each time a Lender loans securities to an Affiliated Borrower pursuant to the Loan Agreement, the Lending Agent will reflect in its records the material terms of the loan, including the securities to be loaned, the required level of collateral, and the fee or rebate payable. The fee or rebate payable for each loan will be effected at arm's-length terms, and such terms will be in no case less favorable to the Client Plan than the pricing established according to the schedule described below. The rebate rates, which are established for cash collateralized loans made by the Lender, will take into account the potential demand for the loaned securities, the applicable benchmark cost of funds (typically the U.S. Federal Funds rate established by the Federal Reserve System), the overnight "repo" rate, or the like and the anticipated investment returns on the investment of cash collateral. Further, the lending fees with respect to loans collateralized by other than cash will be set daily to reflect conditions as influenced by potential market demand. The Applicant represents that the securities lending agent fee paid to the Lending Agent will comply with the requirements of PTE 2006-16 Part IV or another applicable exemption.

29. The Lending Agent will establish each day a written schedule of lending fees<sup>47</sup> and rebate rates<sup>48</sup> with respect to new loans of designated classes of securities, such as U.S. Government securities, U.S. equities and corporate bonds, international fixed income securities and non-U.S. equities, in

<sup>47</sup>The Lending Agent will adopt minimum daily lending fees for non-cash collateral payable by Affiliated Borrowers to the Lending Agent on behalf of a Lender. Separate minimum daily lending fees will be established with respect to loans of designated classes of securities. With respect to each designated class of securities, the minimum lending fee will be stated as a percentage of the principal value of the loaned securities. The Lending Agent will submit the method for determining such minimum daily lending fees to an authorizing fiduciary of the Client Plan, in the case of a Separate Account, for approval before initially lending any securities to Affiliated Borrowers on behalf of such Client Plan. The Lending Agent will submit the method for determining such minimum daily lending fees to an authorizing fiduciary of each Client Plan involved in or planning to invest in a Commingled Fund pursuant to the procedure described in paragraph 24, above.

<sup>48</sup>Separate maximum daily rebate rates will be established with respect to loans of securities collateralized with cash as described in paragraph 24, above.

order to assure uniformity of treatment among borrowers and to limit the discretion the Lending Agent would have in negotiating securities loans to Affiliated Borrowers. Loans to all borrowers of a given security on that day will be made at rates or lending fees on the relevant daily schedules or at rates or lending fees which are more advantageous to the Lenders. The Applicant represents that in no case will loans be made to Affiliated Borrowers at rates or lending fees that are less advantageous to the Lenders than those on the relevant schedules. In addition, it is represented that the method of determining the daily securities lending rates (fees and rebates) will be disclosed to each Client Plan, whether in Separate Accounts or Commingled Funds. For those Client Plans invested in Commingled Funds, disclosure will be by the special procedure described in paragraph 24.

30. When a loan of securities by a Lender is collateralized with cash, the Lending Agent will transfer such cash to an investment vehicle that the Client Plan has authorized, and will rebate a portion of the earnings on such collateral to the appropriate Affiliated Borrower as agreed to in the securities lending agreement between Lender and the Borrower. The Lending Agent will share with the Client Plan the income earned on the investment of cash collateral for the Lending Agent's provision of lending services, which will reduce the income earned by the Client Plans (whether in a Commingled Fund or Separate Account) from the lending of securities. The Lending Agent may receive a separate management fee for providing cash collateral investment services. Where collateral other than cash is used, the Affiliated Borrower will pay a fee to the Lender based on the value of the loaned securities. These fees will also be shared between the Client Plans (whether in a Commingled Fund or Separate Account) and the Lending Agent. Any income or fees shared will be net of cash collateral management fees and borrower rebate fees. The sharing of income and fees will be in accordance with the arrangements authorized by the Client

<sup>49</sup>Separate respect to loans of securities within the designated classes identified above. Such rebate rates will be based upon an objective methodology which takes into account several factors, including potential demand for loaned securities, the applicable benchmark cost of fund indices, and anticipated investment return on overnight investments permitted by the Client Plan's independent fiduciary. The Lending Agent will submit the method for determining such maximum daily rebate rates to such fiduciary before initially lending any securities to an Affiliated Borrower on behalf of the Client Plan.

Plan in advance of commencement of the lending program.

31. The Lending Agent will negotiate rebate rates for cash collateral payable to each borrower, including Affiliated Borrowers, on behalf of a Lender. The fees or rebate rates negotiated will be effected at arm's-length terms, and in no case will be less favorable to the Client Plan than the pricing established according to the schedule described in paragraph 29.

32. With respect to any loan to an Affiliated Borrower, the Lending Agent, at the inception of such loan, will not negotiate and agree to a rebate rate with respect to such loan which it expects would produce a zero or negative return to the Lender over the life of the loan (assuming no default on the investments made by the Lending Agent where it has investment discretion over the cash collateral or on investments expected to be made by the Client Plan's designee, where the Lending Agent does not have investment discretion over cash collateral).

33. The Lending Agent may, depending on market conditions, reduce the lending fee or increase the rebate rate on any outstanding loan to an Affiliated Borrower, or any other borrower. Except in the case of a change resulting from a change in the value of any third party independent index with respect to which the fee or rebate is calculated, such reduction in lending fee or increase in rebate shall not establish a lending fee below the minimum or a rebate above the maximum set in the schedule of fees and rebates described in paragraph 29. If the Lending Agent reduces the lending fee or increases the rebate rate on any outstanding loan from a Separate Account to an Affiliated Borrower (except in the case of a change resulting from a change in the value of any third party independent index with respect to which the fee or rebate is calculated), the Lending Agent, by the close of business on the date of such adjustment, will provide the independent fiduciary of the Client Plan invested in the Separate Account with notice (including by electronic means) that it has reduced such fee or increased the rebate rate to such Affiliated Borrower and that the Client Plan may terminate such loan at any time.

34. Except as otherwise expressly provided in the exemption, the Applicant represents that all procedures regarding the securities lending activities will, at a minimum, conform to the applicable provisions of PTE 2006-16 or another applicable exemption, as amended or superseded.

35. Under the Loan Agreement, an Affiliated Borrower domiciled in the U.S. agrees to indemnify and hold harmless the Client Plans in the United States (including the sponsor and fiduciaries of such Client Plans) for any transactions covered by this exemption with a foreign Affiliated Borrower so that the Client Plan may collect on any indemnification from a U.S. domiciled affiliate of MS&Co or UB. Such indemnification will be against any and all reasonably foreseeable losses, costs and expenses (including reasonable attorneys fees, disbursements, transfer taxes and stamp duties), excluding any indirect or consequential damages which the Lender may incur or suffer arising from any impermissible use by an Affiliated Borrower of the loaned securities, from an event of default arising from the failure of an Affiliated Borrower to deliver loaned securities when due in accordance with the provisions of the Loan Agreement or from an Affiliated Borrower's other failure to comply with the terms of the Loan Agreement, except to the extent that such losses are caused by the Client Plan's own negligence.

36. If any event of default occurs, to the extent that (i) liquidation of the pledged Collateral or (ii) additional cash received from the Affiliated Borrower does not provide sufficient funds on a timely basis, the Client Plan will have the right to purchase securities identical to the borrowed securities (or their equivalent as discussed above) and apply the Collateral to the payment of the purchase price. If the Collateral is insufficient to accomplish such purchase, the Affiliated Borrower will indemnify the Client Plan invested in a Separate Account or Commingled Fund in the United States with respect to the difference between the replacement cost of securities and the market value of the Collateral on the date the loan is declared in default, together with expenses incurred by the Client Plan plus applicable interest at a reasonable rate, including reasonable attorney's fees incurred by the Client Plan for legal action arising out of default on the loans, or failure by the Affiliated Borrower to properly indemnify the Client Plan. The Affiliated Borrower's indemnification will enable the Client Plan to collect on any indemnification from a U.S.-domiciled affiliate of the Affiliated Borrower.

37. The "market value" of any securities listed on a national securities exchange in the United States will be the last sales price on such exchange on the preceding business day or, if there is no sale on that day, the last sale price on the next preceding business day on

which there is a sale on such exchange, as quoted on the consolidated tape. If the principal market for securities to be valued is the over-the-counter market, the securities' market value will be the closing sale price as quoted on the National Association of Securities Dealers Automated Quotation System (NASDAQ) on the preceding business day or the opening price on such business day if the securities are issues for which last sale prices are not quoted on NASDAQ. If the securities to be valued are not quoted on NASDAQ, their market value shall be the highest bid quotation appearing in The Wall Street Journal, National Quotation Bureau pink sheets, quotation sheets of registered market makers and, if necessary, independent dealers' telephone quotations on the preceding business day. (In each case, if the relevant quotation does not exist on such day, then the relevant quotation on the next preceding business day in which there is such a quotation would be the market value.)

38. The Lender will be entitled to receive the equivalent of all distributions made to holders of the borrowed securities during the term of the loan, including but not limited to, interest and dividends, shares of stock as a result of a stock split and rights to purchase additional securities, or other distributions during the loan period.<sup>49</sup>

39. Prior to a Client Plan's authorization of a securities lending program, the Lending Agent will provide a Plan fiduciary with a copy of the proposed exemption until the final exemption is granted, and then the proposed and final exemption. With respect to the Existing Loans, prior to the publication date of the grant of this exemption, this condition will be satisfied provided: (i) UB provides to such Client Plans that have consented to securities lending prior to such publication date, a copy of the requested exemption and (ii) UB advises each such Client Plan that unless the Client Plan notifies UB to the contrary within 30 days, its consent to make loans to Morgan Stanley will be presumed.

40. In order to provide the means for monitoring lending activity in Separate Accounts and Commingled Funds, a quarterly report will be provided to each

<sup>49</sup>The Applicant represents that dividends and other distributions on foreign securities payable to a Lender may be subject to foreign tax withholdings. Under the circumstances, the applicable Affiliated Borrower, where necessary, will gross-up the in-lieu-of-payment (in respect of such dividend or distribution it makes) to the Lender so that the Lender will receive back what it otherwise would have received (by way of dividend or distribution) had it not loaned the securities.

Client Plan. This report will show the fees or rebates (as applicable) on loans to Affiliated Borrowers compared with loans to other borrowers, as well as the level of collateral on the loans. The Applicant represents that the quarterly report will show, on a daily basis, the market value of all outstanding security loans to Affiliated Borrowers and to other borrowers as compared to the total collateral held for both categories of loans. Further, the quarterly report will state the daily fees where collateral other than cash is utilized and will specify the details used to establish the daily rebate payable to all borrowers where cash is used as collateral. The quarterly report also will state, on a daily basis, the rates at which securities are loaned to Affiliated Borrowers compared with those at which securities are loaned to other borrowers. In the event an authorizing fiduciary of a Plan invested in a Commingled Fund submits a notice in writing to the Lending Agent objecting to the continuation of the lending program to the Affiliated Borrowers, the Plan on whose behalf the objection was tendered will be given the opportunity to terminate its investment in the Commingled Fund, without penalty to the Plan, no later than 35 days after the notice of withdrawal is received in accordance with the terms of the Commingled Fund.

41. Notwithstanding the foregoing, this condition will be satisfied with respect to the Existing Loans, provided: (i) UB provides to such client Plans no later than July 31, 2009, the material described in paragraph 40 above with respect to the period from October 1, 2008, through June 30, 2009.

42. To ensure that any lending of securities to an Affiliated Borrower will be monitored by an authorizing fiduciary of above average experience and sophistication in matters of this kind, only Client Plans with total assets having an aggregate market value of at least \$50 million will be permitted to lend securities to the Affiliated Borrowers. However, in the case of two or more Client Plans which are maintained by the same employer, controlled group of corporations or employee organization, whose assets are commingled for investment purposes in a single master trust or any other entity the assets of which are "plan assets" under 29 CFR 2510.3-101 (the Plan Asset Regulation), which entity is engaged in securities lending arrangement with the Lending Agent, the foregoing \$50 million requirement will be deemed satisfied if such trust or other entity has aggregate assets which are in excess of \$50 million; provided that if the fiduciary responsible for



making the investment decision on behalf of such master trust or other entity is not the employer or an affiliate of the employer, such fiduciary must have total assets under its management and control, exclusive of the \$50 million threshold amount attributable to plan investment in the commingled entity, which are in excess of \$100 million. In the case of two or more Client Plans which are not maintained by the same employer, controlled group of corporations or employee organization, whose assets are commingled for investment purposes in a group trust or any other form of entity the assets of which are "plan assets" under the Plan Asset Regulation, which entity is engaged in securities lending arrangements with the Lending Agent, the foregoing \$50 million requirement will be satisfied if such trust or other entity has aggregate assets which are in excess of \$50 million (excluding the assets of any Client Plan with respect to which the fiduciary responsible for making the investment decision on behalf of such group trust or other entity or any member of the controlled group of corporations including such fiduciary is the employer maintaining such Plan or an employee organization whose members are covered by such Plan). However, the fiduciary responsible for making the investment decision on behalf of such group trust or other entity must have full investment responsibility with respect to plan assets invested therein, and must have total assets under its management and control, exclusive of the \$50 million threshold amount attributable to plan investment in the commingled entity, which are in excess of \$100 million. In addition, none of the entities described above may be formed for the sole purpose of making loans of securities.

43. With respect to any calendar quarter, at least 50 percent or more of the outstanding dollar value of securities loans negotiated on behalf of Lenders by the Lending Agent will be to borrowers unrelated to MS&Co., UB, and their affiliates. Thus, the competitiveness of the loan fee will be continuously tested in the marketplace. Accordingly, the Applicant believes that loans to Affiliated Borrowers should result in competitive fee income to the Lenders.

44. With respect to foreign Affiliated Borrowers, the Applicant represents that each such entity is regulated by the host country's supervisory authority (e.g., the UK FSA) and is, therefore, authorized to conduct an investment banking business in and from the host country (e.g., the United Kingdom) as a broker-dealer. The proposed exemption will be

applicable only to transactions effected by a Lending Agent with an Affiliated Borrower which is registered as a broker-dealer with the host country's supervisory authority (the Foreign Authority) and in compliance with Rule 15a-6 under the Securities Exchange Act of 1934 (Rule 15a-6). The Applicant represents that the role of a broker-dealer in a principal transaction in each of the foreign countries is substantially identical to that of a broker-dealer in a principal transaction in the United States. The Applicant further represents that registration of a broker-dealer with the Foreign Authority is equivalent to registration of a broker-dealer with the SEC under the 1934 Act. The Applicant maintains that the Foreign Authority has promulgated rules for broker-dealers which are equivalent to SEC rules relating to registration requirements, minimum capitalization, reporting requirements, periodic examinations, fund segregation, client protection, and enforcement. The Applicant represents that the rules and regulations set forth by the Foreign Authority and the SEC share a common objective: the protection of the investor by the regulation of securities markets. The Applicant explains that under each Foreign Authority's rules, a person who manages investments or gives advice with respect to investments must be registered as a "registered representative". If a person is not a registered representative and, as part of his duties, makes commitments in market dealings or transactions, that person must be registered as a "registered trader". The Applicant represents that the Foreign Authority's rules require each firm which employs registered representatives or registered traders to have positive tangible net worth and to be able to meet its obligations as they fall due, and that the Foreign Authority's rules set forth comprehensive financial resource and reporting/disclosure rules regarding capital adequacy. In addition to demonstration of capital adequacy, the Applicant states that the Foreign Authority's rules impose reporting/disclosure requirements on broker-dealers with respect to risk management, internal controls, and all records relating to a counterparty, and that all records must be produced at the request of the Foreign Authority at any time. The Applicant states that Foreign Authority's registration requirements for broker-dealers are backed up by potential fines and penalties and rules which establish a comprehensive disciplinary system.

45. In addition to the protections afforded by registration with the Foreign Authority, the Applicant represents that the Affiliated Borrower will comply with the applicable provisions of Rule 15a-6 (described below). The Applicant represents that compliance by the Affiliated Borrower with the requirements of Rule 15a-6 will offer additional protections in lieu of registration with the SEC. The Applicant represents that Rule 15a-6 provides an exemption from U.S. broker-dealer registration for a foreign broker-dealer that induces or attempts to induce the purchase or sale of any security (including over-the-counter equity and debt options) by a "U.S. institutional investor" or a "major U.S. institutional investor", provided that the foreign broker-dealer, among other things, enters into these transactions through a U.S. registered broker-dealer intermediary. The term "U.S. institutional investor", as defined in Rule 15a-6(b)(7), includes an employee benefit plan within the meaning of the Act if (a) the investment decision is made by a plan fiduciary, as defined in section 3(21) of the Act, which is either a bank, savings and loan association, insurance company or registered investment advisor, (b) the employee benefit plan has total assets in excess of \$5,000,000, or (c) the employee benefit plan is a self-directed plan with investment decisions made solely by persons that are "accredited investors" as defined in Rule 501(a)(1) of Regulation D of the Securities Act of 1933, as amended. The term "major U.S. institutional investor" is defined as a person that is a U.S. institutional investor that has, or has under management, total assets in excess of \$100 million, or is an investment adviser registered under section 203 of the Investment Advisers Act of 1940 that has total assets under management in excess of \$100 million. The Applicant represents that the intermediation of the U.S. registered broker-dealer imposes upon the foreign broker-dealer the requirement that the securities transaction be effected in accordance with a number of U.S. securities laws and regulations applicable to U.S. registered broker-dealers.

46. The Applicant represents that, under Rule 15a-6, a foreign broker-dealer that induces or attempts to induce the purchase or sale of any security by a U.S. institutional or major U.S. institutional investor in accordance with Rule 15a-6 must, among other things:

a. Consent to service of process for any civil action brought by, or

proceeding before, the SEC or any self-regulatory organization;

b. Provide the SEC with any information or documents within its possession, custody or control, any testimony of any foreign associated persons,<sup>50</sup> and any assistance in taking the evidence of other persons, wherever located, that the SEC requests and that relates to transactions effected pursuant to Rule 15a-6; and

c. Rely on the U.S. registered broker-dealer through which the transactions with the U.S. institutional and major U.S. institutional investors are effected to (among other things):

1. Effect the transactions, other than negotiating their terms;

2. Issue all required confirmations and statements;

3. As between the foreign broker-dealer and the U.S. registered broker-dealer, extend or arrange for the extension of credit in connection with the transactions;

4. Maintain required books and records relating to the transactions, including those required by Rules 17a-3 (Records to be Made by Certain Exchange Members) and 17a-4 (Records to be Preserved by Certain Exchange Members, Brokers and Dealers) of the 1934 Act;

5. Receive, deliver and safeguard funds and securities in connection with the transactions on behalf of the U.S. institutional investor or major U.S. institutional investor in compliance with Rule 15c3-3 of the 1934 Act (Customer Protection-Reserves and Custody of Securities); and

6. Participate in all oral communications (e.g., telephone calls) between a foreign associated person and the U.S. institutional investor (other than a major U.S. institutional investor), and accompany the foreign associated person on all visits with both U.S. institutional and major U.S. institutional investors. By virtue of this participation, the U.S. registered broker-dealer would become responsible for the content of all these communications.

47. All collateral will be maintained in United States dollars or U.S. dollar-denominated securities or letters of credit or other collateral permitted under PTE 2006-16 (as amended or superseded). All collateral will be held in the United States and the Lending Agent will maintain the situs of the

Loan Agreements (evidencing the Lender's right to return of the loaned securities and the continuing interest in and lien on or title to the collateral) in the United States under an arrangement that complies with the indicia of ownership requirements under section 404(b) of the Act and the regulations promulgated under 29 CFR 2550.404(b)-1.

48. Prior to a transaction involving a foreign Affiliated Borrower, the foreign Affiliated Borrower will (a) agree to submit to the jurisdiction of the courts of the United States; (b) agree to appoint a Process Agent for service of process in the United States, which may be an affiliate; (c) consent to service of process on the Process Agent; and (d) agree that enforcement by a Client Plan of the indemnity provided by U.S. Affiliated Borrower may occur in the United States Courts.

49. In summary, the Applicant represents that the proposed transactions will satisfy the statutory criteria for an exemption under section 408(a) of the Act because:

a. For each Client Plan, neither the MS&Co., UB, nor any affiliate will have or exercise discretionary authority or control with respect to the investment of the assets of Client Plans involved in the transaction or will render investment advice with respect to such assets, including decisions concerning a Client Plan's acquisition or disposition of securities available for loan.

b. Any arrangement for the Lending Agent to lend securities will be approved in advance by a Plan fiduciary who (except in the case of an Affiliated Plan as described above in paragraph 8) is independent of MS&Co., UB, and their affiliates.

c. The terms of each loan of securities by a Lender to an Affiliated Borrower will be at least as favorable to such Separate Account or Commingled Fund as those of a comparable arm's-length transaction between unrelated parties.

d. Upon termination of a loan, the Affiliated Borrowers will transfer securities identical to the borrowed securities (or the equivalent thereof) to the Lender within one of the following time periods, whichever is least: (1) The customary delivery period for such securities; (2) five business days; or (3) the time negotiated for such delivery by the Client Plan, in a Separate Account, or by the Lending Agent, as lending agent to a Commingled Fund, and the Affiliated Borrowers.

e. The Lender will receive from each Affiliated Borrower collateral consisting of U.S. currency, securities issued or guaranteed by the United States Government or its agencies or

instrumentalities, irrevocable bank letters of credit issued by a U.S. bank (other than Morgan Stanley, Union Bank or any subsequent parent corporation of the Lending Agent, or an affiliate thereof, or any combination thereof) or other collateral permitted under PTE 2006-16 (as amended or superseded), which will be held in a depository account separate from the Affiliated Borrower.

f. In return for lending securities, the Lender either will receive a reasonable fee, which is related to the value of the borrowed securities and the duration of the loan, or will have the opportunity to derive compensation through the investment of cash collateral.

g. A U.S. Affiliated Borrower agrees to indemnify and hold harmless the Client Plans in the United States (including the sponsor and fiduciaries of such Client Plans) for any transactions covered by this exemption with an Affiliated Borrower so that the Client Plans do not have to litigate, in the case of a foreign Affiliated Borrower, in a foreign jurisdiction nor sue to realize on the indemnification.

h. All loans involving foreign Affiliated Borrowers will involve Affiliated Borrowers that are registered as broker-dealers subject to regulation by the Foreign Authority and that are in compliance with all applicable provisions of Rule 15a-6.

i. Prior to a transaction involving a foreign Affiliated Borrower, the foreign Affiliated Borrower will: agree to submit to the jurisdiction of the United States; agree to appoint a Process Agent in the United States; consent to service of process on the Process Agent; and agree that enforcement by a Client Plan of the indemnity provided by Morgan Stanley or Union Bank may occur in the United States courts.

#### *Notice to Interested Persons*

Written notice will be provided to all interested parties by first class mail within 15 calendar days of publication of this Notice in the **Federal Register**. Any written comments and/or requests for a hearing must be received by the Department from interested persons within 30 days of the publication of this proposed exemption in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Karen E. Lloyd of the Department, 202-693-8554. (This is not a toll free number.)

#### **General Information**

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section

<sup>50</sup> A foreign associated person is defined in Rule 15a-6(b)(2) as any natural person domiciled outside the United States who is an associated person, as defined in section 3(a)(18) of the 1934 Act, of the foreign broker or dealer, and who participates in the solicitation of a U.S. institutional investor or a major U.S. institutional investor under Rule 15a-6(a)(3).

408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the

employees of the employer maintaining the plan and their beneficiaries:

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or

statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

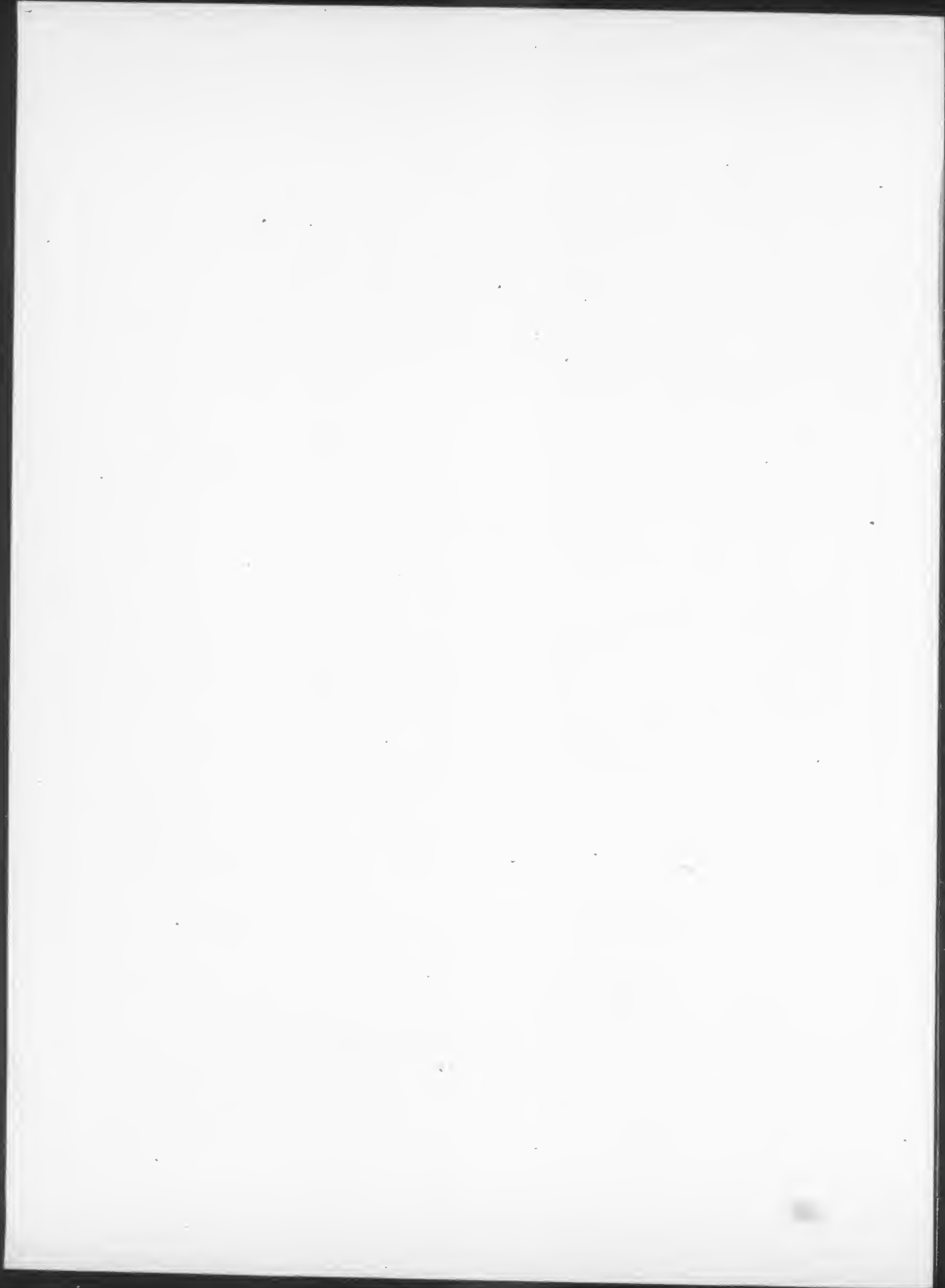
Signed at Washington, DC.

**Ivan Strasfeld,**

*Director of Exemption Determinations,  
Employee Benefits Security Administration,  
U.S. Department Of Labor.*

[FR Doc. 2010-593 Filed 1-15-10; 8:45 am]

**BILLING CODE 4510-29-P**





# Federal Register

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Tuesday,  
January 19, 2010

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Part IV

## Department of Commerce

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National Oceanic and Atmospheric  
Administration

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Application Numbers and Proposed  
Exemptions; Notice

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

[Docket No. 0907081109-91435-03; I.D. GF001]

RIN 0648-ZC10

**Availability of Grant Funds for Fiscal Year 2010 and Request for Comments on Proposed Implementation Guidelines for the Coral Reef Conservation Program**

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice.

**SUMMARY:** The National Oceanic and Atmospheric Administration publishes this notice to provide the general public with a consolidated source of program and application information related to its competitive grant and cooperative agreement (CA) award offerings for fiscal year (FY) 2010. This Omnibus notice is designed to replace the multiple **Federal Register** notices that traditionally advertised the availability of NOAA's discretionary funds for its various programs. It should be noted that additional program initiatives unanticipated at the time of the publication of this notice may be announced through subsequent **Federal Register** notices. All announcements will also be available through the Grants.gov Web site. In addition, this notice solicits comments on Proposed Implementation Guidelines for the Coral Reef Conservation Program.

**DATES:** Proposals must be received by the date and time indicated under each program listing in the **SUPPLEMENTARY INFORMATION** section of this notice.

**ADDRESSES:** Proposals must be submitted to the addresses listed in the **SUPPLEMENTARY INFORMATION** section of this notice for each program. The **Federal Register** and Full Funding Opportunity (FFO) notices may be found on the Grants.gov Web site. The URL for Grants.gov is <http://www.grants.gov>.

**FOR FURTHER INFORMATION CONTACT:** Please contact the person listed within this notice as the information contact under each program.

**SUPPLEMENTARY INFORMATION:** Applicants must comply with all requirements contained in the Federal Funding Opportunity announcement for each of the programs listed in this omnibus notice. These Federal Funding Opportunities are available at <http://www.grants.gov>.

There is no guarantee that sufficient funds will be available to make awards for all qualified projects. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives. Publication of this notice does not oblige NOAA to award any specific project or to obligate any available funds.

It is possible that additional funding may be allocated beyond that stated for any listed program in the current or a future Fiscal Year. If additional allocations of funding are made available, the responsible program, at the discretion of the Program Manager, may fund additional qualified projects rather than re-compete the funding.

The list of entries below describe the basic information and requirements for competitive grant/cooperative agreement programs offered by NOAA. These programs are open to any applicant who meets the eligibility criteria provided in each entry. To be considered for an award in a competitive grant/cooperative agreement program, an eligible applicant must submit a complete and responsive application to the appropriate program office. An award is made upon conclusion of the evaluation and selection process for the respective program.

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- 2. 2010 Marine Education and Training Mini Grant Program
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#### I. Background

Each of the following grant opportunities provide: A description of the program, funding availability, statutory authority, catalog of federal domestic assistance (CFDA) number, application deadline, address for submitting proposals, information contacts, eligibility requirements, cost sharing requirements, and intergovernmental review under Executive Order 12372.

In addition, this notice announces information related to a request for comments on Proposed Implementation Guidelines for the Coral Reef Conservation Program.

#### II. Electronic Access

The full funding announcement for each program is available via the Grants.gov web site at: <http://www.grants.gov>. Electronic applications for the NOAA Programs listed in this announcement may be accessed, downloaded, and submitted to that Web site. The due dates and times for paper and electronic submissions are identical. NOAA strongly recommends that you do not wait until the application deadline to begin the application process through Grants.gov. Your application must be received and validated by Grants.gov no later than the due date and time. **Please Note:** Validation or rejection of your application by Grants.gov may take up to 2 business days after your submission.

Please consider the Grants.gov validation/rejection process in developing your application submission time line.

#### Grants.gov

Getting started with Grants.gov is easy. Users should note that there are

two key features on the Web site: Find Grant Opportunities and Apply for Grants. The site is designed to support these two features and your use of them.

While you can begin searching for grant opportunities immediately, it is recommended that you complete the steps to Get Started (below) ahead of time. This will help ensure you are ready to go when you find an opportunity for which you would like to apply.

#### *Applications From Individuals*

In order for you to apply as an individual the announcement must specify that the program is open to individuals and it must be published on the Grants.gov Web site. Individuals must register with the Credential Provider (see Step 3 below) and with Grants.gov (see Step 4 below).

Individuals do not need a DUNS number to register (see Step 4 below) and submit their applications. The system will generate a default value in that field.

#### *Grants.gov Application Submission and Receipt Procedures*

This section provides the application submission and receipt instructions for NOAA program applications. Please read the following instructions carefully and completely.

1. Electronic Delivery. NOAA is participating in the Grants.gov Initiative that provides the Grant Community a single site to find and apply for grant funding opportunities. NOAA encourages applicants to submit their applications electronically through: [http://www.grants.gov/applicants/apply\\_for\\_grants.jsp](http://www.grants.gov/applicants/apply_for_grants.jsp).

2. The following describes what to expect when applying on line using Grants.gov/Apply:

a. Instructions. On the site, you will find step-by-step instructions which enable you to apply for NOAA funds. The Grants.gov/Apply feature includes a simple, unified application process that makes it possible for applicants to apply for grants online. There are six "Get Started" steps to complete at Grants.gov. The information applicants need to understand and execute the steps can be found at: [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp).

Applicants should read the Get Started steps carefully. The site also contains registration checklists to help you walk through the process. NOAA recommends that you download the checklists and prepare the information requested before beginning the registration process. Reviewing and assembling required information before beginning the registration process will

make the process fast and smooth and save time.

b. DUNS Requirement. All applicants applying for funding, including renewal funding, must have a Dun and Bradstreet Universal Data Numbering System (DUNS) number. The DUNS number must be included in the data entry field labeled "Organizational Duns" on the form SF-424. Instructions for obtaining a DUNS number can be found at the following Web site: [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp).

c. Central Contractor Registry. In addition to having a DUNS number, applicants applying electronically through Grants.gov must register with the Federal Central Contractor Registry. The <http://www.grants.gov> Web site at [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp) provides step-by-step instructions for registering in the Central Contractor Registry. All applicants filing electronically must register with the Central Contractor Registry and receive a User Name and password from Grants.gov in order to apply on line. Failure to register with the Central Contractor Registry will result in your application being rejected by the Grants.gov portal. The registration process is a separate process from submitting an application. Applicants are, therefore, encouraged to register early. The registration process can take approximately two weeks to be completed. Therefore, registration should be done in sufficient time to ensure it does not impact your ability to meet required submission deadlines. You will be able to submit your application online anytime after you receive your e-authentication credentials.

d. Electronic Signature. Applications submitted through Grants.gov constitute submission as electronically signed applications. The registration and e-authentication process establishes the Authorized Organization Representative (AOR). When you submit the application through Grants.gov, the name of your authorized organization representative on file will be inserted into the signature line of the application. Applicants must register the individual who is able to make legally binding commitments for the applicant organization as the Authorized Organization Representative.

3. Instructions on how to submit an electronic application to NOAA via Grants.gov/Apply:

Grants.gov has a full set of instructions on how to apply for funds on its Web site at <http://www.grants.gov/applicants/>

[apply\\_for\\_grants.jsp](#). The following provides simple guidance on what you will find on the Grants.gov/Apply site. Applicants are encouraged to read through the page entitled, "Complete Application Package" before getting started.

Grants.gov allows applicants to download the application package, instructions and forms that are incorporated in the instructions, and work off line. In addition to forms that are part of the application instructions, there will be a series of electronic forms that are provided utilizing an Adobe Reader.

**Note** for the Adobe Reader, Grants.gov is only compatible with versions 8.1.1 and above. Please do not use lower versions of the Adobe Reader. Mandatory Fields on Adobe Reader Forms. In the Adobe forms you will note fields that appear with a yellow background and red outline color. These fields are mandatory and must be completed to successfully submit your application. Completion of SF-424 Fields First. The Adobe forms are designed to fill in common required fields such as the applicant name and address, DUNS number, etc., on all Adobe electronic forms. To trigger this feature, an applicant must complete the SF-424 information first. Once it is completed the information will transfer to the other forms.

Customer Support. The Grants.gov Web site provides customer support via (800) 518-4726 (this is a toll-free number) or through e-mail at [support@grants.gov](mailto:support@grants.gov). The Contact Center is open from 7 a.m. to 9 p.m. Eastern time, Monday through Friday, except federal holidays, to address Grants.gov technology issues. For technical assistance to program related questions, contact the number listed in the Program Section of the program to which you are applying.

4. Timely Receipt Requirements and Proof of Timely Submission.

a. Electronic Submission. All applications must be received by [http://www.grants.gov/applicants/apply\\_for\\_grants.jsp](http://www.grants.gov/applicants/apply_for_grants.jsp) by the Time on the due date established for each program. Proof of timely submission is automatically recorded by Grants.gov. An electronic time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant will receive an acknowledgement of receipt and a tracking number from Grants.gov with the successful transmission of their application. Applicants should print this receipt and save it, along with facsimile receipts for information provided by facsimile, as proof of timely

submission. When NOAA successfully retrieves the application from Grants.gov, Grants.gov will provide an electronic acknowledgment of receipt to the e-mail address of the AOR. Proof of Timely submission shall be the date and time that Grants.gov receives your application. Applications received by Grants.gov, after the established due date for the program will be considered late and will not be considered for funding by NOAA. **Please Note:** Validation or rejection of your application by Grants.gov may take up to 2 business days after your submission. Please consider the Grants.gov validation/rejection process in developing your application submission time line.

NOAA suggests that applicants submit their applications during the operating hours of Grants.gov, so that if there are questions concerning transmission, operators will be available to walk you through the process. Submitting your application during the Contact Center hours will also ensure that you have sufficient time for the application to complete its transmission prior to the application deadline. Applicants using dial-up connections should be aware that transmission may take some time before Grants.gov receives it. Grants.gov will provide either an error or a successfully received transmission message. Grants.gov reports that some applicants abort the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application. Uploading and transmitting many files, particularly electronic forms with associated XML schemas, will take some time to be processed.

### III. Evaluation Criteria and Selection Procedures

NOAA has standardized the evaluation and selection process for its competitive assistance programs. There are two separate sets of evaluation criteria and selection procedures (see below), one for project proposals, and the other for fellowship, scholarship, and internship programs.

#### *Project Proposals Review and Selection Process*

Some project proposals may include a pre-application process that provides for feedback to applicants that responded to a call for letters of intent or pre-proposals; however, not all programs will include this pre-application. If a program has a pre-application process, it will be described in the Summary Description section of the announcement and the deadline will be

specified in the Application Deadline section.

Upon receipt of a full application by NOAA, an initial administrative review will be conducted to determine compliance with requirements and completeness of the application. A merit review will also be conducted to produce a rank order of the proposals.

The NOAA Program Officer may review the ranking of the proposals and make recommendations to the Selecting Official based on the administrative and/or merit review(s) and selection factors listed below. The Selecting Official selects proposals after considering the administrative and/or merit review(s) and recommendations of the Program Officer. In making the final selections, the Selecting Official will award in rank order unless the proposal is justified to be selected out of rank order based upon one or more of the selection factors below. The Program Officer and/or Selecting Official may negotiate the funding level of the proposal. The Selecting Official makes final award recommendations to the Grants Officer authorized to obligate the funds.

*Evaluation Criteria.* Each reviewer (one mail and at least three peer review panel reviewers) will individually evaluate and rank proposals using the following evaluation criteria:

1. *Importance and/or relevance and applicability of a proposed project to the program goals:* This ascertains whether there is intrinsic value in the proposed work and/or relevance to NOAA, Federal (other than NOAA), regional, state, or local activities.
2. *Technical/scientific merit:* This assesses whether the approach is technically sound and/or innovative, if the methods are appropriate, and whether there are clear project goals and objectives.
3. *Overall qualifications of applicants:* This ascertains whether the applicant possesses the necessary education, experience, training, facilities, and administrative resources to accomplish the project.

4. *Project costs:* The project's budget is evaluated to determine if it is realistic and commensurate with the project needs and timeframe.

5. *Outreach and education:* NOAA assesses whether this project provides a focused and effective education and outreach strategy regarding its mission to protect the Nation's natural resources.

*Selection Factors.* The merit review ratings will be used to provide a rank order to the Selecting Official for final funding recommendations. A Program Officer may first make recommendations to the Selecting

Official applying the selection factors listed below. The Selecting Official shall award in the rank order unless the proposal is justified to be selected out of rank order based upon one or more of the following factors:

1. Availability of funding.
2. Balance/distribution of funds:
  - a. Geographically,
  - b. By type of institutions,
  - c. By type of partners,
  - d. By research areas, and
  - e. By project types.
3. Whether the project duplicates other projects funded or considered for funding by NOAA or other federal agencies.
4. Program priorities and policy factors.
5. Applicant's prior award performance.
6. Partnerships and/or participation of targeted groups.
7. Adequacy of information necessary for NOAA to make a National Environmental Policy Act determination and draft necessary documentation before funding recommendations are made to the Grants Officer.

#### *Fellowship, Scholarship and Internship Programs*

*Review And Selection Process.* Some fellowship, scholarship and internship programs may include a pre-application process that provides for feedback to the applicants that have responded to a call for letters of intent or pre-proposals; however, not all programs will include this pre-application. If a program has a pre-application process, the process will be described in the Summary Description section of the announcement and the deadline will be specified in the Application Deadline section.

Upon receipt of a full application by NOAA, an initial administrative review will be conducted to determine compliance with requirements and completeness of the application. A merit review will also be conducted to produce a rank order of the proposals.

The NOAA Program Officer may review the ranking of the proposals and make recommendations to the Selecting Official based on the administrative and/or merit review(s) and selection factors listed below. The Selecting Official selects proposals after considering the administrative and/or merit review(s) and recommendations of the Program Officer. In making the final selections, the Selecting Official will award in rank order unless the proposal is justified to be selected out of rank order based upon one or more of the selection factors below. The Program Officer and/or Selecting Official may



negotiate the funding level of the proposal. The Selecting Official makes final award recommendations to the Grants Officer authorized to obligate the funds.

**Evaluation Criteria.** Each reviewer (one mail and at least three peer review panel reviewers) will individually evaluate and rank proposals using the following evaluation criteria.

1. Academic record and statement of career goals and objectives of the student.

2. Quality of project and applicability to program priorities.

3. Recommendations and/or endorsements of the student.

4. Additional relevant experience related to diversity of education; extra-curricular activities; honors and awards; and interpersonal, written, and oral communications skills.

5. Financial need of the student.

**Selection Factors.** The merit review ratings will be used to provide a rank order by the Selecting Official for final funding recommendations. A Program Officer may first make recommendations to the Selecting Official by applying the selection factors listed below. The Selecting Official shall award in the rank order unless the proposal is justified to be selected out of rank order based upon one or more of the following factors:

1. Availability of funds.

2. Balance/distribution of funds:

- a. Across academic disciplines,
- b. By types of institutions, and
- c. Geographically.

3. Program-specific objectives.

4. Degree in scientific area and type of degree sought.

#### IV. NOAA Project Competitions Listed by NOAA Mission Goals

##### 1. *Protect, Restore, and Manage the Use of Coastal and Ocean Resources Through an Ecosystem Approach to Management*

**Summary Description:** NOAA's goal to protect, restore, and manage the use of living marine and coastal and ocean resources is critical to public health and the vitality of the U.S. economy. With its Exclusive Economic Zone of 3.4 million square miles, the United States manages the largest marine territory of any nation in the world. The value of the ocean economy to the United States is more than \$138 billion. The value added annually to the national economy by the commercial and recreational fishing industry alone is over \$47 billion. U.S. aquaculture sales total almost \$1 billion annually. To achieve balance among ecological, environmental, and social influences,

NOAA has adopted an ecosystem approach to management, a concept that is central to the recommendations of the 2004 report of the U.S. Commission on Ocean Policy and the Administration's response to it, the U.S. Ocean Action Plan. NOAA's Ecosystems Goal responds to a specific mandate from Congress for NOAA to be a lead federal agency in this conservation, management, and restoration effort. Recent statutory revisions (e.g., the Magnuson-Stevens Reauthorization Act and the Marine Debris Research, Prevention and Reduction Act) and emerging legislative changes are broadening this mission for NOAA, opening a new chapter in NOAA's stewardship of the nation's living marine resources and management of the coasts. Funded proposals should help achieve the following outcomes:

1. Healthy and productive coastal and marine ecosystems that benefit society

2. A well-informed public that acts as a steward of coastal and marine ecosystems

**Program Names:**

1. NOAA Marine Aquaculture Initiative 2010

2. Dr. Nancy Foster Scholarship Program

3. Marine Debris Prevention and Outreach Partnership Grants

4. Proactive Species Conservation Program

5. 2010 Hawaii Seafood Program

6. 2010 Marine Education and Training Mini Grant Program

7. Fisheries Science Program—FY2010

8. 2010 Western Pacific Demonstration Projects

9. NOAA Great Lakes Habitat Restoration Program Project Grants under the Great Lakes Restoration Initiative

10. Financial Assistance To Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement

11. 2011 Mid-Atlantic Research Set-Aside Program

12. FY10 Bay Watershed Education and Training Program, Adult and Community Watershed Education in the Monterey Bay

13. Coastal and Estuarine Land Conservation Program—FY 2011 Competition

14. FY2010 Integrated Ocean Observing System Community Modeling Environment to Support a Super-Regional Test Bed

2. *Serve Society's Needs for Weather and Water Information*

**Summary Description:** Floods, droughts, hurricanes, tornadoes,

tsunamis, wildfires, and other severe weather events cause \$11.4 billion in damage each year in the United States. Weather is directly linked to public health and safety, and nearly one-third of the U.S. economy (approximately \$4 trillion, in 2005 dollars) is sensitive to weather and climate. With so much at stake, NOAA's role in understanding, observing, forecasting, and warning of environmental events is expanding. NOAA will continue to collect and analyze environmental data and to issue forecasts and warnings that help protect health, life, and property and enhance the U.S. economy. Future needs can be better met by exploring new concepts and applications through robust weather and water research. A commitment to public benefits shapes NOAA's role within the U.S. weather enterprise, including its partners in the private sector, academia, and government. These partners add value to NOAA services and help disseminate critical environmental information. We will work more closely with our partners and will develop new partnerships so that the public understands and is satisfied with our information. Together, NOAA and its partners will continuously improve existing service and expand to support evolving national needs, including space weather, freshwater and coastal ecosystems, and air quality prediction services.

Funded proposals should help achieve the following outcomes:

1. Reduced loss of life, injury, and damage to the economy

2. Better, quicker, and more valuable weather and water information to support improved decisions

3. Increased customer satisfaction with weather and water information and services

**Program Names:**

1. Tsunami Social Science Program

2. NWS Severe Weather Program

3. Financial Assistance To Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement

4. FY2010 Integrated Ocean Observing System Community Modeling Environment to Support a Super-Regional Test Bed

3. *Understand Climate Variability and Change To Enhance Society's Ability To Plan and Respond*

**Summary Description:** Climate variability and change influence the wellbeing of society, the environment, and the economy. Numerous long-term changes in climate already have been observed. The changes include those in arctic surface temperatures and sea ice, ocean salinity and carbonate chemistry,

and frequency and intensity of extreme weather such as heat and cold waves, droughts, and floods. Decision makers are challenged with addressing major climatic events compounded by issues such as population growth, economic growth, public health concerns, changes in geographic distribution of marine species, loss of habitat, and changes in land-use practices. They require a new generation of climate services. Through legislation, executive orders, and international agreements, NOAA has a long-standing commitment to provide reliable and timely climate research and information. To meet the demand for expanded services, the Climate Goal will focus research to improve understanding of complex climate processes and to enhance the predictive capacity of the global climate system. The Climate Goal's priority is to focus on the development and delivery of climate information and services that assist decision makers with national and international policy decision making, and assessing risks to ecosystems and the U.S. economy in sectors and areas that are sensitive to impacts from climate variability and change.

Funded proposals should help achieve the following outcomes:

1. A predictive understanding of the global climate system on time scales of weeks to decades to a century with quantified uncertainties sufficient for making informed and reasoned decisions
2. Use of NOAA's climate products by climate-sensitive sectors and the climate-literate public to support their plans and decisions

Program Names:

1. Dr. Nancy Foster Scholarship Program
  2. Satellite Climate Data Record Program for 2010
  3. Financial Assistance To Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement
  4. FY2010 Integrated Ocean Observing System Community Modeling Environment to Support a Super-Regional Test Bed
4. *Provide Critical Support for NOAA's Mission*

*Summary Description: Satellite Subgoal:* Environmental satellites are a major component of NOAA's global efforts to better observe, understand, and predict various environmental phenomena. The backbone of the NOAA satellites includes the Geostationary Operational Environmental Satellite (GOES) and Polar-orbiting Operational Environmental Satellite (POES)

programs. GOES and POES are operated to provide critical atmospheric, oceanic, climatic, solar, and space data to protect life and property across the United States. The satellites carry scientific instruments and communications equipment to support the delivery of weather information and aid search and rescue operations. NOAA is acquiring the new generation of each satellite system, including ground processing systems. In concert with the National Aeronautics and Space Administration (NASA), acquisition of the next-generation geostationary satellite (GOES-R) series is underway. The Department of Defense (DoD), NASA, and NOAA are joined with industry partners to build the follow-on series of polar orbiting satellites, the National Polar-orbiting Operational Environmental Satellite System. NOAA's satellite systems support other NOAA offices in the delivery of improved severe storm warnings, weather forecasts, climate predictions, oceanic and ecosystems research and analyses, and satellite-aided search and rescue services.

*Fleet Services Subgoal:* NOAA operates a fleet of 20 ships and 10 aircraft to ensure continuous observation of critical environmental conditions. The Fleet Services Subgoal manages these platforms to increase the number of ship operating days and aircraft flight hours to meet NOAA's data collection requirements. It provides ship and aircraft support for NOAA's four Mission Goals, upgrades NOAA's fleet of ships and aircraft, and partners with the programs to facilitate the development, demonstration, and deployment of new observation platforms, such as Autonomous Underwater Vehicles and Unmanned Aerial Systems.

*Modeling And Observing Infrastructure (MOI) Subgoal:* The MOI Subgoal's analyses and operational capabilities provide critical infrastructure and support for the integrated monitoring and improved understanding of the Earth's environment. The subgoal enables NOAA's operational forecast products and services and provides NOAA a strategic investment portfolio recommendation encompassing, observing, modeling, and high-performance computing capabilities. NOAA's internal forecasting, assessment, and stewardship capabilities—as well as the capabilities of partners and customers—require integrated oceanic and atmospheric data. Furthermore, NOAA's operations require modeling support, high-performance computing, observing

system design and analysis, research and development of improved modeling and data assimilation, and guidance on the architecture of observation and data management systems. MOI also manages the integration of NOAA's observing systems and associated data with those of other federal agencies and nations under the GEO System of Systems framework.

*Leadership And Corporate Services Subgoal:* The Leadership and Corporate Services Subgoal strives to produce cost-effective, value-added solutions in the cross-cutting areas of Line Office and Headquarters management, workforce management, acquisition and grants, facilities, financial services, homeland security, IT, and administrative services. This is accomplished by effective and strategic leadership at corporate and Line Office levels that optimize agency performance and mission accomplishment through streamlined, results oriented processes. The development of long-range facility and IT modernization plans provides the investment framework to ensure that NOAA's facility and IT portfolio will continue to support a safe, secure, and state-of-the-art work environment. The development of streamlined acquisition and workforce management processes will enable NOAA to effectively fulfill its research and operational missions with a competent workforce and effective third-party partnerships. The public demand for financial stewardship and accountability requires NOAA to maintain an effective financial and internal control program. The national dependence on NOAA's services and information products compels effective continuity of operations planning and all-hazards incident management.

Funded proposals should help achieve the following outcomes:

1. A continuous stream of satellite data and information with the quality and accuracy to meet users requirements for spatial and temporal sampling and timeliness of delivery
2. Provision of the number of ship operating days and aircraft flight hours needed to meet NOAA's data collection requirements with high customer satisfaction
3. Integration of observing system architectures, data management architectures, and computing and modeling capabilities to better enable NOAA's mission
4. One NOAA working together—guided by a clear strategic vision for planning, programming, and execution—to achieve NOAA's goals

5. Secure, reliable, and robust information flows within NOAA and out to the public
  6. Modern and sustainable facilities providing safe and effective work environment
  7. Efficient and effective financial, administrative, and acquisition management services
  8. Workforce management processes that support a diverse and competent workforce
  9. Integrated Homeland Security and emergency response capabilities
- Program Names:
1. Dr. Nancy Foster Scholarship Program
  2. Financial Assistance To Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement
  3. Environmental Literacy Grants for Informal/Nonformal Science Education

*5. Support the Nation's Commerce With Information for Safe, Efficient, and Environmentally Sound Transportation*

**Summary Description:** NOAA responds to the specific demands of air, sea, and surface transportation with consistent, timely, and accurate information to aid sound and routine operational decision making. All modes of transportation are affected by significant challenges as they operate in the elements of nature. The natural environment is, in turn, affected by our transportation systems. Safe, efficient, and environmentally sound transportation systems are crucial to the nation's commerce, and thus to the nation's economy. For example, more than 78 percent of U.S. overseas trade by weight and 38 percent by value comes and goes by ship. Nine million barrels of oil come through U.S. ports daily, and 8,000 foreign vessels make 50,000 port calls annually. Vessel traffic in the U.S. Marine Transportation System, which ships over 95 percent of foreign trade by tonnage, will double by 2020 and contribute roughly \$2 trillion annually to the U.S. economy. NOAA provides information products for transportation systems, including marine and surface weather forecasts, navigational charts, real-time oceanographic information, and Global Positioning System augmentation. NOAA works with the Federal Aviation Administration and industry to improve the weather resilience of aviation systems. NOAA also provides emergency response services to save lives and money and to protect the coastal environment, including hazardous material spill response and search and rescue functions. NOAA

works with federal, state, and local partners to ensure the efficient and environmentally sound operation and development of ports.

Funded proposals should help achieve the following outcomes:

1. Safe, secure, efficient, and seamless movement of goods and people in the U.S. transportation system
2. Environmentally sound development and use of the U.S. transportation system

**Program Names:**

1. Financial Assistance to Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement
2. Joint Hydrographic Center
3. FY2010 Integrated Ocean Observing System Community Modeling Environment to Support a Super-Regional Test Bed

**V. NOAA Project Competitions**

*National Marine Fisheries Service (NMFS)*

*2010 Hawaii Seafood Program*

**Summary Description:** The National Marine Fisheries Service (NOAA/NMFS) is soliciting competitive applications for the 2010 Hawaii Seafood Program. The 2010 Hawaii Seafood Program is designed to help strengthen and to sustain the economic viability of Hawaii's fishing and seafood industry through activities that promotes Hawaii fisheries products as high-quality and safe domestic seafood produced by a responsible and well-managed fishery. Projects may seek support for cooperative seafood safety research, technical assistance, and/or seafood education.

**Funding Availability:** Total funding available under this notice is anticipated to be approximately \$1,000,000. Actual funding availability for this program is contingent upon FY 2010 Congressional appropriations. Proposals in any amount may be submitted. Award amounts will be determined by the proposals and available funds. There is no set minimum or maximum amount, within the available funding, for any award. There is also no limit on the number of applications that can be submitted by the same applicant; however, multiple applications submitted by the same applicant must clearly identify different projects. If an application for a financial assistance award is selected for funding, NOAA/NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. Notwithstanding verbal or written assurance that may

have been received, pre-award costs are not allowed under the award unless approved by the NOAA Grants Officer.

**Statutory Authority:** The statutory authority for the Hawaii Seafood Program is 15 U.S.C. 713c-3(d).

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.452, Unallied Industry Projects.

**Application Deadline:** Proposals must be received by 5 p.m. Hawaii Standard Time March 5, 2010.

**Address for Submitting Proposals:** Proposals should be submitted through Grants.gov. For those applicants without internet access, proposals should be submitted to NOAA Federal Program Officer, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, Hawaii, 96814.

**Information Contacts:** If you have any questions regarding this proposal solicitation, please contact Scott W.S. Bloom at the NOAA/NMFS Pacific Islands Regional Office, 1601 Kapiolani Blvd, Honolulu, Hawaii, 96814, by phone at 808-944-2218, or by e-mail at [Scott.Bloom@noaa.gov](mailto:Scott.Bloom@noaa.gov).

**Eligibility:** Eligible applicants are individuals, institutions of higher education, other nonprofits, commercial organizations, international organizations, foreign governments, organizations under the jurisdiction of foreign governments, and state, local and Indian tribal governments. Federal agencies, or employees of Federal agencies, are not eligible to apply. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. The Hawaii Seafood Program encourages proposals involving any of the above institutions.

**Cost Sharing Requirements:** No cost sharing or matching is required under this program.

**Intergovernmental Review:** Applications under this program are subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

**2010 Marine Education and Training Mini Grant Program**

**Summary Description:** The National Marine Fisheries Service (NOAA/NMFS) is soliciting competitive applications for the 2010 Pacific Islands Region Marine Education and Training Mini-Grant Program. Projects are being solicited to improve communication, education, and training on marine resource issues throughout the region

and increase scientific education for marine-related professions among coastal community residents, including indigenous Pacific islanders, Native Hawaiians, and other underrepresented groups in the region.

**Funding Availability:** Total funding available under this notice is anticipated to be approximately \$150,000. Actual funding availability for this program is contingent upon FY 2010 Federal appropriations. Proposals in excess of \$15,000 are unlikely to be funded. Award amounts will be determined by the proposals and available funds. There is no limit on the number of applications that can be submitted by the same applicant; however, multiple applications submitted by the same applicant must clearly identify different projects. If an application for a financial assistance award is selected for funding, NOAA/NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. Notwithstanding verbal or written assurance that may have been received, pre-award costs are not allowed under the award unless approved by the NOAA Grants Officer.

**Statutory Authority:** Authority for the 2010 Pacific Islands Region Marine Education and Training Mini-Grant Program is provided under 16 U.S.C. 1855j.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.452, Unallied Industry Projects.

**Application Deadline:** Proposals must be received by 5 p.m. Hawaii Standard Time March 5, 2010.

**Address for Submitting Proposals:** Proposals should be submitted through Grants.gov. For those applicants without internet access, proposals should be submitted to NOAA Federal Program Officer, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, Hawaii, 96814.

**Information Contacts:** If you have any questions regarding this proposal solicitation, please contact Scott W.S. Bloom at the NOAA/NMFS Pacific Islands Regional Office, 1601 Kapiolani Blvd, Honolulu, Hawaii, 96814, by phone at 808-944-2218, or by e-mail at [Scott.Bloom@noaa.gov](mailto:Scott.Bloom@noaa.gov).

**Eligibility:** Eligible applicants are individuals, institutions of higher education, nonprofits, commercial organizations, state, local and Indian tribal governments. Federal agencies, or employees of Federal agencies are not eligible to apply. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of

historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. The 2010 Marine Education and Training Mini-Grant Program encourages proposals involving any of the above institutions.

**Cost Sharing Requirements:** No cost sharing or matching is required under this program.

**Intergovernmental Review:** This federal funding opportunity is subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." An applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed in applying for assistance, if the State has selected the program for review. The names and addresses of these contacts are available at <http://www.whitehouse.gov/omb/grants/spoc.html>. 2010 Western Pacific Demonstration Projects.

**Summary Description:** The National Marine Fisheries Service (NOAA/NMFS) is soliciting applications for financial assistance for Western Pacific Demonstration Projects. Eligible applicants are encouraged to submit projects intended to foster and promote use of traditional indigenous fishing practices and/or develop or enhance Western Pacific community-based fishing opportunities benefiting the island communities in American Samoa, Guam, Hawaii, and the Northern Mariana Islands.

**Funding Availability:** Total funding available under this notice is anticipated to be approximately \$500,000. Actual funding availability for this program is contingent upon FY 2010 Congressional appropriations. Proposals in any amount may be submitted. Award amounts will be determined by the proposals and available funds. There is no set minimum or maximum amount, within the available funding, for any award. There is also no limit on the number of applications that can be submitted by the same applicant; however, multiple applications submitted by the same applicant must clearly identify different projects. If an application for a financial assistance award is selected for funding, NOAA/NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. Notwithstanding verbal or written assurance that may have been received, pre-award costs are not allowed under the award unless approved by the NOAA Grants Officer.

**Statutory Authority:** Authority for the Western Pacific Demonstration Projects is provided under 16 U.S.C. 1855 note.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.452, Unallied Industry Projects

**Application Deadline:** Pre-proposals (letters of intent) must be received at the Pacific Islands Regional Office by 5 p.m. Hawaii Standard Time, February 18, 2010. NOAA reserves 15 days to review pre-proposals against NOAA's mission requirements. If an applicant submitting a pre-proposal is invited to submit a full proposal, it must be received by 5 p.m. Hawaii Standard Time, 75 days after publication in the **Federal Register**. Anticipated start dates will be July 1, 2010.

**Address for Submitting Proposals:** Proposals should be submitted through Grants.gov. For those applicants without internet access, proposals should be submitted to NOAA Federal Program Officer, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, Hawaii 96814.

**Information Contacts:** Points of contact are Scott W.S. Bloom (NMFS), NOAA Federal Program Officer for Western Pacific Demonstration Projects, Pacific Islands Region, National Marine Fisheries Service, 1601 Kapiolani Boulevard, Suite 1110, Honolulu, Hawaii 96814; or by telephone at 808-944-2218, or by e-mail at [Scott.Bloom@noaa.gov](mailto:Scott.Bloom@noaa.gov); or Charles Kaaia, Indigenous Coordinator for the Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, Hawaii, 96813 or by telephone at 808-522-8220, or by e-mail at [Charles.Kaaia@noaa.gov](mailto:Charles.Kaaia@noaa.gov).

**Eligibility:** Eligible applicants are limited to communities in the Western Pacific Regional Fishery Management Area, as defined at section 305(i)(2)(D) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1855(i)(2)(D); and meet the standards for determining eligibility set forth in section 305(i)(2)(B) of the Act, 16 U.S.C. 1855(i)(2)(B). The eligibility criteria developed by the Council and approved by the Secretary was published in the **Federal Register** on April 16, 2002 (67 FR 18512, 18514). The published criteria supplement those set forth in section 305(i)(2)(B) of the Magnuson-Stevens Act and shall be applied equally in determining a party's eligibility to participate in the demonstration project. Given this, applicants must:

1. Be located within the Western Pacific Regional Fishery Management Area (American Samoa, the Northern Mariana Islands, Guam or Hawaii);

2. Consist of community residents descended from aboriginal people indigenous to the western Pacific area who conducted commercial or subsistence fishing using traditional fishing practices in the waters of the western Pacific;

3. Consist of community residents who reside in their ancestral homeland;

4. Have knowledge of customary practices relevant to fisheries of the western Pacific;

5. Have traditional dependence on fisheries of the western Pacific;

6. Experience economic or other barriers that have prevented full participation in the western Pacific fisheries and, in recent years, have not had harvesting, processing or marketing capability sufficient to support substantial participation in fisheries in the area; and,

7. Develop and submit a Community Development Plan to the Western Pacific Council and the National Marine Fisheries Service. For the purposes of determining eligibility to participate and receive funding assistance authorized under Section 111(b) of the Sustainable Fisheries Act, Public Law 104-297, as amended, and published in 16 U.S.C. 1855 note, a project proposal shall be considered a Community Development Plan.

**Cost Sharing Requirements:** No cost sharing or matching is required under this program.

**Intergovernmental Review:** Applications under this program are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs". An applicant should consult the office or official designated as the single point of contact in his or her State for more information on the process the State requires to be followed in applying for assistance, if the State has selected the program for review. The names and addresses of these contacts are available at <http://www.whitehouse.gov/omb/grants/spoc.html>. 2011 Mid-Atlantic Research Set-Aside Program.

**Summary Description:** NMFS, in cooperation with the Mid-Atlantic Fishery Management Council (Council), is soliciting proposals under the 2011 Mid-Atlantic Research Set-Aside (RSA) Program that address research priorities concerning the summer flounder, scup, black sea bass, Loligo squid, Illex squid, Atlantic mackerel, butterfish, bluefish, and tilefish fisheries. The Mid-Atlantic RSA Program was created by the Council as a vehicle to fund research projects through the sale of research quota. Under this program, the Council may set aside up to 3-percent of the total allowable landings (TAL) from the above listed species to fund selected

projects. Proceeds from the sale of research quota are used to pay for research costs and to compensate fishing vessels that harvest research quota. Any additional funds, generated through the sale of the fish harvested under the research quota, above the cost of the research activities, shall be retained by the vessel owner as compensation for use of his/her vessel. Participating vessels may be authorized to harvest and land fish in excess of Federal possession limits and/or during fishery closures. No Federal funds are provided for research under this notification. NMFS and the Council will give priority to funding proposals addressing the research needs identified in Section I-B of the FFO.

**Funding Availability:** No Federal funds are provided for research under this notification, but rather the opportunity to fish with the catch sold to generate research funds and to provide compensation for harvesting of RSA quota. The Federal Government may issue an exempted fishing permit (EFP) to selected projects, which may provide special fishing privileges, such as exemption from possession limits and fishery closures. Funds generated from RSA landings shall be used to cover the cost of the research activities, including vessel costs, and to compensate boats for expenses incurred during the collection of the set-aside species. For example, the funds may be used to pay for gear modifications, monitoring equipment, additional provisions (e.g., fuel, ice, food for scientists), or the salaries of research personnel. The Federal Government is not liable for any costs incurred by the researcher or vessel owner should the sale of RSA quota not fully reimburse the researcher or vessel owner for his/her expenses. Any additional funds, generated through the sale of the fish harvested under the research quota, above the cost of the research activities, shall be retained by the vessel owner as compensation for use of his/her vessel. The Council, in consultation with the Commission, will incorporate RSA quotas for each of the set-aside species for the 2011 fishing year into the Council's annual quota specification recommendations. NMFS will consider the recommended level of RSA as part of the associated rulemaking process. RSA quota available to applicants under the 2011 Mid-Atlantic RSA Program will be established through the 2011 quota specification rulemaking process. The Council is scheduled to adopt quotas, including RSA quotas, by the end of 2010. Based on Council recommendations, NMFS may choose to

adopt less than 3 percent of TAL as a set-aside, or decide not to adopt any set-aside for a given fishery. The value of RSA quota will be dictated by market conditions prevailing at the time the compensation fishing trips are conducted. To help researchers develop proposals and proposal budgets for the 2011 Mid-Atlantic RSA Program, recent quota amount and quota value information is listed below. This information is for guidance purposes only; it does not reflect actual RSA quota amounts or quota values that will be in effect for fishing year 2011. RSA quota amounts are based on 2010 FMP specifications proposed by the Council. RSA quota values are based on landings data taken from Fisheries of the United States, 2008. This information is listed below in the following format: Species/RSA quota amount (lb)/RSA quota total value/RSA value per pound. -Summer flounder/663,900 lb/\$1,656,845/2.50 lb -Scup/423,300 lb/\$478,327/\$1.13 lb -Black sea bass/69,000 lb/\$192,076/\$2.78 lb -Loligo squid/1,256,635 lb/\$1,173,033/\$0.93 lb -Bluefish/877,914 lb/\$376,279/\$0.42 lb -Butterfish/33,069 lb/\$17,282/\$0.52 lb -Illex squid/1,587,328 lb/\$0/\$0.24 lb (no Illex squid was requested) -Atlantic mackerel/0 lb/\$0/\$0.14 (no Atlantic mackerel was requested) -Tilefish/0 lb/\$0/\$2.26 lb (no tilefish RSA was allocated) Starting in 2010, successful projects may not have more than 50 vessels authorized to conduct compensation fishing at any given time unless sufficient rationale can demonstrate that more than 50 vessels are needed. In addition, principal investigators and project coordinators should be aware that it may take NMFS up to 4 weeks to process requests to revise the list of vessels that are authorized to conduct compensation fishing.

**Statutory Authority:** Statutory authority for this program is provided under sections 303(b)(11), 402(e), and 404(c) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1853(b)(11), 16 U.S.C. 1881a(e), and 16 U.S.C. 1881(c), respectively. Statutory authority for entering into cooperative agreements and other financial agreements with non-profit organizations is found at 15 U.S.C. 1540. Framework Adjustment 1 to the Summer Flounder, Scup, and Black Sea Bass FMP, Atlantic Mackerel, Squid, and Butterfish FMP, Bluefish FMP, and Tilefish FMP established the Mid-Atlantic RSA Program (66 FR 42156, August 10, 2001), which is codified in regulations at 50 CFR 648.21(g).

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.454, Unallied Management Projects

**Application Deadline:** Applications must be received on or before 5 p.m. EST on March 22, 2010. Proposals received after the established deadline will be rejected and returned to the sender without consideration. For applications submitted through Grants.gov, a date and time receipt indication will be the basis of determining timeliness. For those not having access to the Internet, one signed original and two hard copy applications must be received by the established due date for the program at the following address: Cheryl A. Corbett, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543. Use of U.S. mail or another delivery service must be documented with a receipt. No facsimile or electronic mail proposals will be accepted. January 1, 2011, should be used as the proposed start date on proposals, unless otherwise directed by the Program Officer.

**Address for Submitting Proposals:** To apply for this NOAA Federal Funding Opportunity, please submit applications to <http://www.grants.gov> and use funding opportunity number NOAA-NMFS-NEFSC-2011-2002247. Applicants who do not have Internet access may submit their application to Cheryl A. Corbett, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543.

**Information Contacts:** Information may be obtained from Kathy Collins, Public Affairs Specialist, Mid-Atlantic Fishery Management Council, by phone 302-674-2331 ext. 14, or via e-mail at [kcollins1@mafmc.org](mailto:kcollins1@mafmc.org), or Cheryl A. Corbett, Cooperative Programs Specialist, NMFS, Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543, or by phone at 508-495-2070, or fax at 508-495-2004, or via e-mail at [cheryl.corbett@noaa.gov](mailto:cheryl.corbett@noaa.gov); or from Ryan Silva, Cooperative Research Liaison, NMFS, Northeast Regional Office, by phone 978-281-9326, or via e-mail at [ryan.silva@noaa.gov](mailto:ryan.silva@noaa.gov).

**Eligibility:** 1. Eligible applicants include institutions of higher education, hospitals, other nonprofits, commercial organizations, individuals, and state, local, and Native American tribal governments. Federal agencies and institutions are not eligible to receive Federal assistance under this notice. Additionally, employees of any Federal agency or Regional Fishery Management Council are ineligible to submit an application under this program. However, Council members who are not Federal employees may submit an application. 2. DOC/NOAA supports cultural and gender diversity and encourages women and minority

individuals and groups to submit applications to the RSA program. In addition, DOC/NOAA is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. DOC/NOAA encourages proposals involving any of the above institutions. 3. DOC/NOAA encourages applications from members of the fishing community and applications that involve fishing community cooperation and participation.

**Cost Sharing Requirements:** None required.

**Intergovernmental Review:** Applicants will need to determine if their state participates in the intergovernmental review process. This information can be found at the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>. This information will assist applicants in providing either a Yes or No response to Item 16 of the Application Form, SF-424, entitled "Application for Federal Assistance." Fisheries Science Program—FY2010.

**Summary Description:** The NOAA Chesapeake Bay Office (NCBO) is directed by congressional mandate to provide technical assistance in: (1) Identifying science-based management options for restoration and protection of living resources and their habitats; (2) monitoring and assessing the status of living resources and their habitats; and, (3) evaluating the effectiveness of management plan implementation. For FY2010, it is anticipated that approximately \$500k could be made available for projects that address multiple species interactions and stock assessment research as identified in the Program Priority Section (I.B.1 and I.B.2) of FFO.

**Funding Availability:** This solicitation announces approximately \$500,000 in federal funds that may be available in FY 2010 in award amounts to be determined by the proposals. It is expected that these funds will provide support for 5-10 projects at approximately \$50,000 to \$100,000 per project. Funding for subsequent years of work will depend on the performance of grantees to successfully conduct activities as determined by the Federal Program Officer through performance reports, site visits, and compliance with award conditions. There is no guarantee that sufficient funds will be available to make awards for all qualified projects. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives.

Publication of this notice does not oblige NOAA to award any specific project or to obligate any available funds. If applicants incur any costs prior to an award being made, they do so at their own risk of not being reimbursed by the government. Notwithstanding verbal or written assurance that may have been received, there is no obligation on the part of NOAA to cover pre-award costs unless approved by the Grants Officer as part of the terms when the award is made.

**Statutory Authority:** The Secretary is authorized under the Fish and Wildlife Coordination Act, as amended, at 16 U.S.C. 661, to provide assistance to, and cooperate with, Federal, State, and public or private agencies and organizations in the development, protection, rearing, and stocking of all species of wildlife, resources thereof, and their habitat, in controlling losses of the same from disease or other causes, and in minimizing damages from overabundant species.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.457, Chesapeake Bay Studies

**Application Deadline:** Full proposals must be received by 5:00 pm eastern time March 5, 2010.

**Address for Submitting Proposals:** Applications submitted in response to this announcement are strongly encouraged to submit via <http://www.grants.gov>. Electronic access to the full funding announcement for this program is also available at this site. If internet access is unavailable, paper applications (a signed original and two copies) may also be submitted to the NOAA Chesapeake Bay Office, 410 Severn Avenue, Suite 107A, Annapolis, MD 21403. No facsimile applications will be accepted. Institutions are encouraged to submit Letters of Intent to NCBO within 30 days of this announcement to aid in planning the review processes. Letters of Intent may be submitted via e-mail to [Derek.Orner@noaa.gov](mailto:Derek.Orner@noaa.gov). Information should include a general description of the program administration proposal.

**Information Contacts:** For further information about the Chesapeake Bay Fisheries Science Program, please visit the NOAA Chesapeake Bay Office Web site at: <http://noaa.chesapeakebay.net/>. For assistance with forms, application requirements, or submission procedures please contact Derek Orner, NOAA Chesapeake Bay Office; 410 Severn Avenue, Suite 107A, Annapolis, MD 21403, or by phone at 410-267-5676, or fax to 410-267-5666, or via Internet at [derek.orn@noaa.gov](mailto:derek.orn@noaa.gov).

**Eligibility:** Eligible applicants are institutions of higher education, other

nonprofits, commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, international organizations, state, local and Indian tribal governments. Federal agencies or institutions are not eligible to receive Federal assistance under this notice. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that work in underserved areas. The NCBO encourages proposals involving any of the above institutions.

**Cost Sharing Requirements:** No cost sharing is required under this program, however, the NCBO strongly encourages applicants to share as much of the project costs as possible. Funds from other Federal awards may not be considered matching funds. The nature of the contribution (cash versus in kind) and the amount of matching funds will be taken into consideration in the review process. Priority selection will be given to proposals that propose cash rather than in-kind contributions.

**Intergovernmental Review:** Applications under this program (CFDA 11.457, Chesapeake Bay Studies) are subject to Executive Order 12372, Intergovernmental Review of Federal Programs. NOAA Great Lakes Habitat Restoration Program Project Grants under the Great Lakes Restoration Initiative

**Summary Description:** NOAA delivers funding and technical expertise to restore Great Lakes coastal habitats. These habitats support valuable fisheries and protected resources; improve the quality of our water; provide recreational opportunities for the public's use and enjoyment; and buffer our coastal communities from the impacts of changing lake levels. Projects funded through NOAA have strong on-the-ground habitat restoration components that provide social and economic benefits for people and their communities in addition to long-term ecological habitat improvements. Through this solicitation, NOAA seeks to openly compete funding available for habitat restoration under the Great Lakes Restoration Initiative as proposed in the President's FY2010 Budget. Applications should be submitted for any project that is to be considered for this funding, even for those projects already submitted as applications to other NOAA competitions including the recent American Recovery and Reinvestment Act solicitation.

Competition will ensure that the most beneficial restoration projects are selected to realize significant ecological gains and ensure that projects are truly "shovel-ready." Applications selected for funding through this solicitation will be implemented through a grant or cooperative agreement, with awards dependent upon the amount of funds made available to NOAA for this purpose by the Environmental Protection Agency. NOAA anticipates up to \$10 million may be available for Great Lakes coastal habitat restoration; typical awards are expected to range between \$1 million to \$1.5 million. Funds will be administered by NOAA's Great Lakes Habitat Restoration Program (GLHRP).

**Funding Availability:** NOAA anticipates that up to \$10 million may be available for Great Lakes coastal habitat restoration; typical awards are expected to range between \$1 million and \$1.5 million. NOAA will not accept applications requesting less than \$500,000 or more than \$2.5 million of federal funds under this solicitation. There is no guarantee that sufficient funds will be available to make awards for all applications. The number of awards to be made as a result of this solicitation will depend on the number of eligible applications received, the amount of funds requested for habitat restoration projects by the applicants, the merit and ranking of the applications, and the amount of funds made available. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives. Publication of this document does not obligate NOAA to award any specific project or obligate all or any parts of any available funds.

**Statutory Authority:** The Secretary of Commerce is authorized under the following statutes to provide grants and cooperative agreements for habitat restoration:—Fish and Wildlife Coordination Act 16 U.S.C. 661, as amended by the Reorganization Plan No. 4 of 1970;—Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006, 16 U.S.C. 1891a;—Marine Debris Research, Prevention, and Reduction Act, 33 U.S.C. 1951 *et seq.*;—Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1451 *et seq.*—National Marine Sanctuaries Act, 16 U.S.C. 1431 *et seq.*

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.463, Habitat Conservation.

**Application Deadline:** Applications must be postmarked, provided to a delivery service, or received by [www.grants.gov](http://www.grants.gov) by 11:59 p.m. EST on

February 16, 2010. Use of U.S. mail or another delivery service must be documented with a receipt. No facsimile or electronic mail applications will be accepted. Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline.

**Address for Submitting Proposals:** If an applicant does not have internet access, a hard copy application must be postmarked, or provided to a delivery service and documented with a receipt, by 11:59 p.m. EST on February 16, 2010 and sent to: NOAA Restoration Center (F/HC3) NOAA Fisheries, Office of Habitat Conservation, 1315 East West Highway, Rm. 14730, Silver Spring, MD 20910 *Attn:* Great Lakes Habitat Restoration Project Applications. Applications postmarked or provided to a delivery service after 11:59 p.m. EST February 1, 2010 will not be considered for funding. Applications submitted via the U.S. Postal Service must have an official postmark; private metered postmarks are not acceptable. In any event, applications received later than 5 business days following the postmark closing date will not be accepted. No facsimile or electronic mail applications will be accepted. Paper applications should be printed on 8.5" x 11" paper (12-point font with 1" margins; reviewers generally prefer 1.5 line spacing) and should not be bound in any manner.

**Information Contacts:** For further information contact Jenni Wallace at (301) 713-0174 ext. 183, or by e-mail at [Jenni.Wallace@noaa.gov](mailto:Jenni.Wallace@noaa.gov). Prospective applicants are invited to contact NOAA staff before submitting an application to discuss whether their project ideas are within the scope of the Great Lakes Restoration Initiative's objectives and NOAA's mission and goals. Additional information on habitat restoration can be found on the World Wide Web at <http://www.nmfs.noaa.gov/habitat/restoration/>.

**Eligibility:** Eligible applicants are institutions of higher education, nonprofits, industry and commercial (for profit) organizations, organizations under the jurisdiction of foreign governments, international organizations, and state, local and Indian tribal governments. Applications from Federal agencies or employees of Federal agencies will not be considered. Federal agencies are strongly encouraged to work with states, non-governmental organizations, municipal and county governments, conservation corps organizations and others that are eligible to apply. The Department of Commerce/National Oceanic and

Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic-serving institutions, tribal colleges and universities, and institutions that work in under-served areas. The GLHRP encourages applications involving any of the above institutions.

**Cost Sharing Requirements:** There is no statutory matching requirement for this funding. NOAA typically leverages its Federal funding with matching contributions and/or partnerships from a broad range of sources in the public and private sector to implement locally important coastal habitat restoration. To this end, applicants are encouraged to demonstrate a 1:1 non-federal match for GLHRP funds requested to conduct the proposed project. Applicants with less than 1:1 match will not be disqualified, however, applicants should note that cost sharing is an element considered in Evaluation Criterion #4 "Project Costs" (Section V.A.4. of the FFO). Match to NOAA funds can come from a variety of public and private sources and can include in-kind goods and services and volunteer labor.

Applicants are permitted to combine contributions from non-federal partners, as long as such contributions are not being used to match any other federal funds and are available within the project period stated in the application. Federal sources cannot be considered for matching funds, but can be described in the budget narrative to demonstrate additional leverage.

Applicants are also permitted to apply federally negotiated indirect costs in excess of Federal share limits as described in Section IV.E. "Funding Restrictions" of the FFO. Applicants whose proposals are selected for funding will be bound by the percentage of cost sharing reflected in the award document signed by the NOAA Grants Officer. Successful applicants should be prepared to carefully document matching contributions, including the overall number of volunteers and in-kind participation hours devoted to habitat restoration projects. Letters of commitment for any secured resources that will be used as match for an award under this solicitation should be submitted as an attachment to the application, see Section IV.B. of the FFO.

**Intergovernmental Review:** Applications submitted by state and local governments are subject to the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." Any applicant submitting an application for funding is required to

complete item 19 on SF-424 regarding clearance by the State Single Point of Contact (SPOC) established as a result of EO 12372. To find out about and comply with a State's process under EO 12372, the names, addresses and phone numbers of participating SPOCs are listed in the Office of Management and Budget's home page at: <http://www.whitehouse.gov/omb/grants/s poc.html>.

#### *Proactive Species Conservation Program*

**Summary Description:** The NMFS is seeking to provide federal assistance, in the form of grants or cooperative agreements, to support conservation efforts for the current list of marine and anadromous species under the Proactive Species Conservation Program. The program supports voluntary conservation efforts designed to conserve marine and anadromous species before they reach the point at which listing as threatened or endangered under the Endangered Species Act (ESA) becomes necessary. Such proactive conservation efforts can serve as an efficient, non-regulatory, and cost-effective means of managing potentially at-risk species. To raise awareness of potentially at-risk species and to foster their proactive conservation, the NMFS created a 'species of concern' list in April 2004 (69 FR 19975). 'Species of concern' are species that are potentially at risk of becoming threatened or endangered or may potentially require protections under the ESA, yet for which sufficient data are lacking. The species-of-concern status carries no procedural or regulatory protections under the ESA. The list of species of concern and descriptions of each species are available at <http://www.nmfs.noaa.gov/pr/species/concern/#list>. Under this solicitation, any state, territorial, tribal, or local entity that has authority to manage or regulate these species or activities that affect these species is eligible to apply to this grant program. This document describes how to submit proposals for funding in fiscal year (FY) 2010 and how the NMFS will determine which proposals will be funded. This document should be read in its entirety, as some information has changed from the previous year.

**Funding Availability:** This solicitation announces that approximately \$200,000 may be available for distribution in FY 2010 under the PSCP; there are no restrictions on minimum or maximum funding requests. Applicants may apply for funds for up to 5 years (see below) so the total amount requested over the life of the project may be more than \$200,000, but the limit for FY 2010

should be \$200,000. Actual funding availability for this program is contingent upon Fiscal Year 2010 Congressional appropriations. Applicants are hereby given notice that funds have not yet been appropriated for this program. There is no guarantee that sufficient funds will be available to make awards for all qualified projects.

Publication of this notice does not oblige the NMFS to award any specific project or to obligate any available funds; and, if an application is selected for funding, the NMFS has no obligation to provide any additional funding in connection with that award in subsequent years. There is also no limit on the number of applications that can be submitted by the same applicant. Multiple applications submitted by the same applicant must clearly identify distinct projects, and single applications should not include multiple, unrelated projects. Notwithstanding verbal or written assurance that may have been received, pre-award costs are not allowed under the award unless approved by the Grants Officer in accordance with 2 CFR Part 225.

**Statutory Authority:** Authority for the Proactive Species Conservation Program is provided by 16 U.S.C. 661.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.472, Unallied Science Program.

**Application Deadline:** Applications must be postmarked, provided to a delivery service, or received by <http://www.grants.gov> by 11:59 p.m. Eastern Standard Time on February 11, 2010. Use of a delivery service other than U.S. mail must be documented with a receipt. PLEASE NOTE: It may take Grants.gov up to two business days to validate or reject an application. Please keep this in mind when developing your submission timeline.

**Address for Submitting Proposals:** For applicants without internet access, paper applications can be mailed to NOAA/NMFS/Office of Protected Resources, Attn: Dwayne Meadows, NMFS Office of Protected Resources F/PR3, 1315 East-West Highway, SSMC3, Silver Spring, MD 20910. If it is necessary to submit a paper application, then one signed original and two signed copies (including supporting information) must be submitted; paper applications should not be bound in any manner.

**Information Contacts:** If you have any questions regarding this proposal solicitation, please contact Dwayne Meadows at the NMFS Office of Protected Resources F/PR3, Endangered Species Division, 1315 East-West Highway, Silver Spring, MD 20910, by phone at 301-713-1401 x199, or by e-



mail at [Dwayne.Meadows@noaa.gov](mailto:Dwayne.Meadows@noaa.gov). You may also contact one of the following people in your region for further guidance: Sarah Laporte, Northeast Regional Office ([Sarah.Laporte@noaa.gov](mailto:Sarah.Laporte@noaa.gov), 978-282-8477), Calusa Horn, Southeast Regional Office ([Calusa.Horn@noaa.gov](mailto:Calusa.Horn@noaa.gov), 727-824-5312), Krista Graham, Pacific Islands Regional Office ([Krista.Graham@noaa.gov](mailto:Krista.Graham@noaa.gov), 808-944-2238), Susan Wang, Southwest Regional Office ([Susan.Wang@noaa.gov](mailto:Susan.Wang@noaa.gov), 562-980-4199), Eric Murray, Northwest Regional Office ([Eric.Murray@noaa.gov](mailto:Eric.Murray@noaa.gov), 503-872-2791), Brad Smith, Alaska Regional Office ([Brad.Smith@noaa.gov](mailto:Brad.Smith@noaa.gov), 907-271-3023).

**Eligibility:** Eligible applicants are U.S. state, territorial, tribal, or local governments that have regulatory or management authority over one or more SOC or activities that affect one or more SOC. A current list of SOC can be found at <http://www.nmfs.noaa.gov/pr/species/concern/#list> or obtained from the Office of Protected Resources (see Section VII, Agency Contacts, of the FFO). Applicants are not eligible to submit a proposal under this program if they are a federal employee; however, federal employees may serve as Cooperators. In addition, NMFS employees are not allowed to actively engage in the preparation of proposals or write letters of support for any application. However, if applicable, NMFS employees can write a letter verifying that they are collaborating with a particular project. NMFS contacts (see Section VII of the FFO) are available to provide information regarding programmatic goals and objectives associated with the PSCP, other ongoing ESA programs, regional funding priorities, and, along with other Federal Program Officers, can provide information on application procedures and completion of required forms.

**Cost Sharing Requirements:** There are no cost-sharing or matching requirements under this solicitation.

**Intergovernmental Review:** Applications submitted by state and local governments are subject to the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." Any applicant submitting an application for funding is required to complete item 16 on SF-424 regarding clearance by the State Single Point of Contact (SPOC) established as a result of EO 12372. To find out about and comply with a State's process under EO 12372, the names, addresses and phone numbers of participating SPOC's are listed on the Office of Management and Budget's home page at: <http://www.whitehouse.gov/omb/grants/spoc.html>.

[www.whitehouse.gov/omb/grants/spoc.html](http://www.whitehouse.gov/omb/grants/spoc.html).

National Ocean Service (NOS) Coastal and Estuarine Land Conservation Program—FY 2011 Competition

**Summary Description:** The purpose of this document is to advise eligible coastal states and territories (requirements described below) that OCRM is soliciting coastal and estuarine land conservation project proposals for competitive funding under the CELCP. States and territories must have submitted to NOAA a CELCP plan on or before February 19, 2010, in order to be eligible to participate in the FY2011 funding opportunity. Funding is contingent upon the availability of FY 2011 Federal appropriations. It is anticipated that projects funded under this announcement will have a grant start date between June 1, 2011 and October 1, 2011. The program authority is 16 U.S.C. 1456-1.

**Funding Availability:** NOAA anticipates that approximately 20-60 projects may be included on a competitively-ranked list of projects that are ready and eligible for funding in FY 2011. Funding for projects selected for the prioritized list is contingent upon availability of Federal appropriations for FY 2011. Applicants are hereby given notice that funds have not yet been appropriated for this program. The FY 2011 President's Budget request for CELCP is \$15 million. Annual appropriated funding levels for the CELCP have ranged from \$8-\$50 million from FY 2002-2009. Eligible coastal states and territories may select and submit up to three projects for this competition, including subsequent phases of projects previously funded by CELCP. Applicants may include multiple parcels in a project proposal if the parcels are related; however, please note that NOAA will evaluate project readiness and feasibility for completion within the required 18 month timeframe. For such projects, NOAA recommends that applicants limit the scope to acquiring no more than 5 separate parcels (including parcels that would be acquired directly with CELCP funds as well as those that would be counted an in-kind match). See Section III.C of the FFO for additional details. The maximum amount that may be requested for the Federal share of each project is \$3,000,000.

The amount of funding per award in previous years has ranged from \$105,000 to \$3,000,000 for competitively selected projects, depending on the amount requested, size, and type of project. There is no guarantee that sufficient funds will be

available to make awards for all qualified projects. Publication of this notice and the list of projects deemed ready and eligible does not obligate NOAA to award any specific project or to obligate any available funds. If an applicant incurs any costs prior to receiving an award agreement signed by an authorized NOAA official, they do so at their own risk of these costs not being included under the award. In no event will NOAA or the Department of Commerce be responsible for proposal preparation or other project costs if this program fails to receive funding or is cancelled because of other agency priorities. Recipients and sub-recipients are subject to all Federal laws and agency policies, regulations, and procedures applicable to Federal financial assistance awards. NOAA is committed to continual improvement of the grants process and accelerating the award of financial assistance to qualified recipients in accordance with the recommendations of the NOAA Program Review Team. If funding is appropriated in FY 2011 for projects recommended through this competition, NOAA will request final grant applications from successful applicants as soon as feasible in order to expedite the grant process (see VI. Award Administration Information). Applicants must be in good standing with all existing NOAA grants in order to receive funds.

**Statutory Authority:** Authority for the CELCP is 16 U.S.C. 1456-1 (formerly authorized under 16 U.S.C. 1456d).

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.419, Coastal Zone Management Administration Awards.

**Application Deadline:** Applications must be received by Grants.gov or be delivered to the OCRM office (address listed in this announcement) no later than 6:00 p.m. Eastern Daylight Time on April 9, 2010. No facsimile or electronic mail applications will be accepted. Paper applications delivered after the deadline will not be accepted, regardless of postmark date. Please note that it may take Grants.gov up to two (2) business days to validate or reject an application. Please keep this in mind when developing your submission timeline; do not wait until the last day to submit an application.

**Address for Submitting Proposals:** The proposal may be submitted electronically through Grants.gov online at: <http://www.grants.gov> or by mailing a signed original and four copies of each proposal to Attn: Elaine Vaudreuil, NOAA, Ocean and Coastal Resource Management, National Policy and Evaluation Division (N/ORM7), 1305

East-West Highway, SSMC4, Station 10657, Silver Spring MD 20910.

**Information Contacts:** CELCP Program Manager, Elaine Vaudreuil, Phone: (301) 713-3155 ext 103, E-mail: [Elaine.Vaudreuil@noaa.gov](mailto:Elaine.Vaudreuil@noaa.gov).

**Eligibility:** Only coastal states and territories with Coastal Zone Management Programs or National Estuarine Research Reserves approved under the CZMA, and that have submitted a draft CELCP plan to NOAA on or before February 19, 2010, are eligible to participate in the FY 2011 CELCP competition. A list of the status of each state and territory's CELCP plan, including the states and territories eligible for this competition, is available at [http://coastalmanagement.noaa.gov/land/media/CELCPplans\\_web.pdf](http://coastalmanagement.noaa.gov/land/media/CELCPplans_web.pdf), and will be updated as of February 19, 2010. The designated lead agency for implementing CELCP in each state or territory ("lead agency") is eligible to submit projects for funding under this competition. The lead agency is presumed to be the agency designated as lead for implementing the state or territory's coastal management program, as approved under the CZMA, unless otherwise designated by the Governor. A list of lead contacts for each state and territory is available on the CELCP Web site at <http://coastalmanagement.noaa.gov/land/media/celcpstateleadcontacts.pdf>. The designated lead agency may solicit, and include in their application, project proposals from additional eligible state or territorial agencies, local governments as defined at 15 CFR 24.3, or entities eligible for assistance under section 306A(e) of the CZMA (16 U.S.C. 1455a(e)), provided that each has the authority to acquire and manage land for conservation purposes. As defined at 15 CFR 24.3, local government means a county, municipality, city, town, township, local public authority (including any public and Indian housing agency under the United States Housing Act of 1937), school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under State law), any other regional or interstate government entity, or any agency or instrumentality of a local government. Under section 306A(e) of the CZMA, an eligible entity may be a local government, an areawide agency designated under Chapter 41, Subchapter II, Section 3334 of Title 42, a regional agency, or an interstate agency. The public agencies/entities, or types of entities, considered to be eligible within each state or territory may be identified within the state or territory's CELCP plan. A list of Web

sites for state or territory CELCP plans is available at [http://coastalmanagement.noaa.gov/land/media/CELCPplans\\_web.pdf](http://coastalmanagement.noaa.gov/land/media/CELCPplans_web.pdf). The lead agency will be responsible for: Ensuring that projects are consistent with land conservation priorities outlined in the state or territory's draft or approved CELCP plan; reviewing proposals for completeness and eligibility requirements; prioritizing proposals according to CELCP plan criteria; and nominating up to three proposals to the national selection process at a requested funding level not to exceed \$3 million per proposal. For selected projects, NOAA may make financial assistance awards to the lead agency, which will be responsible for ensuring that allocated funds are used for the purposes of and in a manner consistent with this program, including any funds awarded to an eligible sub-applicant. NOAA may, with concurrence of the state or territory's CELCP lead agency, make a grant directly to the identified sub-applicant in order to expedite completion of an approved project. In such cases, the sub-applicant (as the grant recipient) will be responsible for ensuring that allocated funds are used for the approved purposes and in a manner consistent with this program. Interested parties should contact the appropriate CELCP lead in each state or territory for additional information on their project solicitation process. (See <http://coastalmanagement.noaa.gov/land/media/celcpstateleadcontacts.pdf> for a list of lead contacts for each state and territory.)

**Cost Sharing Requirements:** Federal funds awarded under this program must be matched with non-Federal funds at a ratio of 1:1, with the following exception. In accordance with 48 U.S.C. 1469a(d), the 1:1 matching requirement is waived for any project under \$200,000 for Insular Areas, defined as the jurisdictions of the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. For any project equal to or greater than \$200,000, the matching requirement would be waived for the portion under \$200,000. The 1:1 match requirement would apply to the portion equal to or above \$200,000. **Please note:** Eligible applicants choosing to apply 48 U.S.C. 1469a(d) should note the use of the waiver and the total amount of funds requested to be waived in the matching funds section of the project proposal. Non-Federal matching funds may be derived from state, local, non-governmental or private sources in the form of cash or in-kind contributions. Eligible sources of match

and other cost-sharing requirements are specified in Section 2.7 of the CELCP Guidelines as well as in the 2009 CELCP authorization (16 U.S.C. 1456-1), and are outlined in detail in Section III.C. "Other Criteria that Affect Eligibility" of the FFO. The following costs may not be counted toward the non-Federal matching share: (1) Costs associated with CELCP-funded properties that are incurred prior to the grant award. (2) Lands or services previously used as match to a Federal grant. Any funds or in-kind contributions, including the value of donated lands or services, that have been previously used to satisfy the matching requirements of this program or that that have been or will be used to satisfy another Federal grant, may not be counted toward the non-Federal matching share. (3) Lands or services acquired with Federal funds. Unless otherwise provided by Federal law, the value of property, interests in property or services acquired with Federal funding may not be used as non-Federal match. (4) Cash contribution of Federal funds. Unless otherwise provided by Federal law, funding that originated from Federal sources may not be used as non-Federal match.

**Intergovernmental Review:** Applications under this program are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs" for states that participate in this process. A list of the participating states and the clearinghouse points of contact can be found at <http://www.whitehouse.gov/omb/grants/spoc.html>.

**FY10 Bay Watershed Education and Training Program, Adult and Community Watershed Education in the Monterey Bay**

**Summary Description:** The California B-WET Program, Adult and Community Watershed Education, is a competitively based program that supports existing environmental education programs, fosters the growth of new programs, and encourages the development of partnerships among environmental education programs throughout the Monterey Bay watershed. Funded projects provide meaningful watershed education to adults and communities. The term meaningful watershed education is defined as outcome-based programs that educate citizens about their role in protecting water quality and demonstrate behavioral changes that improve water quality and promote environmental stewardship.

**Funding Availability:** This solicitation announces that approximately \$200,000 may be available in FY 2010 in award amounts to be determined by the

proposals and available funds. The Office of National Marine Sanctuaries anticipates that approximately 3–6 grants will be awarded with these funds and that typical project awards will range from \$20,000 to \$60,000. The California B–WET Program should not be considered a long-term source of funds; applicants must demonstrate how ongoing programs, once initiated, will be sustained.

There is no guarantee that sufficient funds will be available to make awards for all qualified projects. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives. Publication of this notice does not oblige NOAA to award any specific project or to obligate any available funds. If applicants incur any costs prior to an award being made, they do so at their own risk of not being reimbursed by the government. Notwithstanding verbal or written assurance that may have been received, there is no obligation on the part of NOAA to cover pre-award costs unless approved by the Grants Officer as part of the terms when the award is made.

*Statutory Authority:* 33 U.S.C. 893 a(a).

*Catalog of Federal Domestic Assistance (CFDA) Number:* 11.429, Marine Sanctuary Program

*Application Deadline:* Applications must be received and validated by Grants.gov on or before 5 p.m. PST on February 12, 2010. Please Note: It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Both hard copy and electronic proposals received after that time will not be considered for funding and will be returned to the applicant.

*Address for Submitting Proposals:* Application packages should be submitted through Grants.gov. If an applicant does not have Internet access, the applicant should send the application package to: Seaberry Nachbar, B–WET Program Manager, Monterey Bay National Marine Sanctuary Office, 299 Foam Street, Monterey, CA 93940.

*Information Contacts:* Please visit the Office National Marine Sanctuaries B–WET Web site for further information at: <http://sanctuaries.noaa.gov/BWET> or contact Seaberry Nachbar, Monterey Bay National Marine Sanctuary Office; 299 Foam Street, Monterey, CA 93940, or by phone at 831–647–4204, or fax to 831–647–4250, or via Internet at [seaberry.nachbar@noaa.gov](mailto:seaberry.nachbar@noaa.gov).

*Eligibility:* Eligible applicants are institutions of higher education,

nonprofit organizations, state or local government agencies, and Indian tribal governments. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of historically black colleges and universities, Hispanic serving institutions, tribal colleges and universities, and institutions that service undeserved areas. The National Marine Sanctuary Program encourages proposals involving any of the above institutions.

*Cost Sharing Requirements:* No cost sharing is required under this program; however, the National Marine Sanctuary Program strongly encourages applicants to share as much of the costs of the award as possible. Funds from other Federal awards will not be accepted as matching funds. The nature of the contribution (cash versus in-kind) and the amount of matching funds will be taken into consideration in the review process with cash being the preferred method of contribution.

*Intergovernmental Review:* Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

*FY2010 Integrated Ocean Observing System Community Modeling Environment To Support a Super-Regional Test Bed*

*Summary Description:* The Integrated Ocean Observing System (IOOS) is working to link national and regional observations (observations subsystem), data management (data management and communications subsystem), and modeling and analysis subsystem to provide required data and information on local to global scales to address IOOS seven societal goals of: (1) Improve predictions of climate change and weather and their effects on coastal communities and the nation, (2) Improve the safety and efficiency of maritime operations, (3) More effectively mitigate the effects of natural hazards, (4) Improve national and homeland security, (5) Reduce public health risks, (6) More effectively protect and restore healthy coastal ecosystems, and (7) Enable the sustained use of ocean and coastal resources.

The IOOS modeling and analysis (MA) subsystem supports the ocean, coastal and Great Lakes nowcasting/forecasting/hindcasting and decision making capabilities of IOOS that are needed to address these societal goals. IOOS observing subsystem and data management and communication subsystems are supporting elements for

the MA system. Modeling expertise is available within the IOOS Regional Associations, other academic and research institutes, private sector entities, the Federal, local and state government. NOAA, along with other IOOS stakeholders, views the development of a community modeling environment that successfully demonstrates the capability for modeling scientists to share the use of a wide range of oceanic, coastal, atmospheric, hydrologic, and ecological models and associated data, tools and techniques that supports systematic testing, evaluation and transition as appropriate, into operations, as essential to a sustained and operational IOOS. This modeling environment should be designed with the potential to be used for a variety of different modeling problems and over different geographies.

The program priorities for this funding opportunity are to conduct a super-regional test bed demonstration of the community modeling environment by transitioning models, tools, toolkits and other capabilities to a Federal operational facility to improve the understanding, prediction, and mitigation of the consequences of extreme events and chronic conditions affecting the U.S. Atlantic and Gulf Coasts. Of particular interest are phenomena that intersect the mission goals of NOAA, other operational agencies and the IOOS Regional Associations. This demonstration should also include estimates of the potential costs and benefits of improvements in the current modeling systems at Federal operational agencies.

NOAA seeks proposals for a single cooperative agreement that will define and implement the community modeling environment and demonstration of a super-regional test bed. This test bed is a common environment in which identical variables, boundary conditions, initial conditions, parameterizations and other inputs used in various models to rigorously test and evaluate forecasting skill and the requirements needed for transition to a Federal operational facility or other entities as appropriate. The community environment and associated test bed must also enable data integration and dissemination, and enable scientists to share use of numerical models, observations, and tools; and in addition, provide an environment for identifying, prioritizing and resolving issues associated with interoperable coupling of a range of models such as coastal, oceanic, atmospheric, hydrologic and ecological. Such a test bed and community

modeling environment should include no less than 20 academic partners and research institutions, and partnerships with appropriate Federal operational modeling groups to guarantee it is multi-disciplinary, inclusive of community-modeling, and able to address operational constraints inherent in transitioning models into an operational Federal environment.

Submitted proposals should address the following: (1) In collaboration with Federal partners, development of metrics and a system to evaluate the potential feasibility, costs, and benefits of improvement to existing operational capabilities of transitioning current and emerging community-based ocean, coastal and Great Lakes models into Federal operational facilities. Cooperative development of strategies and specific steps needed to transition existing models or modeling systems into Federal operational facilities including addressing issues of transition costs, reliability, expanded coverage, etc. (2) Define and transition into a Federal operational facility one or more models, tools, toolkits or other capabilities to advance an operational capability to predict an environmental extreme event in the U.S. Atlantic and Gulf Coasts. The transition to a Federal operational agency is not intended to imply a model, tool or other capability is operational, but rather has been implemented by the agency under pre-operational conditions. (3) Use and build upon existing infrastructure, models and expertise to maximize the benefits to the modeling community and leverage existing resources, capacities and capabilities. (4) Define roles and responsibilities of academic, government and private sector modeling experts, infrastructure and capabilities in the community modeling environment and test bed demonstration. (5) Demonstrate engagement of customer or end users that define the requirements for modeling improvements and provide feedback and evaluation from beginning to end of the project. (6) Conduct the end-to-end modeling process of data access and assimilation, interoperable model coupling, model output delivery, model testing and evaluation, analysis, visualization, skill assessment and user evaluation. (7) Describe suggested strategies for sustaining the modeling test bed infrastructure and expanding to other areas, models or problems.

**Funding Availability:** Total anticipated funding for the cooperative agreement is subject to the availability of appropriations. The anticipated federal funding for this announcement is up to \$4,500,000.00 for a single

award. While the full funding amount will be awarded in year one, applicants may submit proposals that identify how this project will be implemented within a 1–3 year period.

**Statutory Authority:** Statutory authority for this program is provided under the Integrated Coastal and Ocean Observation System Act of 2009, 33 U.S.C. 3601–3610.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.012, Integrated Ocean Observing System (IOOS).

**Application Deadline:** Applications must be received no later than 5 p.m. EST, February 18, 2010. For applications submitted through <http://grants.gov/>, a date and time receipt indication by Grants.gov will be the basis of determining timeliness. Hard copy applications delivered by mail will be date and time stamped when they are received. Applications received after that time will not be reviewed or considered. Important: All applicants, both electronic and paper, should be aware that adequate time must be factored into applicant schedules for delivery of the application. Electronic applicants are advised that volume on Grants.gov is currently extremely heavy, and if Grants.gov is unable to accept applications electronically in a timely fashion, applicants are encouraged to exercise their option to submit applications in paper format. Paper applicants should allow adequate time to ensure a paper application will be received on time, taking into account that guaranteed overnight carriers are not always able to fulfill their guarantees.

**Address for Submitting Proposals:** If an applicant does not have Internet access, the applicant must submit through surface mail one set of originals (signed) and two copies of the proposals and related forms to the NOAA IOOS Program. No e-mail or fax copies will be accepted. Application packages for proposals are available through Grants.gov APPLY. Full proposal application packages submitted by mail must be received no later than the deadline. Any U.S. Postal Service correspondence should be sent to the attention of Regina Evans, NOAA IOOS; 1100 Wayne Avenue, Suite 1225, Silver Spring, Maryland 20910; or by phone at 301-427-2422, fax at 301-427-2073, or e-mail at [Regina.Evans@noaa.gov](mailto:Regina.Evans@noaa.gov).

**Information Contacts:** For questions regarding this announcement, contact: Regina Evans, NOAA IOOS; 1100 Wayne Avenue, Suite 1225, Silver Spring, Maryland 20910; or by phone at 301-427-2422, fax at 301-427-2073, or e-mail at [Regina.Evans@noaa.gov](mailto:Regina.Evans@noaa.gov).

**Eligibility:** Eligible funding applicants are institutions of higher education, non-profit and for-profit organizations, and state, local and Indian tribal governments. Federal agencies or institutions and foreign governments may not be the primary recipient of awards under this announcement, but are encouraged to partner with applicants when appropriate. If a federal partner is a NOAA office, the funds will be transferred internally. If the Federal partner is an agency other than NOAA, they must demonstrate that they have legal authority to accept funds in excess of their appropriation. Because they would be receiving funds from a non-Federal source, the Economy Act (31 U.S.C. 1535) would not be an appropriate authority.

**Cost Sharing Requirements:** There is no requirement for cost sharing or matching. NOAA appreciates that the proposers may utilize existing modeling and information technology investments to further extend the results of this funding opportunity. While a cost share of funding is not required, applicants are encouraged to provide a description of complementary funding and in-kind contributions from project partners so that the government has a more complete picture of the overall project and can better interpret progress reports and other project outputs.

**Intergovernmental Review:** Funding applications under the Center are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." It is the state agency's responsibility to contact their state's Single Point of Contact (SPCO) to find out about and comply with the state's process under EO 12372. To assist the applicant, the names and addresses of the SPOCs are listed on the Office of Management and Budget's Web site <http://www.whitehouse.gov/omb/grants/spoc.html>.

#### *Joint Hydrographic Center*

**Summary Description:** The purpose of this notice is to solicit proposals for a single cooperative agreement between NOAA and an institution of higher learning to operate and maintain a Joint Hydrographic Center as authorized in the Ocean and Coastal Mapping Integration Act and the Hydrographic Services Improvement Act. Proposals submitted in response to this announcement should advance the purposes of the Acts including research and development of hydrographic technologies necessary to ensure safe and efficient navigation; research and development of innovative ocean and coastal mapping technologies, equipment, and data products; mapping

of the United States Outer Continental Shelf and other regions; data processing for nontraditional data and uses; advancing the use of remote sensing technologies, for related issues, including mapping and assessment of essential fish habitat and of coral resources, ocean observations, and ocean exploration; and providing graduate education and training in ocean and coastal mapping sciences. The program priorities for this opportunity support NOAA's mission goal of: Support the Nation's commerce with information for safe, efficient, and environmentally sound transportation.

**Funding Availability:** This will be a 5-year, multiyear award. The intent is to make a single 5-year award. Total anticipated funding for this award is approximately \$32,500,000 with approximately \$6,500,000 to be released in FY 2010 and each subsequent year of the 5 years. This award and the subsequent annual releases of funds are subject to the availability of FY 2010 appropriations and the appropriations of each subsequent FY.

The initial award and subsequent annual release of funds will be adjusted based on available funding.

**Statutory Authority:** Statutory authority for this program is provided under 33 U.S.C. 883a and 883d, the Coastal and Ocean Mapping Integration Act, and the Hydrographic Services Improvement Act.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.400, Geodetic Surveys and Services (Applications of the National Geodetic Ref System)

**Application Deadline:** Letters of Intent must be received by the Office of Coast Survey no later than 4 p.m. ET February 3, 2010. Full proposals must be received by the Office of Coast Survey no later than 4 p.m. ET on March 5, 2010.

**Address for Submitting Proposals:** Letters of intent (LOI) may be sent via e-mail to [gretchen.imahori@noaa.gov](mailto:gretchen.imahori@noaa.gov). Insert "FY 2010 Joint Hydrographic Center LOI" as the subject line of the e-mail. If hard-copy LOIs are submitted, an original and 3 copies should be sent to the attention of Gretchen Imahori at the Office of Coast Survey, 1315 East West Highway, SSMC3 Station 6715, Silver Spring, MD 20910-3282, tel. 301-713-2777 ext. 123. Full proposal application packages, including any letters of support, should be submitted through Grants.gov APPLY. The standard NOAA funding application package is available at [www.grants.gov](http://www.grants.gov). Please be advised that potential funding applicants must register with Grants.gov before any application materials can be

submitted. An organization's one time registration process may take up to three weeks to complete so please allow sufficient time to ensure applications are submitted before the closing date. The Grants.gov site contains directions for submitting an application, the application package (forms), and is also where the completed application is submitted. If an applicant does not have Internet access, one set of originals (signed) and 3 copies of the proposals and related forms should be mailed to the attention of Gretchen Imahori at the Office of Coast Survey, 1315 East West Highway, SSMC3 Station 6715, Silver Spring, MD 20910-3282, tel. 301-713-2777 ext. 123. No e-mail or fax copies of the full proposal will be accepted. Full proposal application packages, including any letters of support, should be submitted together in one package.

**Information Contacts:** For administrative and technical questions, contact Gretchen Imahori at the Office of Coast Survey, 1315 East West Highway, SSMC3 Station 6715, Silver Spring, MD 20910-3282, or contact her at 301-713-2777 ext. 123 or via e-mail [gretchen.imahori@noaa.gov](mailto:gretchen.imahori@noaa.gov).

**Eligibility:** Eligible funding applicants are institutions of higher education in the United States. Federal agencies are not allowed to receive funds under this announcement but may serve as collaborative project partners and may contribute services in kind.

**Cost Sharing Requirements:** There is no requirement for cost sharing.

**Intergovernmental Review:** Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

#### *Marine Debris Prevention and Outreach Partnership Grants*

**Summary Description:** The NOAA Marine Debris Program (MDP), mandated by the Marine Debris Research, Prevention and Reduction Act in 2006, has a lead role in addressing marine debris affecting the marine environment and navigation safety in the United States. The MDP defines marine debris as any persistent solid material that is manufactured or processed and directly or indirectly, intentionally or unintentionally, disposed of or abandoned into the marine environment or the Great Lakes. The MDP conducts reduction, prevention, and research activities, as well as supports grants, partnerships, cooperative agreements, and contracts to address marine debris. It has held regional, national, and international workshops and an information exchange forum, and established an interactive

Web site ([www.marinedebris.noaa.gov](http://www.marinedebris.noaa.gov)) which includes a nation-wide web educational campaign. The MDP invites the public to submit applications\* requesting funding to establish multi-year national and regional partnerships focusing on utilizing existing networks and expanding on existing resources to address marine debris through prevention, education, and outreach activities, and the dissemination and/or development of tools to support these activities. Partnerships are expected to catalyze the public or a target audience to address marine debris in a way that will benefit living marine resources and/or navigation safety. NOAA envisions working jointly on such partnerships through its Marine Debris Program to identify, evaluate, fund, and administer projects that address marine debris and help to restore NOAA trust resource species and habitats.

This document describes the types of marine debris partnerships that NOAA envisions establishing, portrays the qualities that NOAA has found to be ideal in previous partnerships, and describes criteria under which applications will be evaluated for funding consideration. Partnership applications selected through this announcement will be implemented through a cooperative agreement, and will involve joint selection of any multiple marine debris projects funded as sub-awards made through the partner organization. Funding requested to establish partnerships in FY2010 is expected to be greater than funds available for this purpose and the selection process is anticipated to be highly competitive. This is not a request for individual project proposals addressing marine debris, rather it is a focused effort to establish partnerships between the applicant and the MDP that will lead to joint projects addressing marine debris prevention and outreach. Funding is contingent upon the availability of Fiscal Year 2010 appropriations.

**Funding Availability:** Total anticipated funding for all partnership awards is approximately \$500,000 and is subject to the availability of FY 2010 appropriations. Annual funding is anticipated to maintain partnerships for up to 3 years duration, but this is dependent upon the level of funding made available by Congress. Funding for subsequent years will also depend on the ability of partners to successfully perform partnership activities as stated in their applications. Multiple awards are anticipated from this announcement. The anticipated federal funding per partnership award (min-max) is approximately \$20,000 to \$150,000 per

year. The anticipated number of partnerships ranges from one (1) to ten (10), approximately, and will be adjusted based on available funding. NOAA will not accept proposals with a single year budget under \$15,000 or over \$175,000 under this solicitation. Applicants can request increases to continue scaling up partnership activities in subsequent budget periods to a limit of 10% per year, however annual funding levels and any increases over FY 2010 levels for successful applicants will be dependent upon partnership success, regional priorities, and the level of funding provided by Congress in the future.

In accordance with the NOAA Marine Debris Program Grant Program Guidelines published on December 21, 2009 in the **Federal Register**, the NOAA Marine Debris Division Chief (Chief) will determine the proportion of funds available to the MDP on an annual basis that will be obligated to national and regional partnerships each year. The number of partnership awards to be made as a result of this solicitation will depend on the number of eligible applications received, the amount of funds requested for initiating partnerships by the applicants, the merit and ranking of the proposals, and the amount of funds made available to the MDP by Congress. NOAA anticipates that between 1 and 10 awards will be made as a result of this solicitation. There is no guarantee that sufficient funds will be available to initiate partnerships where funding has been recommended, and the number of national and regional partnerships established will be up to the discretion of the Chief. The exact amount of funds that may be awarded to work within a marine debris outreach partnership will be determined in pre-award negotiations between the applicant and NOAA representatives, and multi-year funding requests are expected to be funded incrementally on an annual basis. Publication of this document does not obligate NOAA to establish any specific partnership proposed or to obligate all or any parts of the available funds for partnership activities.

**Statutory Authority:** The Administrator is authorized under the Marine Debris Research, Prevention, and Reduction Act (MDRPR Act), 33 U.S.C. 1952, to provide grants and cooperative agreements to address marine debris.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.463, Habitat Conservation

**Application Deadline:** Full proposals must be received and validated by Grants.gov, postmarked, or provided to

a delivery service on or before 11:59 p.m. Eastern Time February 18, 2010. Validation or rejection of your application by Grants.gov may take up to 2 business days after submission. Please consider this process in developing your submission timeline. Use of a delivery service must be documented with a receipt. No facsimile or electronic mail applications will be accepted.

**Address for Submitting Proposals:** Applications should be submitted via www.grants.gov. If grants.gov cannot reasonably be used, applications must be postmarked, or provided to a delivery service and documented with a receipt, by January 30, 2010 and sent to: *Attn:* MD Prevention and Outreach Partnership Applications. NOAA Marine Debris Division (N/ORR), Office of Response and Restoration, N/ORR, 1305 East West Highway, 10th Floor, Silver Spring, MD 20910.

**Information Contacts:** For further information contact Sarah Morison at 301-713-2989, or by fax 301-713-4389, or via e-mail at *Sarah.Morison@noaa.gov*.

**Eligibility:** Eligible applicants are institutions of higher education, hospitals, other non-profits, commercial (for-profit) organizations, Regional Fishery Management Councils and Commissions, organizations under the jurisdiction of foreign governments, international organizations, state, local and Indian tribal governments whose applications propose to benefit NOAA trust resources. Applications from federal agencies or employees of federal agencies will not be considered. Federal agencies are strongly encouraged to work with states, non-governmental organizations, national service clubs or youth corps organizations and others that are eligible to apply. The Department of Commerce National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of Historically Black Colleges and Universities, Hispanic Serving Institutions, and Tribal Colleges and Universities in its educational and research programs. The DOC/NOAA vision, mission, and goals are to achieve full participation by Minority Serving Institutions (MSI) in order to advance the development of human potential, to strengthen the nation's capacity to provide high-quality education, and to increase opportunities for MSIs to participate in, and benefit from, Federal financial assistance programs. DOC/NOAA encourages proposals for innovative national and regional partnerships involving MSIs according to the criteria in this document, to

strengthen the capacity of MSIs to foster student careers, research and workforce competitiveness in addressing marine debris through identification, development, implementation and monitoring of marine debris projects on a national or regional scale.

**Cost Sharing Requirements:** A major goal of the MDP is to provide seed money to partnerships that leverage funds and other contributions from a broad public and private sector to implement locally, regionally or nationally important activities to benefit living marine resources and navigation safety. To this end, the MDRPR Act requires applicants to demonstrate a minimum 1:1 non-Federal match for MDP funds requested for the proposed partnership. In addition to formal match, NOAA strongly encourages applicants to leverage as much investment as possible. However, the MDRPR Act allows the Administrator to waive all or part of the matching requirement if the applicant can demonstrate that: (1) No reasonable means are available through which applicants can meet the matching requirement and (2) the probable benefit of such project outweighs the public interest in such matching requirement. In addition, the MDP may waive any requirement for matching funds by an Insular Area (Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Government of the Northern Mariana Islands). Under 48 U.S.C. 10.1469a(d.ji.i), any department or agency may waive any requirement for matching funds otherwise required by law to be provided by the Insular Area involved. Insular Area applicants wishing to waive the match requirement must include a letter specifically requesting the match waiver. All applicants should note that cost sharing is an element considered in Evaluation Criterion #4, "Project Costs." Match can come from a variety of public and private sources and can include in-kind goods and services such as private boat use and volunteer labor. Applicants are permitted to combine contributions from non-federal partners, as long as such contributions are not being used to match any other funds and are available within the project period stated in the application. Federal sources cannot be considered for matching funds, but can be described in the budget narrative to demonstrate additional leverage. Applicants are permitted to combine contributions from multiple non-federal partners in order to meet the 1:1 match recommendation, as long as such contributions are not being used to

match any other funds. Applicants are also permitted to apply federally negotiated indirect costs in excess of federal share limits as described in Section IV.E.2. "Indirect Costs" of the FFO.

Applicants should also note that the following activities, in general, will not be considered as match under project awards: (1) Activities that constitute legally required mitigation for the adverse effects of an activity regulated or otherwise governed by local, state or Federal law; (2) activities that constitute restoration for natural resource damages under Federal, state or local law; and (3) activities that are required by a separate consent decree, court order, statute or regulation. However, the MDRPR Act allows the Administrator to authorize, as appropriate, the non-Federal share of the cost of a project to include money paid pursuant to, or the value of any in-kind service performed under, an administrative order on consent or judicial consent decree that will remove or prevent marine debris. Applicants whose proposals are selected for funding will be bound by the percentage of cost sharing reflected in the award document signed by the NOAA Grants Officer. Successful applicants should be prepared to carefully document matching contributions, including the names of participating volunteers and the overall number of volunteer or community participation hours devoted to individual marine debris partnerships. Letters of commitment for any secured resources expected to be used as match for an award should be submitted as an attachment to the application.

**Intergovernmental Review:** Funding applications under NOAA are subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." It is the state agency's responsibility to contact their state's Single Point of Contact (SPCO) to find out about and comply with the state's process under EO 12372. To assist the applicant, the names and addresses of the SPOCs are listed on the Office of Management and Budget's Web site <http://www.whitehouse.gov/omb/grants/spoc.html>.

#### National Weather Service (NWS)

##### NWS Severe Weather Program

**Summary Description:** This funding opportunity will support a study that evaluates how customers and the public receive and interpret operational products, and then make critical decisions. The study should apply social science research techniques to evaluate the effectiveness of current

operational products, including graphics and uncertainty information, and to suggest more effective alternatives. It is expected the results of this study will be of interest to operational units, as well as emergency managers, public officials, and the weather enterprise as a whole.

**Funding Availability:** The total funding amount available for proposals is anticipated to be approximately \$125,000. However, there is no appropriation of funds at this time and no guarantee that there will be. An individual annual award in the form of a cooperative agreement is limited to a maximum of \$125,000 for one year. We anticipate making one award.

**Statutory Authority:** Authority for the Severe Weather program is provided by the following: 15 U.S.C. 313; 49 U.S.C. 44720(b); 33 U.S.C. 883d; 15 U.S.C. 2904; 15 U.S.C. 2934.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.467, Meteorologic and Hydrologic Modernization Development

**Application Deadline:** Full proposals must be received by Grants.gov or by mail on or before 5 p.m. EDT, March 1, 2010. For proposals submitted through grants.gov, a date and time receipt indication is included and will be the basis of determining timeliness. Please note: Validation or rejection of your application by Grants.gov may take up to 2 business days after submission. Please consider this process in developing your submission timeline. Hard copy proposals will be date and time stamped when they are received in the program office. Applications received after the deadline will be rejected/returned to the sender without further consideration. No facsimile or electronic mail applications will be accepted.

**Address for Submitting Proposals:** Proposals should be submitted through [www.grants.gov](http://www.grants.gov). For those organizations without internet access, proposals may be sent to Suzanne Lenihan, NOAA/NWS, 1325 East-West Highway, Room 14356, Silver Spring, Maryland 20910.

**Information Contacts:** The point of contact is Suzanne Lenihan, NOAA/NWS; 1325 East-West Highway, Room 14356; Silver Spring, Maryland 20910-3283, or by phone at 301-713-1792 ext. 121, by fax to 301-713-3107, or via e-mail at [suzanne.lenihan@noaa.gov](mailto:suzanne.lenihan@noaa.gov). An alternate point of contact is Jennifer Sprague, NOAA/NWS; 1325 East-West Highway, Room 11404; Silver Spring, Maryland 20910-3283, or by phone at 301-713-0217, by fax to 301-713-1239, or via e-mail at [jennifer.sprague@noaa.gov](mailto:jennifer.sprague@noaa.gov). Questions

concerning this announcement must be made via e-mail to [suzanne.lenihan@noaa.gov](mailto:suzanne.lenihan@noaa.gov) or [jennifer.sprague@noaa.gov](mailto:jennifer.sprague@noaa.gov).

**Eligibility:** Eligible applicants are institutions of higher education, other nonprofits, commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, and international organizations, state, local and Indian tribal governments.

**Cost Sharing Requirements:** No cost sharing is required under this program.

#### Intergovernmental Review:

Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

#### Tsunami Social Science Program

**Summary Description:** The Tsunami Program's mission is to provide reliable tsunami forecasts and warnings and promote community resilience and the program is committed to ensuring that all customers can receive, understand, and respond appropriately to NOAA forecast and warning products. The Tsunami Program recognizes the need to integrate social science information to support and improve its mission-related activities. This RFA requests social science research support to address three primary objectives: (1) Improve Tsunami Warning Center (TWC) products, including warnings, advisories, watches, and information statements, (2) Evaluate the Tsunami Ready Program Improvement, and (3) Assess previous and on-going tsunami-related social science studies including regional, state, and local efforts, to determine how to best integrate such information at the national level.

**Funding Availability:** The total funding amount available to the applicants over the course of the project is anticipated to be \$500,000.00. It is anticipated there will be one recipient of this award. Individual annual awards are limited to a maximum of \$166,667 per year for no more than three years.

**Statutory Authority:** 33 U.S.C. 3205.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.467, Meteorologic and Hydrologic Modernization Development.

**Application Deadline:** February 19, 2010

**Address for Submitting Proposals:** Applications must be submitted through [www.grants.gov](http://www.grants.gov) unless an applicant does not have internet access. In that case, hard copies with original signatures may be sent to: Jennifer Rhoades, NOAA/NWS, 1325 East West Highway, Room 13118, Silver Spring, Maryland 20910. Phone: 301-713-1677

x102; e-mail: [jenifer.rhoades@noaa.gov](mailto:jenifer.rhoades@noaa.gov). E-mail and fax submissions will not be accepted.

**Information Contacts:** Jenifer Rhoades, NOAA/NWS, 1325 East West Highway, Room 13118, Silver Spring, Maryland 20910, Phone: 301-713-1677 x102, e-mail: [jenifer.rhoades@noaa.gov](mailto:jenifer.rhoades@noaa.gov). Lewis Kozlosky, NOAA/NWS, 1325 East West Highway, Room 13123, Silver Spring, Maryland 20910, Phone: 301-713-1677 x108, e-mail: [lewis.kozlosky@noaa.gov](mailto:lewis.kozlosky@noaa.gov). Jennifer Sprague, NWS Strategic Planning and Policy, NOAA/NWS, 1325 East West Highway, Room 11404, Silver Spring, Maryland 20910, Phone: 301-713-0217, e-mail: [Jennifer.sprague@noaa.gov](mailto:Jennifer.sprague@noaa.gov).

**Eligibility:** Eligible applicants are institutions of higher education, other nonprofits, commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, and international organizations, state, local and Indian tribal governments.

**Cost Sharing Requirements:** No cost sharing is required under this program.

**Intergovernmental Review:** Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

**Oceanic and Atmospheric Research (OAR)**

NOAA Marine Aquaculture Initiative 2010.

**Summary Description:** The National Oceanic and Atmospheric Administration (NOAA) is seeking preliminary proposals and full proposals for a two-level competition supporting the development of environmentally and economically sustainable ocean, coastal, or Great Lakes aquaculture. This competition falls under the NOAA Mission to Protect, Restore and Manage the Use of Coastal and Ocean Resources Through Ecosystem-Based Management. Small grant projects will support regional or national outreach or informational dissemination activities including, but not limited to, symposia, conferences, web resources and synthesis publications dealing with important marine aquaculture issues, with an emphasis on evaluating the social, economic and environmental impacts of marine aquaculture on local coastal communities. Large grant projects will support innovative, applied research that results in short-term implementation of technologies that advance economically and environmentally sustainable marine aquaculture.

The top priorities for large grant and small grant projects FY 2010 and FY

2011 are: (1) Development of technologies and practices to advance integrated multi-trophic systems. (2) development of environmental and carrying capacity models and GIS tools to aid site selection for new facilities in the context of marine spatial planning and coastal management, and (3) development of alternative feedstuffs and diets that reduce the use of marine forage fish for marine culture species. Large grant projects that involve multiple partners (e.g., industry, academia, and community collaboration), outreach, and specific resource leveraging are encouraged and will be given higher rank and consideration.

Projects funded under this competition must support the NOAA Five-Year Research Plan performance objective to increase environmentally sound aquaculture production and NOAA's broader goals for its marine aquaculture program to: (a) Establish a comprehensive regulatory program for the conduct of marine aquaculture operations; (b) Develop appropriate technologies to support commercial marine aquaculture and enhancement of wild stocks; (c) Establish and implement procedures for the environmental assessment and monitoring of marine aquaculture activities; (d) Conduct education and outreach activities to establish a well informed public on marine aquaculture; and (e) Meet international obligations to promote environmentally sustainable practices for the conduct of marine aquaculture. Accomplishment of these goals should lead to a well-managed marine aquaculture industry in the United States; a well informed public that understands U.S. aquaculture issues, and improved access to the latest aquaculture research results.

**Funding Availability:** Depending on the FY 2010 and FY 2011 Congressional appropriations and the quality of proposals, NOAA expects to have available up to \$4 million for FY 2010 and FY 2011, with individual small grant projects up to \$50,000 for a two-year period; and large grant projects up to \$500,000 for a two-year period. Some funds in FY 2011 may be used to finish out projects started in FY 2010. We intend to fund projects for the full two-year project period (2010 and 2011) using FY 2010 funds. However, some funds in FY 2011 may be used to complete projects started in FY 2010. In addition we may use FY 2011 funds to start other two year projects identified through this competition. We also reserve the option to use some FY 2012 funds to finish projects started in FY 2011. It is anticipated that we will make

approximately three small grant awards and five large grant awards over the two-year cycle.

**Statutory Authority:** 33 U.S.C. 1121 et seq.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.417, Sea Grant Support.

**Application Deadline:** This is a two-level competition covering fiscal years 2010 and 2011. NOAA administers a biennial competition for marine aquaculture projects. This announcement is for the 2010-2011 cycle. This Federal Funding Opportunity includes information on application and criteria for two levels of grant proposal. "Small grants" are defined as those that request up to \$50,000 in federal funding for a two-year period. "Large grants" are those that request \$50,001-\$500,000 in federal funding for a two-year period. The timing of the application deadlines and review period differs for proposals submitted under each level. Small grant projects only require a full proposal. Small grant full proposals must be received and validated by Grants.gov on or before by 4 p.m. EST on December 3, 2009. Large grants require both a preliminary and a full proposal. Large grant preliminary proposals must be received by 4 p.m. EST on August 25, 2009. Feedback for large grant preliminary proposals is anticipated to be provided by NOAA to project applicants by October 14, 2009. Large grant full proposals must be received and validated by Grants.gov on or before 4 p.m. EST on December 10, 2009. The anticipated start date for both small grant and large grant projects is June 1, 2010.

**Address for Submitting Proposals:** Full proposals must be submitted through Grants.gov. Preliminary proposals for large grants must be sent via electronic mail to [oar.hq.sg.aquaculture@noaa.gov](mailto:oar.hq.sg.aquaculture@noaa.gov). For those applicants without proven internet access, preliminary and full proposals can be sent by hardcopy to Dr. Gene Kim, NOAA Sea Grant; 1315 East-West Highway, SSMC3, R/SG; Silver Spring, MD 20910. Facsimiles will not be accepted.

**Information Contacts:** Address to submit large grant preliminary proposals: [oar.hq.sg.aquaculture@noaa.gov](mailto:oar.hq.sg.aquaculture@noaa.gov). Agency contact for information regarding the NOAA Marine Aquaculture Initiative: Dr. Gene Kim, 301-734-1281; via e-mail at [Gene.Kim@noaa.gov](mailto:Gene.Kim@noaa.gov), Mailing Address: NOAA Sea Grant; 1315 East-West Highway, SSMC3, R/SG; Silver Spring,



MD 20910. No facsimiles will be accepted.

**Eligibility:** Institutions of higher education, nonprofit organizations, commercial organizations, Federal, State, local and Indian tribal governments and individuals are eligible. Only those who submit preliminary proposals by the preliminary proposal deadline are eligible to submit large grant full proposals. Small grant projects do not require preliminary proposals, but do require a full proposal. **Please note:** Before non-NOAA Federal applicants may be funded, they must demonstrate that they have legal authority to receive funds from another Federal agency in excess of their appropriation. Because this announcement is not proposing to procure goods or services from applicants, the Economy Act (31 U.S.C. 1535) is not an appropriate legal basis for federal eligibility.

**Cost Sharing Requirements:** Matching funds are NOT required. However, non-federal matching funds offered by the applicant will be considered positively in the Evaluation Criteria of Project Costs. Further, those proposals that combine resources from different institutions (e.g., private industry, universities, State agencies, foundations) to address national or regional issues will be considered in relation to Criteria One (Impacts) and Four (Project Cost and Budget) in this solicitation. Any matching funds offered by the applicant must be used as proposed and tracked and reported as a condition of the award.

**Intergovernmental Review:**

Applications under this Program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

**Office of the Under Secretary (USEC)**

Dr. Nancy Foster Scholarship Program

**Summary Description:** The Dr. Nancy Foster Scholarship Program provides support for independent graduate-level studies in oceanography, marine biology or maritime archaeology (including all science, engineering, and resource management of ocean and coastal areas), particularly to women and minorities. Individuals who are U.S. citizens and are applying to or have been accepted to a graduate program at a U.S. accredited institution may apply. Scholarship selections are based on academic excellence, letters of recommendations, research and career goals, and financial need. Applicants must have and maintain a minimum 3.0 grade point average each term and cumulatively and maintain full-time student status for the

duration of the appointment. Dr. Nancy Foster Scholarships may provide, subject to appropriations, yearly support of up to \$42,000 per student (a 12-month stipend of \$30,000 in addition to an education allowance of up to \$12,000), and up to \$10,000 support for a four to six week research collaboration at a NOAA facility. A maximum of \$94,000 may be provided to masters students (up to 2 years of support and one research collaboration opportunity) and up to \$188,000 may be provided to doctoral students (up to 4 years of support and two research collaboration opportunities). Dr. Nancy Foster Scholarship Program recipients will travel to Silver Spring, MD, during the week of May 31, 2010, for a NOAA Orientation and to meet with National Marine Sanctuaries Program staff. Awards will include travel expenses to attend the mandatory Scholarship Program orientation. Dr. Nancy Foster Scholarship recipients will also be required to participate in a research collaboration at a NOAA facility. Master's candidates will be supported for one research collaboration opportunity and Doctoral candidates will be supported for up to two research collaboration opportunities over the duration of the scholarship.

The research collaboration opportunity is designed to allow scholars to conduct their research at a NOAA facility and on NOAA mission research for four to six weeks. Scholars are required to provide their own health insurance coverage during the research collaboration. Federal support for the research opportunity may be used toward allowable travel costs such as: travel to and from the NOAA facility, housing, and per diem; while conducting research at the NOAA facility. Applicants who are awarded the Nancy Foster Scholarship will identify their research collaboration opportunity(s) topic and NOAA facility during the initial scholarship year. NOAA approval is required prior to embarking on the research collaboration. Additional Information about the scholarship can be obtained in the Federal Funding Opportunity announcement.

**Funding Availability:** Subject to appropriations, approximately \$500,000 will be available for FY 2010. Up to 10 new awards may be made, based on the availability of funds. The Dr. Nancy Foster Scholarship Program provides yearly support of up to \$42,000 per student (a 12-month stipend of \$30,000 in addition to a tuition allowance of up to \$12,000) and up to \$10,000 support for a four to six week research collaboration at a NOAA facility. A

maximum of \$94,000 may be provided to masters students (up to 2 years of support and one research collaboration opportunity) and up to \$188,000 may be provided to doctoral students (up to 4 years of support and up to two research collaboration opportunities). Travel support will also be provided to Dr. Nancy Foster Scholarship Program recipients to attend a NOAA orientation in Silver Spring, MD, where they will also meet with National Marine Sanctuaries Program leadership and staff.

**Statutory Authority:** 16 U.S.C. 1445c-1 and 16 U.S.C. 1445c.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.481, Educational Partnership Program

**Application Deadline:** Completed applications must be received by the Program Manager between January 1, 2010, and March 17, 2010, at 5 p.m. Eastern Standard Time. **Please Note:** All applicants, both electronic and paper, should be aware that adequate time must be factored into applicant schedules for delivery of the application. It may take Grants.gov up to two (2) business days to validate or reject the application. Please keep this in mind in developing your submission timeline. Electronic applicants are advised that volume on Grants.gov can be extremely heavy resulting in further delays. If Grants.gov is unable to accept applications electronically in a timely fashion, applicants are encouraged to exercise their option to submit applications in paper format. Paper applicants should allow adequate time to ensure a paper application is received on time, taking into account that guaranteed overnight carriers are not always able to fulfill their guarantees.

**Address for Submitting Proposals:** Except for institute certification, transcripts, and letters of recommendation, as discussed in Sections IV.B.6., IV.B.7, and IV.B.8. of the FFO, respectively, applications must be submitted through Grants.gov. If an applicant does not have internet access to complete the application through Grants.gov, hard copy applications may be submitted in one envelope to: Dr. Nancy Foster Scholarship Program Attn: Dr. Priti Brahma NOAA Office of Education 1315 East West Highway SSMC3, Room 10725 Silver Spring, MD 20910. Failure to submit all application items, except transcripts and letters of recommendation, in one envelope will result in disqualification of the application.

**Information Contacts:** Send requests for information to [fosterscholars@noaa.gov](mailto:fosterscholars@noaa.gov) or mail requests to Dr. Nancy Foster

Scholarship Program, ATTN: Dr. Priti Brahma, Office of Education, 1315 East-West Highway, SSMC3, Room 10725, Silver Spring, MD 20910.

**Eligibility:** Only individuals who are United States citizens currently pursuing a masters or doctoral level degree in oceanography, marine biology or maritime archaeology (including all science, engineering, and resource management of ocean and coastal areas) at a U.S. accredited graduate institution are eligible for an award under this scholarship program. In addition, students must have and maintain a minimum cumulative and term grade point average of 3.0 and maintain full-time student status for every term and for the duration of their award. Universities or other organizations may not apply on behalf of an individual. Prospective scholars do not need to be enrolled in a graduate program at the time of application, but must be admitted to a graduate level program in order to be awarded this scholarship. Eligibility must be maintained for each succeeding year of support and annual reporting requirements, to be specified at a later date, will apply.

**Cost Sharing Requirements:** There are no matching requirements for this award.

**Intergovernmental Review:** Applications under this program are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs.

Environmental Literacy Grants for Informal/Nonformal Science Education

**Summary Description:** The goal of this funding opportunity is to support projects that engage the public in educational activities that utilize emerging and/or advanced technologies and leverage NOAA assets to improve understanding, and stewardship of the local and global environment. There is specific interest in projects that use emerging and/or advanced technologies to (1) facilitate outdoor experiences involving scientific inquiry and exploration of the natural world apart from formal K-12 curricula and (2) visualize, display, and interpret data to improve understanding and provide a systems perspective of Earth's dynamic processes. This program has two priorities. Priority 1 is for large-scale projects that occur over a longer duration with regional to national implementation. Priority 2 is for small-scale projects that occur over a shorter duration with local to regional implementation. Funded projects will be between one and five years in duration. This program meets NOAA's Mission Support goal to provide critical

support for NOAA's mission. It is anticipated that awards under this announcement will be made by September 30, 2010 and that projects funded under this announcement will have a start date no earlier than October 1, 2010. **Note:** a PDF version of this announcement is available at [http://www.oesd.noaa.gov/funding\\_opps.html](http://www.oesd.noaa.gov/funding_opps.html).

**Funding Availability:** NOAA anticipates the availability of approximately \$7,500,000 of total Federal financial assistance in FY 2010 and FY 2011 anticipated for Environmental Literacy Grants for Informal/Nonformal science education. Approximately 5 to 10 awards in the form of grants or cooperative agreements will be made. For Priority 1, the total Federal amount that may be requested from NOAA shall not exceed \$1,250,000 for all years including direct and indirect costs. The minimum Federal amount that must be requested from NOAA for all years for the direct and indirect costs for this priority is \$500,001. Applications requesting Federal support from NOAA of more than \$1,250,000 or less than \$500,001 total for all years will not be considered for funding. For Priority 2, the total Federal amount that may be requested from NOAA shall not exceed \$500,000 for all years including direct and indirect costs. The minimum Federal amount that must be requested from NOAA for all years for the direct and indirect costs for this priority is \$200,000. Applications requesting Federal support from NOAA of less than \$200,000 or more than \$500,000 total for all years will not be considered for funding. The amount of funding available through this announcement will be dependent upon final FY 10 and FY 11 appropriations. Publication of this notice does not obligate NOAA to award any specific project or to obligate any available funds. It is likely that there will be no additional funding opportunity issued for these types of projects in FY 11. If an applicant incurs any costs prior to receiving an award agreement from an authorized NOAA Grants Officer, the applicant would do so solely at one's own risk of such costs not being included under the award. The exact amount of funds that may be awarded will be determined in pre-award negotiations between the applicant and NOAA representatives.

**Statutory Authority:** Authority for this program is provided by the 33 U.S.C. 893a(a).

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.008, Mission-Related Education Awards.

**Application Deadline:** The deadline for letters of intent is 5:00 PM EST

February 16, 2010. The deadline for applications is 5 p.m. EDT on April 6, 2010. Applications submitted through [Grants.gov](http://Grants.gov) are automatically date/time stamped when they are validated and submitted to the Agency. Hard copy applications must be provided to an expedited shipping service by the deadline and proof of this must be provided by the applicant. **Please Note:** When submitting through [Grants.gov](http://Grants.gov), you will receive 2 e-mails. An initial e-mail will be sent to confirm your attempt to submit a proposal. This is NOT a confirmation of acceptance of your application. It may take [Grants.gov](http://Grants.gov) up to two (2) business days to validate or reject the application and send you a second e-mail. Please keep this in mind in developing your submission timeline. An informational teleconference with the program officers will occur on January 21st 2010 (time TBD). Interested applicants should register by contacting [oed.grants@noaa.gov](mailto:oed.grants@noaa.gov) and include in the Subject line of the e-mail: "Interested in FFO Teleconference—Need Details" and provide the interested parties name, institution and telephone number in the body of the e-mail. Whenever possible people from the same institution should try to call in through the same phone line.

**Address for Submitting Proposals:** Address to submit letters of intent: Letters of intent must be submitted by e-mail to [oed.grants@noaa.gov](mailto:oed.grants@noaa.gov). If applicant does not have Internet access, a hard copy of the letter will be accepted and should be delivered to: Stacey Rudolph, Dept. of Commerce, NOAA Office of Education, 1401 Constitution Avenue NW, HCHB 6863, Washington, DC 20230; Telephone: 202-482-3739. **Please note:** hard copy applications submitted via the US Postal Service can take up to 4 weeks to reach this office; therefore applicants are advised to send hard copy applications via expedited shipping methods (e.g., Airborne Express, DHL, Fed Ex, UPS). Address to submit applications: Applications must be submitted through [Grants.gov](http://Grants.gov) APPLY (<http://www.grants.gov>). However, if an applicant does not have Internet access or [Grants.gov](http://Grants.gov) is overwhelmed with traffic, hard copy applications will be accepted and should be delivered to: Stacey Rudolph, Dept. of Commerce, NOAA Office of Education, 1401 Constitution Avenue NW, HCHB 6863, Washington, DC 20230; Telephone: 202-482-3739. Please note: hard copy applications submitted via the US Postal Service can take up to 4 weeks to reach this office; therefore applicants are

advised to send hard copy applications via expedited shipping methods (e.g., Airborne Express, DHL, Fed Ex, UPS).— See the Office of Education's frequently asked questions site: [http://www.oesd.noaa.gov/elg/elg\\_faqs.html](http://www.oesd.noaa.gov/elg/elg_faqs.html) for more details.

**Information Contacts:** Please visit the OEd Web site for further information at [http://www.oesd.noaa.gov/funding\\_opps.html](http://www.oesd.noaa.gov/funding_opps.html) or contact the Program Officers: Carrie McDougall at 202-482-0875; or Sarah Schoedinger at 704-370-3528; or John McLaughlin at 202-482-2893 or by e-mailing any of them at [oed.grants@noaa.gov](mailto:oed.grants@noaa.gov). Projects involving spherical display systems require consultation with John McLaughlin, [john.mclaughlin@noaa.gov](mailto:john.mclaughlin@noaa.gov), 202-482-2893 or Carrie McDougall [carrie.mcdougall@noaa.gov](mailto:carrie.mcdougall@noaa.gov), 202-482-0875 prior to submission of the application. For those applicants without Internet access, hard copies of referenced documents may be requested from NOAA's Office of Education by contacting Stacey Rudolph at 202-482-3739 or sending a letter to: Stacey Rudolph; Dept. of Commerce, NOAA Office of Education, 1401 Constitution Avenue NW., HCHB 6863, Washington, DC 20230; Telephone: 202-482-3739.

**Eligibility:** Eligible applicants are institutions of higher education, other nonprofits, and state, local and Indian tribal governments in the United States. For-profit organizations, K-12 public and independent schools and school systems, foreign institutions, foreign organizations and foreign government agencies are not eligible to apply. For-profit and foreign organizations can be project partners. Federal agencies are not eligible to receive Federal assistance under this announcement, but may be project partners. The Department of Commerce/National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to increasing the participation of Minority Serving Institutions (MSIs), i.e., Historically Black Colleges and Universities, Hispanic-serving institutions, Tribal colleges and universities, Alaskan Native and Native Hawaiian institutions, and institutions that work in underserved communities. Applications are encouraged that involve any of the above types of institutions. An individual may apply only once as principal investigator (PI) through this funding opportunity. However institutions may submit more than one application and individuals may serve as co-PIs or key personnel on more than one application.

**Cost Sharing Requirements:** There is no cost share requirement.

**Intergovernmental Review:** Applications submitted to this funding opportunity are not subject to Executive Order 12372, Intergovernmental Review of Federal Programs. Financial Assistance to Establish five NOAA Cooperative Science Centers at Minority Serving Institutions Announcement.

**Summary Description:** The purpose of this document is to announce to the public that in the spring of 2010, NOAA's Office of Education (OEd), Educational Partnership Program (EPP) with MSIs anticipates soliciting applications from accredited postsecondary MSIs to establish five NOAA Cooperative Science Centers (CSCs). These five Centers are designed to create collaborative partnerships among MSIs and NOAA's five Line Offices (LOs) including: National Environmental Satellite, Data, and Information Service (NESDIS); National Marine Fisheries Service (NMFS); National Weather Service (NWS); National Ocean Service (NOS); and, Office of Oceanic and Atmospheric Research (OAR). NOAA's mission as stated in the FY2009-2014 NOAA Strategic Plan, is understand and predict changes in Earth's environment and conserve and manage coastal and marine resources to meet our nation's economic, social, and environmental needs. Additional information about NOAA may be found on the Web site: [www.noaa.gov](http://www.noaa.gov). Each NOAA Cooperative Science Center must conduct research and education that directly supports NOAA's mission. The purpose of these Centers at Minority Serving Institutions is to: (1) Conduct research in collaboration with NOAA to better understand the significance of changes in the Earth's ocean, coasts, Great Lakes, weather and climate; (2) educate students in science, technology, engineering, and mathematics (STEM) related to the Centers' research to expand the size and diversity of NOAA and the nations STEM workforce; and, (3) build capacity and sustainability at all Center institutions. The Centers are to collaborate with NOAA by partnering with NOAA employees to conduct research and education that supports NOAA's mission. The Centers are to leverage this research and education to train and graduate students in NOAA-mission STEM fields. The Centers are to build sustainable capacity, including upgraded lab facilities, additional faculty and other research capacity that will enhance their ability to conduct NOAA research and education that contributes to a pipeline of students trained in STEM fields. The EPP is designed to enhance capacity at MSIs

that educate, train, and graduate students in STEM and serve the purpose of increasing environmental literacy by establishing partnerships with academia, the private sector, and other Federal, state, tribal and local agencies. The program description of EPP may be found on the Web site:

[www.epp.noaa.gov](http://www.epp.noaa.gov). Please consult both the Federal Register Notice (FRN) and the Federal Funding Opportunity announcement that will be available spring 2010. Letters of Intent (LOI) are not required. However, interested parties may submit LOI to NOAA EPP no later than 2 p.m. Eastern Standard Time, January 22, 2010. The LOIs will assist NOAA in determining the number and locations for programmatic informational sessions. NOAA plans to announce dates of the programmatic information sessions in the spring 2010 FRN.

**Funding Availability:** Subject to Congressional appropriations, NOAA anticipates making awards in the summer 2011. Awards will be made annually for a five-year period and are subject to the availability of funds and acceptable performance.

**Statutory Authority:** 15 U.S.C. 1540, 49 U.S.C. 44720, 33 U.S.C. 883d, 33 U.S.C. 1442, 16 U.S.C. 1854(e), 16 U.S.C. 661, 16 U.S.C. 753(a), 16 U.S.C. 1451 et seq., 16 U.S.C. 1431, 33 U.S.C. 883a; Executive Orders 13230, 13256, 13270, 13336, and 13339; and, America Competes Act H.R. 2272.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.481, Educational Partnership Program.

**Application Deadline:** The application is July 19, 2010.

**Address for Submitting Proposals:** Letters of Intent may be e-mailed to [jacqueline.j.rousseau@noaa.gov](mailto:jacqueline.j.rousseau@noaa.gov) or [meka.laster@noaa.gov](mailto:meka.laster@noaa.gov). Hard copies may be sent to Jacqueline Rousseau or Meka Laster, NOAA Office of Education, Educational Partnership Program, 1315 East-West Highway, Silver Spring, MD 20910. The LOI may be faxed to 301-713-9465 and directed to Jacqueline Rousseau or Meka Laster. In the Letters of Intent please include the following information: (1) The name of the MSI per the Department of Education web pages (see eligibility below); (2) the full name of the Ph.D.-granting institution; and, (3) the NOAA LO with which the Center will partner.

**Information Contacts:** Administrative and technical questions: Jacqueline Rousseau (Federal Program Officer), telephone 301-713-9437 ext. 124, fax 301-713-9465, or e-mail [jacqueline.j.rousseau@noaa.gov](mailto:jacqueline.j.rousseau@noaa.gov). The alternative technical contact is Meka

Laster, telephone 301-713-9437 ext. 147.

**Eligibility:** For the purpose of this program, Historically Black Colleges and Universities, Hispanic-Serving Institutions, Indian Tribally Controlled Colleges and Universities, Alaska Native-Serving Institutions, and Native Hawaiian-Serving Institutions, as identified on the 2007 United States Department of Education, Accredited Postsecondary Minority Institution list (<http://www.ed.gov/about/offices/list/ocr/edlite-minorityinst.html> and <http://www.ed.gov/about/offices/list/ocr/edlite-minorityinst-list-tab.html>) are eligible to apply. A proposed Center's principal academic institution must be an accredited MSI with a Ph.D. -granting degree program in a STEM field that supports NOAA's mission. Applications will not be accepted from non-profit organizations (that are not classified as Institutions of Higher Education), foundations, auxiliary services or any other entity submitted on behalf of MSIs.

**Cost Sharing Requirements:** Not Applicable.

**Intergovernmental Review:** Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

**National Environmental Satellite Data and Information Service (NESDIS)**

Satellite Climate Data Record Program for 2010

**Summary Description:** For this program, NOAA announces an amendment to the Federal Funding Opportunity (NESDIS-NESDISPO-2009-2001589) entitled "Scientific Data Stewardship Project Office for 2009," which was originally announced in the **Federal Register** on Monday, October 6, 2008 (73 FR 58129). This change concerns the Funding Availability published in the October 6, 2008 notice. In FY2010, the Satellite Climate Data Record Program (CDRP) does not plan to solicit or accept new proposals for FY2010 funding. FY2010 funds will be used to issue additional awards for applications submitted in response to the FY2009 announcement. All other requirements published in the original solicitation remain unchanged.

**Funding Availability:** The total anticipated federal funding in FY 2010 is \$1,500,000.00 for new awards. The anticipated number of new awards is from 3 to 8.

**Statutory Authority:** 49 U.S.C. 4472(b) and 33 U.S.C. 883d.

**Catalog of Federal Domestic Assistance (CFDA) Number:** 11.440,

Environmental Sciences, Applications, Data, and Education.

**Application Deadline:** N/A.

**Address for Submitting Proposals:** N/A.

**Information Contacts:** Satellite CDRP Manager: Jeff Privette, NOAA Satellite Climate Data Record Program Office, 151 Patton Ave, Asheville, NC 28801; Phone: 828-271-4331; E-mail: [Jeff.Privette@noaa.gov](mailto:Jeff.Privette@noaa.gov). Satellite CDRP Grants Manager: Linda S. Statler, NOAA Satellite Climate Data Record Program Office, 151 Patton Ave, Asheville, NC 28801; Phone: 828-271-4657; E-mail: [Linda.S.Statler@noaa.gov](mailto:Linda.S.Statler@noaa.gov).

**Eligibility:** N/A.

**Cost Sharing Requirements:** N/A.

**Intergovernmental Review:** N/A.

**VI. Request for comments on Proposed Implementation Guidelines for the Coral Reef Conservation Program**

**Summary**

This is a request for comments on NOAA's proposed revisions to the Grant Program Implementation Guidelines (Guidelines) for the Coral Reef Conservation Program (Program) under the Coral Reef Conservation Act of 2000 (Act). The Act authorizes the Secretary of Commerce (Secretary), through the NOAA Administrator (Administrator) and subject to the availability of funds, to provide matching grants of financial assistance for coral reef conservation projects under the Act. NOAA has developed this set of proposed Implementation Guidelines for the Grant Program for Fiscal Year (FY) 2011 through FY 2015. NOAA proposes to utilize several existing grant programs and mechanisms to implement the Program. Specific Program information including available funding, dates, detailed application requirements and proposal evaluation criteria will be published annually in separate **Federal Register** solicitations. In accordance with the Act, NOAA developed a National Coral Reef Action Strategy (Strategy) in 2002 to provide an implementation plan to advance coral reef conservation, including a basis for funding allocations to be made under the Program. In response to an external program review in 2007, a new program manager, development of a "Roadmap" for the future of the Program, and publication in 2009 of the Program's new 20-year Goals and Objectives and International Strategy, the Program is revising its Grant Program Implementation Guidelines to align more closely with the Program's new direction. The Final Grant Program Implementation Guidelines will be published concurrently with the FY

2011 solicitations in mid-2010. The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696), will be applicable to solicitations under this Program. This request is not a solicitation for project proposals.

**Dates**

In order to be considered, comments on this document must be received by NOAA on or before February 12, 2010.

**Addresses**

Only written comments will be accepted. Please send your comments by mail, e-mail or fax to: Jenny Waddell, NOAA Coral Reef Conservation Program, Office of Ocean and Coastal Resource Management, NOAA National Ocean Service, 1305 East-West Highway, 10th floor, Silver Spring, MD 20910, Fax: 301-713-4389. E-mail transmission of comments should be directed to [Jenny.Waddell@noaa.gov](mailto:Jenny.Waddell@noaa.gov).

**FURTHER INFORMATION CONTACT:** For further information, contact Jenny Waddell, Grants and External Funding Coordinator, OCRM/Coral Conservation Division, NOAA National Ocean Service, 1305 East-West Highway, Silver Spring, MD 20910; 301-713-3155 extension 150, Internet: [jenny.waddell@noaa.gov](mailto:jenny.waddell@noaa.gov); or Jennifer Koss, NMFS Habitat Conservation, NOAA National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910; 301-713-3459 extension 195, E-mail: [Jennifer.Koss@noaa.gov](mailto:Jennifer.Koss@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Coral Reef Conservation Act of 2000 (16 U.S.C. 6401 *et seq.*) was enacted on December 14, 2000, for the following purposes:

1. To preserve, sustain and restore the condition of coral reef ecosystems;
2. To promote the wise management and sustainable use of coral reef ecosystems to benefit local communities and the Nation;
3. To develop sound scientific information on the condition of coral reef ecosystems and the threats to such ecosystems;
4. To assist in the preservation of coral reefs by supporting conservation programs, including projects that involve affected local communities and non-governmental organizations;
5. To provide financial resources for those programs and projects; and
6. To establish a formal mechanism for the collecting and allocating of monetary donations from the private

sector to be used for coral reef conservation projects.

Under section 6403 of the Act, the Secretary, through the NOAA Administrator (Administrator) and subject to the availability of funds, is authorized to provide matching grants of financial assistance for coral reef conservation projects. Section 6408(c) of the Act authorizes up to \$8,000,000 annually for projects under the Program. As required under section 6403(j) of the Act, NOAA developed Implementation Guidelines for the Program in 2002 and through this request, is refining those Guidelines. The revised guidelines proposed herein are intended to update and replace the existing guidelines in order to shift focus toward implementation of the Program's 20-year Goals and Objectives and International Strategy in an effort to narrow and sharpen the focus of the Program. NOAA is making the revised guidelines in this request available for public review and comment in advance of implementation.

Each fiscal year the Program will publish Federal Register notices to describe the availability of funds under each grant category and solicit project proposals. These annual solicitations provide greater detail on the year's program priorities, application process, and proposal evaluation criteria. This request is not a solicitation for project proposals.

#### Electronic Access

The Coral Reef Conservation Act of 2000 can be found on the Internet at: <http://thomas.loc.gov/> (Select Bill Text, then select 106th Congress, search on Bill Number HR 1653, select H.R. 1653.EH). Information on the U.S. Coral Reef Task Force, established June 11, 1998 under Executive Order 13089, can be found at: <http://coralreef.gov>. The National Coral Reef Action Strategy, which was published in 2002, is available at: <http://coris.noaa.gov/activities/actionstrategy/>. The Program's 20-year Goals and Objectives, which were published in 2009, can be found at: [http://coralreef.noaa.gov/aboutcrp/strategy/currentgoals/resources/3threats\\_go.pdf](http://coralreef.noaa.gov/aboutcrp/strategy/currentgoals/resources/3threats_go.pdf) and the International Strategy, also published in 2009, is available at: [http://coralreef.noaa.gov/aboutcrp/strategy/currentgoals/resources/intl\\_strategy.pdf](http://coralreef.noaa.gov/aboutcrp/strategy/currentgoals/resources/intl_strategy.pdf).

#### Coral Reef Conservation Program

The objective of the Grant Program is to provide financial assistance for coral reef conservation programs and projects consistent with the Act, the National Coral Reef Action Strategy, and the Program's 20-year Goals and Objectives

and International Strategy, which were published in June 2009. NOAA's role in administering the Program is to strengthen and support the development and implementation of sound coral reef conservation projects, as well as ensure that the most beneficial projects are recommended for funding.

#### Applicant Eligibility Requirements

As per section 6403(c) of the Act, eligible applicants include: Any natural resource management authority of a state or other government authority with jurisdiction over coral reefs or whose activities directly or indirectly affect coral reefs or coral reef ecosystems, or educational or non-governmental institutions with demonstrated expertise in the conservation of coral reefs. Each category of funding under this Program, as described in Section VII of the FFO, encompasses a specific subgroup of eligible applicants.

As a matter of policy, funding of Federal agency activities under this Program will be a low priority unless such activities are an essential part of a cooperative project with other eligible governmental or non-governmental entities.

NOAA agencies are not eligible for funding under this Program, as funding for such activities is provided for under section 6406 of the Act (National Program).

#### Eligible Coral Reef Conservation Activities

As described in section 6403(g) of the Act, projects considered for funding under this Program must be consistent with the National Coral Reef Action Strategy. Concordance with the Program's 20-year Goals and Objectives and International Strategy guidance documents published in 2009 to narrow and sharpen the priorities included in the National Coral Reef Action Strategy will be an additional criterion in evaluating eligible projects and activities. In addition, coral reef management priorities identified by states, territories and commonwealths containing coral reef ecosystems through a formal management priority setting process will be considered when evaluating and selecting proposals once those processes have been completed in 2010. Further, per the same section, the Administrator may not approve a project proposal unless it will enhance the conservation of coral reefs by addressing at least one of the following:

1. Implementing coral conservation programs which promote sustainable development and ensure effective, long-term conservation of coral reefs;

2. Addressing the conflicts arising from the use of environments near coral reefs or from the use of corals, species associated with coral reefs, and coral products;

3. Enhancing compliance with laws that prohibit or regulate the taking of coral products or species associated with coral reefs or regulate the use and management of coral reef ecosystems;

4. Developing sound scientific information on the condition of coral reef ecosystems or the threats to such ecosystems, including factors that cause coral disease;

5. Promoting and assisting to implement cooperative coral reef conservation projects that involve affected local communities, nongovernmental organizations, or others in the private sector;

6. Increasing public knowledge and awareness of coral reef ecosystems and issues regarding their long term conservation;

7. Mapping the location and distribution of coral reefs;

8. Developing and implementing techniques to monitor and assess the status and condition of coral reefs;

9. Developing and implementing cost-effective methods to restore degraded coral reef ecosystems; or

10. Promoting ecologically sound navigation and anchorages near coral reefs.

#### Program Funding and Distribution

Section 6408(c) of the Act authorizes up to \$8,000,000 annually for financial assistance awards administered by the Coral Reef Conservation Program. The number of individual awards to be made each year will depend on the total amount of funds appropriated for coral reef activities within NOAA and the portion of those funds that are allocated to this Program.

More information about each category of funding, including the total annual Program funding amount, suggested ranges for funding requests, and specific funding categories under which an applicant may choose to be considered, will be published in the Program's annual **Federal Register** solicitations.

Program funding awarded during any given fiscal year will be distributed, per section 6403(d) of the Act, in the following manner:

1. No less than 40 percent of funds available shall be awarded for coral reef conservation projects in the Pacific Ocean within the maritime areas and zones subject to the jurisdiction or control of the United States;

2. No less than 40 percent of funds available shall be awarded for coral reef conservation projects in the Atlantic

Ocean, Gulf of Mexico and the Caribbean Sea within the maritime areas and zones subject to the jurisdiction or control of the United States; and

3. Remaining funds shall be awarded for projects that address emerging priorities or threats, including international priorities or threats, identified by the Administrator. When identifying emerging threats or priorities, the Administrator may consult with the Coral Reef Task Force.

#### *Funding Categories and Mechanisms*

In order to ensure adequate funding for each of the purposes envisioned under the Act and provide for a balanced overall Program, existing NOAA programs will be used to award funds in the funding categories described below. Each of the categories references the general activity and applicant eligibility requirements associated with proposals submitted therein. Specific activity and applicant eligibility information and proposal evaluation criteria for each category, consistent with Guideline sections: Applicant Eligibility Requirements, Program Funding and Distribution, Matching Funds, Application Process, and Project Review, will be published in each year's solicitations for proposals.

1. Coral Reef Management and Monitoring Cooperative Agreements support U.S. state and territorial government coral reef conservation management and monitoring activities, as described in section V(1-10) of the Guidelines (section 6403(g) of the Act) for the purposes of monitoring and comprehensively managing coral reef ecosystems and associated fisheries within their jurisdictions. Monitoring of coral reef ecosystems under this category includes the collection, analysis, and reporting of long-term coral reef monitoring data pursuant to scientifically valid methodologies and protocols. Eligibility to receive an award is limited to one agency in each state or territory with jurisdiction over coral reefs, as designated by the respective governors. These proposals will be reviewed and awarded by the National Ocean Service (NOS) Office of Ocean and Coastal Resource Management (OCRM) and awarded under Catalog of Federal Domestic Assistance (CFDA) number 11.419.

2. General Coral Reef Conservation Grants provide funding to non-governmental entities not eligible under other categories, for the purpose of implementing cooperative coral reef conservation, protection, restoration, or education projects, as described in section V(1-10) of the Guidelines (section 6403(g) of the Act) and

consistent with the Program's 20-year Goals and Objectives, published in 2009. These proposals will be reviewed and awarded by the National Ocean Service (NOS) Office of Ocean and Coastal Resource Management (OCRM) under CFDA 11.419.

3. Fishery Management Council Cooperative Agreements support projects to develop, improve, or amend Fishery Management Plans to conserve, protect and restore coral reef habitats and associated fishery populations within the U.S. Exclusive Economic Zone, with the overall goal of improving the management of coral reefs and associated organisms through the avoidance of fishing impacts, ecosystem management or similar approaches and practices, as described in section V(3) of the Guidelines (section 6403(g)(3) of the Act) and consistent with the Program's 20-year Goals and Objectives, published in 2009. Eligible applicants include Regional Fishery Management Councils with jurisdiction over coral reefs, as established under the Magnuson-Stevens Fishery Conservation and Management Act (16 USC 1801 *et seq.*). These proposals will be reviewed and awarded by the NMFS Office of Habitat Conservation under CFDA 11.441.

4. International Grants and Cooperative Agreements will be awarded for the purpose of implementing cooperative coral reef conservation activities as described in section V(1-10) of the Guidelines (section 6403(g) of the Act) and consistent with priorities identified in the Program's International Strategy published in June 2009. Eligible applicants include international governmental and non-governmental entities, including those in the Freely Associated States of the Pacific. These proposals will be reviewed and awarded by the NOS International Programs under CFDA 11.463.

Annual solicitations published in the **Federal Register** will establish the range of funds available and specific evaluation criteria for each funding category. NOAA may add additional funding categories in the annual solicitation based on available funding and/or the Program's coral reef conservation priorities. Applicants will be required to specify in their application the category(s) under which they are applying for funding. Selected applications may be funded and awards administered by NOAA, through either NMFS or NOS. Generally, one award will be made for each proposal accepted for funding.

NOAA will determine the most appropriate funding mechanisms (grant, cooperative agreement, or interagency

agreement) for selected individual projects, in consultation with the applicant, based on the degree of direct NOAA involvement with the project beyond the provision of financial assistance. Substantial federal involvement in cooperative agreements may include participation of NOAA/CRCP staff in the planning, development and implementation of projects and/or provision of technical assistance, and will vary based on the category of funding, type of project, and type and experience of the award recipient. Proposals from non-Federal applicants that are selected for funding will be funded either through a project grant or cooperative agreement. Selected Federal proposals will be funded through interagency agreements; however, under the Program, such agreements must include a local sponsor of the coral reef conservation project.

#### *Matching Funds*

As per section 6403(b)(1) of the Act, Federal funds for any coral conservation project funded under this Program may not exceed 50 percent of the total costs of such project, and NOAA strongly encourages applicants to leverage as much investment as possible. Matching funds may comprise a variety of public and private sources and can include in-kind contributions and other non-cash support, but all matching funds must be from non-Federal sources. Federal funds may not be considered as matching funds. For applicants who cannot meet the match requirement, as per section 6403(b)(2) of the Act, the Secretary may waive all or part of the matching requirement if the Administrator determines that the project meets the following two requirements:

1. No reasonable means are available through which an applicant can meet the matching requirement, and
2. The probable benefit of such project outweighs the public interest in such matching requirement.

Applicants must specify in their proposal the source and amount of the proposed match and may be asked to provide letters of commitment to confirm stated contributions. In the case of a waiver request, the applicant must provide a detailed justification explaining the need for the waiver, as described in section IX(6) of these Guidelines. Notwithstanding any other provision herein, and in accordance with 48 U.S.C. 1469a(d), this Program shall waive any requirement for local matching funds for any project under \$200,000 (including in-kind contributions) to the governments of Insular Areas, defined as the jurisdictions of the U.S. Virgin Islands,

Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

#### Application Process

NOAA will publish in the **Federal Register** annual notifications soliciting project proposals under the categories described above and pursuant to these Guidelines. Applications submitted in response to solicitation notices will be screened for eligibility and conformance with the Program Guidelines.

To submit a proposal, a complete NOAA standard grants application package must be filed in accordance with the guidelines in this document and instructions in the Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of February 11, 2008 (73 FR 7696).

A more detailed description of specific application requirements will be published in the annual solicitation; however, pursuant to section 6403(e) of the Act, each application must include the following elements:

1. A cover sheet with the name of the individual or entity responsible for conducting the project;

2. A description of the qualifications of the individual(s) who will conduct the project;

3. A succinct statement of the purpose(s) of the project, including the specific geographic location where the project will be carried out;

4. An estimate of the funds and time required to complete the project including: a detailed breakdown by category of cost estimates as they relate to specific aspects of the project, with appropriate justification for both the Federal and non-Federal shares;

5. Evidence of support for the project by appropriate representatives of states or other government jurisdictions in which the project will be conducted, including obtaining or proceeding to obtain all applicable State and/or Federal permits, consultations, and consistencies. U.S. state or territorial applicants must also provide evidence of coordination with all relevant state or territorial agencies, including a list of agencies consulted in developing the proposal;

6. Information regarding the amount of matching funding available to the applicant. In the case of a waiver request, the applicant must provide a detailed justification explaining the need for the waiver including attempts to obtain sources of matching funds, how the benefit of the project outweighs the public interest in providing match, and any other extenuating

circumstances preventing the availability of match;

7. A description of how the project meets one or more of the goals and objectives stated in section V of the Guidelines (section 6403(g) of the Act) and contributes to the conservation needs identified in the Program's 20-year Goals and Objectives and/or addresses jurisdiction-specific management priorities established through CRCP's management priority setting processes; and

8. Any other information the Administrator considers necessary for evaluating the eligibility of the project for funding under this title.

Applicants must indicate under which category(s) (as described in the "Funding Categories and Mechanisms" section of these Guidelines) they are seeking funds, and are encouraged to submit only one comprehensive application per solicitation.

#### Project Review

As per section 6203(f) of the Act, NOAA will review eligible coral reef conservation proposals using an external governmental review and merit-based peer review. After such reviews, NOAA will implement an internal ranking and selection process. The overall project review and selection process will include the following five steps:

1. NOAA will request and consider written comments on the proposal from each Federal agency, state government, or other government jurisdiction, including the relevant regional Fishery Management Councils established under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), or any National Marine Sanctuary, with jurisdiction or management authority over coral reef ecosystems in the area where the project is to be conducted. Pursuant to this requirement of the Act, NOAA will apply the following standard in requesting comments: (A) Proposals for projects in state or territorial waters, including Federal marine protected areas in such waters (e.g. National Marine Sanctuaries), will be submitted to that state or territorial government's designated U.S. Coral Reef Task Force point of contact for comment; (B) Proposals for projects in Federal waters will be submitted to the relevant Fishery Management Council for comment; (C) Proposals for projects which require Federal permits will be submitted to the Federal agency which issued the permit for comment; (D) Proposals for projects in Federal marine protected areas managed by Federal agencies (e.g. National Wildlife Refuges, National

Parks, National Marine Sanctuaries, etc.) will be submitted to the respective Federal management authority for comment; and (E) NOAA will seek comments from other government entities, authorities, and/or jurisdictions, including international entities for projects proposed outside of U.S. waters, as necessary based on the nature and scope of the proposed project. Specifically, agencies will be requested to comment on: the extent to which the project is consistent with locally established coral reef conservation priorities and projects; whether the project has been coordinated with existing or planned projects; suggestions for improving project coordination and/or technical approach; and appropriate staff points of contact. Each entity will be provided 21 days to review and comment on subject proposals. Comments submitted will be part of the public record.

2. Each NOAA program office will provide for a merit-based peer review and standardized documentation of that review for proposals considered appropriate for funding under their respective category(s). Each proposal will be reviewed by a minimum of three individuals with knowledge of the subject of the proposal. Each reviewer will submit a separate and individual review and reviewers will not provide a consensus opinion. The identities of the peer reviewers will be kept anonymous to the degree permitted by law. Specific evaluation criteria for projects submitted under each funding category will be published in the category's respective annual **Federal Register** solicitation.

3. Each NOAA Coral Reef Conservation Program Office will subsequently implement an internal review process to rank each proposal that is appropriate for funding under their program based upon consideration of: comments and recommendations from the reviews under paragraphs (1) and (2), and their evaluation of each proposal consistent with the five following criteria: (A) Direct Benefit to Coral Reef Resources and Ecosystems. NOAA will evaluate proposals based on the potential of the project to meet goals and objectives stated in section 6403(g) of the Act. (B) Technical Merit and Adequacy of Implementation Plan. Proposals will be evaluated on the technical feasibility of the project and the qualifications of project leaders and/or partners based on demonstrated abilities to: (i) Deliver the conservation objective stated in the proposal; (ii) Provide educational benefits, where appropriate; (iii) Incorporate assessment of project success in terms of meeting

the proposed objectives; (iv) Demonstrate that the conservation activity will be sustainable and long-lasting; (v) Provide assurance that implementation of the project will meet all state environmental laws and Federal consistency requirements by obtaining or proceeding to obtain applicable permits and consultations; and (C) Past Performance. Proposals will be evaluated on the previous accomplishments of the applicants in achieving coral reef conservation objectives similar to those outlined in section V. Eligible Coral Reef Conservation Activities of these Guidelines. This includes the timely submission of all required financial and progress reports and project products, including data and FGDC-compliant metadata records if applicable. Applicants submitting their first coral reef conservation project should document past experience in successfully carrying out related grant-funded activities; (D) Consistency with the National Coral Reef Action Strategy, the National Action Plan to Conserve Coral Reefs, and the Program's 20-year Goals and Objectives and International Strategy. Proposals will be evaluated on how well they align with the programmatic priorities outlined in these guidance documents and the jurisdiction-specific priorities established in the CRCP's management priority setting processes. Applicants are strongly encouraged to review all relevant documents and identify in their application the specific conservation objectives that their project proposal will achieve; and (E) Cost-effectiveness and Budget Justification. Proposals will be evaluated on their ability to demonstrate that significant benefit will be generated for the most reasonable cost. Projects will also be reviewed in terms of their need for funding and the ability of NOAA funds to act as a catalyst to implement projects and precipitate partnerships and other sources of funding to achieve conservation objectives. Preference will be given to projects that will be completed within a period of 12 months from the time the awards are distributed;

4. A NOAA review panel made up of representatives from each relevant Program office will review the project rankings from each program office and make consensus-based, final project selections and funding recommendations to be presented to the NOAA Administrator, or his designee, for final approval. The review panel and Administrator, or designee, will ensure that the Act requirements for geographic

funding distribution and consistency with the overall Program goals have been met. NOAA reserves the right to consult with applicants, prior to making an award, to determine the exact amount of funds to be awarded, as well as the most appropriate funding category and mechanism under which to consider the project for funding; and 5. NOAA will provide written notification of a proposal's approval or disapproval to each applicant within 9 months of submitting a coral reef conservation proposal. Similarly, NOAA will also provide written notification of a project's approval to each State or other government jurisdiction that provided comments and/or reviews.

#### Definitions

In this Program:

1. Administrator means the Administrator of the National Oceanic and Atmospheric Administration.
2. Conservation means the use of methods and procedures necessary to preserve or sustain corals and associated species as diverse, viable, and self-perpetuating coral reef ecosystems, including all activities associated with resource management, such as assessment, conservation, protection, restoration, sustainable use, and management of habitat; mapping; habitat monitoring; assistance in the development of management strategies for marine protected areas and marine resources consistent with the National Marine Sanctuaries Act (16 U.S.C. 1431 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*); law enforcement; conflict resolution initiatives; community outreach and education; and that promote safe and ecologically sound navigation.
3. Cooperative Agreement means a legal instrument reflecting a relationship between the Department of Commerce (DoC) and a recipient whenever: (1) The principal purpose of the relationship is to transfer money, property, services or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute, and (2) substantial involvement (e.g. collaboration, participation, or intervention by DoC in the management of the project) is anticipated between DoC and the recipient during performance of the contemplated activity.
4. Coral means species of the phylum Cnidaria, including—(A) all species of the orders Antipatharia (black corals), Scleractinia (stony corals), Gorgonacea (horny corals), Stolonifera (organpipe corals and others), Alcyonacea (soft corals), and Coenothecalia (blue coral),

of the class Anthozoa; and (B) all species of the order Hydrocorallina (fire corals and hydrocorals) of the class Hydrozoa.

5. Coral Reef means any reefs or shoals composed primarily of corals.

6. Coral Reef Ecosystem means coral and other species of reef organisms (including reef plants) associated with coral reefs, and the non-living environmental factors that directly affect coral reefs, that together function as an ecological unit in nature.

7. Coral Products means any living or dead specimens, parts, or derivatives, or any product containing specimens, parts, or derivatives, of any species referred to in paragraph (3).

8. Grant means a legal instrument reflecting a relationship between DoC and a recipient whenever: (1) The principal purpose of the relationship is to transfer money, property, services, or anything of value in order to accomplish a public purpose of support or stimulation authorized by Federal statute, and (2) no substantial involvement is anticipated between DoC and the recipient during the performance of the contemplated activity.

9. Interagency Agreement, for the purposes of these Guidelines, means a written document containing specific provisions of governing authorities, responsibilities, and funding, entered into between NOAA and another Federal agency where NOAA is funding the other Federal agency, pursuant to the Act.

10. Secretary means the Secretary of Commerce.

11. State means any State of the United States that contains a coral reef ecosystem within its seaward boundaries, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands, and any other territory or possession of the United States, or separate sovereign in free association with the United States, that contains a coral reef ecosystem within its seaward boundaries.

Classification: This is a continuing Program and is included in the Catalog of Federal Domestic Assistance under the Coastal Zone Management Act (11.419), NOS International Programs (11.463), and Habitat Conservation (11.441). The Program uses existing NOAA Federal assistance application package requirements per 15 CFR parts 14 and 24.

The program will determine NEPA compliance on a project by project basis. This action has been determined to be not significant for purposes of Executive Order 12866.



This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, 424C, 424D, and SF-LLL has been approved by OMB under the respective control numbers 4040-0004/0348-0043; 4040-0006/0348-0044; 4040-0007/0348-0040; 4040-0008/0348-0041; 4040-0009/0348-0042; and 0348-0046. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. The proposed guidelines also contain new collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. These requirements will be submitted to OMB for approval. Public reporting burden for these collections of information is estimated to average one hour per request for a matching funds waiver (section IX(6) of these Guidelines) and one hour per comment on proposals (section X(1) of these Guidelines), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NOAA Office of Ocean and Coastal Resource Management at the address above, and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer).

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the Paperwork Reduction Act, unless that collection displays a currently valid OMB control number.

### Classification

#### Limitation of Liability

Funding for programs listed in this notice is contingent upon the availability of Fiscal Year 2010 appropriations. Applicants are hereby given notice that funds have not yet been appropriated for the programs listed in this notice. In no event will NOAA or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige NOAA to award any specific project or to obligate any available funds.

#### Universal Identifier

Applicants should be aware that, they are required to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number during the application process. See the October 30, 2002 **Federal Register**, (67 FR 66177) for additional information. Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or via the Internet <http://www.dunandbradstreet.com>.

#### National Environmental Policy Act (NEPA)

NOAA must analyze the potential environmental impacts, as required by the National Environmental Policy Act (NEPA), for applicant projects or proposals which are seeking NOAA federal funding opportunities. Detailed information on NOAA compliance with NEPA can be found at the following NOAA NEPA Web site: <http://www.nepa.noaa.gov/> including our NOAA Administrative Order 216-6 for NEPA, <http://www.nepa.noaa.gov/NAO216-6-TOC.pdf>, NEPA Questionnaire, <http://www.nepa.noaa.gov/questionnaire.pdf>, and the Council on Environmental Quality implementation regulations, <http://ceq.eh.doe.gov/nepa/regs/ceq/toc-ceq.htm>. Consequently, as part of an applicant's package, and under their description of their program activities, applicants are required to provide detailed information on the activities to be conducted, locations, sites, species and habitat to be affected, possible construction activities, and any environmental concerns that may exist (e.g., the use and disposal of hazardous or toxic chemicals, introduction of non-indigenous species, impacts to endangered and threatened species, aquaculture projects, and impacts to coral reef systems). In addition to providing specific information that will

serve as the basis for any required impact analyses, applicants may also be requested to assist NOAA in drafting of an environmental assessment, if NOAA determines an assessment is required. Applicants will also be required to cooperate with NOAA in identifying feasible measures to reduce or avoid any identified adverse environmental impacts of their proposal. The failure to do so shall be grounds for not selecting an application. In some cases if additional information is required after an application is selected, funds can be withheld by the Grants Officer under a special award condition requiring the recipient to submit additional environmental compliance information sufficient to enable NOAA to make an assessment on any impacts that a project may have on the environment.

#### Compliance With Department of Commerce Bureau of Industry and Security Export Administration Regulations

(a) This clause applies to the extent that this financial assistance award involves access to export-controlled information or technology.

(b) In performing this financial assistance award, the recipient may gain access to export-controlled information or technology. The recipient is responsible for compliance with all applicable laws and regulations regarding export-controlled information and technology, including deemed exports. The recipient shall establish and maintain throughout performance of the financial assistance award effective export compliance procedures at non-NOAA facilities. At a minimum, these export compliance procedures must include adequate controls of physical, verbal, visual, and electronic access to export-controlled information and technology.

#### (c) Definitions

(1) Deemed export. The Export Administration Regulations (EAR) define a deemed export as any release of technology or source code subject to the EAR to a foreign national, both in the United States and abroad. Such release is "deemed" to be an export to the home country of the foreign national. 15 CFR 734.2(b)(2)(ii).

(2) Export-controlled information and technology. Export-controlled information and technology is information and technology subject to the EAR (15 CFR parts 730 *et seq.*), implemented by the DOC Bureau of Industry and Security, or the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130), implemented by the Department of

State, respectively. This includes, but is not limited to, dual-use items, defense articles and any related assistance, services, software or technical data as defined in the EAR and ITAR.

(d) The recipient shall control access to all export-controlled information and technology that it possesses or that comes into its possession in performance of a financial assistance award, to ensure that access is restricted, or licensed, as required by applicable Federal laws, Executive Orders, and/or regulations.

(e) Nothing in the terms of this financial assistance award is intended to change, supersede, or waive the requirements of applicable Federal laws, Executive Orders or regulations.

(f) The recipient shall include this clause, including this paragraph (f), in all lower tier transactions (sub awards, contracts, and subcontracts) under the financial assistance award that may involve access to export-controlled information technology.

*NOAA implementation of Homeland Security Presidential Directive—12*

If the performance of a financial assistance award, if approved by NOAA, requires recipients to have physical access to Federal premises for more than 180 days or access to a Federal information system, any items or services delivered under a financial assistance award shall comply with the Department of Commerce personal identity verification procedures that implement Homeland Security Presidential Directive -12, FIPS PUB 201, and the Office of Management and Budget Memorandum M-05-24. The recipient shall insert this clause in all subawards or contracts when the subaward recipient or contractor is required to have physical access to a Federally controlled facility or access to a Federal information system.

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements.

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the Federal Register notice of February 11, 2008 (73 FR 7696) are applicable to this solicitation.

*Paperwork Reduction Act*

This document contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, 424C, 424D, and SF-LLL has been approved by OMB under the respective control numbers 4040-0004/0348-0043; 4040-0006/0348-0044; 4040-0007/0348-0040; 4040-0008/0348-0041; 4040-0009/0348-0042; and 0348-0046.

As part of its application process, the Coral Reef Conservation Program will be implementing new collection-of-information that is subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. These requirements will be submitted to OMB for approval. Public reporting burden for these collections of information is estimated to average one hour per request for a matching funds waiver (section IX(6) of these Guidelines) and one hour per comment on proposals (section X(1) of these Guidelines), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of

information technology. Send comments on these or any other aspects of the collection of information to NOAA Office of Ocean and Coastal Resource Management at the address above, and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (*Attention: NOAA Desk Officer*).

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

*Executive Order 12866*

This notice has been determined to be not significant for purposes of Executive Order 12866.

*Executive Order 13132 (Federalism)*

It has been determined that this notice does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

*Administrative Procedure Act/Regulatory Flexibility Act*

Prior notice and an opportunity for public comment are not required by the Administrative Procedure Act or any other law for rules concerning public property, loans, grants, benefits, and contracts (5 U.S.C. 553(a)(2)). Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Dated: January 8, 2010.

**Mitchell J. Ross,**

*Director, Acquisition and Grants Office,  
Contracting Officer, National Oceanic and  
Atmospheric Administration.*

[FR Doc. 2010-721 Filed 1-15-10; 8:45 am]

**BILLING CODE 3510-12-P**



# Federal Register

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Tuesday,  
January 19, 2010

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**Part V**

**Securities and  
Exchange  
Commission**

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17 CFR Parts 200 and 202

Delegations of Authority to the Director  
of Its Division of Enforcement and Policy  
Statement Concerning Cooperation by  
Individuals in Its Investigations and  
Related Enforcement Actions; Final Rules

**SECURITIES AND EXCHANGE COMMISSION****17 CFR Part 200**

[Release No. 34-61339]

**Delegations of Authority to the Director of Its Division of Enforcement****AGENCY:** Securities and Exchange Commission.**ACTION:** Final rule.

**SUMMARY:** The Securities and Exchange Commission ("Commission") is amending its rules to delegate authority to the Director of the Division of Enforcement ("Division") to submit witness immunity order requests to the Department of Justice for witnesses who have provided or have the potential to provide substantial assistance in the Commission's investigations and related enforcement actions. This delegation is intended to conserve Commission resources, enhance the Division's ability to detect violations of the federal securities laws, increase the effectiveness and efficiency of the Division's investigations, and improve the success of the Commission's enforcement actions.

**DATES:** *Effective Date:* January 19, 2010.

**FOR FURTHER INFORMATION CONTACT:** Joan McKown, Chief Counsel, (202) 551-4933; or Jordan A. Thomas, Assistant Chief Litigation Counsel, (202) 551-4475.

**SUPPLEMENTARY INFORMATION:** The Commission today is amending its rules governing delegations of authority to the Director of the Division of Enforcement. The amendment to Rule 30-4 (17 CFR 200.30-4) authorizes the Director of the Division of Enforcement ("Director") to submit witness immunity order requests to the Department of Justice for witnesses who have provided or have the potential to provide substantial assistance in the Commission's investigations and related enforcement actions. This delegation is intended to conserve Commission resources, enhance the Division's ability to detect violations of the federal securities laws, increase the effectiveness and efficiency of the Division's investigations, and improve the success of the Commission's enforcement actions.

Nevertheless, the Division may submit matters to the Commission for consideration, as it deems appropriate.

The Commission finds, in accordance with the Administrative Procedure Act ("APA") (5 U.S.C. 553(b)(3)(A)), that this revision relates solely to agency organization, procedures, or practices. It is therefore not subject to the provisions

of the APA requiring notice and opportunity for comment. Accordingly, it is effective January 19, 2010.

**List of Subjects in 17 CFR Part 200**

Administrative practice and procedure, Authority delegations (Government agencies).

**Text of Amendment**

■ For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

**PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS**

■ 1. The authority citation for Part 200, Subpart A, continues to read in part as follows:

**Authority:** 15 U.S.C. 77o, 77s, 77sss, 77d, 78d-1, 78d-2, 78w, 78j(d), 78mm, 80a-37, 80b-11, and 7202, unless otherwise noted.

\* \* \* \* \*

■ 2. Section 200.30-4 is amended by adding paragraph (a)(14) to read as follows:

**§ 200.30-4 Delegation of authority to Director of Division of Enforcement.**

\* \* \* \* \*

(a) \* \* \*

(14) To submit witness immunity requests to the U.S. Attorney General for approval to seek an order compelling an individual to give testimony or provide other information pursuant to a subpoena that may be necessary to the public interest in connection with investigations and related enforcement actions pursuant to section 22(b) of the Securities Act of 1933 (15 U.S.C. 77v(b)), section 21(c) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(c)), section 42(c) of the Investment Company Act of 1940 (15 U.S.C. 80a-41(c)) and section 209(c) of the Investment Advisers Act of 1940 (15 U.S.C. 80b-9(c)).

\* \* \* \* \*

By the Commission.

Dated: January 13, 2010.

**Elizabeth M. Murphy,**  
Secretary.

[FR Doc. 2010-842 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P****SECURITIES AND EXCHANGE COMMISSION****17 CFR Part 202**

[Release No. 34-61340]

**Policy Statement Concerning Cooperation by Individuals in Its Investigations and Related Enforcement Actions****AGENCY:** Securities and Exchange Commission.**ACTION:** Policy statement.

**SUMMARY:** The Securities and Exchange Commission is issuing a policy statement announcing the analytical framework it uses to evaluate cooperation by individuals.

**DATES:** *Effective Date:* January 19, 2010.

**FOR FURTHER INFORMATION CONTACT:** Joan McKown, Chief Counsel, (202) 551-4933; or Jordan A. Thomas, Assistant Chief Litigation Counsel, (202) 551-4475.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission is issuing a policy statement announcing the analytical framework it uses to evaluate cooperation by individuals. This framework serves two important purposes: it promotes the fair and effective exercise of discretion by the Commission, and it enhances confidence on the part of the public and cooperating individuals that decisions regarding cooperation in the Commission's investigations and related enforcement actions will be made in an appropriate and consistent manner.

The provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. 553, regarding notice of proposed rulemaking, opportunities for public comment, and prior publication are not applicable to general statements of policy, such as this policy statement. Similarly, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601-602, apply only when notice and comment are required by the APA or another statute and are therefore not applicable.

**List of Subjects in 17 CFR Part 202**

Administrative practice and procedure.

**Text of Amendment**

■ For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

**PART 202—INFORMAL AND OTHER PROCEDURES**

1. The authority citation for Part 202 continues to read, in part, as follows:

**Authority:** 15 U.S.C. 77s, 77t, 77sss, 77uuu, 78d-1, 78u, 78w, 78l(d), 80a-37, 80a-41, 80b-9, 80b-11, 7202 and 7211 *et seq.*, unless otherwise noted.

\* \* \* \* \*

■ 2. Add § 202.12 to read as follows:

**§ 202.12 Policy statement concerning cooperation by individuals in its investigations and related enforcement actions.**

Cooperation by individuals and entities in the Commission's investigations and related enforcement actions can contribute significantly to the success of the agency's mission. Cooperation can enhance the Commission's ability to detect violations of the federal securities laws, increase the effectiveness and efficiency of the Commission's investigations, and provide important evidence for the Commission's enforcement actions. There is a wide spectrum of tools available to the Commission and its staff for facilitating and rewarding cooperation by individuals, ranging from taking no enforcement action to pursuing reduced charges and sanctions in connection with enforcement actions. As with any cooperation program, there exists some tension between the objectives of holding individuals fully accountable for their misconduct and providing incentives for individuals to cooperate with law enforcement authorities. This policy statement sets forth the analytical framework employed by the Commission and its staff for resolving this tension in a manner that ensures that potential cooperation arrangements maximize the Commission's law enforcement interests. Although the evaluation of cooperation requires a case-by-case analysis of the specific circumstances presented, as described in greater detail below, the Commission's general approach is to determine whether, how much, and in what manner to credit cooperation by individuals by evaluating four considerations: the assistance provided by the cooperating individual in the Commission's investigation or related enforcement actions ("Investigation"); the importance of the underlying matter in which the individual cooperated; the societal interest in ensuring that the cooperating individual is held accountable for his or her misconduct; and the appropriateness of cooperation credit based upon the profile of the cooperating individual. In the end, the

goal of the Commission's analysis is to protect the investing public by determining whether the public interest in facilitating and rewarding an individual's cooperation in order to advance the Commission's law enforcement interests justifies the credit awarded to the individual for his or her cooperation.

(a) *Assistance provided by the individual.* The Commission assesses the assistance provided by the cooperating individual in the Investigation by considering, among other things:

- (1) The value of the individual's cooperation to the Investigation including, but not limited to:
  - (i) Whether the individual's cooperation resulted in substantial assistance to the Investigation;
  - (ii) The timeliness of the individual's cooperation, including whether the individual was first to report the misconduct to the Commission or to offer his or her cooperation in the Investigation, and whether the cooperation was provided before he or she had any knowledge of a pending investigation or related action;
  - (iii) Whether the Investigation was initiated based on information or other cooperation provided by the individual;
  - (iv) The quality of cooperation provided by the individual, including whether the cooperation was truthful, complete, and reliable; and
  - (v) The time and resources conserved as a result of the individual's cooperation in the Investigation.
- (2) The nature of the individual's cooperation in the Investigation including, but not limited to:
  - (i) Whether the individual's cooperation was voluntary or required by the terms of an agreement with another law enforcement or regulatory organization;
  - (ii) The types of assistance the individual provided to the Commission;
  - (iii) Whether the individual provided non-privileged information, which information was not requested by the staff or otherwise might not have been discovered;
  - (iv) Whether the individual encouraged or authorized others to assist the staff who might not have otherwise participated in the Investigation; and
  - (v) Any unique circumstances in which the individual provided the cooperation.

(b) *Importance of the underlying matter.* The Commission assesses the importance of the Investigation in which the individual cooperated by considering, among other things:

(1) The character of the investigation including, but not limited to:

- (i) Whether the subject matter of the Investigation is a Commission priority;
- (ii) The type of securities violations;
- (iii) The age and duration of the misconduct;
- (iv) The number of violations; and
- (v) The isolated or repetitive nature of the violations.

(2) The dangers to investors or others presented by the underlying violations involved in the Investigation including, but not limited to:

- (i) The amount of harm or potential harm caused by the underlying violations;
- (ii) The type of harm resulting from or threatened by the underlying violations; and
- (iii) The number of individuals or entities harmed.<sup>1</sup>

(c) *Interest in holding the individual accountable.* The Commission assesses the societal interest in holding the cooperating individual fully accountable for his or her misconduct by considering, among other things:

- (1) The severity of the individual's misconduct assessed by the nature of the violations and in the context of the individual's knowledge, education, training, experience, and position of responsibility at the time the violations occurred;
- (2) The culpability of the individual, including, but not limited to, whether the individual acted with scienter, both generally and in relation to others who participated in the misconduct;
- (3) The degree to which the individual tolerated illegal activity including, but not limited to, whether he or she took steps to prevent the violations from occurring or continuing, such as notifying the Commission or other appropriate law enforcement agency of the misconduct or, in the case of a violation involving a business organization, by notifying members of management not involved in the misconduct, the board of directors or the equivalent body not involved in the misconduct, or the auditors of such business organization of the misconduct;
- (4) The efforts undertaken by the individual to remediate the harm caused by the violations including, but not limited to, whether he or she paid or agreed to pay disgorgement to injured investors and other victims or assisted these victims and the authorities in the recovery of the fruits and instrumentalities of the violations; and

<sup>1</sup> Cooperation in Investigations that involve priority matters or serious, ongoing, or widespread violations will be viewed most favorably.

(5) The sanctions imposed on the individual by other federal or state authorities and industry organizations for the violations involved in the investigation.

(d) *Profile of the individual.* The Commission assesses whether, how much, and in what manner it is in the public interest to award credit for cooperation, in part, based upon the cooperating individual's personal and professional profile by considering, among other things:

(1) The individual's history of lawfulness, including complying with securities laws or regulations;

(2) The degree to which the individual has demonstrated an acceptance of responsibility for his or her past misconduct; and

(3) The degree to which the individual will have an opportunity to commit future violations of the federal securities laws in light of his or her occupation—including, but not limited to, whether he or she serves as: A licensed individual, such as an attorney or accountant; an associated person of a regulated entity, such as a broker or dealer; a fiduciary for other individuals or entities regarding financial matters; an officer or director of public companies; or a member of senior management—together with any existing or proposed safeguards based upon the individual's particular circumstances.

**Note to § 202.12.** Before the Commission evaluates an individual's cooperation, it

analyzes the unique facts and circumstances of the case. The above principles are not listed in order of importance nor are they intended to be all-inclusive or to require a specific determination in any particular case. Furthermore, depending upon the facts and circumstances of each case, some of the principles may not be applicable or may deserve greater weight than others. Finally, neither this statement, nor the principles set forth herein creates or recognizes any legally enforceable rights for any person.

Dated: January 13, 2010.

By the Commission.

**Elizabeth M. Murphy,**  
*Secretary.*

[FR Doc. 2010-843 Filed 1-15-10; 8:45 am]

**BILLING CODE 8011-01-P**

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**H.R. 4314/P.L. 111-123**  
To permit continued financing of Government operations. (Dec. 28, 2009; 123 Stat. 3483)

**H.R. 4284/P.L. 111-124**  
To extend the Generalized System of Preferences and

the Andean Trade Preference Act, and for other purposes. (Dec. 28, 2009; 123 Stat. 3484)

**H.R. 3819/P.L. 111-125**  
To extend the commercial space transportation liability regime. (Dec. 28, 2009; 123 Stat. 3486)

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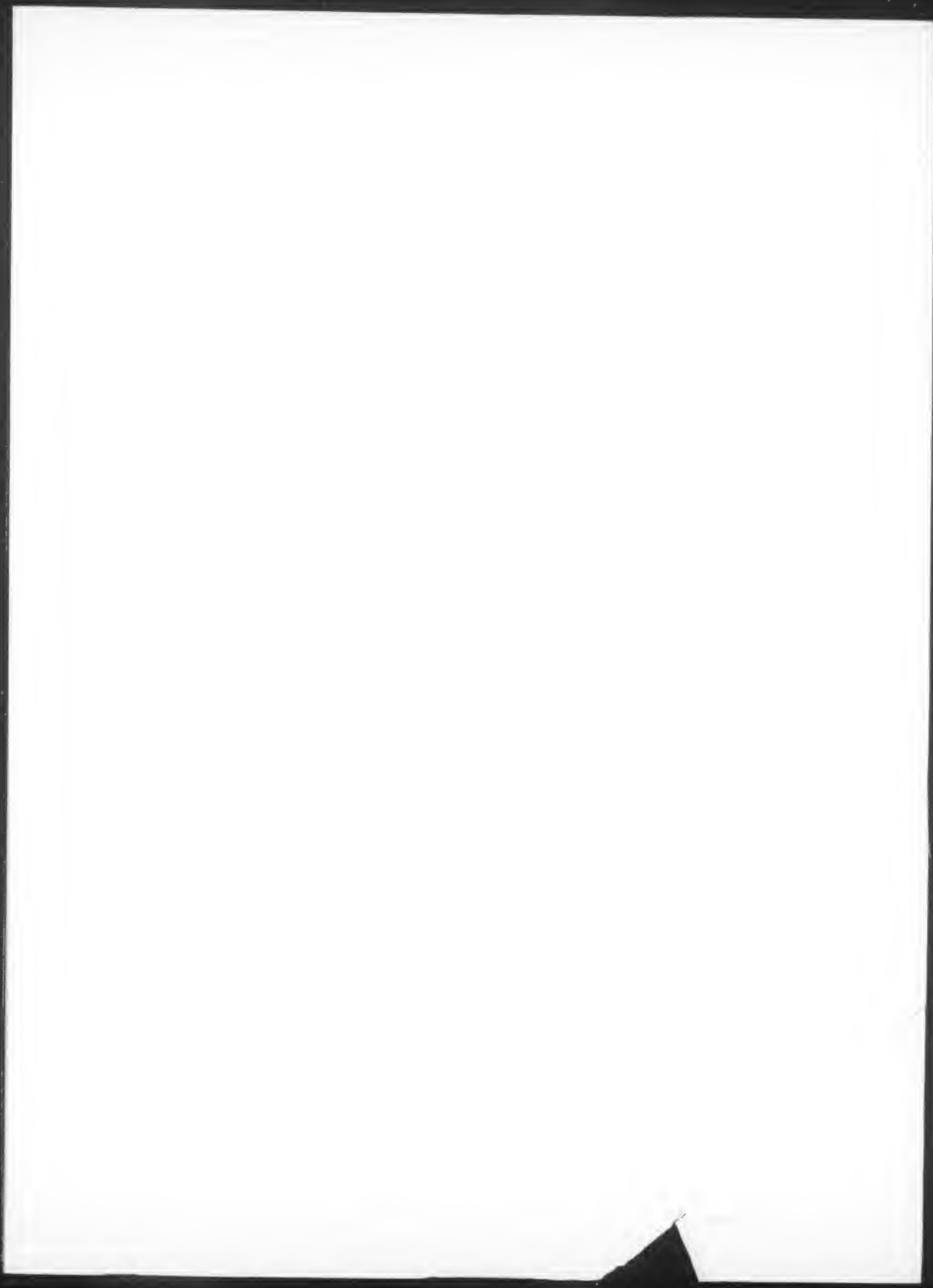
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