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9:00 a.m.–Noon

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004–NM–37–AD; Amendment 39–14180; AD 2005–14–03]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–145 and EMB–135 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain EMBRAER Model EMB–145 and EMB–135 series airplanes, that requires replacement of the engine-driven hydraulic pump. This action is necessary to prevent engine oil leakage at the coupling seal between the hydraulic pump and the engine gearbox from causing low engine oil levels, which could lead to in-flight engine shutdown and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective August 10, 2005.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 10, 2005.

ADDRESSES: The service information referenced in this AD may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343–CEP 12.225, Sao Jose dos Campos–SP, Brazil. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain EMBRAER Model EMB–145 and EMB–135 series airplanes was published in the **Federal Register** on April 27, 2004 (69 FR 22743). That action proposed to require replacement of the engine-driven hydraulic pump.

Explanation of New Relevant Service Information

The proposed AD refers to EMBRAER Service Bulletin 145–29–0018, Revision 03, dated December 2, 2003, as the appropriate source of service information for replacing the engine-driven hydraulic pump for Model EMB–145 and EMB–135 series airplanes. Since the issuance of that service bulletin, Embraer has issued Revision 04, dated March 16, 2005. Revision 04 of the service bulletin is essentially the same as Revision 03, but it removes a certain airplane from the in-service effectivity and adds two airplanes to the in-production effectivity. We have changed paragraph (a)(1) of this AD to refer to Revision 04 of the service bulletin as the appropriate source of service information for Model EMB–145 and EMB–135 series airplanes, and revised the applicability to refer to Revision 04 for those airplanes. In addition, we have added Revision 03 of the service bulletin to paragraph (d) of this AD to give credit for previously accomplishing the actions in accordance with that revision.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received from a single commenter.

Request To Clarify Statement of Unsafe Condition

The commenter, the airplane manufacturer, asks that we clarify the statement of the unsafe condition as specified in the proposed AD. The commenter suggests we add the word ''engine'' in front of the term ''oil leakage'' for clarification. We agree and have added the word ''engine'' to clarify the statement of the unsafe condition in the AD.

Extend Compliance Time Specified in Paragraph (c) of the Proposed AD

The commenter also asks that the compliance time of ''as of the effective date of this AD'' specified in paragraph (c) of the proposed AD be extended. The commenter states that it does not concur with accepting only the new part number (P/N) for installation as of the effective date of the AD. The commenter notes that this compliance time is not consistent with the period of 1,000 flight hours defined for hydraulic pump replacement, and may affect operators that may not have enough time to modify their spare parts. The commenter suggests the adoption of a period similar to the Brazilian airworthiness directive referenced in the proposed AD, which provides a compliance time of approximately two months for stock upgrade. The commenter proposes the following compliance time: ''No later than 31 March 2004, modify all hydraulic pumps P/N 971808 held in stock, to the new P/N 971808 MOD A—Brazilian airworthiness directive date: 29 January 2004.''

We do not agree. We have determined that the compliance time specified in the AD will ensure an acceptable level of safety and allow the replacement to be done with no airplane out-of-service time during scheduled maintenance intervals for most affected operators. In developing the technical information on which every AD is based, we consider the availability of spare parts that the AD will require to be installed. We have not changed the AD in this regard.

Explanation of Change to Final Rule

In Table 1 of the proposed AD we referenced an incorrect number for EMBRAER Service Bulletin 145LEG–29–0001. We inadvertently referenced 145LEG–31–0001 instead of 145LEG–29–0001. We have corrected the error in this final rule.

Conclusion

After careful review of the available data, including the comments noted above, we have determined that air safety and the public interest require the

adoption of the rule with the changes described previously. These changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 548 airplanes of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per airplane to accomplish the actions, and that the average labor rate is $65 per work hour. The manufacturer will provide replacement parts at no cost. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $142,480, or $260 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Authority for This Rulemaking

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

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

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

2005–14 Empresa Brasileira De Aeronautica S.A. (Embraer): Amendment 39–14180. Docket 2004–NM–37–AD.

Applicability: Model EMB–145 and EMB–135 series airplanes, certificated in any category, as listed in EMBRAER Service Bulletin 145–29–0018, Revision 04, dated March 16, 2005; and EMBRAER Service Bulletin 145LEG–29–0001, Revision 01, dated November 11, 2003.

Compliance: Required as indicated, unless accomplished previously.

To prevent engine oil leakage at the coupling seal between the hydraulic pump and the engine gearbox from causing low engine oil levels, which could lead to in-flight engine shutdown and consequent reduced controllability of the airplane, accomplish the following:

Service Bulletin References

(a) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of the following service bulletins, as applicable:

(1) For Model EMB–145 and EMB–135 (except Model EMB–135BJ) series airplanes: EMBRAER Service Bulletin 145–29–0018, Revision 04, dated March 16, 2005; and

(2) For Model EMB–135BJ series airplanes: EMBRAER Service Bulletin 145LEG–29–0001, Revision 01, dated November 11, 2003.

Note 1: EATON Service Bulletin 971808–29–02, dated May 1, 2001, has been incorporated into the EMBRAER service bulletins as an additional source of service information for accomplishing the modification of the hydraulic pump.

Replacement of Hydraulic Pump

(b) Within 1,000 flight hours after the effective date of this AD, replace the engine-driven hydraulic pump, part number (P/N) 971808, with a new or modified pump, P/N 971808 MOD A, in accordance with the Accomplishment Instructions of the applicable service bulletin.

Parts Installation

(c) As of the effective date of this AD, no person may install a hydraulic pump having P/N 971808 on any airplane, unless that pump has been modified and reidentified as P/N 971808 MOD A, per Part II of the Accomplishment Instructions of the applicable service bulletin.

Actions Accomplished Per Previous Issues of Service Bulletins

(d) Actions accomplished before the effective date of this AD, in accordance with the applicable service bulletin listed in Table 1 of this AD, are considered acceptable for compliance with the corresponding actions specified in this AD.

TABLE 1.—PREVIOUS ISSUES OF SERVICE BULLETINS

EMBRAER service bulletin	Revision and date
145–29–0018	Original Issue, June 6, 2002.
145–29–0018	Revision 01, October 9, 2002.
145–29–0018	Revision 02, August 25, 2003.
145–29–0018	Revision 03, December 2, 2003.
145LEG–29–0001	Original Issue, October 9, 2002.

Alternative Methods of Compliance

(e) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(f) Unless otherwise specified in this AD, the actions must be done in accordance with EMBRAER Service Bulletin 145–29–0018, Revision 04, dated March 16, 2005; and EMBRAER Service Bulletin 145LEG–29–0001, Revision 01, dated November 11, 2003; as applicable. EMBRAER Service Bulletin 145–29–0018, Revision 04, dated March 16, 2005, contains the following list of effective pages:

Page No.	Revision level shown on page	Date shown on page
1–3	04	March 16, 2005.
4–14	03	December 2, 2003.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of this service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), PO Box 343–CEP 12.225, Sao Jose dos Campos–SP, Brazil. To inspect copies of this service information, go to the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Note 2: The subject of this AD is addressed in Brazilian airworthiness directive 2004–01–03, effective January 29, 2004.

Effective Date

(g) This amendment becomes effective on August 10, 2005.

Issued in Renton, Washington, on June 24, 2005.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–13142 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20474; Directorate Identifier 2004–NM–221–AD; Amendment 39–14178; AD 2005–14–01]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2–203 and B4–203 Airplanes; Model A310–200 and –300 Series Airplanes; and Model A300 B4–600, B4–600R, and F4–600R Series Airplanes, and Model A300 C4–605R Variant F Airplanes (Collectively Called A300–600 Series Airplanes)

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus transport category airplanes. This AD requires an inspection to determine if suspect part numbers (P/Ns) and serial numbers of certain Thales Avionics equipment are installed, and replacement of any suspect part with a modified part having a new P/N. This AD is prompted by reports of loss of the digital distance radio magnetic indicator and subsequent loss of both very high frequency omnidirectional range indicators, both distance measuring equipment, and one centralized maintenance computer. We are issuing this AD to prevent loss of navigation indications on the primary flight display requiring continuation of the flight on emergency instruments, which could lead to reduced ability to control the airplane in adverse conditions.

DATES: This AD becomes effective August 10, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of August 10, 2005.

ADDRESSES: For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Washington, DC. This docket number is FAA–2005–20474; the directorate identifier for this docket is 2004–NM–221–AD.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Airbus Model A300 B2–203 and B4–203 airplanes; Model A310–200 and –300 series airplanes; and Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model C4–605R Variant F airplanes (collectively called A300–600 series airplanes). That action, published in the **Federal Register** on March 3, 2005 (70 FR 10339), proposed to require an inspection to determine if suspect part numbers (P/Ns) and serial numbers of certain Thales Avionics equipment are installed, and replacement of any suspect part with a modified part having a new P/N.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that has been submitted on the proposed AD.

Request To Expand Applicability

One commenter, the airplane manufacturer, notes that French airworthiness directive F–2004–037, issued March 17, 2004, which also addresses the subject of the proposed AD, applies to Airbus Model A300 B4–220 airplanes, as well as the other airplane models identified in the proposed AD. The commenter points out that the proposed AD does not mention Airbus Model A300 B4–220 airplanes.

We agree with the commenter's statements, but find that we do not need to change the AD in this regard. Airbus Model A300 B4–220 airplanes are not listed on the U.S. type certificate data sheet; thus, we do not need to issue an AD against those airplanes.

Explanation of Change to Applicability

We have revised the applicability of this AD to identify model designations as published in the most recent type certificate data sheet for the affected models.

Conclusion

We have carefully reviewed the available data, including the comment that was submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD will affect about 158 Model A310–200 and –300 series airplanes, and Mode A300–600 series airplanes of U.S. registry. The required inspection will take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of this AD for these U.S. operators is $10,270, or $65 per airplane.

Currently, there are no affected Model A300 B2–203 and B4–203 airplanes on the U.S. Register. However, if an affected airplane is imported and placed on the U.S. Register in the future, the required actions will take about 1 work hour, at an average labor rate of $65 per work hour. Based on these figures, we

estimate the cost of this AD for Model A300 B2–203 and B4–203 series airplanes to be $65 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 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 that this AD:

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

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

(3) 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. 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, Incorporation by reference, 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 airworthiness directive (AD):

2005–14–01 Airbus: Amendment 39–14178. Docket No. FAA–2005–20474; Directorate Identifier 2004–NM–221–AD.

Effective Date

(a) This AD becomes effective August 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the airplanes in paragraphs (c)(1) through (c)(3) of this AD, certificated in any category, equipped with at least one of the Thales Avionics equipment part numbers listed in Table 1 of this AD.

(1) Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model C4–605R Variant F airplanes (collectively called A300–600 series airplanes);

(2) Airbus Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; and

(3) Airbus Model A300 B2–203 and B4–203 airplanes with a forward facing crew cockpit configuration.

TABLE 1.—AFFECTED THALES AVIONICS EQUIPMENT

Equipment	Part No. (P\N)
Altimeter indicator	65205–211–2, –3, or –4; 65205–230–1, –2, or –3; or 65205–235–1.
Radio magnetic indicator (RMI)/automatic direction finder (ADF) indicator.	63540–040–1 or 63540–031–2.
RMI/very high frequency omnidirectional range (VOR) indicators/distance measuring equipment (DME).	63540–170–2 or 63540–156–3.
Vertical speed indicator (VSI)	65285–220–2 or 65285–230–1.

Unsafe Condition

(d) This AD was prompted by reports of loss of the digital distance radio magnetic indicator and subsequent loss of both VORs, both DMEs, and one centralized maintenance computer. We are issuing this AD to prevent loss of navigation indications on the primary flight display requiring continuation of the flight on emergency instruments, which could lead to reduced ability to control the airplane in adverse conditions.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletins

(f) The term ''Airbus service bulletin,'' as used in this AD, means the Accomplishment Instructions of the applicable service bulletin in Table 2 of this AD.

TABLE 2.—AIRBUS SERVICE BULLETINS

For model—	Airbus service bulletin—
(1) A300–600 series airplanes	A300–34A6145, Revision 01, dated October 17, 2003.
(2) A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.	A310–34A2178, Revision 01, dated October 17, 2003.
(3) A300 B2–203 and B4–203 airplanes	A300–34A0173, Revision 01, dated December 18, 2003.

(g) Each Airbus service bulletin in Table 2 of this AD refers to the Thales Avionics service bulletins in Table 3 of this AD as additional sources of service information for accomplishing the inspection and replacement if necessary.

TABLE 3.—THALES AVIONICS SERVICE BULLETINS

Thales Avionics service bulletin—	Revision—	Dated—
(1) 354–34–051	03	October 13, 2003.
(2) 354–34–053	02	October 10, 2003.
(3) 520–34–014	04	April 22, 2004.
(4) 520–34–015	04	July 1, 2004.
(5) 520–34–016	03	November 20, 2003.
(6) 520–34–017	03	July 1, 2004.
(7) 528–34–006	03	June 29, 2004.
(8) 528–34–007	02	October 10, 2003.

Inspection and Replacement

(h) Within 6 months after the effective date of this AD, do an inspection to determine if the suspect P/Ns and serial number (S/N) of the Thales Avionics equipment is installed, in accordance with the Airbus service bulletin. If any suspect P/N and S/N is found, within 6 months after the effective date of this AD, replace the suspect part with a modified part having a new P/N, in accordance with the Airbus service bulletin.

Parts Installation

(i) As of the effective date of this AD, no person may install any Thales Avionics equipment specified in Table 1 of this AD on any airplane.

Reporting Requirement

(j) Within 6 months after the effective date of this AD, submit a report of all P/Ns and S/N of overhauled equipment found during the inspection required by paragraph (h) of this AD to Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; fax 011–33–561934251. Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

Alternative Methods of Compliance (AMOCs)

(k) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(l) French airworthiness directive F–2004–037, issued March 17, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(m) You must use the service information listed in Table 4 to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

TABLE 4.—MATERIAL INCORPORATED BY REFERENCE

Airbus service bulletin	Revision level	Date
A300–34A0173	01	December 18, 2003.
A300–34A6145	01	October 17, 2003.
A310–34A2178	01	October 17, 2003.

Issued in Renton, Washington, on June 22, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–13143 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19764; Directorate Identifier 2004–NM–02–AD; Amendment 39–14182; AD 2005–14–05]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 and –300 Series Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 777–200 and –300 series airplanes. This AD requires applying an anti-static conductive coating to the fuel access and thermal anti-icing blowout doors at the location of the bonding fasteners on the leading edge of the wings, and performing a resistance test on the new coating to ensure correct ground path resistance. This AD is prompted by a report that an anti-static coating was not applied correctly on doors located within a flammable fluid leakage zone. We are issuing this AD to prevent an uncontrollable fire in the leading edge of the wing, which could damage critical wing structures and cause a fuel tank explosion.

DATES: This AD becomes effective August 10, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of August 10, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing

Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Docket: The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Washington, DC. This docket number is FAA–2004–19764; the directorate identifier for this docket is 2004–NM–02–AD.

FOR FURTHER INFORMATION CONTACT: Margaret Langsted, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6500; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Boeing Model 777–200 and -300 series airplanes. That action, published in the **Federal Register** on December 7, 2004 (69 FR 70574), proposed to require applying an anti-static conductive coating to the fuel access and thermal anti-icing blowout doors at the location of the bonding fasteners on the leading edge of the wings, and performing a resistance test on the new coating to ensure correct ground path resistance.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD.

Support for the Proposed AD

One commenter, the manufacturer, supports the proposed AD.

Request To Remove a Service Bulletin Action To Maintain Certain Coating Thickness

One commenter concurs with the AD. However, the commenter states that Boeing Special Attention Service Bulletin 777–57–0046, dated September 25, 2003, which is referenced in the proposed AD as the appropriate source of service information, specifies an action to maintain a certain coating thickness that is impractical to perform. The commenter states that Note (b) of Figures 1 and 2 in the Accomplishment Instructions of the service bulletin specifies that the conductive coating be applied at a thickness of 0.0004 to 0.0008 inch. The commenter states that there is no practical method to measure the thickness and that they have confirmation from the manufacturer that the intent of Note (b) is to ensure that the coating application is continuous. The commenter also notes that the manufacturer plans to delete the thickness dimension and revise the wording in Note (b) in the next revision of the service bulletin.

We agree with the commenter that the intent of Note (b) of the service bulletin is to ensure a continuous coating and that the measured thickness is not relevant. Although Note (b) specifies maintaining the thickness of the applied conductive coating between 0.0004 and 0.0008 inch, we have revised paragraph (f) of this AD to clarify the manufacturer's intent: to apply a uniform coating to avoid runs, sags, or wrinkles, and to ensure the anti-static coating touches the anti-static coating exposed during surface preparation.

We have coordinated this difference with the manufacturer. The manufacturer has informed us that a revision of the service bulletin that contains a revised Note (b) is planned for release. Once the revision has been issued, under the provisions of paragraph (g) of this AD, affected operators may request approval to use the later revision of the referenced service bulletin as an alternative method of compliance.

Request To Reduce the Compliance Time

One commenter requests that the compliance time be reduced. The commenter suggests that the simplicity and low cost of the task would allow airlines to perform the task sooner.

We do not agree with the request to shorten the compliance time. After considering all the available information, including the fact that there have been no reports of in-service arcing or sparking as a result of the missing anti-static coating, we determined that the compliance time, as proposed, represents an appropriate interval in which the anti-static coating can be applied in a timely manner within the fleet, while still maintaining an adequate level of safety. In developing the compliance time for this AD action, we considered not only the safety implications of the identified unsafe condition, but the average utilization rate of the affected fleet, the practical aspects of an orderly modification of the fleet during regular maintenance periods, the availability of required parts, and the time necessary for the rulemaking. However, if additional data are presented that would justify a shorter compliance time, we may consider further rulemaking on this issue. Operators are always permitted to accomplish the requirements of an AD at a time earlier than the specified compliance time.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD will affect about 65 airplanes worldwide and 18 airplanes of U.S. registry. The actions will take about 5 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of this AD for U.S. operators is $5,850, or $325 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 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 that this AD:

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

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

(3) 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. 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, Incorporation by reference, 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 airworthiness directive (AD):

2005–14–05 Boeing: Amendment 39–14182. Docket No. FAA–2004–19764; Directorate Identifier 2004–NM–02–AD.

Effective Date

(a) This AD becomes effective August 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 777–200 and –300 series airplanes, certificated in any category; as listed in Boeing Special Attention Service Bulletin 777–57–0046, dated September 25, 2003.

Unsafe Condition

(d) This AD was prompted by a report that an anti-static coating was not applied correctly on doors located within a flammable fluid leakage zone. We are issuing this AD to prevent an uncontrollable fire in the leading edge of the wing, which could damage critical wing structures and cause a fuel tank explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modification and Resistance Test

(f) Within 18 months after the effective date of this AD, apply an anti-static conductive coating to the fuel access and thermal anti-icing blowout doors at the location of the bonding fasteners, and perform a resistance test on the new coating, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–57–0046, dated September 25, 2003. Where Note (b) of Figures 1 and 2 of the Accomplishment Instructions of the service bulletin specifies to maintain the thickness of the conductive coating between 0.0004 and 0.0008 inch, this AD requires applying a uniform coating to avoid runs, sags, or wrinkles, and to ensure the anti-static coating touches the anti-static coating exposed during surface preparation.

(1) If the resistance measured between the door surface and a fastener located within the doors' surrounding support structure is within the limits specified in the service bulletin, no further action is required by this paragraph.

(2) If the resistance measured between the door surface and a fastener located within the doors' surrounding support structure is outside the limits specified in the service bulletin, before further flight, repeat the actions as required by paragraph (f) of this AD up to five times, as applicable. If the results of the fifth test exceed the limits specified in the service bulletin, before further flight, contact the Manager, Seattle Aircraft Certification Office (ACO), FAA, for disposition of repairs.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(h) You must use Boeing Special Attention Service Bulletin 777–57–0046, dated September 25, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on June 24, 2005.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–13224 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. PL05–11–000]

Policy Statement Regarding Evaluation of Independent Ownership and Operation of Transmission

Issued June 27, 2005.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Policy statement.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is adopting this Policy Statement to clarify the ownership structures that could qualify for passive ownership in regards to independent ownership and operation.

DATES: *Effective Date:* The Policy Statement will become effective immediately.

FOR FURTHER INFORMATION CONTACT:

Sebastian Tiger (Technical Information), Office of Market Oversight and Investigations, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6079.

Andre Goodson (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8560.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Pat Wood, III, Chairman; Nora Mead Brownell, Joseph T. Kelliher, and Suedeen G. Kelly.

I. Introduction

1. The Commission is issuing this Policy Statement to provide clarity and remove barriers to the formation of independent transmission companies. Specifically, the Policy Statement clarifies that the Commission would be willing to accept proposals from independent transmission companies (ITCs) which have market participants as passive minority equity owners. On various occasions, the Commission has allowed innovative rate treatments both to facilitate the creation of ITCs and to stimulate investment in transmission infrastructure by ITCs.[1]

[1] These incentive proposals include: enhanced returns on equity, within the zone of reasonableness; hypothetical or imputed capital structures; recovery of deferred income tax liabilities; cost deferrals; Construction Work in Progress (CWIP) in rate base; accelerated book depreciation; and expensing of pre-certification

Continued

2. The Policy Statement describes a non-exclusive list of the factors which the Commission will consider when evaluating rate proposals by ITCs to ensure that passive ownership does not affect the independent operation, planning and construction of their transmission systems. The Commission will evaluate the merits of such proposals on an individual basis.

3. The Commission recently demonstrated additional flexibility in a case involving the initial public offering of shares in an ITC that allows for the potential that market participants could purchase a small percentage of its shares in the public equity markets. In ITC Holdings II,[2] the order authorizing the disposition of jurisdictional facilities and confirming the independence of ITC Holdings, the Commission confirmed that International Transmission would continue to be independent of market participants and remain eligible for innovative rate treatment after a change in ownership is effected through an initial public offering of its shares. International Transmission adopted certain safeguards to ensure its continued independence, including limits on potential ownership by market participants as well as a corporate governance structure that assures that market participants that do purchase limited stakes in the company would not be able to influence its independent operation. Several commenters at an April 22, 2005 technical conference at the Commission noted that allowing market participant sellers to retain a passive ownership stake in stand-alone transmission companies (with appropriate safeguards to ensure their independence) could facilitate transactions creating such stand-alone transmission companies as ITCs.[3]

II. Factors the Commission Will Evaluate in Determining if Market Participants Are Passive Equity Owners in Proposed Independent Transmission Companies

4. In this Policy Statement, the Commission is identifying a non-exclusive list of the relevant considerations that it intends to take into account in evaluating if market participants are truly passive owners in any application for incentive rate treatment filed by ITCs or stand-alone transmission companies under section 205 of the Federal Power Act (FPA).[4] These factors include:

- The percentage ownership held by market participants;
- Composition of the board of directors and the responsibilities and rights of the board;
- The corporate governance structure of the applicant;
- The nature of the applicant's capital investment planning and policies;
- The relationship, if any, of capital investment policies with those governing capital contributions or dividend reinvestment by passive equity holders;
- The role of executive compensation agreements and other management incentives in shaping independent operation and investment decisions; and
- The nature and strictness of limits on contractual service and legacy relationships with ex-affiliates that are market participants.

5. In evaluating any proposed passive ownership structure in an ITC application, the Commission will focus on the ability of the applicant to operate free of market participant control or influence. When determining if an applicant could qualify as an ITC, the Commission will consider proposals involving passive minority participation of up to 49 percent ownership by a single market participant. In addition, as in ATC, the Commission would be willing to consider applications in which multiple market participants owned greater than 49 percent of the applicant's equity. The Commission is concerned about the level of voting control (if any) held by market participants. In ITC Holdings II, for example, the applicants committed to prohibit a market participant that does acquire five percent or more of any class of ITC Holdings' stock from voting, giving consent in respect of, or directing or controlling five percent or more of ITC Holdings stock, in order to limit direct or indirect voting control over the applicant. The Commission will continue to use this standard in evaluating ITC applicants with passive ownership. In determining the applicant's level of independence from market participant control or influence to determine if it should qualify as an ITC, the Commission will also consider the applicant's governance structure and any rights that could allow market participant owners to directly or indirectly affect the applicant's operation, planning or investment decisions.

6. Evaluation of the ITC applicant's board of directors will weigh the representation (if any) by market participants, and consider factors such as the composition and responsibilities of the board committees (e.g., compensation, audit and investment committees) and the extent and nature of corporate actions for which company management must obtain prior board approval. We appreciate the need for market participant representation to consider significant business decisions such as a sale of or merger of the company. However, the Commission will review the need (if present) for management to seek board approval in the normal course of operations for capital investments above a certain size. The degree to which market participant board members have granular knowledge of or ability to influence individual investment decisions would influence the appropriateness of allowing incentive rate treatments.

7. The Commission will consider the potential role that equity holders that are market participants play in financing ongoing investments by the independent transmission company, to gauge if there is a risk that those equity holders could frustrate investment in transmission infrastructure either by disapproving a plan or by denying capital to projects in the plan.

8. In evaluating the independence of applicants, the Commission will review executive compensation and deferred compensation plans to understand if those plans involve financial interests in market participants that would be inconsistent with independent operation, planning and expansion of the applicant's transmission system.[5]

costs associated with new transmission. In addition, the Commission is willing to consider further incentives for independent transmission companies, among which are 100 percent recovery of CWIP, 100 percent recovery of abandoned plant costs, and accelerated depreciation. See Michigan Electric Transmission Co., LLC, 105 FERC ¶ 61,214 (2003) (METC) ; ITC Holdings Corp., 102 FERC ¶ 61,182, reh'g denied, 104 FERC ¶ 61,033 (2003); American Transmission Co. and Midwest Independent Transmission Operator, Inc., 105 FERC ¶ 61,388 (2003), order dismissing reh'g as moot, providing clarification and approving uncontested settlement, 107 FERC ¶ 61,117 (2004) (ATC).

[2] ITC Holdings Corp. and International Transmission Co., 111 FERC ¶ 61,149 (2005) (ITC Holdings *II*).

[3] E.g., Transmission Independence and Investment, Docket No. AD05–5–000, Tr. 190–91 (Paul McCoy, Trans-Elect, Inc. (Trans-Elect)); Tr. 195–97 (Dale Landgren, American Transmission Company); Docket No. AD05–5–000, Supplemental Comments of Trans-Elect at 3–4; Supplemental Comments of National Grid USA at 18–19.

[4] 16 U.S.C. 824d (2000).

[5] In discussing independence, the Commission has previously highlighted the importance of separation from financial interests in market participants. See Regional Transmission Organizations, Order No. 2000, 65 FR 809 (Jan. 6, 2000), FERC Statutes & Regulations, Regulations Preambles July 1996–December 2000 ¶ 31,089 (1999), order on reh'g, Order No. 2000–A, 65 FR 12–088 (Mar. 8, 2000), FERC Statutes & Regulations, Regulations Preambles July 1996–December 2000 ¶ 31,092 (2000), aff'd sub nom. *Public Utility District. No. 1 of Snohomish County, Washington* v. *FERC,*

9. In evaluating the applicability of incentive rate treatment for structures allowing equity interests by market participants, the Commission will not limit its consideration to passive participation by integrated sellers who wish to retain a financial stake. The Commission will also consider ownership structures that facilitate participation by municipalities, cooperatives, and other transmission dependent users of the grid to the degree that corporate governance structures provide for independent operation, planning and investment. The Commission has approved the creation of a stand-alone transmission company, and allowed innovative rate treatments, for American Transmission Company (ATC), which is jointly-owned by investor-owned utilities which contributed their systems, and by public power customers which contributed cash in return for equity stakes in ATC with limited voting and governance rights.[6] The Commission remains comfortable that the governance structure of ATC allows some degree of participation by market participants, but ensures the operational and managerial independence of the stand-alone transmission company.

Document Availability

10. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. E.t.) at 888 First Street, NE., Room 2A, Washington DC 20426.

11. From FERC's Home page on the Internet, this information is available in the eLibrary. The full text of this document is available on elibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

12. User assistance is available for eLibrary and the FERC's website during normal business hours from our Help line, toll-free at (866) 208–3676 or for TTY, contact (202) 502–8659. The Public Reference Room may be reached at (202) 502–8371, or by e-mail at, *public.referenceroom@ferc.gov.*

Effective Date

13. This Policy Statement is effective immediately.

By the Commission.

Magalie R. Salas,

Secretary.

[FR Doc. 05–13200 Filed 7–5–05; 8:45 am]

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272 F.3d 607 (D.C. Cir. 2001), where the Commission stated:

We reaffirm the NOPR proposal that the RTO, its employees and any non-stakeholder directors must not have any financial interests in market participants. As noted in the NOPR, our focus will be on current financial interests. Since this principle raises a number of specific issues, especially with respect to pension rights and benefits, we will continue our current policy of implementing this principle on a case-by-case basis.

Order No. 2000 at 31,063.

[6] See American Transmission Co. and Midwest Independent Transmission Operator, Inc., 105 FERC ¶ 61,388 at P 24–31 (2003) (allowing ATC to apply innovative rate treatment, but only to projects that are accepted by Midwest ISO's Transmission Expansion Plan, and providing that ATC's incentive rates could remain effective only so long as ATC remains a member of Midwest ISO), order dismissing reh'g as moot, providing clarification and approving uncontested settlement, 107 FERC ¶ 61,117 (2004) (ATC), which is also discussed further in the Appendix to this Policy Statement; see also Docket No. AD05–5–000, Tr. 195–96 (Dale Landgren, ATC) (''Our form of governance is a variation on passive ownership in that the larger owners each have a seat on our board along with independent members. ATC demonstrates that this form of governance does not inhibit us from operating independently from market participants, which is after all the real objective.''). Further, each ATC board member has one vote per owner, regardless of their size. Docket No. AD05–5–000, Tr. 196 (Dale Landgren, ATC).

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC94

Fire Island National Seashore, Personal Watercraft Use

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: This rule designates areas where personal watercraft (PWC) may be used in Fire Island National Seashore, New York. This rule implements the provisions of the National Park Service (NPS) general regulations authorizing parks to allow the use of PWC by promulgating a special regulation. The *NPS Management Policies 2001* require individual parks to determine whether PWC use is appropriate for a specific park area based on an evaluation of that area's enabling legislation, resources and values, other visitor uses, and overall management objectives.

EFFECTIVE DATE: This rule is effective July 6, 2005.

ADDRESSES: Mail inquiries to Superintendent, Fire Island National Seashore, 120 Laurel Street, Patchogue, NY 11772. E-mail: *michael_reynolds@nps.gov.* (631) 289 4810 x225.

FOR FURTHER INFORMATION CONTACT: Jerry Case, Regulations Program Manager, National Park Service, 1849 C Street, NW., Room 7241, Washington, DC 20240. Phone: (202) 208–4206. E-mail: *Jerry_Case@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

Personal Watercraft Regulation

On March 21, 2000, the National Park Service published a regulation on the management of PWC use within all units of the national park system (65 FR 15077). This regulation prohibits PWC use in all national park units unless the NPS determines that this type of waterbased recreational activity is appropriate for the specific park unit based on the legislation establishing that park, the park's resources and values, other visitor uses of the area, and overall management objectives. The regulation banned PWC use in all park units effective April 20, 2000, except 21 parks, lakeshores, seashores, and recreation areas. The regulation established a 2-year grace period following the final rule publication to provide these 21 park units time to consider whether PWC use should be allowed.

Description of Fire Island National Seashore

Fire Island National Seashore is a vital part of America's national system of parks, monuments, battlefields, recreation areas, and other natural and cultural resources. Located on a 32-mile long barrier island off the south shore of Long Island, New York, Fire Island National Seashore encompasses approximately 19,500 acres—many of which are bay and ocean waters—available to more than 4 million visitors each year. The National Seashore is interspersed with 17 local private communities, the William Floyd Estate, a maritime forest known as the Sunken Forest, and the Otis Pike Wilderness Area—the only Federal wilderness area in New York State. Together, these components comprise a seashore ecosystem of wildlife, private communities, and outdoor recreational activities, such as the use of personal watercraft (PWC).

The Fire Island National Seashore extends from the easterly boundary of the main unit of Robert Moses State Park eastward to Moriches Inlet and includes Fire Island proper and the surrounding islands and marshlands in

the Great South Bay, Bellport Bay, and Moriches Bay adjacent to Fire Island. Included in the boundaries are Sexton Island, West Fire and East Fire Islands, Hollins Island, Ridge Island, Pelican Island, Pattersquash Island, and Reeves Island and other small and adjacent islands, marshlands, and wetlands that lend themselves to contiguity and reasonable administration within the National Seashore and the waters surrounding the National Seashore to distances of 1,000 feet in the Atlantic Ocean and up to 4,000 feet in Great South Bay and Moriches Bay. The NPS mainland terminal and headquarters are on the Patchogue River within Suffolk County, New York.

Fire Island National Seashore is fragmented by public and private beaches. Fire Island National Seashore includes the Otis Pike Wilderness Area established in 1981, the Sunken Forest, Watch Hill, Sailors Haven, the Fire Island Lighthouse (placed on the National Register of Historic Places in 1981), and the William Floyd Estate (placed on the National Register of Historic Places in 1980).

The resources and values that define the natural environment of Fire Island National Seashore include a diverse assemblage of wildlife, vegetation communities, water resources, geological features, and physical processes reflecting the complexity of the land/sea interface along the North Atlantic coast. Wildlife resources are a myriad of aquatic and terrestrial species inhabiting estuarine, dune and beach habitats. The indigenous plant communities reflect the adaptive extremes necessary for survival on a barrier island, where exposure to salt spray, lack of freshwater, and shifting sands create a harsh and dynamic environment.

The aquatic habitats of Fire Island and the adjacent coastal bays are central to the significance of the National Seashore. The inshore waters are part of a network of coastal lagoons that parallel the south shore of the Long Island coast from Breezy Point, off the tip of southern Manhattan, over 100 miles east to South Hampton. Fire Island lies in the middle of this complex system. The bays are uniformly shallow with an average depth of 1.2 meters (4 feet) and are generally characterized as poorly flushing due to restricted inlet tidal exchange.

From a regional perspective, Fire Island National Seashore includes the highest percentage of remaining undeveloped barrier islands of the south shore of the Long Island barrier island system. Extensive salt marshes, intertidal flats, and the broad shallow margins of the coastal bays within and adjacent to Fire Island are key components of an estuarine system crucial to the maintenance of regional biological diversity and ecosystem health.

Fire Island National Seashore provides important habitat for a number of federally listed threatened and endangered species, including but not limited to the peregrine falcon, roseate tern, loggerhead, Kemp's ridley, leatherback, hawksbill, and green sea turtles, bald eagle, piping plover, and sea beach amaranth. Of these species, the National Seashore provides critical habitat for piping plover and sea beach amaranth and is a focal point for North Atlantic conservation and restoration efforts. The eastern 8 miles of the park provide the most favorable conditions for piping plover breeding activity and support a majority of the local population of the species.

In addition to the piping plover, the National Seashore provides important habitat for a multitude of bird species throughout the year. The island is renowned for the autumn migration of hawks and abundance of wintering waterfowl and is of critical importance as wintering, staging, and breeding habitat for a myriad of bird species. Shorebirds, colonial waterbirds, neotropical migratory songbirds, and a variety of wading birds intensively utilize park habitats, and in general, occur in greater abundance and diversity than on the adjacent mainland.

The coastal waters within Fire Island National Seashore are regularly used by a variety of marine mammals on a seasonal or transitory basis. More than fifteen species have been documented in the National Seashore, all of which are protected under the Marine Mammal Protection Act of 1972. The most commonly observed species are seals, harbor porpoise, and bottlenose dolphin, generally occurring in ocean nearshore waters. Seals are most commonly observed during the fall and winter months, while bottlenose dolphins are present largely during the summer.

Oceanic and estuarine waters and their associated animal and plant life (biota) also play a dominant role in recreational use of the National Seashore. Over 90 percent of visits to the park involve the use of aquatic habitats. The primary recreational activities include swimming, walking, sightseeing, wildlife photography and observation, picnicking, and saltwater fishing.

Purpose of Fire Island National Seashore

Fire Island National Seashore was authorized on September 11, 1964 (Pub. L. 88–587) ''for the purpose of conserving and preserving for the use of future generations certain relatively unspoiled and undeveloped beaches, dunes, and other natural features within Suffolk County, New York, which possess high values to the Nation as examples of unspoiled areas of great natural beauty * * * to establish an area to be known as the 'Fire Island National Seashore.' ''

The purposes of Fire Island National Seashore, as stated in its *Strategic Plan* (available at *http://www.nps.gov/fiis/stratplanFY01–05.htm*), are as follows:

- Preserve the natural and cultural resources within administrative boundaries.
- Permit hunting, fishing, and shellfishing within boundaries in accordance with U.S. and New York State laws.
- Preserve the Sunken Forest tract from bay to ocean without developing roads therein.
- Preserve the main dwelling, furnishings, grounds, and outbuildings of the William Floyd Estate, home of the Floyd family for eight generations.
- Administer mainland ferry terminal and headquarters sites not to exceed 12 acres on the Patchogue River.
- Preserve the Otis Pike Fire Island High Dunes Wilderness.
- Provide for public access, use, and enjoyment.
- Work with the communities within the park to mutually achieve the goals of both the park and the residents.

Authority and Jurisdiction

The National Park Service is granted broad authority under 16 U.S.C. 1 *et seq.*, the NPS' ''Organic Act,'' to regulate the use of the Federal areas known as national parks. In addition, the Organic Act (16 U.S.C. 3) authorizes the NPS, through the Secretary of the Interior, to ''make and publish such rules and regulations as he may deem necessary or proper for the use and management of the parks * * *''

16 U.S.C. 1a–1 states, ''The authorization of activities shall be conducted in light of the high public value and integrity of the National Park System and shall not be exercised in derogation of the values and purposes for which these various areas have been established * * *''

The NPS's regulatory authority over waters subject to the jurisdiction of the United States, including navigable waters and areas within their ordinary

reach, is based upon the Property and Commerce Clauses of the U.S. Constitution. In regard to the NPS, Congress in 1976 directed the NPS to ''promulgate and enforce regulations concerning boating and other activities on or relating to waters within areas of the National Park System, including waters subject to the jurisdiction of the United States * * *'' (16 U.S.C. 1a–2(h)). In 1996 the NPS published a final rule (61 FR 35136, July 5, 1996) amending 36 CFR 1.2(a)(3) to clarify its authority to regulate activities within the National Park System boundaries occurring on waters subject to the jurisdiction of the United States.

PWC Use at Fire Island National Seashore

PWC use at Fire Island National Seashore is a relatively recent phenomenon, paralleling the national trend of increasing popularity and sales of PWC during the 1980s and 1990s.

Personal watercraft use began within the Fire Island National Seashore boundaries in the Great South Bay over 20 years ago, as soon as they were available and on the market. PWC users can access Fire Island National Seashore in a variety of ways; however, there are no public boat ramps or public roads located within the National Seashore boundaries. PWC users access the National Seashore via marinas located in the private communities and by landing on and launching from undeveloped beaches or larger vessels.

A variety of sources within the region provided estimates of typical PWC use in the Great South Bay and Fire Island National Seashore area. Staff from the Suffolk County Department of Parks and the Police Marine Bureau, local municipalities, local dealerships, and local marinas provided estimates of PWC use ranging from 5 to 25% of all watercraft on the water at any given time of the day during peak season. Although no annual counts are conducted of visitors accessing the park by boat or personal watercraft, the National Park Service conducted an informal survey on Saturdays and Sundays during the month of July 1999. During this survey, NPS staff counted the number of boats, including PWC, that were present. Based on the 1999 survey, the estimated number of boats during that time period was between 200 and 300 watercraft. Approximately 20% of the total, or between 40 and 60 watercraft, were PWC. The waterways on the bayside of Fire Island are often congested, with a variety of recreational and fishing boats accessing the waters of the National Seashore from the Great South Bay.

PWC use is typically localized within Fire Island National Seashore, occurring in areas near the private communities, ferryways and navigation channels, and in areas near boat ramps. Park staff indicate that the heaviest usage and highest general visitation area for watercraft of any type is the western end of the island. PWC use is also prevalent along the eastern boundary in Moriches Bay near Smith Point County Park.

As previously stated, on April 20, 2000, the NPS adopted a final rule for managing PWC use in areas of the National Park System. The rule was implemented to ensure a prudent approach to PWC management that would potentially allow their use, yet protect park resources, sensitive natural areas, plants and wildlife, and reduce conflicts between park visitors. The final rule prohibited PWC use in all National Park System areas unless the NPS determined that this type of waterbased activity was appropriate for a specific park based upon the legislation establishing the area, the park's resources and values, other visitor uses of the area, and overall management objectives.

Prior to April 22, 2002, PWC use was allowed throughout Fire Island National Seashore. On April 22, 2002 all of the waters within the National Seashore were closed to PWC use consistent with the 2000 NPS PWC rule (36 CFR 3.24).

Notice of Proposed Rulemaking and Environmental Assessment

On August 23, 2004, the National Park Service published a Notice of Proposed Rulemaking (NPRM) for the operation of PWC at Fire Island National Seashore (69 FR 51788). The proposed rule for PWC use was based on alternative C (one of four alternatives considered) in the Environmental Assessment (EA) prepared by NPS for Fire Island National Seashore. The EA was available for public review and comment from September 3, 2002, through November 11, 2002, and the NPRM was available for public comment from August 23, 2004, through October 22, 2004.

The purpose of the EA was to evaluate a range of alternatives and strategies for the management of PWC use at Fire Island National Seashore to ensure the protection of park resources and values while offering recreational opportunities as provided for in the National Seashore's enabling legislation, purpose, mission, and goals. In March 2004 an errata was issued. The changes to the EA described in the errata were made to modify the preferred alternative and its analysis, to address public comments on the draft EA, and to clarify the text.

The four alternatives considered included three alternatives to continue PWC use under certain conditions: Alternative A would establish, through regulation, the PWC policies that existed prior to 2000 when PWC use was permitted throughout Fire Island National Seashore; alternative B would limit PWC use to areas adjacent to beach communities; and modified alternative C would continue to allow PWC access to the national seashore with additional management and geographic restrictions. The additional geographic restrictions west of Sunken Forest would include a 1,000 foot buffer around all shorelines, with access to beach communities only through established access channels and ferryways. East of the western boundary of Sunken Forest PWC use would be forbidden in Seashore waters, except for access to beach communities only through established access channels and ferryways. In addition, a no-action alternative was considered that would discontinue all PWC use within the National Seashore. The four alternatives were evaluated with respect to PWC impacts on water quality, air quality, soundscapes, wildlife, wildlife habitat, shoreline vegetation, visitor conflicts, and visitor safety.

Based on the analysis NPS determined that modified alternative C is the environmentally preferred alternative. (For the remainder of this document ''alternative C'' refers to modified alternative C.) Alternative C best fulfills NPS responsibilities as trustee of Fire Island National Seashore's sensitive habitat; ensuring safe, healthful, productive, and aesthetically and culturally pleasing surroundings; and attaining a wider range of beneficial uses of the environment without degradation, risk of health or safety, or other undesirable and unintended consequences. Alternative C is the preferred alternative for fulfilling the park's environmental mission without restricting valid and lawful use. This final rule contains regulations to implement alternative C at Fire Island National Seashore.

Summary of Comments

A proposed rule was published for public comment on August 23, 2004, with the comment period lasting until October 22, 2004. The National Park Service received 528 timely written responses regarding the proposed regulation. Of the responses, 527 were signatures on a petition supporting the no action alternative and one was from an individual opposing PWC use in national parks. The National Park Service received approximately 4,600

comment letters regarding the EA. More than 1,300 were in support of continuing PWC use as currently managed and approximately 740 supported the no action alternative, or the complete ban of PWC within Fire Island National Seashore. Approximately 1,600 comments opposed the preferred alternative as originally proposed, prompting the development of the modified alternative C. While the proposed rule reflected changes to alternative C made as a result of comments on the EA, the NPRM did not describe or discuss responses to those comments. Therefore, this preamble addresses those comments. Within the following discussion, the term ''commenter'' refers to an individual, organization, or public agency that responded. The term ''comments'' refers to statements made by a commenter.

General Comments

1. Several commenters stated that PWC should not be singled out for analysis and restriction.

NPS Response: The EA was not designed to determine if personal watercraft caused more environmental damage to park resources than other boats, but rather, to determine if personal watercraft use was consistent with the park's enabling legislation and management goals and objectives.

2. One commenter stated that allowing PWC use violates the park's enabling legislation and NPS mandate to protect resources from harm.

NPS Response: No part of the settlement agreement or NPS analysis of PWC use has violated or overturned Fire Island National Seashore's enabling legislation. Both the personal watercraft settlement agreement and the authorizing legislation for Fire Island were considered when developing alternatives for the EA. The objective of the EA, as described in the ''Purpose and Need'' chapter, was derived from the enabling legislation for the national seashore. As further stated in that chapter, a special analysis on the management of personal watercraft was also provided under each alternative to meet the terms of the settlement agreement between the Bluewater Network and the National Park Service. As a result, the alternatives presented in the EA protect resources and values while providing recreational opportunities at Fire Island National Seashore. As required by NPS policies, the impacts associated with personal watercraft and other recreational uses are evaluated under each alternative to determine the potential for impairment to park resources. Alternative C would not result in impairment of park resources and values for which the national seashore was established.

The seashore's mission statement grows from the park's legislative mandate and is a synthesis of the park's mandated purpose and its primary significances. It includes a commitment ''to providing access and recreational and education opportunities to Fire Island National Seashore visitors in this natural and cultural setting close to densely populated urban and suburban areas.''

3. One commenter states that the EA does not use the best available data and violates the court settlement with the Bluewater Network.

NPS Response: A summary of the NPS rulemaking and associated personal watercraft litigation is provided in Chapter 1, Purpose of and Need for Action, Background of the EA. NPS believes it has complied with the court order and has assessed the impacts of personal watercraft on those resources specified, as well as other resources that could be affected. This analysis was done for every applicable impact topic with the best available data, as required by Council on Environmental Quality Regulations (40 CFR 1502.22). Where data was lacking, best professional judgment prevailed using assumptions and extrapolations from scientific literature, other park units where personal watercraft are used, and personal observations of park staff. The NPS believes that the EA is in full compliance with the settlement agreement and that the rationale for limited PWC use within the national recreation area has been adequately analyzed and explained.

4. One commenter is concerned about the use of Federal Aid in Sport Fish Restoration Act (FASFRA) funds to construct boat launches and facilities.

NPS Response: There are no provisions within the proposed alternative for boat launches and facilities. Landing zones are designated by the NPS for access only by PWC users. No FASFRA funds are used within the national recreation area to construct boat launches.

5. Several commenters stated that the decision violates the Organic Act, and other NPS laws, and will result in the impairment of resources.

NPS Response: The ''Summary of Laws and Policies'' section in the ''Environmental Consequences'' chapter of the EA summarizes the three overarching laws that guide the National Park Service in making decisions concerning protection of park resources. These laws, as well as others, are also reflected in the NPS *Management Policies.* An explanation of how the Park Service applied these laws and policies to analyze the effects of personal watercraft on Fire Island National Seashore resources and values can be found under ''Impairment Analysis'' in the ''Methodology'' section of the EA.

An impairment to a particular park resource or park value must rise to the magnitude of a major impact, as defined by its context, duration, and intensity and must also affect the ability of the National Park Service to meet its mandates as established by Congress in the park's enabling legislation. For each resource topic, the EA establishes thresholds or indicators of magnitude of impact. An impact approaching a ''major'' level of intensity is one indication that impairment could result. For each impact topic, when the intensity approached ''major,'' the park would consider mitigation measures to reduce the potential for ''major'' impacts, thus reducing the potential for impairment.

The PWC Use Environmental Assessment is a proactive measure to protect national seashore resources from harm. The purpose of the EA is to assess the impacts of PWC use on identified resources within the seashore boundaries. The National Park Service finds that the revised preferred alternative (alternative C), when implemented under this final rule, will not result in an impairment of park resources and values for which the Fire Island National Seashore was established.

Comments Regarding the Preferred Alternative

6. Approximately 36 percent of all EA comments on the alternatives addressed alternative A. The 1,320 comments received regarding alternative A included one petition with 1,228 respondents and one petition with four respondents in support of Alternative A. Less than one percent of all EA comments on the alternatives addressed alternative B. Approximately 44 percent of all EA comments on the alternatives concerned Alternative C. Comments included a petition with 73 respondents that opposed Alternative C. Many comments questioned the enforceability of a buffer and suggested a ban would be more effective. Approximately 20 percent of all EA comments on the alternative were in favor of the no-action alternative. Three petitions in favor of this alternative were received including 44 respondents from the Bluewater Network, 297 respondents from an unknown source, and 66 respondents from another unknown

petition. The majority of comments received for the no-action alternative were in support of a complete ban on PWC. All 528 comments received on the proposed rule were in favor of the no-action alternative.

Several commenters stated that the area restrictions in the preferred alternative seem arbitrary and difficult to enforce.

NPS Response: Alternative C, the preferred alternative, was revised before issuance of the NPRM to address the public comments received on the EA. The revised alternative C, as adopted in this final rule, will continue to allow PWC in the areas adjacent for access to the national seashore with additional management and geographic restrictions. PWC will be allowed to operate in Great South Bay from the western boundary of the national seashore adjacent to Robert Moses State Park, east to the western boundary of the Sunken Forest, excluding any area within 1,000 feet of the shoreline including East Fire Island and West Fire Island; navigation channels marked by buoys or identified on the NOAA navigational chart (12352) to include access channels to and from Fair Harbor, Dunewood, Lonelyville, Atlantique, Cherry Grove, Fire Island Pines, Davis Park, Great Gun Beach, Moriches Inlet, and to the communities of Kismet, Saltaire, Ocean Beach, Ocean Bay Park, Point O'Woods, Oakleyville, and Water Island at ''flat wake speed'; and the Long Island Intracoastal Waterway within the park boundaries.

PWC will be prohibited from operation in all waters from the shoreline to 1,000 feet offshore between the west boundary of Moriches Inlet to the east boundary of Robert Moses State Park on the Atlantic Ocean side of the national seashore.

Alternative C, as implemented in this final rule, allows for access throughout the park in designated channels and ferryways; thus, maintaining an equilibrium between visitor use and the protection of resources.

Comments Regarding Water Quality

7. One commenter stated that the analysis disregarded or overlooked relevant research regarding impacts to water quality from PWC use.

NPS Response: The protection of water quality within the national seashore has been addressed in the EA in a conservative evaluation of surface water quality impacts. Estimated minimum threshold volumes of water were determined for the PWC use areas where concentrations of gasoline constituents discharged from personal watercraft and other outboard engines could potentially be toxic to aquatic organisms or humans. Using the estimated threshold volumes, volumes of the areas being evaluated, PWC and other motorboat high-use-day loadings of chemicals identified as constituents of gasoline, and water quality benchmarks, it is possible to identify potentially unacceptable impacts to human health or the environment. Chronic water quality benchmarks protective of aquatic populations and protective of human health were acquired from various sources, including U.S. EPA water quality criteria. Potential impacts to wildlife and plants from personal watercraft were addressed in other sections of the EA.

The evaluation of water quality impacts examined impacts from PWCs alone and in combination with other outboard motorboats. Impacts are estimated to range from ''negligible'' to ''major'' for the various combinations of alternatives, chemicals, PWCs and/or boats, and years (2002 and 2012). The descriptions for each level of water quality impacts are provided on page 95 of the EA. There is no conclusion in the EA that PWC would have ''little impact'' on water quality in Fire Island National Seashore as described in the comment. Further, it is not conjectured that ''all petroleum compounds evaporate into the atmosphere.''

8. One commenter stated that the analysis represents an outdated look at potential emissions from an overstated PWC population of conventional 2-stroke engines, and underestimated the accelerating changeover to 4-stroke and newer 2-stroke engines. The net effect is that the analysis overestimates potential PWC hydrocarbon emissions, including benzene and polyaromatic hydrocarbons (PAHs).

NPS Response: The NPS recognizes that the assumption of all personal watercraft using 2-stroke engines in 2002 is conservative but believes it was appropriate to be protective of park resources. The assumption is consistent with emission data available in California Air Resources Board (CARB) (1998) and Bluewater Network (2001). The emission rate of 3 gallons per hour at full throttle is a mid-point between 3 gallons in two hours (1.5 gallons per hour; NPS 1999) and 3.8 to 4.5 gallons per hour for an average 2000 model year personal watercraft (Personal Watercraft and Bluewater Network 2001). The assumption also is reasonable in view of the initiation of production line testing in 2000 (EPA 1997) and expected full implementation of testing by 2006 (EPA 1996).

Reductions in emissions used in the water quality impact assessment are in accordance with the overall hydrocarbon emission reduction projections published by the EPA (1996). EPA (1996) estimates a 52% reduction by personal watercraft by 2010 and a 68% reduction by 2015. The 50% reduction in emissions by 2012 (the future date used in the EA) is a conservative interpolation of the emission reduction percentages and associated years (2010 and 2015) reported by the EPA (1996) but with a one-year delay in production line testing (EPA 1997).

The estimate of 2.8 mg/kg for benzo(a)pyrene in gasoline used in the calculations is considered conservative, yet realistic, since it is within the range of concentrations measured in gasoline, according to Gustafson *et al.* (1997).

Comments Regarding Air Quality

9. One commenter stated that the analysis failed to mention the impact of PWC permeation losses on local air quality.

NPS Response: Permeation losses of volatile organic compounds (VOCs) from personal watercraft were not included in the calculation of air quality impacts primarily because these losses are insignificant relative to emissions from operating personal watercraft. Using the permeation loss numbers in the comment (estimated to be half the total of 7 grams of losses per 24 hours from the fuel system), the permeation losses per hour are orders of magnitude less than emissions from operating personal watercraft. Therefore, including permeation losses would have no effect on the results of the air quality impact analyses. Also, permeation losses were not included because of numerous related unknown contributing factors, such as the number of personal watercraft refueling at the reservoir and the location of refueling (inside or outside of the airshed).

10. One commenter stated that the use of the study by Kado et al to suggest that the changeover from two-stroke carbureted to two-stroke direct injection engines may increase emissions of PAH is in error.

NPS Response: The criteria for analysis of impacts from PWC to human health are based on the National Ambient Air Quality Standards (NAAQSs) for criteria pollutants, as established by the U.S. Environmental Protection Agency (EPA) under the Clean Air Act, and on criteria pollutant annual emission levels. This methodology was selected to assess air quality impacts for all NPS EAs to promote regional and national

consistency, and identify areas of potential ambient standard exceedances. PAHs are not assessed specifically as they are not a criteria pollutant. However, they are indirectly included as a subset of Total Hydrocarbons (THC), which are assessed because they are the focus of the EPA's emissions standards directed at manufacturers of spark ignition marine gasoline engines (see 61 FR 52088; October 4, 1996). Neither peak exposure levels nor NIOSH nor OSHA standards are included as criteria for analyzing air quality related impacts except where short-term exposure is included in a NAAQS. The methodology for assessing air quality impacts was based on a combination of annual emission levels and the NAAQSs, which are aimed at protection of the public. OSHA and NIOSH standards are intended primarily for workers and others exposed to airborne chemicals for specific time periods. The OSHA and NIOSH standards are not as suitable for application in the context of local and regional analysis of a park or recreational area as are the ambient standards, nor are they intended to protect the general public from exposure to pollutants in ambient air.

11. One commenter expressed concern on the use of SUM06 data and requested a more detailed analysis of the air quality impacts associated with opening corridors to PWC use because the alternatives considered in the EA, other than the no action alternative, do not comply with General Conformity Regulations.

NPS Response: To assess the impact of ozone on plants, the 5-year ozone index value was calculated and is represented as SUM06. The Air Resources Division of the National Park Service, based on local monitoring site data, developed SUM06 values used in each analysis.

The air quality impacts of the various alternatives were assessed by considering the existing air quality levels and the air quality related values present, and by using the estimated emissions and any applicable, EPA-approved air quality models. Cumulative impacts were analyzed quantitatively for all recreational watercraft. Fire Island National Seashore maintains vehicular access to the park for cars, trucks, and recreational vehicles; emissions from these vehicles and other local and regional sources of air pollutants were not assessed quantitatively but were considered qualitatively in the cumulative impact assessment.

Located within the ozone non-attainment area, the proposed actions are subject to the requirements and emission threshold set by the Federal conformity rules (40 CFR part 93), in which the emission threshold set for ozone precursor pollutants—nitrogen oxides (NO_X) or volatile organic compounds (VOC)—is 25 tons/year. All ambient air quality levels except ozone meet the national ambient air quality standards.

The Fire Island National Seashore area, located in Suffolk County, New York, is designated by the U.S. Environmental Protection Agency as in severe nonattainment for ozone, and as in attainment for all other criteria pollutants (CO, NO_X, SO_2, PM_{10}, and lead). The Division of Air Resources within the New York State Department of Environmental Conservation has included control measures and has accounted for limited growth related to ozone precursor sources, such as nonroad marine engines, in the State Implementation Plan. The Division of Air Resources predicts that Suffolk County will attain the national air quality standard for ozone by 2007 (allowances for emissions of these pollutants are documented in appendix N of the State Implementation Plan). The proposed action and alternatives are subject to Federal conformity review but are not predicted to add pollutants not already included in the State plan; therefore, the proposed action and alternatives are presumed to conform with the State plan, and a conformity determination is not required (40 CFR 93.158).

12. Several commenters stated that research indicated that direct-injection 2-stroke engines are dirtier than 4-stroke engines.

NPS Response: It is agreed that two-stroke carbureted and two-stroke DI engines generally emit greater amounts of pollutants than four-stroke engines. Only 4 of the 20 PAHs included in the analyses were detected in water: naphthalene, 2-methylnaphthalene, fluorene, and acenaphthylene. Some pollutants (benzene, toluene, ethylbenzene, and xylene, collectively referred to as BTEX, and formaldehyde) were reported by CARB in the test tanks after 24 hours at approximately 50% the concentrations seen immediately following the test. No results for PAH concentrations after 24 hours were seen in the CARB (2001) results, but a discussion of sampling/analyses of PAHs in the six environmental compartments was presented.

EPA NONROAD model factors differ from those of CARB. As a result of the EPA rule requiring the manufacturing of cleaner PWC engines, the existing carbureted 2-stroke PWC will, over time, be replaced with PWC with less-polluting models. This replacement, with the anticipated resultant improvement in air quality, is parallel to that experienced in urban environments as the automobile fleet becomes cleaner over time.

13. One commenter stated that the EA erroneously assumes that none of the PWC operating in Fire Island National Seashore would meet the CARB standards. The quantitative emissions analysis performed by Sierra Research also refutes the EA's use of the term ''major'' to describe current impact of ozone precursors emitted by PWC.

NPS Response: The NPS emissions calculations are conservative only in the sense that they do not specifically account for watercraft that have already been or will be converted to meet CARB standards. Any reductions in emissions resulting from implementing control strategies were taken into account, as were changes in emissions resulting from increased or decreased usage. In addition, located within the ozone non-attainment area, the proposed actions are subject to the requirements and emission threshold set by the Federal conformity rules (40 CFR part 93), in which the emission threshold set for ozone precursor pollutants—nitrogen oxides (NO_X) or volatile organic compounds (VOC)—is 25 tons/year. All ambient air quality levels except ozone meet the national ambient air quality standards.

Comments Regarding Soundscapes

14. One commenter stated that continued PWC use at Fire Island National Seashore will not result in sound emissions that exceed the applicable Federal or State noise abatement standards since technological innovations by the PWC companies will continue to result in substantial noise reductions.

NPS Response: The NPS concurs that on-going and future improvements in engine technology and design would likely further reduce the noise emitted from PWC. However, given that the ambient noise levels at the national seashore are negligible to minor in most cases, improved technology reductions would not significantly reduce ambient noise levels.

15. One commenter stated that the NPS methodology was unclear and should clarify between decibels and A-weighting.

NPS Response: The impacts for the EA were weighed in decibels.

16. One commenter stated that the EA fails to recognize seashore visitor's desires to hear natural sounds.

NPS Response: The EA considered the cumulative impact of PWC and other

watercraft, while qualitatively considering ambient noise levels; which could include airplanes, etc. While specific background noise studies are not available at Fire Island National Seashore, certain conditions have been taken into account given the number of PWC users in the identified study areas and land use patterns surrounding those areas. For example, it is assumed that the soundscape throughout the majority of area I is that of an active suburban area, while area II is an area of day use, and area III is more characteristic of a quiet rural town with associated tourism.

17. One commenter stated that the analysis did not include *Drowning in Noise: Noise Costs of PWC in America* and therefore the noise analysis under represents the actual impacts.

NPS Response: One of the initial tasks in developing the Fire Island National Seashore EA was a literature search. *Drowning in Noise: Noise Costs of Jet Skis in America* was one of the many studies reviewed. The reference to that study (Komanoff and Shaw 2000) was discussed in the ''Summary of Available Research on the Effects of Personal Watercraft'' section of the EA.

Comments Regarding Shoreline/ Submerged Aquatic Vegetation

18. One commenter stated that there has been no documentation of any adverse effects to shoreline vegetation from PWC use.

NPS Response: We agree there has been no current adverse impact to shoreline vegetation. The analysis recognizes that PWC use to date has resulted in only negligible adverse impacts to this vegetation, mostly from PWC operators leaving their vessels and trampling vegetation. The regulation creates a 1000′ no PWC use zone from the shoreline to protect shoreline and wetlands vegetation.

Comments Regarding Wildlife and Wildlife Habitat

19. Two commenters stated that the analysis lacked site-specific data for impacts to fish, wildlife, and threatened and endangered species at Fire Island National Seashore.

NPS Response: The scope of the EA did not include conducting site specific studies regarding potential effects of PWC use on wildlife species at Fire Island National Seashore. Analysis of potential impacts of PWC use on wildlife at the national seashore was based on best available data and input from park staff.

20. One commenter stated that PWC use and human activities associated with their use may not be any more disturbing to wildlife species than any other type of motorized or non-motorized watercraft. The commenter cites research by Dr. James Rodgers of the Florida Fish and Wildlife Conservation Commission, whose studies have shown that PWC are no more likely to disturb wildlife than any other form of human interaction. That PWC use posed less of a disturbance than other vessel types. Dr. Rodgers' research clearly shows that there is no reason to differentiate PWC from motorized boating based on claims of wildlife disturbance.

NPS Response: Based on the documents provided as part of this comment, it appears that personal watercraft are no more apt to disturb wildlife than are small outboard motorboats. In addition to this conclusion, Dr. Rodgers recommends that buffer zones be established, creating minimum distances between boats (personal watercraft and outboard motorboats) and nesting and foraging waterbirds. In Fire Island National Seashore, a 1000-ft buffer and no-wake zones are established by this regulation. With these restrictions in mind, impacts to wildlife and wildlife habitat were judged to be negligible to minor at most locations along the shoreline.

Comments Associated With Visitor Use, Experience, and Safety

21. One commenter stated that the reported accident numbers involving PWC are higher because they get reported more often than other boating accidents.

NPS Response: We disagree. Incidents involving watercraft of all types, including personal watercraft, are reported to and logged by National Park Service staff. A very small proportion of watercraft accidents at Fire Island National Seashore are estimated to go unreported.

22. One commenter stated that the analysis did not adequately address PWC fire hazards.

NPS Response: According to the National Marine Manufacturers Association, PWC manufacturers have sold roughly 1.2 million watercraft during the last ten years. Out of 1.2 million PWC sold, the U.S. Coast Guard had only 90 reports of fires/explosions in the years from 1995–1999. This is less than 1% of PWC boats having reports of problems associated with fires/explosions. As far as the recall campaigns conducted by Kawasaki and Bombardier, the problems that were associated with fuel tanks were fixed. Kawasaki conducted a recall for potentially defective fuel filler necks and fuel tank outlet gaskets on 23, 579 models from the years 1989 and 1990. The fuel tank problems were eliminated in Kawasaki's newer models, and the 1989 and 1990 models are most likely not in use anymore since life expectancy of a PWC is only five to seven years according to PWIA. Bombardier also did a recall for its 1993, 1994, and 1995 models to reassess possible fuel tank design flaws. However, the number of fuel tanks that had to be recalled was a very small percent of the 1993, 1994, and 1995 fleets because fuel tank sales only amounted to 2.16% of the total fleet during this period (Bombardier, Inc.). The replacement fuel tanks differed from those installed in the watercraft subject to the recall in that the replacement tanks had revised filler neck radiuses, and the installation procedure now also requires revised torque specifications and the fuel system must successfully complete a pressure leak test. Bombardier found that the major factor contributing to PWC fires/explosions was over-torquing of the gear clamp. Bombardier was legally required by the U.S. Coast Guard to fix 9.72% of the recalled models. Out of 125, 349 recalls, the company repaired 48,370 units, which was approximately 38% of the total recall, far exceeding their legal obligation to repair units with potential problems.

Further fuel tank and engine problems that could be associated with PWC fires has been reduced significantly since the National Marine Manufacturers Association set requirements for meeting manufacturing regulations established by the U.S. Coast Guard. Many companies even choose to participate in the more stringent Certification Program administered by the National Marine Manufacturers Association (NMMA). The NMMA verifies annually, or whenever a new product is put on the market, boat model lines to determine that they satisfy not only the U.S. Coast Guard Regulations but also the more rigorous standards based on those established by the American Boat and Yacht Council.

Accident data specific to Fire Island National Seashore shows no incidents of PWC catching on fire or exploding at the park. Based on the regulations imposed upon PWC manufacturers by the U.S. Coast Guard and manufacturing associations, and the continued cooperation of manufacturers to assess and fix any potential design flaws, the National Park Service does not think PWC use presents any unusual fire hazard at Fire Island National Seashore.

23. Several commenters stated that the analysis does not adequately assess

the safety threat posed to park visitors by PWC use.

NPS Response: The EA has been revised to acknowledge the reference (ACA 2001). According to New York State PWC accident trends, the number of accidents reported in the State has fluctuated from 31 reported accidents in 1994 to 140 reported accidents in 1996. However, the manufacturers of personal watercraft provide training videos with each watercraft they sell, and to date, 24 States, including New York, require some type of boater education in order to operate a personal watercraft.

Incidents involving watercraft of all types, including personal watercraft, are reported to and logged by the National Park Service, Suffolk County Marine Bureau, and the USCG or local constables. Eleven accidents or incidents involving personal watercraft have been reported at Fire Island National Seashore in the past five years. Accident information generated by the U. S. Coast Guard has been incorporated into the ''Summary of National Information of the Effects of Personal Watercraft'' section of the ''Purpose and Need'' chapter of the Final EA.

The inclusion of a buffer and the requirement of the flat-wake speeds within the specified navigation channels, as detailed in modified alternative C, will provide greater protection for swimmers, fishermen, boats at the shoreline, and people in the water and at the shoreline. Because of these measures under the modified preferred alternative (alternative C), the National Park Service has found personal watercraft use at Fire Island National Seashore to be compatible with park management objectives and values under certain regulation.

24. One commenter states that the EA also falls short of adequately examining the adverse impacts of PWC use to canoeist and kayakers. There is no evidence that NPS surveyed canoeist and kayakers regarding how PWC impact their visitor experience of affect the likelihood of return visits.

NPS Response: The regulation prohibits PWC use within 1000′ of the shoreline between the park's western boundary and the western boundary of Sunken Forest and a complete prohibition in all other waters to the east. These are the area most often used by kayakers and canoeists. The seashore's mission includes a commitment ''to providing access and recreational and education opportunities to Fire Island National Seashore visitors in this natural and cultural setting close to densely populated urban and suburban areas.'' The scope of the EA did not include the conduct of visitor surveys beyond the annual survey conducted by the park. Analysis of potential impacts of PWC use on visitors to the national seashore was based on best available data, input from park staff, and the results of analysis using that data.

Comments Related to Socioeconomics

25. One commenter stated that the economic impacts should not outweigh environmental impacts.

NPS Response: We agree. The national seashore's mission includes a commitment ''to providing access and recreational and education opportunities to Fire Island National Seashore visitors in this natural and cultural setting close to densely populated urban and suburban areas.'' The park and the Superintendent are not just considering economic impacts or environmental impacts, but must also consider the potential impacts to their visitors as well as their park mission.

Changes to the Final Rule

Based on the preceding comments and responses, the NPS has made no changes to the proposed rule language with regard to PWC operations.

Compliance With Other Laws

Regulatory Planning and Review (Executive Order 12866)

This document is not a significant rule and has not been reviewed by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The National Park Service has completed the report ''Economic Analysis of Personal Watercraft Regulations in Fire Island National Seashore'' (Law Engineering and Environmental Sciences, Inc.) dated March 2002. The report found that this rule will not have a negative economic impact. In fact this rule, which will not directly impact local PWC dealerships and rental shops, may have an overall positive impact on the local economy. This positive impact to the local economy is a result of an increase of other users, most notably canoeists, swimmers, anglers and traditional boaters seeking solitude and quiet, and improved water quality.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Actions taken under this rule will not interfere with other agencies or local government plans, policies, or controls. This is an agency specific rule.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. This rule will have no effects on entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. No grants or other forms of monetary supplements are involved.

(4) This rule does not raise novel policy issues. This regulation is one of the special regulations being issued for managing PWC use in National Park Units. The National Park Service published the general regulations (36 CFR 3.24) in March 2000, requiring individual park areas to adopt special regulations to authorize PWC use. The implementation of the requirements of the general regulation continues to generate interest and discussion from the public concerning the overall effect of authorizing PWC use and National Park Service policy and park management.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based upon the finding in a report prepared by the National Park Service entitled, ''Economic Analysis of Personal Watercraft Regulations in Fire Island National Seashore'' (Law Engineering and Environmental Sciences, Inc., March 2002). The focus of this study was to document the impact of this rule on two types of small entities, PWC dealerships and PWC rental outlets. This report found that the potential loss for these types of businesses as a result of this rule would be minimal to none.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The National Park Service has completed an economic analysis to make this determination. This rule:

a. Does not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. This rule is an agency specific rule and imposes no other requirements on other agencies, governments, or the private sector.

Takings (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant taking implications. A taking implication assessment is not required. No takings of personal property will occur as a result of this rule.

Federalism (Executive Order 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This rule only affects use of NPS administered lands and waters. It has no outside effects on other areas and only allows use within a small portion of the park.

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This regulation does not require an information collection from 10 or more parties and a submission under the Paperwork Reduction Act is not required. An OMB Form 83–I is not required.

National Environmental Policy Act

The National Park Service has analyzed this rule in accordance with the criteria of the National Environmental Policy Act and has prepared an Environmental Assessment (EA). The EA was open for public review and comment from September 3, 2002, to November 11, 2002. A copy of the EA and the errata is available by contacting the Superintendent, Fire Island National Seashore,120 Laurel Street, Patchogue, New York 11772. E-mail: *michael_bilecki@nps.gov,* Fax: (631) 289–4898, or on the Internet at *http://www.nps.gov/fiis/pwc.htm.* A Finding of No Significant Impact (FONSI) was approved on May 12, 2005. Copies of the FONSI may be downloaded at *http://www.nps.gov/fiis* or obtained by calling (631) 289 4810 x225 or writing to the Superintendent, Fire Island National Seashore,120 Laurel Street, Patchogue, New York 11772.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29,1994, ''Government to Government Relations With Native American Tribal Governments'' (59 FR 22951) and 512 DM 2, we have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects.

Administrative Procedure Act

This final rule is effective upon publication in the **Federal Register.** In accordance with the Administrative Procedure Act, specifically, 5 U.S.C. 553(d)(1), this rule, 36 CFR 7.20(d), is exempt from the requirement of publication of a substantive rule not less than 30 days before its effective date.

As discussed in this preamble, the final rule is a part 7 special regulation for Fire Island National Seashore that relieves the restrictions imposed by the general regulation, 36 CFR 3.24. The general regulation, 36 CFR 3.24, prohibits the use of PWC in units of the national park system unless an individual park area has designated the use of PWC by adopting a part 7 special regulation. The proposed rule was published in the **Federal Register** (69 FR 51788) on August 23, 2004, with a 60-day period for notice and comment consistent with the requirements of 5 U.S.C. 553(b). The Administrative Procedure Act, pursuant to the exception in paragraph (d)(1), waives the section 553(d) 30-day waiting period when the published rule ''grants or recognizes an exemption or relieves a restriction.'' In this rule the NPS is authorizing the use of PWCs, which is otherwise prohibited by 36 CFR 3.24. As a result, the 30-day waiting period before the effective date does not apply to the Fire Island National Seashore final rule.

List of Subjects in 36 CFR Part 7

National Parks, Reporting and Recordkeeping requirements.

■ For the reasons stated in the preamble, the National Park Service amends 36 CFR part 7 as follows:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for Part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q), 462(k); Sec. 7.96 also issued under D.C. Code 8–137 (1981) and D.C. Code 40–721 (1981).

■ 2. Add new paragraph (d) to § 7.20 to read as follows:

§ 7.20 Fire Island National Seashore.

* * * * *

(d) *Personal watercraft.* (1) Personal watercraft (PWC) may operate in the following locations and under the following conditions:

(i) Great South Bay from the western boundary of the national seashore adjacent to Robert Moses State Park, east to the western boundary of the Sunken Forest, excluding any area within 1,000 feet of the shoreline, except as provided in (ii), including the area surrounding East Fire Island and West Fire Island.

(ii) Navigation channels marked by buoys or identified on the NOAA navigational chart (12352) to include access channels to and from Fair Harbor, Dunewood, Lonelyville, Atlantique, Cherry Grove, Fire Island Pines, Davis Park, Moriches Inlet, Kismet, Saltaire, Ocean Beach, Ocean Bay Park, Point O'Woods, Oakleyville, and Water Island.

(iii) The Long Island Intracoastal Waterway within the park boundaries.

(iv) At ''flat wake'' speeds (maximum 6 mph) within designated marked channels to access town/community docks and harbors/marinas.

(2) The Superintendent may temporarily limit, restrict or terminate access to the areas designated for PWC use after taking into consideration public health and safety, natural and cultural resource protection, and other management activities and objectives.

Dated: June 24, 2005.

Paul Hoffman,

Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 05–13209 Filed 7–5–05; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. 2005–T–056]

RIN 0651–AB88

Requirements To Receive a Reduced Fee for Filing an Application Through the Trademark Electronic Application System

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is amending its rules to permit an applicant to pay a reduced fee under certain circumstances when the applicant uses the Trademark Electronic Application System (TEAS) to file a trademark or service mark application for registration on the Principal Register under section 1 and/or section 44 of the Trademark Act. The Office will offer a reduced fee to TEAS applicants if the application meets certain filing requirements beyond those required to receive a filing date. The applicant must also file communications regarding the application through TEAS, and agree to receive communications concerning the application by electronic mail (e-mail) during the pendency of the application. TEAS applications that qualify for the reduced fee option will be referred to as ''TEAS Plus'' applications. The reduced fee option will not apply to applications filed pursuant to section 66(a) of the Act, because they cannot be filed through TEAS.

DATES: *Effective Date:* July 18, 2005.

FOR FURTHER INFORMATION CONTACT: Mary E. Hannon, Office of the Deputy Commissioner for Trademark Examination Policy, by telephone at (571) 272–9569, by e-mail to *mary.hannon@uspto.gov,* or by facsimile to (571) 273–9569.

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** (70 FR 17636) on April 7, 2005, and in the Official Gazette on May 3, 2005. Two organizations, three attorneys, one law firm, and two individuals submitted written comments.

The Office will offer a reduced fee to TEAS applicants who use the Office's Trademark/Servicemark Application, Principal Register form if: (1) The application meets the additional filing requirements specified in § 2.22(a); (2) the applicant files certain communications regarding the application through TEAS; and (3) the applicant agrees to receive communications concerning the application by e-mail. The application will be referred to as a TEAS Plus application. The applicant must pay an additional fee set forth in § 2.6(a)(1)(iv) if, at any time during examination of the TEAS Plus application, the Office determines that: (1) The application did not meet the filing requirements of § 2.22(a) on the filing date; (2) the applicant filed one of the communications listed in § 2.23(a) on paper; or (3) the applicant refused to receive correspondence from the Office by e-mail.

References in this notice to ''the Act,'' ''the Trademark Act,'' or ''the statute'' refer to the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.*, as amended.

Background

This final rule is in accordance with the Consolidated Appropriations Act, 2005, Sec. 2, Division B, Title VIII, Sec. 802 of Public Law 108–447, 118 Stat. 2809, 2929, enacted on December 8, 2004. The Appropriations Act amends the Trademark Act of 1946 to require that:

> During fiscal years 2005 and 2006, under such conditions as may be prescribed by the Director, the fee under § 31(a) of the Trademark Act * * * for: (1) The filing of a paper application for the registration of a trademark shall be $375; (2) the filing of an electronic application shall be $325; and (3) the filing of an electronic application meeting certain additional requirements prescribed by the Director shall be $275 * * *.

Effective January 31, 2005, application filing fees were amended in accordance with the provisions of 15 U.S.C. 1113(a), as amended by the Appropriations Act. A final rule was published at 70 FR 2952 (Jan. 19, 2005). The filing fee for paper applications filed under section 1 or 44 of the Trademark Act is now $375.00 per class, and the filing fee for TEAS applications filed under section 1 or 44 of the Trademark Act is now $325.00 per class.

Requirements for a TEAS Plus Application

This rule sets forth the requirements for TEAS applications that must be satisfied in order to be eligible for a reduced fee of $275.00 per class. The rule only applies to TEAS applications filed on the Office's Trademark/Servicemark Application, Principal Register form. Under § 2.22, to obtain a reduced filing fee an application must include the following:

(1) The applicant's name and address;

(2) The applicant's legal entity;

(3) The citizenship of an individual applicant, or the state or country of incorporation or organization of a juristic applicant;

(4) If the applicant is a partnership, the names and citizenship of the applicant's general partners;

(5) A name and address for correspondence;

(6) An e-mail address for correspondence and an authorization for the Office to send correspondence concerning the application to the applicant or applicant's attorney by e-mail;

(7) One or more basis or bases for filing under section 1 and/or section 44 of the Act that satisfy all the requirements of § 2.34. If more than one basis is set forth, the applicant must comply with the requirements of § 2.34 for each asserted basis;

(8) Correctly classified goods and/or services, with an identification of goods and/or services from the Office's Acceptable Identification of Goods and Services Manual (Goods and Services Manual). In an application based on section 44 of the Act, the scope of goods and/or services covered by the section 44 basis may not exceed the scope of the goods and/or services in the foreign application or registration;

(9) If the application contains goods and/or services in more than one class, compliance with § 2.86;

(10) A filing fee for each class of goods and/or services as required by § 2.6(a)(iii);

(11) A verified statement that meets the requirements of § 2.33, dated and signed by a person properly authorized to sign on behalf of the applicant pursuant to § 2.33(a);

(12) A clear drawing of the mark. If the applicant does not claim standard characters, the applicant must attach a digitized image of the mark in .JPG format. If the mark includes color, the drawing must show the mark in color;

(13) If the mark is in standard characters, a mark comprised of only characters in the Office's standard character set available at *http://www.uspto.gov/teas/standardCharacterSet.html,* typed in the appropriate field of the TEAS Plus form;

(14) If the mark includes color, a statement naming the color(s) and describing where the color(s) appears on the mark, and a claim that the color(s) is a feature of the mark;

(15) If the mark is not in standard characters, a description of the mark;

(16) If the mark includes non-English wording, an English translation of that wording;

(17) If the mark includes non-Latin characters, a transliteration of those characters;

(18) If the mark includes an individual's name or portrait, either: (1) a statement that identifies the living individual whose name or likeness the mark comprises and written consent of the individual, or (2) a statement that the name or portrait does not identify a living individual (see section 2(c) of the Act);

(19) If the applicant owns one or more registrations for the same mark, a claim of ownership of the registration(s), identified by the U.S. registration number(s), pursuant to § 2.36; and

(20) If the application is a concurrent use application, compliance with § 2.42.

In addition to the TEAS Plus application filing requirements in § 2.22, a TEAS Plus applicant must comply with the requirements set forth in § 2.23. The applicant must: (1) Continue to receive communications from the Office by e-mail; and (2) file the following documents through TEAS: response(s) to Office action(s); request(s) to change the correspondence address; appointment or revocation of power of attorney; appointment or revocation of domestic representative; preliminary amendment(s); amendment(s) to allege use under section 1(c) of the Act; statement(s) of use under section 1(d) of the Act; request(s) for extensions of time to file a statement of use under section 1(d) of the Act; and request(s) to delete a section 1(b) basis.

Discussion of Specific Rules

The Office is adding § 2.22, and amending §§ 2.6, 2.23, 2.53, and 7.25.

The Office is revising § 2.6(a)(1) to add new subsections (iii) and (iv). Section 2.6(a)(1)(iii) adds a new fee in the amount of $275.00 per class for filing a TEAS Plus application under § 2.22. Section 2.6(a)(1)(iv) adds a new fee in the amount of $50.00 per class for processing a TEAS Plus application filed under § 2.22 that does not meet the requirements of §§ 2.22 and 2.23. The additional fee is the difference between the filing fee for a regular TEAS application and the reduced fee for a TEAS Plus application.

The Office is adding a new § 2.22. Section 2.22(a) sets forth the requirements for filing a TEAS Plus application. To file a TEAS Plus application, an applicant must use the electronic Trademark/Servicemark Application, Principal Register form, accessed from *http://teas.uspto.gov,* and choose the reduced fee option presented as the TEAS Plus form on the initial screen.

For most of the filing requirements in § 2.22(a), an applicant must enter the information in the appropriate data fields on the TEAS Plus form. To enter the identification of goods/services, an applicant will be instructed to enter search terms appropriate for the desired goods/services within the identified field on the TEAS Plus form. The system will then retrieve relevant entries from the Goods and Services Manual, and the applicant must select one or more of the entries to add to the TEAS Plus form. The Goods and Services Manual, available on the Office's web site at: *http://www.uspto.gov,* contains more than 20,000 listings of acceptable identifications of goods and services.

Section 2.22(b) provides that if a TEAS Plus application does not meet the filing requirements of paragraph (a), the applicant must pay the fee required by § 2.6(a)(1)(iv). The application will retain its original filing date if the initial application met the minimum application filing requirements of § 2.21. Section 2.22(b) applies where an application is initially designated as a TEAS Plus application, but upon examination, the Office determines that the application did not meet the TEAS Plus filing requirements as of the filing date.

Section 2.22(c) lists the types of TEAS applications that are not eligible for the reduced fee option under paragraph (a). Applications for certification marks, collective marks, collective membership marks and applications for registration on the Supplemental Register cannot be filed as TEAS Plus applications because the Office does not have TEAS Plus forms for these types of applications.

The Office is removing the provisions of the current § 2.23, which sets forth the Office practice of assigning serial numbers to applications and informing applicants of serial numbers and filing dates. The Office has no intention of changing this practice, but is merely deleting this administrative information from the rules of practice. Such administrative practices are generally set forth in the Office's Trademark Manual of Examining Procedure (TMEP).

The Office is adding new subsections §§ 2.23(a) and 2.23(b). Section 2.23(a) sets forth additional examination requirements for a TEAS Plus application. Section 2.23(a)(1) requires that applicant file the following communications through TEAS: (1) Responses to Office actions (except notices of appeal); (2) Requests to change the correspondence address or owner's address; (3) Appointment or revocation of power of attorney; (4) Appointment or revocation of domestic representative; (5) Preliminary amendments; (6) Amendments to allege use under section 1(c) of the Act; (7) Statements of use under section 1(d) of the Act; (8) Request(s) for extensions of time to file a statement of use under section 1(d) of the Act; and (9) Requests to delete a section 1(b) basis.

Applicants are encouraged to file notices of appeal through the Electronic System for Trademark Trials and Appeals (ESTTA), available on-line at *http://www.uspto.gov,* but this is not mandatory.

Proposed §§ 2.23(a)(2) and 2.62(b) required that applicants file responses to Office actions within two months of the mailing date, but the Office has withdrawn this proposal.

Section 2.23(a)(2) requires that the applicant continue to receive communications from the Office by electronic mail.

Section 2.23(b) requires that the applicant pay the additional fee set forth in § 2.6(a)(1)(iv) if the applicant fails to meet any of the requirements in § 2.23(a) during the pendency of the application.

The Office is revising § 2.53(a) to break it into subsections (a)(1) and (a)(2). Section 2.53(a)(1) provides that in a TEAS Plus application, an applicant who seeks registration of a standard character mark must enter the mark in the appropriate field on the TEAS Plus form. Section 2.53(a)(2) provides that in all other TEAS submissions, an applicant seeking registration of a standard character mark must either (1) enter the mark in the appropriate field on the TEAS form, or (2) attach a digitized image of the mark that meets the requirements of § 2.53(c), and check the box to claim that the mark consists of standard characters. Thus, a TEAS Plus applicant will not have the option of attaching a digitized image of a standard character mark. The TEAS Plus applicant must enter a mark comprised of characters from the Office's standard character set, currently available at *http://www.uspto.gov/teas/standardCharacterSet.html*, and the Office will generate a digitized image of the mark in .JPG format and attach the image to the TEAS Plus form.

When issuing an Office action in a TEAS Plus application, the examining attorney will require that the applicant either respond through TEAS, or, if responding on paper, include the additional $50.00 per class fee with the response.

The Office is amending § 7.25(a) to add §§ 2.22 and 2.23 to the list of rules in part 2 of this chapter that do not apply to requests for extension of

protection of international registrations to the United States. A request for extension of protection to the United States is not eligible for examination as a TEAS Plus application because it cannot be filed directly through TEAS.

Responses to Comments

Identification of Goods/Services

Comment: Three comments note that the Office's Goods and Services Manual includes many ''open-ended'' listings that require an applicant to complete parenthetical information, such as ''headgear, namely (specify type, *e.g.*, hats, caps),'' and ask whether a TEAS Plus filer will be able to complete the parenthetical information without being subject to the higher fee.

Response: The TEAS Plus form will permit an applicant to select any identification in the Manual, including those that require the applicant to complete parenthetical information. When the applicant selects an ''open-ended'' identification, that identification will permit the applicant to type the necessary information, as per the instructions within the listing (*e.g.*, ''specify the function of the programs''). If an applicant attempts to use such a listing without completing the required information, TEAS Plus will generate an error message.

Comment: One comment asks whether an applicant will lose TEAS Plus status if the applicant completes the parenthetical information in an open-ended identification, but is later required to amend the parenthetical information because it is deemed indefinite.

Response: The applicant will not lose TEAS Plus status in this situation, unless the applicant uses the free-text field to insert an additional list of items into the identification, or fills it with inappropriate information.

Comment: One comment asks whether an applicant will lose TEAS Plus status if the applicant is required to add a class to its application, or to amend the goods or services in a single class of a multi-class application, and, if so, whether the additional fee will apply only to the newly added or amended class.

Response: Section 2.22(a)(8) requires that the goods/services be correctly classified. An applicant will lose TEAS Plus status if amendment of the classification is required because the applicant classified the goods/services in the wrong class, and will be required to pay the additional fee for all classes in the application. However, it is extremely unlikely that an application will lose its TEAS Plus status because the goods/services are incorrectly classified, because the TEAS Plus form is designed to automatically provide the correct class for goods/services selected from the Goods and Services Manual, and it will not permit an applicant to edit the classification field on the form.

The application will not lose its TEAS Plus status if the examining attorney determines during examination that the original identification of goods/services is inaccurate and requires amendment of the identification or classification.

Comment: Three comments note that there are many goods and services that are new and not yet listed in the Goods and Services Manual. Two comments suggest that § 2.22(a)(8) be amended to include an exception for goods and services that are not yet included in the Manual, but are otherwise acceptable. Two comments urge the Office to act promptly on suggestions for supplementing the Manual, to enable more applicants to take advantage of TEAS Plus.

Response: The suggestion to include an exception for goods and services that are not yet included in the Manual has not been adopted. It is not feasible to provide such exceptions to the TEAS Plus rule, because processing the exceptions would be time-consuming and costly, and would thus defeat the purpose of TEAS Plus.

The Office continually updates its Goods and Services Manual, and actively seeks suggestions from interested members of the public. See Request for Suggestions from the Public for Additions to the Trademark Acceptable Identification of Goods and Services Manual, *1269 TMOG 29* (April 1, 2003). Suggestions can be sent to *tmidsuggest@uspto.gov.* The Office will act upon these suggestions promptly, so as to enable as many applicants as possible to take advantage of TEAS Plus.

Drawings

Comment: Two comments note that the Office's standard character set at *http://www.uspto.gov/teas/standardCharacterSet.html* currently includes both supported and unsupported standard characters, and that an applicant whose mark includes unsupported characters must attach a .JPG image of its mark, which is not permitted in a TEAS Plus application. The comments urge the Office to permit applicants to file TEAS Plus applications for marks that include the characters that are currently unsupported.

Response: The characters that are unsupported in a regular TEAS application will be supported in TEAS Plus. The TEAS Plus form is designed to support all characters in the Office's standard character set.

Comment: One comment notes that proposed § 2.22(a)(12) required a drawing that meets the requirements of 37 CFR 2.51 and 2.52, and urges the Office to change these rules to permit applicants to file drawings that contain gray tones to show shading.

Response: The language in proposed § 2.22(a)(12) has been changed. The final rule requires ''a clear drawing of the mark'' in a TEAS Plus application, the same standard used in § 2.21(a)(3), which sets forth the requirements for receipt of an application filing date. Thus, an applicant whose drawing meets the requirements of § 2.21(a)(3) will be entitled to use TEAS Plus even if the drawing does not meet all the requirements of §§ 2.51 and 2.52.

It is noted that the Office now accepts drawings that contain the color gray, or stippling that produces gray tones. See TMEP § 807.07(e); Exam Guide 1–05, issued May 20, 2005, posted at *http://www.uspto.gov/web/offices/tac/notices/examguide1–05.htm.*

Requirement for Signed Application

Comment: One comment urges the Office to withdraw the requirement for a signature on a TEAS Plus application. The comment asserts that attorneys encounter difficulties in obtaining signatures from their clients, and that if these attorneys deferred filing until they secured the required signature, their clients could miss a deadline for claiming priority. The comment notes that applications are currently not examined until 5–6 months after filing, and suggests that the Office permit applicants to provide a signature within a short time period after filing, such as 2–3 months.

Response: The suggestion has not been adopted. TEAS Plus will lower the cost of examination and reduce pendency in large part because most applications will be complete when filed, and will therefore, result in the issuance of fewer Office actions. Allowing applicants to submit signatures ''within a short time after filing'' could often result in the need for an Office action, which would be costly and burdensome and defeat the purpose of TEAS Plus.

Type of Mark or Type of Application

Comment: One comment notes that regular TEAS forms are available for applications on the Supplemental Register, and for collective and certification mark applications, and questions the rationale for excluding these types of applications from TEAS Plus.

Response: At this time, the Office does not have TEAS Plus forms for applications for registration on the Supplemental Register, or for collective and certification marks.

An applicant will lose its TEAS Plus status if the mark later has to be amended to a collective or certification mark. However, the applicant will not lose TEAS Plus status if the application is amended from the Principal to the Supplemental Register, as long as the amendment is filed through TEAS.

TEAS Validation

Comment: Two comments suggest that the Office take steps to ensure that the TEAS Plus form will flag missing items during validation.

Response: TEAS Plus will flag missing items and will not accept the transmission if the applicant omits one of the elements that is required for all TEAS Plus applications. However, TEAS Plus will accept the transmission of an application that omits an item that is required for some applications but not others, e.g., a translation of non-English wording. Omission of such an item could trigger a requirement for the additional fee. Moreover, the additional fee may be required if an applicant enters inappropriate information in a required field. For example, if an applicant enters ''???'' as its state of incorporation, TEAS Plus will accept the transmission, but applicant will be required to pay the $50 fee to convert the application to a regular TEAS application. Accordingly, applicants should review their TEAS Plus applications carefully before transmitting them.

Filing Responses to Office Actions Through TEAS

Comment: Two comments assert that scanning multiple page documents into .JPG format is cumbersome and time-consuming, since each page of a document must be scanned separately, and urge the Office to begin accepting alternative formats.

Response: At this time, each page must be scanned separately, and only 50 pages can be attached to a single .JPG submission. The Office is working to resolve this problem, and expects to be able to accept files in .PDF format in the future. At this time, however, an applicant whose attachment is not in .JPG format cannot use TEAS Plus.

Comment: Two comments assert that TEAS does not accommodate all types of communications which a filer might need to make when responding to an Office action, and request that an exception be made for situations in which TEAS fails to provide an electronic method to make a particular filing. The examples given were the inability to file a response on the same day that the action is sent; the inability to send a certified copy of a foreign registration, and the inability to send evidence of radio and television commercials.

Response: TEAS can accommodate most responses to Office actions. Certified copies of foreign registrations are not required during examination. A photocopy, which can easily be scanned into a .JPG file, is sufficient. 15 U.S.C. 1126(e); 37 CFR 2.34(a)(3)(ii).

At this time, TEAS does not have the technical capability to accept a response to an Office action before the Trademark Applications and Registrations Retrieval (TARR) system is updated, which could take up to 72 hours after the action is issued. However, waiting for up to 72 hours is not overly burdensome to applicants. It has been the experience of the Office that very few responses to Office actions are filed within 72 hours after an Office action is issued.

It is true that attachments comprising audio or video tapes cannot be sent directly through TEAS. However, for sound marks there is a process in place to handle these filings electronically. The sound mark can be sent in an e-mail attachment as a .WAV file or MP3 file directly to the TEAS Support Team, at *teas@uspto.gov.* TMEP §§ 807.09 and 1202.15. Because the TEAS form will require a .JPG attachment for the specimen, the applicant must still create a .JPG file for this purpose; however, it will merely consist of a statement that ''A .WAV file (or MP3 file) has been sent directly to the TEAS Support Team for processing.'' TEAS Plus will allow for this same work-around solution. It is not possible to adapt TEAS Plus to accept every conceivable type of filing. TEAS Plus offers a reduced fee for filings that meet the TEAS Plus requirements, because these filings require less work by Office personnel, and the Office is passing these cost savings on to applicants. Filings that do not or cannot meet these requirements are subject to the higher fee because of the additional work that is required. Exception processing, apart from the work-around solution already in place for sound marks, is costly and time-consuming, and would defeat the purpose of TEAS Plus.

Two-Month Response Deadline

Comment: Four comments oppose the two-month response deadline for TEAS Plus applications. It is asserted that docketing two different deadlines would be burdensome for applicants and their attorneys; that the requirement would discriminate against foreign applicants, small businesses and individual applicants, and benefit wealthier, more technologically advanced applicants; that there is insufficient justification for imposing a two-month response deadline absent a corresponding benefit to applicants or the Office; that the two-month deadline does not appear to have any bearing on the cost of examination or on the ease or ability of the Office to correspond with applicants; that attorneys may be unable to meet the deadline due to difficulties in communicating with clients, particularly foreign clients, small entities and clients located in less-developed nations; that there is no need to reduce the response time in order to accomplish the purposes of TEAS Plus; that Congress established a six-month response period and applicants should not have to give up their right to the statutory response period in order to use TEAS Plus; that while average pendency may be reduced, TEAS Plus applications could not be abandoned until after expiration of the statutory six-month deadline; and that the two-month deadline is problematic because the TEAS system does not recognize the situation that a deadline expires on a weekend or holiday and responses filed the next day are considered timely, which poses a potential trap for applicants who respond near the end of the two-month deadline.

Response: The Office has withdrawn the proposed requirement for a two-month response deadline.

It is noted that, while there was a time when TEAS did not accept transmission of a response filed on the next business day after a deadline expiring on a weekend or holiday, this problem has been resolved. TEAS now accepts such responses.

Assigning Serial Numbers

Comment: One comment opposes the removal of the current § 2.23, which sets forth the Office's administrative practice of assigning serial numbers to applications and informing the applicant of the serial number and filing date. The comment notes that prompt receipt of a filing date and serial number is extremely important to trademark owners, and asserts that any change in procedure should be subject to public notice and comment.

Response: The Office has no plans to change its procedures for assigning filing dates and serial numbers, or for notifying applicants of serial numbers and filing dates. However, it is unnecessary to set forth these internal administrative procedures in the Code of Federal Regulations. The

requirements for receipt of a filing date are set forth in § 2.21, and any change in these requirements is subject to notice and comment.

E-Mail Communications

Comment: One comment asks how the requirement that an applicant must receive communications from the Office by electronic mail in § 2.23(a)(2) differs from the requirement in § 2.22(a)(6) that the applicant provide an e-mail address and authorize the Office to send correspondence concerning the application by e-mail. The comment also questioned whether a filer will lose TEAS Plus status if the Office's e-mail communication capability is interrupted because of a technical problem, or because the applicant's e-mail address provided at the time of filing has changed or been replaced.

Response: Sections 2.22 and 2.23 differ in that § 2.22 sets forth the requirements that must be met at the time of filing, while § 2.23 sets forth the requirements that must be met during the pendency of the application to maintain TEAS Plus status. Section 2.22(a)(6) requires that the application as filed include an e-mail address for correspondence and an authorization for the Office to send correspondence concerning the application to the applicant by e-mail. Section 2.23(a)(2) requires that the applicant continue to receive correspondence by e-mail throughout the pendency of the application.

If an applicant files a request to have correspondence sent on paper, the applicant will lose TEAS Plus status. However, an applicant will not lose TEAS Plus status if the e-mail transmission does not go through due to a technical problem at the USPTO.

Applicants have a duty to notify the Office of any change of the correspondence address. 37 CFR 2.18; TMEP § 603.03. Therefore, an applicant will lose TEAS Plus status if an e-mail communication does not go through because the applicant failed to notify the Office of a change in the e-mail correspondence address.

Comment: One comment expresses support for the requirement that applicants authorize correspondence by e-mail, but asserts that the Office does not consistently process electronically filed requests to change e-mail addresses, and requests that this issue be addressed.

Response: This problem has been corrected. Requests to change an e-mail correspondence address filed through TEAS are now automatically entered into the Office's automated systems.

Collection of Additional Fee

Comment: One comment asks how the fee required by § 2.6(a)(1)(iv) will be collected from applicants who fail to meet the requirements of §§ 2.22 and 2.23.

Response: The examining attorney will issue a standard Office action requiring payment of the additional fee.

When issuing a non-final action on a TEAS Plus application, the examining attorney will require that the applicant: (1) Respond through TEAS; or (2) submit the additional fee if filing a paper response. If the applicant files a paper response without the additional fee, the requirement for payment of the additional fee will be made final, assuming that the application is otherwise in condition for final refusal.

General Inquiry

Comment: One comment expresses support for a reduced fee, and asks what the requirements will be, and when the rules will go into effect.

Response: The effective date is set forth above, under the heading ''Effective Date,'' and the requirements are set forth below in §§ 2.6, 2.22, 2.23, and 2.53.

Rule Making Requirements

Executive Order 13132

This rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866

This final rule has been determined not to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Regulatory Flexibility Act

The Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the rule changes will not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)).

The current filing fees for trademark applications are $375.00 per class for applications filed on paper and $325.00 per class for trademark applications filed electronically through the Trademark Electronic Application System (TEAS). The sole purpose of the final rule is to provide applicants that electronically file trademark applications through TEAS with the added option of filing the application for a reduced fee of $275.00 per class. Applications filed under the reduced fee option will be referred to as TEAS Plus applications.

In fiscal year 2004, the agency received approximately 245,000 trademark applications. Of that total, the Office estimates that 179,000 trademark applications were filed through TEAS and that 66,000 of the TEAS filers were small entities. The Office projects that it will receive approximately 264,000 trademark applications in fiscal year 2005, that an estimated 211,000 will be filed through TEAS, and that approximately 42,000 TEAS filers will take advantage of the reduced fee option. The Office estimates that of the projected 42,000 TEAS Plus applications filed during fiscal year 2005, approximately 15,500 will be filed by small entities.

Because the final rule merely provides all trademark applicants, including small businesses, with an alternative filing method at a reduced cost, the agency certifies that any economic impact on small entities affected by the rule will not be significant. The agency did not receive any comments in response to the certification in the Regulatory Flexibility Act section of the Notice of Proposed Rule Making published in the **Federal Register** (70 FR 17636) on April 7, 2005.

Paperwork Reduction Act

The rules are in conformity with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*).

Notwithstanding any other provision of law, no person is required to nor shall a 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.

This rule involves collections of information requirements subject to the PRA. The collections of information involved in this rule have been reviewed and previously approved by OMB under the following control numbers: 0651–0009 and 0651–0050. This rule includes provisions that affect the fee structures for approved information collection activities under 0651–0009 Trademark Processing. Changes to the fee structures, as set forth in this rule, will be submitted to the Office of Management and Budget for review and approval at the time of renewal of 0651–0009.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency, (2) the accuracy of the agency's estimate of the burden, (3) ways to enhance the quality, utility,

and clarity of the information to be collected, and (4) ways to minimize the burden of the collection of information to respondents.

Send comments regarding any other aspect of this data collection, including suggestions for reducing the burden, to the Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451 (Attn: Ari Leifman), and to the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW., Washington, DC 20230 (Attn: PTO Desk Officer).

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks.

■ For the reasons given in the preamble and under the authority contained in 35 U.S.C. 2 and 15 U.S.C. 1123, as amended, the Office is amending parts 2 and 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 1. The authority citation for 37 CFR Part 2 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 2. Amend § 2.6 to revise paragraph (a)(1) to read as follows:

§ 2.6 Trademark fees.

* * * * *

(a) * * *

(1) Application filing fees.

(i) For filing an application on paper, per class—$375.00

(ii) For filing an application through TEAS, per class—$325.00

(iii) For filing a TEAS Plus application under § 2.22, per class—$275.00

(iv) Additional processing fee under §§ 2.22(b) and 2.23(b), per class—$50.00

* * * * *

■ 3. Add § 2.22, to read as follows:

§ 2.22 Filing requirements for a TEAS Plus application.

(a) A trademark/service mark application for registration on the Principal Register under section 1 and/or section 44 of the Act will be entitled to a reduced filing fee under § 2.6(a)(1)(iii) if it is filed through TEAS and includes:

(1) The applicant's name and address;

(2) The applicant's legal entity;

(3) The citizenship of an individual applicant, or the state or country of incorporation or organization of a juristic applicant;

(4) If the applicant is a partnership, the names and citizenship of the applicant's general partners;

(5) A name and address for correspondence;

(6) An e-mail address for correspondence, and an authorization for the Office to send correspondence concerning the application to the applicant or applicant's attorney by e-mail;

(7) One or more bases for filing that satisfy all the requirements of § 2.34. If more than one basis is set forth, the applicant must comply with the requirements of § 2.34 for each asserted basis;

(8) Correctly classified goods and/or services, with an identification of goods and/or services from the Office's Acceptable Identification of Goods and Services Manual, available through the TEAS Plus form and at *http://www.uspto.gov.* In an application based on section 44 of the Act, the scope of the goods and/or services covered by the section 44 basis may not exceed the scope of the goods and/or services in the foreign application or registration;

(9) If the application contains goods and/or services in more than one class, compliance with § 2.86;

(10) A filing fee for each class of goods and/or services, as required by § 2.6(a)(1)(iii);

(11) A verified statement that meets the requirements of § 2.33, dated and signed by a person properly authorized to sign on behalf of the applicant pursuant to § 2.33(a);

(12) A clear drawing of the mark. If the applicant does not claim standard characters, the applicant must attach a digitized image of the mark in .jpg format. If the mark includes color, the drawing must show the mark in color;

(13) If the mark is in standard characters, a mark comprised of only characters in the Office's standard character set, currently available at *http://www.uspto.gov,* typed in the appropriate field of the TEAS Plus form;

(14) If the mark includes color, a statement naming the color(s) and describing where the color(s) appears on the mark, and a claim that the color(s) is a feature of the mark;

(15) If the mark is not in standard characters, a description of the mark;

(16) If the mark includes non-English wording, an English translation of that wording;

(17) If the mark includes non-Latin characters, a transliteration of those characters;

(18) If the mark includes an individual's name or portrait, either (i) a statement that identifies the living individual whose name or likeness the mark comprises and written consent of the individual, or (ii) a statement that the name or portrait does not identify a living individual (*see* section 2(c) of the Act);

(19) If the applicant owns one or more registrations for the same mark, a claim of ownership of the registration(s) identified by the registration number(s), pursuant to § 2.36; and

(20) If the application is a concurrent use application, compliance with § 2.42.

(b) If an application does not meet the requirements of paragraph (a) of this section at the time of filing, the applicant must pay the fee required by § 2.6(a)(1)(iv). The application will retain its original filing date, provided that when filed, the application met the filing date requirements of § 2.21.

(c) The following types of applications cannot be filed as TEAS Plus applications under paragraph (a) of this section:

(1) Applications for certification marks (*see* § 2.45);

(2) Applications for collective marks (*see* § 2.44);

(3) Applications for collective membership marks (*see* § 2.44); and

(4) Applications for registration on the Supplemental Register (*see* § 2.47).

■ 4. Revise § 2.23 and its heading to read as follows:

§ 2.23 Additional requirements for TEAS Plus application.

(a) In addition to the filing requirements under § 2.22(a), the applicant must:

(1) File the following communications through TEAS:

(i) Responses to Office actions (except notices of appeal under section 20 of the Trademark Act);

(ii) Requests to change the correspondence address and owner's address;

(iii) Appointment and/or revocation of power of attorney;

(iv) Appointment and/or revocation of domestic representative;

(v) Preliminary amendments;

(vi) Amendments to allege use under section 1(c) of the Act or statements of use under section 1(d) of the Act;

(vii) Request(s) for extensions of time to file a statement of use under section 1(d) of the Act; and

(viii) Request(s) to delete a section 1(b) basis.

(2) Continue to receive communications from the Office by electronic mail.

(b) If an application does not meet the requirements of paragraph (a) of this section, the applicant must pay the fee required by § 2.6(a)(1)(iv).

■ 5. Amend § 2.53 to revise paragraph (a) to read as follows:

§ 2.53 Requirements for drawings filed through the TEAS.

* * * * *

(a)(1) Standard character drawings in TEAS Plus applications filed under § 2.22: If an applicant is filing a standard character drawing, the applicant must enter the mark in the appropriate field on the TEAS Plus form.

(2) Standard character drawings in all other TEAS submissions: If an applicant is filing a standard character drawing, the applicant must either:

(i) Enter the mark in the appropriate field on the TEAS form; or

(ii) Attach a digitized image of the mark to the TEAS submission that meets the requirements of paragraph (c) of this section, and check the box to claim that the mark consists of standard characters.

* * * * *

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARK

■ 6. The authority citation for 37 CFR Part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 7. Amend § 7.25 to revise paragraph (a) to read as follows:

§ 7.25 Sections of part 2 applicable to extension of protection.

(a) Except for §§ 2.22–2.23, 2.130–2.131, 2.160–2.166, 2.168, 2.173, 2.175, 2.181–2.186 and 2.197, all sections in part 2 and all sections in part 10 of this chapter shall apply to an extension of protection of an international registration to the United States, including sections related to proceedings before the Trademark Trial and Appeal Board, unless otherwise stated.

* * * * *

Dated: June 29, 2005.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 05–13301 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RME–OAR–2005–MD–0006; FRL–7933–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Approval of Clarifications of Requirements for Fuel-Burning Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action to approve revisions to the Maryland State Implementation Plan (SIP). The revisions are clarifications to the applicability and compliance methods for particulate matter standards for fuel-burning equipment. The EPA is approving these revisions to Maryland regulations in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on September 6, 2005, without further notice, unless EPA receives adverse written comment by August 5, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number RME–OAR–2005–MD–0006 by one of the following methods:

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

B. Agency Web site: *http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *campbell.dave@epa.gov.*

D. Mail: RME–OAR–2005–MD–0006, David Campbell, Chief, Air Quality Planning, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

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

Instructions: Direct your comments to RME ID No. RME–OAR–2005–MD–0006. 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.docket.epa.gov/rmepub/,* 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Linda Miller, (215) 814–2068, or by e-mail at *miller.linda@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 12, 2004, the State of Maryland submitted a formal revision to

its State Implementation Plan (SIP). The SIP revision consists of minor changes which clarify the applicability and compliance methods for the regulations governing fuel-burning equipment.

II. Summary of SIP Revision

Specifically, the changes in this revision are clarifications to existing regulations. The applicability portion found in COMAR 26.11.09.01 has been revised to include a reference to wood used as fuel. The existing regulation lacked a definition of ''fuel.'' The Maryland Department of the Environment has stated that the intent of the regulation has always been to include wood as a fuel regulated in this section. An incorrect interpretation of the applicability would be that only ''fossil fuel-fired'' equipment is regulated by the regulations in COMAR 26.11.09. The addition of the definition for ''fuel'' clarifies the applicability to include equipment using ''wood or wood products'' as fuel. The revision also clarifies the calculations for particulate matter emissions found in COMAR 26.11.09.03. The clarification distinguishes the calculations used for concentration emission limits from the calculations used for mass emissions requirements. Concentration emission limits (grains per standard cubic foot) require an adjustment for air flow, mass emission limits (such as pounds per million BTU) do not require this adjustment. The final change in the revision is a clarification of the compliance test method for particulate matter emissions in COMAR 26.11.06. EPA test method 5 requires three runs of approximately one hour each. This amendment clarifies that the average of the three test runs is used to determine compliance with particulate matter standards in a manner consistent with EPA test method 5.

III. Final Action

EPA is approving revisions to three sections of regulations for the control of fuel-burning equipment. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. These changes are considered clarifications to existing requirements. The State of Maryland provided public notice and hearing. There were no comments received during the public participation process. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on September 6, 2005, without further notice unless EPA receives adverse comment by August 5, 2005. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial

review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action to approve clarifications to the applicability and compliance methods for particulate matter standards for fuel-burning equipment 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, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 15, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 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 V—Maryland

■ 2. In Section 52.1070, the table in paragraph (c) is amended by revising the entries for COMAR 26.11.09.01, 26.11.09.03 and 26.11.09.06 to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * * [*EPA approved regulations.*]

EPA–APPROVED REGULATIONS IN THE MARYLAND SIP

Code of Maryland administrative regulations (COMAR)	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	* * *
COMAR 26.11.09.01 Control of Fuel-burning Equipment, Stationary Internal Combustion Engines, and Certain Fuel-Burning Installations				
26.11.09.01	Definitions	6/21/04	7/6/05 [Insert page number where the document begins].	Revised Definition of "fuel" in 26.11.09.01.B.2–1.a.
*	*	*	*	* * *
26.11.09.03	General Conditions for Fuel-Burning Equipment.	6/21/04	7/6/05 [Insert page number where the document beings].	Revised paragraphs 26.11.09.03.C.1 and 2.
*	*	*	*	* * *
26.11.09.06	Control of Particulate Matter.	6/21/04	7/6/05 [Insert page number where the document begins].	Addition of paragraph 26.11.09.06C.
*	*	*	*	* * *

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[FR Doc. 05–13281 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R06–OAR–2005–TX–0024; FRL–7928–6]

Approval and Promulgation of Implementation Plans; Texas; Transportation Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving State Implementation Plan (SIP) revisions submitted by the State of Texas on February 23, 2004, and on May 17, 2005. These revisions serve to incorporate recent revisions to the federal conformity rule into the state conformity SIP.

DATES: This rule is effective on September 6, 2005, without further notice, unless EPA receives relevant adverse comment by August 5, 2005. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Materials in EDocket (RME) ID No. R06–OAR–2005–TX–0024, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://docket.epa.gov/rempub/.* Regional Materials in EDocket (RME), EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select "quick search," then key in the appropriate RME Docket identification number. Follow the online instructions for submitting comments.
- EPA Region 6 "Contact Us" Web site: *http://epa.gov/region6/r6coment.htm.* Please click on "6PD" (Multimedia) and select "Air" before submitting comments.
- E-mail: Mr. Thomas Diggs at *diggs.thomas@epa.gov.* Please also send a copy by email to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- Fax: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.

• Mail: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

• Hand or Courier Delivery: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to RME ID No. R06–OAR–2005–TX–0024. EPA's policy is that all comments received will be included in the public file without change and may be made available online at *http://docket.epa.gov/rmepub/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through Regional Materials in EDocket (RME), regulations.gov or e-mail if you believe that it is CBI or otherwise protected from disclosure. The EPA RME Web site and the federal regulations.gov Web site are ''anonymous access'' systems, 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 RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public file and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and should be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the Regional Materials in EDocket (RME) index at *http://docket.epa.gov/rempub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in the official file, which is available at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at 214–665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Peggy Wade, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7247; fax number 214–665–7263; e-mail address *wade.peggy@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Outline

I. What Action is EPA Taking?
II. What is the Background for this Action?
III. What Did the State Submit and How Did We Evaluate It?
IV. Final Action
V. Statutory and Executive Order Reviews

I. What Action Is EPA Taking?

On May 22, 2003, the Texas Commission on Environmental Quality (TCEQ) submitted revisions to its SIP addressing changes to the transportation conformity rule (30 TAC 114.260) adopted by the state on May 1, 2003. Additionally, on May 17, 2005, EPA received another submittal from TCEQ further revising the transportation conformity rule as adopted by the state on April 27, 2005. These revisions incorporate recent changes in the federal transportation conformity rule into the Texas conformity SIP and are described in detail below. EPA is approving these revisions to the Texas conformity SIP.

II. What Is the Background for This Action?

The Federal Clean Air Act Amendments of 1990 (CAA) required each state to submit a revision to its SIP by November 25, 1994, establishing enforceable criteria and procedures for making conformity determinations for metropolitan transportation plans (MTP), transportation improvement programs (TIP), and projects funded by the Federal Highway Administration (FHWA) or the Federal Transit Administration (FTA). The conformity rule assures that in air quality nonattainment or maintenance areas, projected emissions from transportation plans and programs stay within the motor vehicle emissions ceiling in the applicable attainment demonstration or maintenance SIP. The transportation conformity SIP enables the state to implement and enforce the Federal transportation conformity requirements at the state level per 40 CFR 51 subpart T and 40 CFR 93 subpart A.

EPA published final rules regarding conformity requirements on November 24, 1993 (58 FR 62188). Since then, EPA has made several amendments to the transportation conformity rules: August 7, 1995 (60 FR 40098), November 14, 1995 (60 FR 57179), August 15, 1997 (62 FR 43780), April 10, 2000 (65 FR 18911), August 6, 2002 (67 FR 50808), and July 1, 2004 (69 FR 40004). The state of Texas submitted an initial conformity SIP to EPA on November 6, 1994, and we approved this SIP on November 8, 1995 (60 FR 56244). Revisions to this SIP to address the federal rule amendments promulgated up to and including 1997 were submitted by the Governor of Texas on December 10, 1998, and approved by EPA on July 8, 1999 (64 FR 36790). With the current revisions submitted by TCEQ, the state is aligning its rule to the federal conformity rule for all amendments up to and including those promulgated on July 1, 2004.

Specifically, these revisions address a March 2, 1999, ruling by the United States Court of Appeals for the District of Columbia (*Environmental Defense Fund* v. *EPA, et al.*, 167 F. 3d 641, D.C. Cir. 1999). The court's ruling affected provisions of the rule that pertained to the funding of MTPs and TIPs; use of motor vehicle emissions budgets (MVEB) prior to SIP approval; federal transportation projects in areas without a conforming MTP and TIP; timing of conformity consequences following an EPA SIP disapproval; and use of submitted safety margins in areas with

approved SIPs submitted prior to November 24, 1993.

More recent changes to the rule are inclusion of criteria and procedures for implementing conformity in accordance with the new National Ambient Air Quality Standards (NAAQS) addressing eight-hour ozone and particulate matter with an aerodynamic diameter less than or equal to 2.5 micrometers ($PM_{2.5}$). Changes relating to the implementation of these new standards are summarized below.

Changes to 40 CFR 93.101 add new definitions for one-hour ozone NAAQS; eight-hour ozone NAAQS; donut areas; isolated rural nonattainment and maintenance areas; and limited maintenance plans. Other federal changes in the rule include provision of a one-year grace period before conformity is required in newly designated nonattainment areas and the addition of $PM_{2.5}$ to the list of criteria pollutants (40 CFR 93.102). Changes to 40 CFR 93.104 were made to amend the point by which a conformity determination must be made following a state's submission of a control strategy SIP or maintenance SIP for the first time. This new provision requires conformity to be determined within 18 months of EPA's affirmative finding that the SIP's MVEBs are adequate. Changes to the grace period for transportation plan requirements in certain ozone and carbon monoxide nonattainment areas are made in 40 CFR 93.106. 40 CFR 93.109 has been changed to include the applicability of conformity for one-hour ozone nonattainment or maintenance areas until EPA revokes the one-hour ozone NAAQS and additional language related to conformity requirements for the new NAAQS for eight-hour ozone and $PM_{2.5}$. Changes to 40 CFR 93.110 clarify that conformity determinations must be based on the latest planning assumptions in place at the time a conformity analysis begins, rather than at the time of Department of Transportation's conformity finding. Some changes to the methodology of hot-spot analyses were made at 40 CFR 93.116. The rule revisions also made several changes with respect to the MVEB at 40 CFR 93.118 where the adequacy process is discussed. Changes to 40 CFR 93.119 concern use of interim emissions tests in areas without adequate or approved MVEBs. In 40 CFR 93.120, the 120-day grace period previously allowed prior to a conformity freeze has been deleted so that a freeze will occur immediately upon the effective date of a SIP disapproval. EPA amended the rule at 40 CFR 93.121 so that regionally significant, non-federal projects may no longer advance during a conformity lapse unless they have received all necessary state and local approvals prior to the lapse. EPA also made minor revisions to 40 CFR 93.117 and 40 CFR 93.124–93.126. For a comprehensive guide to all changes in the federal rule, please see the reference document at *http://www.epa.gov/otaq/transp/conform/420b04013.pdf* or the transportation conformity final rule at 69 FR 40004.

III. What Did the State Submit and How Did We Evaluate It?

With these two SIP submissions, the state is incorporating by reference the changes made to the federal conformity rule up to and including the final rule issued on July 1, 2004 (69 FR 40004), with the exception of the requirements of 40 CFR 93.105. The federal requirements in 40 CFR 93.105 are addressed in the commission's rule in 30 TAC 114.260(d) and are not being changed with this revision. The TCEQ is also making minor changes to other sections of the state conformity rule to correct typographical errors and reflect updated name and style changes within the Commission in accordance with the Texas Legislative Council Drafting Manual of October 2002.

The SIP revision package submitted to EPA on May 22, 2003, contained a revision to 30 TAC 114.452, Control Requirements. EPA is not acting on 30 TAC 114.452 today. This submitted revision allows commercial operators of lawn and garden equipment additional time to submit an alternate emission reduction plan. However, TCEQ has since repealed this rule and EPA will be acting on the repeal in a subsequent **Federal Register** publication. The package submitted in 2003 also contained a revision to 30 TAC 114.21, Exemptions. EPA is not acting on 30 TAC 114.21 today.

IV. Final Action

EPA is approving the revisions to the Texas conformity SIP and corresponding amendments to 30 TAC 114.260 Transportation Conformity. The EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revisions if relevant adverse comments are received. The rule will be effective on September 6, 2005, without further notice unless we receive adverse comment by August 5, 2005. If we receive adverse comment we will publish a timely withdrawal in the **Federal Register** informing the public this rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of adverse comment.

V. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.'' This 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 it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely

approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it approves a state program.

In reviewing SIP submissions under the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note), EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

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 September 6, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action 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, Carbon monoxide, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 17, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

■ 40 CFR Part 52 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 SS—Texas

■ 2. In § 52.2270, the table in paragraph (c) entitled ''EPA approved regulations in the Texas SIP'' under Chapter 114 is amended by revising section 114.260 to read as follows:

§ 52.2270 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/submittal date	EPA approval date	Explanation
* * *	* * *	* * *	* * *	
Chapter 114 (Reg 4) Control of Air Pollution from Motor Vehicles				
* * *	* * *	* * *	* * *	
Section 114.260	Transportation Conformity	04/27/2005	7/6/2005 [Insert FR page number where document begins]	
* * *	* * *	* * *	* * *	

[FR Doc. 05–13279 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–7933–2]

RIN 2060–AM72

National Emission Standards for Hazardous Air Pollutants: Miscellaneous Coating Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: On May 13, 2005, the EPA issued direct final amendments to the national emission standards for hazardous air pollutants (NESHAP) for Miscellaneous Coating Manufacturing. The amendments were issued as a direct final rule, along with a parallel proposal to be used as the basis for final action in the event EPA received any adverse comments on the direct final amendments. Because an adverse comment was received on one provision, EPA is withdrawing the corresponding parts of the direct final rule. We stated in that direct final rule that if we received adverse comment by June 13, 2005, we would publish a timely withdrawal in the **Federal Register.** We will address the adverse comment in a subsequent final action based on the parallel proposal published on May 13, 2005 (70 FR 25684). As stated in the parallel proposal, we will not institute a second comment period on this action.

DATES: As of July 6, 2005, EPA withdraws the direct final rule revision for 40 CFR 63.8055(b)(4), published on May 13, 2005 (70 FR 25676). The remaining provisions published on May 13, 2005, will be effective on July 12, 2005.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR–2003–0178. All documents in the docket are listed in the index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at: Air and Radiation Docket, EPA/DC, EPA West, Room B102, 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 Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (Mail Code C504–04), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5402, electronic mail address *mcdonald.randy@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 13, 2005, we published a direct final rule (70 FR 25676) and a parallel proposal (70 FR 25684) amending the NESHAP for Miscellaneous Coating Manufacturing (40 CFR part 63, subpart HHHHH). The direct final rule amended the NESHAP by providing additional compliance options and clarifications. Specifically, the direct final rule amendments specified that compliance with a percent reduction emission limit may be demonstrated by measuring total organic compounds (TOC), compliance with the weight percent hazardous air pollutant (HAP) limit in coatings products may be demonstrated based on formulation data, and the cover or lid on a process vessel may be opened for material additions and sampling. The direct final rule amendments also clarified the requirements for cleaning operations, the compliance date for equipment that is added to an existing source, the conditions under which you must determine whether an emission stream is a halogenated vent stream, and the terminology used to describe the emission limits for process vessels. The direct final rule amendments also revised the definition of Group 2 transfer operations to clarify that all product loading operations are part of the miscellaneous coating manufacturing. We stated in the preamble to the direct final rule and parallel proposal that if we received adverse comments by June 13, 2005, (or if a public hearing was requested by May 23, 2005) on one or more distinct provisions of the direct final rule, we would publish a timely notice in the **Federal Register** specifying which provisions will become effective and which provisions will be withdrawn due to adverse comment. We subsequently received adverse comment from one commenter on the amendment to allow compliance with the weight percent HAP limit in coating products may be demonstrated based on formulation data. The commenter's claim is that if EPA does not allow the mass cutoffs of 0.1 percent for OSHA-defined carcinogens or 1 percent for other HAP used in Material Safety Data Sheets (MSDS), then the option is very limited.

Accordingly, we are withdrawing the amendment, 40 CFR 63.8055(b)(4). The amendment is withdrawn as of July 6, 2005. We will take final action on the proposed rule after considering the comment received. We also received a comment regarding chemical processes involving reactions that produce materials that may have a coating-application end use. However, the commenter referred to preamble language merely clarifying existing rule language in overlapping standards, and not new language provided by the direct final rule. We have not changed any of the rule language discussed in the clarification of overlapping standards section of the preamble. Thus, this comment is not an adverse comment on the amendments themselves, but rather an adverse comment on the definition of coating manufacturing in the original rule.

We will not institute a second comment period on this action. The provisions for which we did not receive adverse comment will become effective on July 12, 2005, as provided in the preamble to the direct final rule.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 29, 2005.

Jeffrey R. Holmstead,

Assistant Administrator, Air and Radiation.

[FR Doc. 05–13275 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0294; FRL–7720–9]

Alpha-cyclodextrin, Beta-cyclodextrin, and Gamma-cyclodextrin; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance under 40 CFR 180.950 for residues of alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin when used in or on various food commodities. Wacker Specialties submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act

(FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin.

DATES: This regulation is effective July 6, 2005. Objections and requests for hearings must be received on or before September 6, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2002–0294. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rame Cromwell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9068; e-mail address: *cromwell.rame@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register** '' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of November 14, 2002 (67 FR 220) (FRL–7279–3), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (2E6514) by Wacker Specialities, 3301 Sutton Road, Adrian, MI, 49221–9397. The petition requested that residues of a certain pesticide chemical in or on various food commodities be exempted from the requirement of a tolerance. This notice included a summary of the petition prepared by the petitioner Wacker Specialties. No comment was submitted.

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risk from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of the pesticide chemical. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Description of Alpha-cyclodextrin, Beta-cyclodextrin, and Gamma-cyclodextrin

Alpha-cyclodextrin is a non-reducing cyclic saccharide comprised of six glucose units linked by alpha-1,4 bonds. It is produced by the action of cyclodextrin glucosyltransferase (CGTase) on hydrolyzed starch syrups at neutral pH and moderate temperatures. Beta- cyclodextrin is a cyclic heptamer composed of seven glucose units joined ''head-to-tail'' by alpha-1,4 links. Gamma-cyclodextrin is a ring-shaped molecule made up of eight glucose units linked by alpha-1,4 bonds. Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are naturally occurring compounds derived from the degradation of starch by the glucosyltransferase enzyme (CGTase). They are formed naturally from bacteria and synthetically. The annular (or doughnut-shaped) structure provides a hydrophobic cavity that allows formulation of inclusion complexes with a variety of non-polar organic molecules of appropriate size. The hydrophobic nature of the outer surface of the cyclic structure makes the compounds water soluble. The hydrophobic cavity and the hydrophilic outer surface form the basis for its use in the food industry.

V. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The Joint Expert Food Committee Additives (JEFCA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). In the Food Additive Series 32, 42, and 48, JEFCA reviewed alpha-, beta-, and gamma-cyclodextrins and assigned an acceptable daily intake (ADI) of ''not specified'' to alpha-cyclodextrin. As to beta-cyclodextrin, a temporary ADI of 0–6 milligrams/kilogram (mg/kg) was allocated, based on a no adverse observed effect level (NAOEL) of 2.5% in the diet (equal to 1,230 mg/kg/bwt day) in the study of dogs using a safety factor of 200. As to gamma-cyclodextrin, there were sufficient data to allocate a temporary ADI of ''not specified.'' A ''not specified'' designation is used to refer to a food substance of very low toxicity, with, on the basis of the available data (chemical, biochemical, and other) and the total dietary intake of the substance, does not, in the opinion of the Committee, represent a hazard to health. These compounds are natural occurring cyclic non-reducing torus-shaped maltooligosaccharides. They originate from the decomposition of starch by a bacterial enzyme called cyclodextrin glycosyltransferase. Alpha-, beta-, and gamma-cyclodextrins are comprised of D-glucose molecules.

In its May 20, 2003, response to a Generally Recognized as Safe (GRAS) notification, the Food and Drug Administration (FDA) had no questions regarding a conclusion by qualified experts that alpha-, beta-, and gamma-cyclodextrins meet appropriate food grade specifications and if manufactured in accordance with good manufacturing practices are generally recognized as safe.

Alpha-cyclodextrin was examined by JEFCA for its ability to induce ocular irritation in albino rabbits in two separate studies. In the first study, a dose of 0.062 g instilled in the conjuctival cul-de-sac of the right eye of three rabbits was irritating but not corrosive. In the second study, two groups of three rabbits were given alpha-cyclodextrin as a 14.5% or a 50% dilution in demineralized water. No or minimal irritation was found in the eyes and there was no corrosion.

A sample of 0.5 of alpha-cyclodextrin moistened with tap water was applied to the shaven backs and flanks of three albino rabbits for 4 hours under a semi-occlusive dressing. No skin irritation was observed for up to 72 hours. Similarly, in guinea-pigs, a 10% or 30% solution of alpha-cyclodextrin induced no signs of sensitization in the dermally induced animals.

Short-term (28-day and 90-day) studies of toxicity indicated that alpha-cyclodextrin has little effect when given orally to rats and dogs. Alpha-cyclodextrin is not digested in the gastrointestinal tract but is fermented by the intestinal micro flora. Absorbed alpha-cyclodextrin is excreted rapidly in the urine.

Studies conducted with mice, rabbits, and rats with alpha-cyclodextrin at concentrations of up to 20% did not indicate teratogenic effects.

Beta-cyclodextrin of 0.5 g moistened with 0.5 ml saline was applied to shaved dorsal skin of 3 white rabbits under occlusion for 24 hours. The mean primary irritation score was 0.50 (minimally irritating), and there were no eschar or oedma and the treatment sites were normal by 24 hours after removal of the pad containing the chemical. A primary dermal irritation study in albino rabbits used an abraded skin protocol, and the index of primary cutaneous irritation which was obtained (0.01) classified beta- cyclodextrin as non-irritant.

In an ocular irritancy/corrosion test in albino rabbits, beta-cyclodextrin was classified as slightly irritating.

Gamma-cyclodextrin was not irritating or corrosive to the eyes of albino rabbits. In a skin sensitization assay in guinea-pigs, a 30% solution induced no signs of sensitization.

Short term (28-day and 90-day) studies of toxicity indicate that gamma-cyclodextrin has little toxicity when given orally to rats or dogs. Studies conducted in rats and rabbits with gamma-cyclodextrin at doses up to 20% of the diet did not indicate any teratogenic effects. Similarly, the results of a battery of studies of genotoxicity were negative. Long-term studies of toxicity, carcinogenicity, and reproductive toxicity have not been conducted, but, given the rapid metabolism of this substance to glucose and its lack of genotoxicity, such studies were not required for an evaluation.

VI. Aggregate Exposure

1. *Food.* Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are naturally occurring and are used as food additives. The following was taken from the WHO INCHEM (Food Additives Series 32, 42, 48). Alpha-cyclodextrin is used as a carrier for flavors, colors, and sweeteners in foods such as dry mixes, baked goods, and instant teas and coffee, as a stabilizer for flavors, colors, vitamins, and polyunsaturated fatty acids in dry mixes and dietary supplements (< 1% of the final product), as a flavor modifier in soya milk (< 1%), and as an absorbent (breath freshener) in confectionery products (10–15% of the final product).

Beta-cyclodextrin may serve as a stabilizer of food flavors, food colors and some vitamins.

Gamma-cyclodextrin is used as a carrier for flavors, sweeteners, and colors, and it has been proposed for use in this manner in dry mixes for beverages, soups, dressings, gravies and fillings. It is also used in instant coffee, tea, chewing gum, crackers, and spices. It is also proposed for use as a carrier for vitamins and polyunsaturated fatty acids in dry food mixes and in dietary supplements.

2. *Drinking water exposure.* Alpha-, beta-, and gamma-cyclodextrins are highly soluble in water, non-volatile,

have a low air: water partition coefficient, and will not be mobile in soils and sediments. Cyclodextrins will rapidly biodegrade with primary degradation occurring in a matter of hours and ultimate degradation occurring in days. No significant exposure to alpha-, beta-, and gamma-cyclodextrins via drinking water is anticipated.

Due to the high molecular weight of the alpha-, beta-, and gamma-cyclodextrins, absorption through the skin is expected to be negligible. Therefore, no significant systemic exposure is anticipated for these chemicals from residential use as inert ingredients in pesticide products.

VII. Cumulative Effects

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

Unlike other pesticides chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to alpha-, beta-, and gamma-cyclodextrins and any other substances and they do not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that alpha-, beta-, and gamma-cyclodextrins have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determination and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

VIII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. The Agency believes that alpha-, beta-, and gamma- cyclodextrins to be of low toxicity. EPA has not used a safety factor analysis to assess the risk, and therefore the additional tenfold safety factor is unnecessary.

IX. Determination of Safety for U.S. Population, Infants and Children

Based on the available information demonstrating that alpha-, beta-, and gamma-cyclodextrins are of low toxicity, EPA concludes there is a reasonable certainty no harm will result to the general population including infants and children from aggregate exposure to alpha-, beta-, and gamma-cyclodextrin residues when used as inert ingredients in pesticide products.

X. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing alpha-, beta- and gamma-cyclodextrins for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes because the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for alpha, beta, and gamma-cyclodextrins.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for alpha, beta, or gamma-cyclodextrins nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

E. Response to Comment

No comments were received regarding the Notice of filling (67 FR 220) (FRL–7279–3).

XI. Conclusions

Based on the available information on alpha-, beta-, and gamma-cyclodextrin, there is a low likelihood of concern for substantial exposures to non-target organisms from the use of these chemicals as inert ingredients in pesticide products. EPA concludes that there is a reasonable certainty of no harm from aggregate exposure from residues of alpha-, beta-, and gamma-cyclodextrin. Accordingly, EPA finds that exempting alpha-, beta-, and gamma- cyclodextrins from the requirement of tolerance will be safe to the general population and infants and children.

XII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP –2002–0294. in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 6, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the

information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2002 –0294, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XIII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 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 final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications '' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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.''''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final

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

List of Subjects in 40 CFR Part 180

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

Dated: June 27, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180 —[AMENDED]

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

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

■ 2. Section 180.950 table in paragraph (e) is amended by adding alphabetically the following entries to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e)* * *

Chemical Name	CAS No.
* * * *	*
Alpha - cyclodextrin	10016–20–3
* * * *	*
Beta - cyclodextrin	7585–39–9
* * * *	*
Gamma - cyclodextrin	17465–86–0
* * * *	*

[FR Doc. 05–13263 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0109; FRL–7721–1]

Dimethyl Ether; Exemption from the Requirement of a Tolerance; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of May 18, 2005, establishing a tolerance exemption for dimethyl ether (methane, oxybis-). This document is being issued to correct the CAS Reg. No. for dimethyl ether.

DATES: This final rule is effective on July 6, 2005.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of May 18, 2005.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under the **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET at *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. What Does this Correction Do?

A tolerance exemption for dimethyl ether (methane, oxybis-) was established in the **Federal Register** of May 18, 2005, (70 FR 28436), (FRL–7711–4). In that document the CAS Reg. No. in the tolerance exemption expression was given as 115–10–06. It should be 115–10–6 as expressed in the preamble.

III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely correcting a typographical error in a previously-published final rule in the Chemical Abstracts Service (CAS) numerical designation for a chemical. Notice and public procedures are unnecessary for such a minor change. The initial notice for the final rule and the final rule clearly identified the chemical by name. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

This final rule implements a technical correction to the CFR., and it does not otherwise impose or amend any requirements. As such, the Office of Management and Budget (OMB) has determined that a technical correction is not a ''significant regulatory action'' subject to review by OMB under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Nor does this final rule contain any information collection requirements subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*), or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

Since the Agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the APA or any other statute (see Unit III.), this action is not subject to provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

This action will not result in environmental justice related issues and does not, therefore, require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since this action is not a ''significant regulatory action'' as defined by Executive Order 12866; it does not require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), and is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

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

This technical correction will not have a substantial direct effect on 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, entitled*Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 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 technical correction does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, this technical correction does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 23, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 is corrected as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.910, by amending the entry in the table under ''Dimethyl ether'', by correcting the CAS Reg. No. 115–10–06 to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement a tolerance.

* * *

Inert ingredients	Limits	Uses
* * * * * * *		
Dimethyl ether (methane, oxybis-) (CAS Reg. No. 115–10–6)		Propellant
* * * * * * *		

[FR Doc. 05–13173 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0192; FRL–7723–2]

Fenpropathrin; Re-Establishment of Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes a time-limitedtolerance for residues of the insecticide fenpropathrin in or on currants at 15 parts per million (ppm) for an additional 3–year period. This tolerance will expire and is revoked on June 30, 2008. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use ofthe pesticide on currants. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation is effective July 6, 2005. Objections and requests for hearings must be received on or before September 6, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0192. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will bepublicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legalholidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: *conrath.andrea@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of July 14, 1997 (62 FR 37516) (FRL–5731–3), which announced that on its own initiative under section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), it established a time-limited tolerance for the residues of fenpropathrin in or on currant at 15 ppm, with an expiration date of December 31, 1998. This time-limited tolerance was subsequently extended via **Federal Register** noticespublished on: September 9, 1998 (63 FR 48113) (FRL–6020–2), extending the tolerance until June 30, 2000; August 9, 2000 (65 FR 48617) (FRL–6597–9), extending the tolerance untilDecember 31, 2001; and on December 14, 2001 (66 FR 64768) (FRL–6814–2), extending the tolerance until December 31, 2003. EPA established the tolerance because section 408(l)(6) ofthe FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use ofa pesticide under an emergency exemption granted by EPA under FIFRA section 18. Suchtolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of fenpropathrin on currants for this year's growing season due to the continued problems with controlling currant cane borer and currant stem girdler in currants in Washington, since the cancellation of the insecticide historically used to control these pests. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use offenpropathrin on currants for control of currant cane borer and currant stem girdler in Washington.

EPA assessed the potential risks presented by residues of fenpropathrin in or on currant. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and decided that the necessary tolerance under section 408(l)(6) of the FFDCA wouldbe consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule published in the **Federal Register** of July 14, 1997 (62 FR 37516) (FRL–5731–3). Based on that data and information considered, the Agency reaffirms that re-establishment of the time-limited tolerance will continue to meet the requirements of section 408(l)(6) of the FFDCA. Therefore, the time-limited tolerance is re-established for an additional 3–year period. EPA will publish a document in the **Federal Register**to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on December 31, 2008, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on currant after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to therevocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person mayfile an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessarymodifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0192 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed ordelivered to the Hearing Clerk on or before September 6, 2005.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked

confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0192, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to:*opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administratordetermines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if establishedresolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly AffectEnergy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerationsunder Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132, 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 final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249,November 6, 2000). Executive Order 13175, 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.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175, does not apply to this rule.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, asadded by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeepingrequirements.

Dated: June 27, 2005.

Lois Rossi,

Director, Registration Division, Office of PesticidePrograms.

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

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and371.

§ 180.466 [Amended]

■ 2. In § 180.466, amend the entry in the table underparagraph (b) for ''currant'' by revising the Expiration/Revocation Date ''12/31/03'' to read ''12/31/08.''

[FR Doc. 05–13174 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7932–9]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Direct final notice of deletion of the Fadrowski Drum Disposal Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region V is publishing a direct final notice of deletion of the Fadrowski Drum Disposal Superfund Site (Site), located in Franklin, Wisconsin, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final notice of deletion is being published by EPA with the concurrence of the State of Wisconsin, through the Wisconsin Department of Natural Resources (WDNR) because EPA and WDNR have determined that all appropriate response actions under CERCLA have been completed, other than operation and maintenance and five-year reviews and, therefore, further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final deletion will be effective September 6, 2005 unless EPA receives adverse comments by August 5, 2005. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Comments may be mailed to: Sheila Sullivan, Remedial Project Manager at (*sullivan.sheila@epa.gov*) or U.S. EPA (SR–6J), 77 W. Jackson Blvd., Chicago, IL, USA 60604–3590 or at (312) 886–5251 or 1–800–621–8431.

Information Repositories: Comprehensive information about the Site is available for viewing and copying at the Site information repositories located at: U.S. EPA Region 5 Library, 77 Jackson Blvd., Chicago, IL, USA 60604–3590, (312) 353–5821, Monday through Friday 8 a.m. to 12 p.m.; Franklin Public Library, 9151 W. Loomis Rd., Franklin, WI 53132, (414) 425–8214, Monday through Thursday 10 a.m. to 8:30 p.m., Friday through Saturday 10 a.m. to 5 p.m.; Franklin City Hall, City Clerk's Office, 9229 W. Loomis Rd., Franklin, WI 53132, (414) 275–7500, Monday through Friday 8:30 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Sheila Sullivan, Remedial Project Manager at (312) 886–5251, (*sullivan.sheila@epa.gov*) or Gladys Beard, State NPL Deletion Process Manager at (312) 886–7253, (*beard.gladys@epa.gov*), or 1–800–621–8431, U.S. EPA (SR–6J), 77 W. Jackson Blvd., Chicago, IL, USA 60604–3590.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. 235 NPL Deletion Criteria
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I. Introduction

EPA Region 5 is publishing this direct final notice of deletion of the Fadrowski Drum Disposal Superfund Site from the NPL.

The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective September 6, 2005 unless EPA receives adverse comments by August 5, 2005 on this notice or the parallel notice of intent to delete published in the Proposed Rules section of today's **Federal Register.** If adverse comments are received within the 30-day public comment period on this notice or the notice of intent to delete, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Fadrowski Drum Disposal Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from the NPL where no further response is appropriate. In making a determination to delete a release from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed (Hazardous Substance Superfund Response Trust Fund) response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the deleted site above levels that allow for unlimited use and unrestricted exposure, CERCLA section 121(c), 42 U.S.C. 9621(c) requires that a subsequent review of the site be conducted at least every five years after the initiation of the remedial action at the deleted site to ensure that the action remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a

significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) The EPA consulted with the State of Wisconsin on the deletion of the Site from the NPL prior to developing this direct final notice of deletion.

(2) The State of Wisconsin concurred with deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final notice of deletion, a notice of the availability of the parallel notice of intent to delete published today in the ''Proposed Rules'' section of the **Federal Register** is being published in a major local newspaper of general circulation at or near the Site and is being distributed to appropriate federal, state, and local government officials and other interested parties; the newspaper notice announces the 30-day public comment period concerning the notice of intent to delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the deletion in the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this notice or the companion notice of intent to delete also published in today's **Federal Register,** EPA will publish a timely notice of withdrawal of this direct final notice of deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Location

The Fadrowski Drum Disposal Site (FDDS or ''the Site'') occupies approximately 20 acres of suburban land in the southeast quarter of Section 1, Township 5 North, Range 21 East, Milwaukee County, Wisconsin. The Site is located within the corporate limits of the City of Franklin and is fronted by U.S. 41 (also known as South 27th Street) on the east, Rawson Avenue is about 1,400 feet to the south and College Avenue is located approximately 3,400 feet to the north. An unnamed tributary flows southward along the western boundary of the Site and eventually empties into the Root River approximately three miles southwest of the Site. The tributary carries overflow water from Mud Lake in Grobschmidt Park, approximately one-quarter mile north of the Site and also receives storm water discharge from South 27th Street and other upgradient paved areas. The Site abuts and is downgradient of the defunct Menard lumber and retail facility situated directly to the north. Several commercial retail facilities are situated directly south and southwest of the Site. The new Menard Home Improvement Center is located directly east of the Site, across U.S. 41. Residential subdivisions and multi-unit residential properties are situated west of the unnamed tributary and also along Rawson Avenue.

Site History

Between 1970 and 1982, the FDDS was owned and operated by Edward J. Fadrowski as an unlicensed disposal facility that accepted demolition and construction wastes. Pursuant to applicable state regulations, the operation would have been exempt from regulation had it only accepted solid wastes consisting of clean earth fill and containing less than 25 percent demolition waste. During that time frame, Mr. Fadrowski was also the principal operator of a waste collection and transportation company (Ed's Trucking) which was licensed to collect and transport noncombustible waste, wood, refuse and garbage. The clients of Ed's Trucking included diverse local businesses and industries that generated a variety of wastes. The Wisconsin Department of Natural Resources (WDNR) discovered the unlicensed disposal of nonexempt waste at the Site in 1981 during an inspection. A subsequent WDNR inspection confirmed that the disposal of metal, wood, foundry waste, crushed drums, and slag-type boiler waste had occurred at the Site.

In December 1982, Menard, Inc. of Eau Claire, Wisconsin purchased the FDDS property and two adjacent land parcels to the north and began constructing its lumber and retail facility at 6801 S. 27th Street, Franklin, Wisconsin. The FDDS property was intended as a source of borrow soil to be used during grading and construction of Menard's lumber and retail facility on the adjacent parcels. During excavation at the Site for soil fill material in May 1983, buried drums containing unknown liquids and sludges were uncovered; some of the drums had been ruptured and their contents released. The WDNR sampled the drum contents and found them to be hazardous, as defined by Chapter NR 181 of the 1981 Wisconsin Administrative Code (WAC). The samples revealed high concentrations of lead at 32,700 parts per million (ppm) and chromium at 6,800 ppm. Also identified were trace levels of arsenic (less than 5 ppm), the pesticide DDT at 1,450 ppm, and various petroleum-derived volatile organic compounds (VOCs). Other waste samples collected by the WDNR at the Site were determined to be hazardous because their flash points were below 140 degrees Fahrenheit, indicating ignitability. The EPA's Office of Health and Environmental Assessment determined that the carcinogenic risks from the principal threat, i.e., buried containerized wastes, exceeded EPA's upper threshold of acceptable risk (1×10^{-4}). The EPA and the WDNR believe that a number of potential responsible parties (PRPs) generated the hazardous wastes that were disposed of at the Site and/or caused the release of these substances at the Site.

The Site was proposed for listing on the NPL on October 15, 1984 (49 FR 40320). Pursuant to Section 105 of CERCLA, 42 U.S.C. 9605; the FDDS listing on the NPL was finalized on June 10, 1986 (51 FR 21054). An Administrative Order on Consent (AOC) was signed in May 1987 by the PRPs, U.S. EPA, and WDNR, compelling the PRPs to conduct a Remedial Investigation and Feasibility Study (RI/FS) to determine the nature and extent of the contamination as well as alternatives for cleaning up the Site.

Remedial Investigation and Feasibility Study (RI/FS)

Pursuant to the 1987 AOC, the RI/FS was initiated in May 1987 by INX International Ink Company (INX), formerly ACME Ink Printing Company of Milwaukee, Wisconsin, and was completed in June 1991. The RI results indicated that three generalized geological layers exist at the Site: clay till, sand and gravel, and dolomite bedrock. The uppermost clay till layer is between 80 and 100 feet thick and is continuously saturated up to within 3 to 10 feet of the ground surface; however, the soils are of such low permeability

that this aquifer does not sustain domestic water supply. The underlying sand and gravel aquifer yields adequate amounts of water to sustain domestic use and several domestic wells are screened in this unit. Beginning at about 175 feet below ground surface and ranging up to 320 feet in thickness, the deep dolomite bedrock aquifer is the primary source of domestic water supply in the vicinity of the FDDS. Although there were very few inorganic or organic compounds detected at elevated levels in the groundwater at the FDDS, the RI results confirmed that the groundwater in the clay till aquifer contained cyanide (67 parts per billion or ppb), chromium (13 ppb), and barium (273 ppb), in excess of the 1988 Wisconsin Preventive Action Limits (PALs). During one sampling event, benzene and mercury were also found to exceed the 1988 Wisconsin PALs and Enforcement Standards (ESs); however these results could not be confirmed. The benzene detections have since been attributed to sampling and/or laboratory error. The concentrations of mercury and other inorganic constituents, e.g., chromium, barium, and cyanide, have declined steadily to below the PALs and ESs. Several private wells are located within 2,000 feet of the Site and several emergency back up wells for the cities of Franklin and Oak Creek are located within three miles of the Site; however, testing showed that drinking water has not been impacted by the Site.

Surface water on the Site was contained by a large manmade pond in the west central portion of the Site. The pond intercepted most surface water runoff from the Site and was also a point of groundwater discharge. The pond contained elevated cyanide levels. The water in the unnamed tributary on the western Site boundary was found to contain low levels of VOCs. Other contaminants detected downstream of the Site, namely ethylbenzene and xylenes, were not detected onsite. Cyanide and mercury were detected in both upstream and downstream samples, and were therefore not likely to be site-related. No semi-volatile organic chemicals (SVOCs) were detected in the unnamed tributary water.

The sediments sampled in the onsite pond contained site-related contaminants. Sediments collected downstream of the Site in the unnamed tributary showed higher concentrations of certain polynuclear aromatic hydrocarbons (PAHs) than did the upstream samples. Similarly, total PAHs and inorganics, including aluminum, barium, beryllium, calcium, lead, and magnesium showed higher concentrations in the downstream samples compared to the samples collected upstream of the Site, indicating that the stream sediments may have been contaminated by the Site. Subsequent monitoring results showed that the surface water and sediments in the tributary had not been contaminated by the FDDS, but instead, were more likely to have been affected by urban runoff.

Surface soils from the western slope of the fill pile showed PAH concentrations as high as 10,290 ppb. This was consistent with the character of onsite subsurface soils and indicated that runoff or seeps from the fill pile were impacting surface soil adjacent to the pile and west of the pile near the unnamed tributary. Subsurface soils collected onsite were contaminated with organic compounds—namely toluene at levels ranging from 34 to 1,800 ppb. Total PAHs were also frequently detected in the subsurface soil at levels as high as 24,300 ppb. The subsurface soil borings also revealed DDT at its highest concentration of 310 ppb and the polychlorinated biphenyl, Arochlor 1254, at a maximum concentration of 1,900 ppb. Cyanide was found in one boring at 6,360 ppb and numerous inorganic compounds were also detected.

The draft RI/FS was completed in March 1991. The final FS was completed in June 1991 and provided an in-depth summary and discussion of Site sampling activities and a health risk assessment. Six cleanup alternatives were also evaluated as part of the FS; however, no groundwater alternatives were among the six evaluated due to the low contaminant levels detected in the groundwater and the limited extent of groundwater contamination. The considered alternatives included source-control actions that relied on natural attenuation of groundwater contaminants.

Record of Decision Findings

Based on the results of the RI/FS, a Remedial Action (RA) was selected for cleaning up the Site and was documented in the Record of Decision (ROD) of June 10, 1991, with concurrence from the WDNR. The selected remedy was to eliminate or reduce migration of the contaminants from the Site to the groundwater and to reduce the risk associated with exposure to the contaminated materials, thus protecting human health and environment. The major components of the selected remedy included:

- Excavation of previously identified drums and associated characteristically hazardous soils;
- Construction of trenches to find and excavate additional containerized waste and associated characteristically hazardous soils;
- Off–site recycling or treatment and disposal of drummed wastes;
- Treatment and disposal of contaminated soil;
- Construction of a landfill cover (cap) in compliance with Section NR 504.07, Wisconsin Administrative Code (WAC) landfill closure requirements;
- Use of institutional controls on landfill property to limit land and groundwater use; and,
- Monitoring of groundwater and surface water to ensure effectiveness of the remedial action and to evaluate the need for future groundwater treatment.

Characterization of Risk

The health risk assessment, performed during the RI, indicated that people may have been exposed to hazardous substances by drinking contaminated groundwater and surface water or by accidentally ingesting contaminated soil. Residents in the vicinity of the Site, especially children, may have used the manmade pond located at the eastern edge of the Site for swimming, thereby potentially exposing them to Site contaminants. Most risks from these exposures fell within a risk range of 1×10^{-4} (one in ten-thousand) to 1×10^{-6} (one in one-million), which is considered acceptable by EPA. However, other Site conditions, such as the onsite buried drums of hazardous materials, would pose unacceptable risks to construction workers and possibly residents should the Site be commercially or residentially developed in the future. The RI indicated that some of the drums had ruptured, causing further contamination of the environment. Approximately nine acres of wetlands border the onsite pond on the west. Levels of cyanide in the onsite pond exceeded the Ambient Water Quality Criteria for the protection of aquatic life. Cyanide was also found in the upstream and downstream tributary samples. Prior to the cleanup, runoff from the Site flowed toward the wetlands; however, no threatened or endangered species had been previously identified in this area.

Response Actions

A Remedial Design (RD) was completed by Menard, Inc., a PRP for the Site, under the September 30, 1991 AOC. The RD was approved by the EPA in March 1993 and included the final design of the selected RA alternative. This RA alternative prescribed the removal of drummed waste from the Site, waste consolidation, pond closure,

clay cap installation over the consolidated waste, and the installation of a groundwater monitoring network. One component of the RA—institutional controls—was effected by placing deed restrictions on the portion of the property that included but was not limited to the waste footprint. The deed restrictions, effective since June 1993, prohibit certain activities within the fill area on the Site unless prior written approval is obtained from the EPA, in consultation with the WDNR.

On April 21, 1993, EPA issued a Unilateral Administrative Order (UAO) to the PRPs to implement the Remedial Action (RA) specified in the 1991 ROD. Menard, Inc. undertook the RA field activities in September 1993. The majority of the work was completed by September 1994, including:

- Removal and off-site treatment and disposal of 167 buried drums;
- Excavation, treatment, and disposal of approximately 100 cubic yards of contaminated soils;
- De-watering and backfilling the 2.6 million gallon onsite pond;
- Consolidation of more than 18,000 cubic yards of waste (primarily demolition debris) in order to minimize the capped area;
- Construction of a multilayered landfill cover system and leachate collection system, complicit with section NR 504.07, WAC, for placement over the consolidated wastes;
- Installation of both upgradient and downgradient nested monitoring wells, screened within the three geological units (clay, sand and gravel, and dolomite bedrock) at the Site; and,
- Installation of a perimeter fence.

Since the completion of the RA, the Site has been in the monitoring phase, which was projected to continue for a 30-year period. As part of the RA, the Scope of Work (SOW) required that after two years and five years of respective monitoring, a comprehensive statistical analysis of the data at each of these milestones was to be prepared in order to evaluate the effectiveness of the remedy and the potential for reduced monitoring at the Site. The monitoring network included nine groundwater monitoring wells, one leachate tank, one private well on the southeast side of the Site, and two surface water/sediment sample locations in the unnamed tributary—one each upstream and downstream of the Site. The nine nested monitoring wells intercept three aquifers at the Site (*i.e.*, clay, sand and gravel, dolomite) and are located just outside the four corners of the landfill boundary. The prescribed monitoring included quarterly monitoring of the groundwater for field parameters (temperature, pH, conductivity), EPA Target Analyte List (TAL) parameters (inorganics), EPA Target Compound List (TCL) parameters (VOCs, SVOCs, and pesticides), WAC NR 508 parameters (alkalinity, chemical oxygen demand, hardness, sodium, dissolved iron, chloride, and fluoride), and percent organic material and grain size analysis for stream sediment samples.

Cleanup Standards

Beginning in November 1995, the effectiveness of the remedy was monitored through quarterly sampling of the nine monitoring wells, leachate tank, surface water, and sediments from the unnamed tributary. The requisite two-year statistical evaluation of contaminant levels in the groundwater, leachate, surface water and sediment was prepared by Menard, Inc. using data from eight monitoring events. The data were evaluated to ascertain whether the Site was meeting cleanup requirements and whether the monitoring frequency and parameters needed adjustment. The cleanup requirements for the FDDS, established in the 1991 ROD, are the groundwater quality standards in Chapter NR 140 WAC, 1988. As previously mentioned, these values are referred to as the Wisconsin PALs and ESs. The report concluded that natural attenuation of site-related contaminants was effective; surface water and sediment monitoring could be discontinued, and the monitoring frequency of onsite wells, the private well, and the leachate tank could be reduced from quarterly to semiannual. Concurring with these recommendations, EPA and the WDNR approved the report in November 2000; the revised monitoring schedule was implemented at that time.

The five-year statistical evaluation was completed in June 2003 and utilized data collected from the onsite monitoring wells and leachate tank during fifteen monitoring events, and surface water and sediment data collected during nine monitoring events. The results showed that site-related contaminants follow a declining trend in their respective concentrations. Statistical evaluation of the groundwater data indicated that the PALs had been met for all contaminants except iron, manganese, and fluoride. These three constituents have been consistently detected above their respective PALs in the onsite groundwater at a five percent statistical significance level.

Although fluoride, iron, and manganese exceed their respective PALs, they are also common constituents found naturally in the groundwater of Wisconsin. An evaluation of the background groundwater quality in Milwaukee County, prepared by Menard, Inc. and approved by EPA and WDNR as part of the five-year statistical evaluation, indicated that concentrations of fluoride, iron, and manganese above the 1988 Chapter NR 140 PALs are common. The PAL exceedances reported onsite are, therefore, unlikely to be caused by past FDDS activities and more probably reflect the naturally occurring groundwater quality in the region. The consistency of these onsite groundwater levels with background levels, also exceeding the PALs for these three constituents, demonstrates that the groundwater has been restored to its pre-FDDS condition. This finding also indicates that achieving PALs for these three constituents via natural attenuation or related methods is neither technically nor economically feasible. To address these higher constituent levels in groundwater, an exemption was granted by the WDNR, pursuant to WAC Sections NR 140.28 and NR 507.29, allowing the calculation of Wisconsin alternative concentration levels (WACLs) for iron, fluoride, and manganese in the monitoring wells where the PALs are exceeded. The WACLs, respectively calculated for iron in three monitoring wells, manganese in five wells, and fluoride in two wells (see Table 1), remain protective of human health and the environment and have been approved by the WDNR in its letter of July 29, 2003 to the EPA. These actions have brought the FDDS into full compliance with WAC 1988 Chapter NR 140 Groundwater Quality Standards and the RA cleanup goals set forth in the 1991 ROD and RD/RA SOW. Moreover, Lake Michigan is the source of the municipal water supply for the City of Franklin. The City provides potable water to all of the large commercial establishments and residential developments in the vicinity of the Site. Though several emergency back up wells for the cities of Franklin and Oak Creek are within three miles of the Site, and some private wells still exist within 2,500 feet of the Site, such as those located south of Rawson Avenue, test results show that these wells are not being affected by the Site. The City of Franklin expects to extend its water distribution lines to this area within the next five years, at which time the use of private wells will be unnecessary. Surface water and sediment from the unnamed tributary at the Site have been sampled and analyzed during nine previous monitoring events at both upgradient and downgradient flow locations with respect to the FDDS.

Analytical results indicated that while surface water and sediment quality have been affected by urban runoff, the results do not reflect that surface water and sediment in the unnamed tributary have been affected by the FDDS.

TABLE 1.—WACLS TO BE APPLIED AT THE FADROWSKI DRUM DISPOSAL SITE

Monitoring Well (MW)	Parameter	Mean concentration (mg/l)	PAL/ES (mg/l)	Calculated ACL (mg/l)	Rounded ACL (mg/l)
MW–8 CO	Fluoride	0.74	0.44/2.2	3.6	4.0
MW–9S	Fluoride	1.30	0.44/2.2	1.48	1.5
MW–6COR	Iron	0.05	0.15/0.3	0.347	0.35
MW–6S	Iron	0.10	0.15/0.3	0.303	0.30
MW–7S	Iron	0.06	0.15/0.3	0.372	0.37
MW–6COR	Manganese	0.19	0.025/0.05	0.513	0.51
MW–6S	Manganese	0.15	0.025/0.05	0.235	0.24
MW–8CO	Manganese	0.25	0.025/0.05	0.625	0.63
MW–8D	Manganese	0.04	0.025/0.05	0.056	0.06
MW–9S	Manganese	0.04	0.025/0.05	0.051	0.05

Operation and Maintenance

Menard, Inc. has assumed operation and maintenance (O&M) responsibility since the completion of RA activities through its primary RA contractor, Ayres Associates of Eau Claire, Wisconsin. These responsibilities, listed in Table 2, have been performed by Ayres Associates' subcontractor, Environmental Sampling Corporation of Muskego, Wisconsin.

TABLE 2.—OPERATION AND MAINTENANCE ACTIVITIES AT THE FADROWSKI DRUM DISPOSAL SITE

Activity	Inspection frequency	Maintenance frequency
Site Fencing	Annually	As Required.
Site Access Road	Annually	As Required.
ENVIRONMENTAL MONITORING PROGRAM		
Sample Collection and Monitoring Point Inspection	Each Sampling Event	As Required.
FINAL COVER SYSTEM		
Erosion of Soil Cap	Semi-annually [a]	As Required.
Grass Cover	Semi-annually [a]	As Required.
Storm Water Control Structures	Semi-annually [a]	As Required.
Mowing and Pruning	Twice/Year	Twice/Year [b].
LEACHATE COLLECTION SYSTEM		
Full Tank Monitoring	([c])	([c])
Leachate Level Measure	([c])	([c])
Leachate Disposal		As Required.
Test Cycle Pump	Quarterly	As Required.
Jet Leachate Collection Line	Five-Year Interval [d]	Five-Year Interval.
Tank Leak Detection	Quarterly	As Required.
Cathodic Protection	Annually	As Required.

[a] Inspection of the final cover system will occur semi-annually for the first two years, until vegetation has been established, and annually hereafter.
[b] Mowing of vegetation will occur twice each year during the growing season; usually in early July and late September.
[c] None required as direct discharge permit to Milwaukee Metropolitan Sanitary District sewer has been established.
[d] Leachate collection line will be jet cleaned after two years of operation and at five-year intervals thereafter.

Annual O&M reports are filed each June summarizing the O&M work conducted over the past year and documenting any problems at the Site, corrective actions taken, and changes in the monitoring and reporting requirements. The O&M items of note that have occurred at the Site since RA completion are the following:

1. Installation of a shallow subsurface drain system in 1999 to intercept the surface water seeping from the west slope of the Site. The drain system directed the water via piping to the leachate collection system where it was discharged to the Milwaukee Metropolitan Sanitary District. This system eliminated a seep that was detected; no problems with the cover system have been detected since that time.

2. Miscellaneous repairs and/or replacement of the fencing, locks, and access road, as well as annual mowing of the grass cover at the Site; and,

3. Reduction in groundwater and leachate monitoring frequency from quarterly to semiannually. Surface water and sediment sampling of the unnamed stream were eliminated in 2000 due to the inability to detect site-related contaminants over a two-year period, as documented in the Two-Year Ground Water Monitoring Report approved by the Agencies in November 2000. Under the terms of a Consent Order signed on March 28, 2005 between the WDNR and Menard, Inc., and with the concurrence of EPA, the frequency of groundwater and leachate monitoring was further reduced from semiannually to annually.

Since June 1993, a deed restriction has been in effect for this Site. The deed restriction, specified in the 1991 ROD, prohibits certain activities within the fill area on the Site. These activities include: no consumptive or other use of the groundwater underlying the property; no use of, or activity at, the property that may interfere with the work performed or to be performed under the UAO at the Site, or any activity which may damage any RA component contracted for or installed pursuant to the UAO or otherwise impair the effectiveness of any work to be performed pursuant to the UAO; no installation, construction, removal or use of any buildings, wells, pipes, roads, ditches or any other landfill cap except as approved by the EPA as consistent with the UAO and SOW; and, no residential use of the property.

During the O&M phase, some modifications have occurred in the vicinity of the FDDS. On July 24, 2001, EPA and WDNR rescinded portions of the existing deed restrictions on the private property adjacent to the Site, thereby allowing commercial development of the property outside the Site boundary fencing, as appropriate. These areas had previously been considered buffer areas around the Site; however, due to the stable Site conditions, the agencies have allowed limited development in these areas. This development is consistent with current Site conditions and has not caused storm water management or unauthorized Site access problems to develop. This area of the City of Franklin is considered to be an active commercial district and future development will likely occur in the vicinity of the FDDS. The Final Close-Out Report, signed August 8, 2003, documented that Menard, Inc. completed all response actions for the FDDS in accordance with OSWER Directive 9320.2–09A–P, *Close Out Procedures for National Priorities List Sites, January 2000,* as overseen by EPA and WDNR. The WDNR will continue to oversee and ensure the performance of O&M activities at the Site by Menard, Inc. using the provisions of its March 28, 2005 Consent Order with Menard, Inc. This oversight will continue for the remaining 22 years of the 30-year O&M phase or until such time as the WDNR determines that the annual groundwater and leachate monitoring requirements may be modified or terminated.

Five-Year Review

The first statutory five-year review for the Site was completed by EPA on September 14, 1998 pursuant to CERCLA section 121 (C) and as provided in OSWER Directive 93 55.7–02, *Structure and Components of Five-Year Reviews, May 23, 1991.* This review was completed five years from the date (September 1993) on which the first contract was awarded by the responsible parties to implement RA.

The second statutory five-year review was completed by EPA on September 25, 2003, about five years from the date of completion of the first five-year review. This review was prepared according to OSWER Directive No. 9355.7–03B–P (EPA 540–R–01–007), *Comprehensive Five-Year Review Guidance, June 2001.*

Community Involvement

Public participation activities have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and CERCLA section 117, 42 U.S.C. 9617. Documents in the deletion docket that EPA relied on for the recommendation of the deletion from the NPL are available to the public in the information repositories.

V. Deletion Action

The EPA, with concurrence of the State of Wisconsin, has determined that all appropriate responses under CERCLA have been completed, and that no further response actions, under CERCLA, other than O&M and five-year reviews, are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective September 6, 2005 unless EPA receives adverse comments by August 5, 2005 on a parallel notice of intent to delete published in the Proposed Rule section of today's **Federal Register.** If adverse comments are received within the 30-day public comment period on the proposal, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect and, EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: June 21, 2005.

Norman Niedergang,

Acting Regional Administrator, EPA Region 5.

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for Part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c) (2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p.193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended under Wisconsin (''WI'') by removing the site name ''Fadrowski Drum Disposal Site'' and the city ''Franklin.''

[FR Doc. 05–13172 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 20, and 43

[WC Docket No. 04–141; FCC 04–266]

Local Telephone Competition and Broadband Reporting

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: On May 26, 2005, the Federal Communications Commission received Office of Management and Budget (OMB) approval for the revised information collection, Local Telephone Competition and Broadband Reporting, WC Docket 04–141, OMB Control No. 3060–0816. The Commission previously stated in the Data Collection Order that the revised information collection requirements had not been approved by OMB, and that it would publish a document announcing the effective date, 69 FR 77912, December 29, 2004. By this document, we announce that OMB Control No. 3060–0816 and the amended rules 47 CFR 1.7001(b), 20.15(b)(1), and 43.11(a) implementing it were effective on May 26, 2005.

DATES: The amendments to 47 CFR 1.7001(b), 20.15(b)(1), and 43.11(a), published at 69 FR 77938, December 29, 2004, became effective on May 26, 2005.

FOR FURTHER INFORMATION CONTACT: Ellen Burton, Assistant Chief, James Eisner, Senior Economist, or Darryl Cooper, Attorney-Advisor, Industry

Analysis and Technology Division, Wireline Competition Bureau, at (202) 418–0940.

SUPPLEMENTARY INFORMATION: In its Data Collection Order, the Commission revised the information collection requirements for FCC Form 477 (69 FR 77912, December 29, 2004). The revisions extend and modify the FCC Form 477 local competition and broadband data gathering program, established by the Commission's Data Gathering Order (65 FR 19675, April 12, 2000). In the Data Collection Order, the Commission stated that the revised information collection requirements had not been approved by OMB. It indicated that the amended rules implementing the revised information collection would become effective only upon OMB approval of the revised information collection. It stated that it would publish a document in the **Federal Register** announcing the effective date.

OMB approved the revised information collection on May 26, 2005. Accordingly, through this document, the Commission announces that May 26, 2005, will function as the effective date of both the revised information collection and the amended rules implementing it. This means that the revised information collection and the amended rules will apply to the Form 477 that entities must file on or before September 1, 2005, reporting data as of June 30, 2005.

Pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13, an agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Questions concerning OMB control numbers and expiration dates should be addressed to Paul J. Laurenzano, Wireline Competition Bureau, at (202) 418–1359 or via the Internet at *Paul.Laurenzano@fcc.gov.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13028 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 63, and 64

[IB Docket No. 04–226; FCC 05–91]

Mandatory Electronic Filing for International Telecommunications Services and Other International Filings

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document is a summary of the Report and Order adopted by the Commission in this proceeding. The Commission adopted rule changes that eliminate paper filings and require applicants to file electronically all applications and other filings related to international telecommunications services. The Report and Order will further the Commission's goals to increase the efficiency of application processing and to expedite the availability of the application information for public use and inspection.

DATES: Effective August 5, 2005 except for 47 CFR 63.19(d), 63.21(a), 63.21(h), 63.21(i), 63.25(b), 63.25(c), 63.25(e), 63.53(a)(1), 63.53(a)(2), 63.701 introductory text and (j), 64.1001(a), 64.1001(f), 64.1002(c) and 64.1002(e) which contain information requirements that have not yet been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of those sections. OMB, the general public, and other Federal agencies are invited to comment on the information collection requirements on or before September 6, 2005.

ADDRESSES: In addition to filing comments with the Office of the Secretary, a copy of any comments on the Paperwork Reduction Act information collection(s) contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judity-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Peggy Reitzel or JoAnn Ekblad, Policy Division, International Bureau, (202) 418–1460. For additional information concerning the Paperwork Reduction Act information collection(s) contained in this document, contact Judith B. Herman at 202–418–0214, or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order* in IB Docket No. 04–226, FCC No. 05–91, adopted April 29, 2005 and released on May 11, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257). The document is also available for download over the Internet at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–05–91A1.pdf.* The complete text may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) located in Room CY-B402, 445 12th Street, SW., Washington, DC 20554. Customers may contact BCPI at their Web site: *http://www.bcpiweb.com* or call 1–800–378–3160.

Summary

The Commission initiated a Notice of Proposed Rulemaking in this proceeding (69 FR 48118, August 9, 2004). In response to the Notice of Proposed Rulemaking, on April 29, 2005, the Commission adopted a Report and Order adopting the proposals contained in the Notice of Proposed Rulemaking. The new rules will mandate electronic filing of applications and other submissions related to the provision of international telecommunications services. Over the years, the Commission has introduced a number of electronic filing systems that a large and growing number of applicants are using to file their applications. For international services, filers submit applications and other filings via the International Bureau Filing System (IBFS). In the Report and Order, the Commission required all filings related to international telecommunications services to be submitted via the IBFS.

The mandatory filing requirements will be implemented in stages as new forms are developed for IBFS. This phased-in implementation will allow for the development of additional forms consistent with the rules. The Commission adopted a sixty-day transition period to allow applicants and carriers time to adjust to the new filing requirements. The sixty-day transition period will begin on the effective date of the new rules and will apply to those applications for which electronic forms are currently available. Thereafter, the International Bureau will issue public notices announcing the availability of new forms and the effective date of the electronic filing requirement. At the end of the sixty-day transition period, the Commission will no longer accept filings in a manual

format, and the filings will be returned to the applicant without processing.

The Report and Order concluded that mandatory electronic filing will allow applicants to make international filings more rapidly and efficiently. In addition, it will improve the speed and efficiency of application processing, and expedite the availability of the application information for public use and inspection. Also, the Commission concluded that electronic filing would not impose any undue burdens on parties.

The Commission will continue with its policies for the confidential treatment of certain materials. Currently, IBFS does not accommodate confidential filings, but the Commission intends to develop the capability of IBFS to accommodate confidentially filed pleadings and applications.

Procedural Matters

Final Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980, as amended (RFA), requires that a regulatory flexibility analysis be prepared for any rule making proceeding that requires notice-and-comment, 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. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).) The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' 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 Small Business Administration (SBA).

Pursuant to the RFA, the Commission incorporated an Initial Regulatory Flexibility Certification into the Notice of Proposed Rulemaking in the Certification. The Commission tentatively concluded that the proposals contained in the Notice of Proposed Rulemaking were in the public interest and would not impose undue burdens on carriers, small or large. Further, any burdens caused by mandating electronic filing would be offset by the fact that services to the public would likely be expedited. We received no comments on the Notice of Proposed Rulemaking or the Initial Regulatory Flexibility Certification.

In the Report and Order, the Commission adopted mandatory electronic filing for applications and other filings associated with international telecommunications services. Mandatory electronic filing is in the public interest and will not impose undue burdens on a significant number of small entities that are now required to file for international telecommunications services. Further, the processing of these filings will be expedited by mandatory electronic filing.

We certify that the requirements of the Report and Order will not have a significant economic impact on a substantial number of entities.

Report to Congress: The Commission will send a copy of the Order, including a copy of the Final Regulatory Flexibility Certification, in a report to Congress. In addition, the Commission will send a copy of the Order, including a copy of the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the SBA. A copy of the Order and Final Regulatory Flexibility Certification will also be published in the **Federal Register.**

Paperwork Reduction Act Analysis

This Report and Order contains either new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It has been submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the modified information collection contained in this proceeding. (*See* 69 FR 48188, August 9, 2004) In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, (*see* 44 U.S.C. 3506 (c)(4)), the Commission previously sought specific comment on how the Commission might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

In the Report and Order, we assessed the effects of mandatory electronic filing of all applications and other filings related to international services. Mandatory electronic filing will allow all applicants, including small entities, to make filings more rapidly and efficiently. The Report and Order also provides for a transition period that will allow all applicants and carriers to adjust to the new rules. Finally, the Report and Order permits an applicant to seek a waiver of the rules in the limited instances where electronic filing may be burdensome.

All comments regarding the requests for approval of the information collection should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov;* phone 202–418–0214.

Ordering Clauses

It is ordered that, pursuant to sections 1, 4(i)–4(j), 201–205, 211, 214, 219–220, 303(r), 309 and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i)–154(j), 201–205, 211, 214, 219–220, 303(r), 309, 403, the policies, rules and requirements discussed herein *are adopted* and parts 1, 63, and 64 of the Commission's rules, 47 CFR 1, 63, and 64 *are amended.*

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Report and Order, including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

It is further ordered that the policies, rules and requirements established in this decision shall take effect August 5, 2005 except for those policies, rules and requirements which contain information requirements that have not yet been approved by the Office of Management and Budget (OMB).

List of Subjects in 47 CFR Parts 1, 63, and 64

Communications common carriers, Reporting and recordkeeping requirements, Telecommunications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

■ For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 1, 63, and 64 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 15 U.S.C. 79 et seq; 47 U.S.C. 151, 154(i), 154(j), 155, 157, 225, and 303(r).

■ 2. Section 1.767 is amended by revising paragraphs (a) introductory text,

(a)(11)(iii), (g)(7), (g)(14), (j), and adding paragraph (n) to read as follows:

§ 1.767 Cable landing licenses.

(a) Applications for cable landing licenses under 47 U.S.C. 34–39 and Executive Order No. 10530, dated May 10, 1954, should be filed in accordance with the provisions of that Executive Order. These applications should contain:

* * * * *

(11) * * *

(iii) An assignee or transferee must notify the Commission no later than thirty (30) days after either consummation of the assignment or transfer or a decision not to consummate the assignment or transfer. The notification shall identify the file numbers under which the initial license and the authorization of the assignment or transfer were granted.

* * * * *

(g) * * *

(7) A *pro forma* assignee or person or company that is the subject of a *pro forma* transfer of control of a cable landing license is not required to seek prior approval for the *pro forma* transaction. A *pro forma* assignee or person or company that is the subject of a *pro forma* transfer of control must notify the Commission no later than thirty (30) days after the assignment or transfer of control is consummated. The notification must certify that the assignment or transfer of control was *pro forma*, as defined in § 63.24 of this chapter, and, together with all previous *pro forma* transactions, does not result in a change of the licensee's ultimate control. The licensee may file a single notification for an assignment or transfer of control of multiple licenses issued in the name of the licensee if each license is identified by the file number under which it was granted;

* * * * *

(14) The licensee must notify the Commission within thirty (30) days of the date the cable is placed into service. The cable landing license shall expire twenty-five (25) years from the in-service date, unless renewed or extended upon proper application. Upon expiration, all rights granted under the license shall be terminated.

* * * * *

(j) *Applications for streamlining.* Each applicant seeking to use the streamlined grant procedure specified in paragraph (i) of this section shall request streamlined processing in its application. Applications for streamlined processing shall include the information and certifications required by paragraph (k) of this section. On the date of filing with the Commission, the applicant shall also send a complete copy of the application, or any major amendments or other material filings regarding the application, to: U.S. Coordinator, EB/CIP, U.S. Department of State, 2201 C Street, NW., Washington, DC 20520–5818; Office of Chief Counsel/NTIA, U.S. Department of Commerce, 14th St. and Constitution Ave., NW., Washington, DC 20230; and Defense Information Systems Agency, Code RGC, 701 S. Courthouse Road, Arlington, Va. 22204, and shall certify such service on a service list attached to the application or other filing.

* * * * *

(n) Subject to the availability of electronic forms, all applications and notifications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53 of this chapter.

* * * * *

■ 3. Section 1.768 is amended by revising paragraphs (h) and (i) and adding a new paragraph (j) to read as follows:

§ 1.768 Notification by and prior approval for submarine cable landing licensees that are or propose to become affiliated with a foreign carrier.

* * * * *

(h) All licensees are responsible for the continuing accuracy of information provided pursuant to this section for a period of forty-five (45) days after filing. During this period if the information furnished is no longer accurate, the licensee shall as promptly as possible, and in any event within ten (10) days, unless good cause is shown, file with the Commission a corrected notification referencing the FCC file numbers under which the original notification was provided.

(i) A licensee that files a prior notification pursuant to paragraph (a) of this section may request confidential treatment of its filing, pursuant to § 0.459 of this chapter, for the first twenty (20) days after filing.

(j) Subject to the availability of electronic forms, all notifications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

* * * * *

■ 4. Section 1.10006 is revised to read as follows:

§ 1.10006 Is electronic filing mandatory?

Electronic filing is mandatory for all applications for international and satellite services for which an International Bureau Filing System (IBFS) form is available. Applications for which an electronic form is not available must be filed by paper until new forms are introduced. *See* §§ 63.20 and 63.53. As each new IBFS form becomes available for electronic filing, the Commission will issue a public notice announcing the availability of the new form and the effective date of mandatory filing for this particular type of filing. As each new form becomes effective, manual filings will not be accepted by the Commission and the filings will be returned to the applicant without processing. Mandatory electronic filing requirements for applications for international and satellite services are set forth in parts 1, 25, 63, and 64 of this chapter. A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 and the IBFS homepage at *http://www.fcc.gov/ibfs.*

■ 5. Section 1.10007 is amended by removing paragraph (a), redesignating paragraphs (b) through (d) as paragraphs (a) through paragraph (c), and by revising newly resdesignated paragraph (a) to read as follows:

§ 1.10007 What applications must be filed electronically?

(a) For a complete list of applications or notifications that must be filed electronically, see the IBFS Web site at *http://www.fcc.gov/ibfs.*

* * * * *

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

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

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

■ 6a. Section 63.11 is amended by removing paragraph (g), redesignating paragraphs (h) through (j) as paragraphs (g) through (i) and by revising newly redesignated paragraphs (h) through (i) and by adding new paragraph (j) to read as follows:

§ 63.11 Notification by and prior approval for U.S. international carriers that are or propose to become affiliated with a foreign carrier.

* * * * *

(h) All authorized carriers are responsible for the continuing accuracy of information provided pursuant to this section for a period of forty-five (45) days after filing. During this period if the information furnished is no longer accurate, the authorized carrier shall as promptly as possible, and in any event within ten (10) days, unless good cause is shown, file with the Commission a corrected notification referencing the FCC file numbers under which the original notification was provided, except that the carrier shall immediately inform the Commission, if at any time, not limited to the forty-five (45) days, the representations in the ''special concessions'' certification provided under paragraph (e)(6) of this section or § 63.18(n) are no longer true. *See* § 63.18(n).

(i) A carrier that files a prior notification pursuant to paragraph (a) of this section may request confidential treatment of its filing, pursuant to § 0.459 of this chapter, for the first twenty (20) days after filing.

(j) Subject to the availability of electronic forms, notifications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 7. Section 63.18 is amended by revising the introductory text and adding paragraph (q) to read as follows:

§ 63.18 Contents of applications for international common carriers.

Except as otherwise provided in this part, any party seeking authority pursuant to Section 214 of the Communications Act of 1934, as amended, to construct a new line, or acquire or operate any line, or engage in transmission over or by means of such additional line for the provision of common carrier communications services between the United States, its territories or possessions, and a foreign point shall request such authority by formal application. The application shall include information demonstrating how the grant of the application will serve the public interest, convenience, and necessity. Such demonstration shall consist of the following information, as applicable:

* * * * *

(q) Subject to the availability of electronic forms, all applications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 8. Section 63.19 is amended by adding paragraph (d) to read as follows:

§ 63.19 Special procedures for discontinuances of international services.

* * * * *

(d) Subject to the availability of electronic forms, all filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 9. Section 63.20 is amended by revising the section heading and paragraph (a) to read as follows:

§ 63.20 Electronic filing, copies required; fees; and filing periods for international service providers.

(a) Subject to the availability of electronic forms, all filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* Each application shall be accompanied by the fee prescribed in subpart G of part 1 of this chapter. For applications filed electronically it is not necessary to send the original or any copies with the fee payment. For applications and other filings that are not submitted electronically, an original and five (5) copies of the submission must be filed with the Commission. Upon request by the Commission, additional copies shall be furnished.

* * * * *

■ 10. Section 63.21 is amended by revising paragraphs (a), (h), (i) and adding paragraph (j) to read as follows:

§ 63.21 Conditions applicable to all international Section 214 authorizations.

* * * * *

(a) Each carrier is responsible for the continuing accuracy of the certifications made in its application. Whenever the substance of any such certification is no longer accurate, the carrier shall as promptly as possible and, in any event, within thirty (30) days, file with the Commission a corrected certification referencing the FCC file number under which the original certification was provided. The information may be used by the Commission to determine whether a change in regulatory status may be warranted under § 63.10. *See also* § 63.11.

* * * * *

(h) Subject to the requirement of § 63.10 that a carrier regulated as dominant along a route must provide service as an entity that is separate from its foreign carrier affiliate, and subject to any other structural-separation requirement in Commission regulations, an authorized carrier may provide service through any wholly owned direct or indirect subsidiaries. The carrier must, within thirty (30) days after the subsidiary begins providing service, file with the Commission a notification referencing the authorized carrier's name and the FCC file numbers under which the carrier's authorizations were granted and identifying the subsidiary's name and place of legal organization. This provision shall not be construed to authorize the provision of service by any entity barred by statute or regulation from itself holding an authorization or providing service.

(i) An authorized carrier, or a subsidiary operating pursuant to paragraph (h) of this section, that changes its name (including the name under which it is doing business) must notify the Commission within thirty (30) days of the name change. Such notification shall reference the FCC file numbers under which the carrier's authorizations were granted.

(j) Subject to the availability of electronic forms, all notifications and other filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part

1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 11. Section 63.24 is amended by revising paragraphs (e)(4), (f)(2), and (f)(3) and adding paragraph (h) to read as follows:

§ 63.24 Assignments and transfers of control.

* * * * *

(e) * * *

(4) An assignee or transferee must notify the Commission no later than thirty (30) days after either consummation of the proposed assignment or transfer of control, or a decision not to consummate the proposed assignment or transfer of control. The notification shall identify the file numbers under which the initial authorization and the authorization of the assignment or transfer of control were granted.

(f) * * *

(2) A *pro forma* assignee or a carrier that is subject to a *pro forma* transfer of control must file a notification with the Commission no later than thirty (30) days after the assignment or transfer is completed. The notification must contain the following:

* * * * *

(3) A single notification may be filed for an assignment or transfer of control of more than one authorization if each authorization is identified by the file number under which it was granted.

* * * * *

(h) Subject to the availability of electronic forms, all applications and notifications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 12. Section 63.25 is amended by revising paragraphs (b), (c) introductory text, (d)(2) and adding paragraph (e) to read as follows:

§ 63.25 Special provisions relating to temporary or emergency service by international carriers.

* * * * *

(b) Applicants seeking immediate authorization to provide temporary service or emergency service must file their request with the Commission. Requests must set forth why such immediate authority is required; the nature of the emergency; the type of facilities proposed to be used; the route kilometers thereof; the terminal communities to be served, and airline kilometers between such communities; how these points are currently being served by the applicant or other carriers; the need for the proposed service; the cost involved, including any rentals, the date on which the service is to begin, and where known, the date or approximate date on which the service to is terminate.

(c) Without regard to the other requirements of this part, and by application setting forth the need therefore, any carrier may request continuing authority, subject to termination by the Commission at any time upon ten (10) days' notice to the carrier, to provide temporary or emergency service by the construction or installation of facilities where the estimated construction, installation, and acquisition costs do not exceed $35,000 or an annual rental of not more than $7,000 provided that such project does not involve a major action under the Commission's environmental rules. (*See* subpart I of part 1 of this chapter.) Any carrier to which continuing authority has been granted under this paragraph shall, not later than the 30th day following the end of each 6-month period covered by such authority, file with the Commission a statement making reference to this paragraph and setting forth, with respect to each project (construction, installation, lease, including any renewals thereof), which was commenced or, in the case of leases, entered into under such authority, and renewal or renewals thereof which were in continuous effect for a period of more than one week, the following information:

* * * * *

(d) * * *

(2) Such request shall make reference to this paragraph and set forth the points between which applicant desires to operate facilities of other carriers and the nature of the traffic to be handled.

* * * * *

(e) Subject to the availability of electronic forms, all applications and notifications described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 13. Section 63.51 is amended by revising paragraph (c) to read as follows:

§ 63.51 Additional Information.

* * * * *

(c) Any additional information which the Commission may require must be submitted in the same manner as was the original filing. For information on filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs,* and § 63.20.

■ 14. Section 63.53 is amended by revising paragraphs (a)(1), (a)(2) and paragraph (b) to read as follows:

§ 63.53 Form.

(a)(1) Applications for international service under section 214 of the Communications Act must be filed electronically with the Commission. For applications filed electronically it is not necessary to send the original or any copies with the fee payment. Subject to the availability of electronic forms, all applications and other filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20.

(2) Applications for international service under section 214 of the Communications Act that are not filed through IBFS shall be submitted on paper not more than 21.6 cm (8.5 in) wide and not more than 35.6 cm (14 in) long with a left-hand margin of 4 cm (1.5 in). This requirement shall not apply to original documents, or admissible copies thereof, offered as exhibits or to specially prepared exhibits. The impression shall be on one side of the paper only and shall be double-spaced, except that long quotations shall be single-spaced and indented. All papers, except charts and maps, shall be typewritten or prepared by mechanical processing methods, other than letter press, or printed. The foregoing shall not apply to official publications. All copies must be clearly legible.

(b) Applications for domestic authorizations under section 214 of the Communications Act shall be submitted on paper not more than 21.6 cm (8.5 in) wide and not more than 35.6 cm (14 in) long with a left-hand margin of 4 cm (1.5 in). This requirement shall not apply to original documents, or admissible copies thereof, offered as exhibits or to specially prepared exhibits. The impression shall be on one side of the paper only and shall be double-spaced, except that long

quotations shall be single-spaced and indented. All papers, except charts and maps, shall be typewritten or prepared by mechanical processing methods, other than letter press, or printed. The foregoing shall not apply to official publications. All copies must be clearly legible.

* * * * *

■ 15. Section 63.701 is amended by revising the introductory text and adding paragraph (j) to read as follows:

§ 63.701 Contents of Application.

Except as otherwise provided in this part, any party requesting designation as a recognized operating agency within the meaning of the International Telecommunication Convention shall file a request for such designation with the Commission. A request for designation as a recognized operating agency within the meaning of the International Telecommunication Convention shall include a statement of the nature of the services to be provided and a statement that the party is aware that it is obligated under Article 6 of the ITU Constitution to obey the mandatory provisions thereof, and all regulations promulgated thereunder, and a pledge that it will engage in no conduct or operations that contravene such mandatory provisions and that it will otherwise obey the Convention and regulations in all respects. The party must also include a statement that it is aware that failure to comply will result in an order from the Federal Communications Commission to cease and desist from future violations of an ITU regulation and may result in revocation of its recognized operating agency status by the United States Department of State. Such statement must include the following information where applicable:

* * * * *

(j) Subject to the availability of electronic forms, all filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

PART 64—MISCLLANEOUS RULES RELATING TO COMMON CARRIERS

■ 16. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 154, 254(k); secs. 403(b)(2)(B), (c), Public Law 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 228, and 254(k) unless otherwise noted.

■ 16a. Section 64.1001 is amended by revising paragraph (a) and adding paragraph (f) to read as follows:

§ 64.1001 Requests to modify international settlement arrangements.

(a) The procedures set forth in this rule apply to carriers that are required to file with the International Bureau, pursuant to § 43.51(e) of this chapter, requests to modify international settlement arrangements. Any operating agreement or amendment for which a modification request is required to be filed cannot become effective until the modification request has been granted under paragraph (e) of this section.

* * * * *

(f) Subject to the availability of electronic forms, all modifications and related submissions described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

■ 17. Section 64.1002 is amended by revising paragraph (c) and adding paragraph (e) to read as follows:

§ 64.1002 International settlements policy.

* * * * *

(c) A carrier that seeks to add a U.S. international route to the list of routes that are exempt from the international settlements policy must make its request to the International Bureau, accompanied by a showing that a U.S. carrier has entered into a benchmark-compliant settlement rate agreement with a foreign carrier that possesses market power in the country at the foreign end of the U.S. international route that is the subject of the request. The required showing shall consist of an effective accounting rate modification, filed pursuant to § 64.1001, that includes a settlement rate that is at or below the Commission's benchmark settlement rate adopted for that country in IB Docket No. 96–261, Report and Order, 12 FCC Rcd 19,806, 62 FR 45758, Aug. 29, 1997, available on the International Bureau's World Wide Web site at *http://www.fcc.gov/ib.*

* * * * *

(e) Subject to the availability of electronic forms, all filings described in this section must be filed electronically through the International Bureau Filing System (IBFS). A list of forms that are available for electronic filing can be found on the IBFS homepage. For information on electronic filing requirements, see part 1, §§ 1.1000 through 1.10018 of this chapter and the IBFS homepage at *http://www.fcc.gov/ibfs.* See also §§ 63.20 and 63.53.

* * * * *

[FR Doc. 05–12937 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 05–24; FCC 05–121]

DTV Tuner Requirements

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document modifies the schedule by which new broadcast television receivers with screen sizes 25–36″ are required to include the capability to receive over-the-air digital television (DTV) broadcast signals. This action was initiated in response to a Petition for Rulemaking from the Consumer Electronics Association and the Consumer Electronics Retailers Association (CEA–CERC) requesting that we eliminate the 50 percent requirement for the 25–36″ mid-size receivers and instead advance the date by which 100 percent of these receivers would include DTV tuners to March 1, 2006. This action will serve to minimize any difficulties with the 50 percent provision at the earliest practicable date and will also serve to promote the expeditious completion of the transition from analog to digital broadcast television service.

DATES: Effective August 5, 2005.

FOR FURTHER INFORMATION CONTACT: Alan Stillwell, Office of Engineering and Technology, (202) 418–2925, e-mail: *Alan.Stillwell@fcc.gov,* TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, ET Docket No. 05–24, FCC 05–121, adopted June 9, 2005, and released June 9, 2005. The full text of this document is available on the Commission's Internet site at *http://www.fcc.gov*. It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission's duplication contractor, Best Copy and

Printing Inc., Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554; telephone (202) 488–5300; fax (202) 488–5563; e-mail *FCC@BCPIWEB.COM.*

Congressional Review Act

The Commission will send a copy of this Report & Order, in a report to be sent to Congress and the General Accounting Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

Summary of the Report and Order

1. In the *Report and Order* (R&O), the Commission modified the schedule by which new broadcast television receivers with screen sizes 25–36″ are required to include the capability to receive over-the-air digital television (DTV) broadcast signals. This provision of the rules is an element of the Commission's phase-in plan for requiring that all new broadcast television receivers include DTV reception capability. The DTV reception requirement, which is also often termed the ''DTV tuner requirement,'' is being implemented by applying the requirement first to large screen receivers and then progressively to smaller screen units and other devices over a period of several years. The decision maintains the existing plan to require that 50 percent of 25–36″ receivers that are imported or shipped in interstate commerce include DTV tuners beginning July 1, 2005, but modifies the date on which 100 percent of such receivers must include DTV tuners by advancing that date from July 1, 2006, to March 1, 2006. The action was initiated in response to a Petition for Rulemaking from the Consumer Electronics Association and the Consumer Electronics Retailers Association (CEA–CERC) requesting that we eliminate the 50 percent requirement for the 25–36″ mid-size receivers and instead advance the date by which 100 percent of these receivers would include DTV tuners to March 1, 2006. While we understand CEA–CERC's concern that the 50 percent requirement may have posed some difficulties for manufacturers and retailers, we nonetheless concluded that maintaining this approach for the mid-size 25–36″ receivers prior to March 1, 2006, will most effectively ensure that DTV tuner equipped sets are available to consumers this year, and especially for the 2005 holiday and 2006 Super Bowl seasons. In this regard, we continue to believe that it is essential that DTV reception capability be provided to consumers in new TV receivers as rapidly as possible in order to promote an expeditious completion of the transition from analog to digital broadcast television service. We also concluded that advancing the date by which all 25–36″ receivers must include DTV reception capability to March 1, 2006, will serve to minimize any difficulties with the 50 percent provision at the earliest practicable date and will also serve to expedite the provision of DTV reception capability to consumers.

2. In their petition for rulemaking, CEA–CERC requested that we eliminate the July 1, 2005, requirement for 50 percent of TV receivers with screen sizes 25–36″ to include DTV reception capability and instead advance from July 1, 2006, to March 1, 2006, the date for all such receivers to include a DTV tuner. CEA–CERC submitted that manufacturers' and retailers' experience with the 50 percent provision for 36″ and larger receivers is that the 50 percent aspect of the phase-in plan is antithetical to the purpose of the DTV tuner requirement. They stated that, in practice, the 50 percent requirement has proven to be unduly disruptive in the marketplace in ways unforeseen and, in fact, threatens to slow, rather than speed, consumer migration to TV receivers with DTV tuners. They indicated that this is because the experience with 36″ and larger sets is that consumers typically choose a lower-priced product with otherwise similar features except for the DTV tuner rather than a set with a DTV tuner. CEA–CERC argued that eliminating the 50 percent rule for 25–36″ receivers and moving up the date for 100 percent compliance by such receivers would better align the policy behind the DTV tuner rule with market forces and consumer expectations.

3. In response to the CEA–CERC petition, we issued a *Notice of Proposed Rulemaking* (NPRM), 70 FR 13139, March 18, 2005, to consider adjusting the schedule by which new broadcast television receivers with screen sizes 25–36″ are required to include the capability to receive digital television signals. In the NPRM, we requested comment on whether there is need to revise the implementation schedule of the DTV tuner requirement for receivers with screen sizes 25–36″ to address the concerns raised by CEA–CERC and, if so, how that schedule should be revised to achieve our goal that all new television receivers include DTV tuning capability by July 1, 2007. We specifically requested comment on the approach suggested by CEA–CERC whereby the requirement that 50 percent of receivers with screen sizes 25–36″ incorporate a DTV tuner in the period from July 1, 2005, to July 1, 2006, would be eliminated and replaced with a new provision requiring that all receivers with screen sizes 25–36″ be required to include a DTV tuner effective March 1, 2006. We also invited alternative approaches for addressing the market situation described in the CEA–CERC petition and indicated that we intend to consider the full range of options that are consistent with our stated goals. However, we also advised commenting parties that we did not intend to extend the July 1, 2007, date by which all broadcast television receivers include DTV reception capability.

4. After review of the record in this proceeding, we conclude that while the partial production elements of our DTV tuner implementation plan may have caused some confusion in the market, that approach remains workable and will best serve to ensure that DTV tuner equipped receivers in the 25–36″ mid-size range are available to consumers until the 100 percent DTV tuner requirement goes into effect for these receivers. We also find that it is in the interests of consumer electronics manufacturers and retailers and consistent with our goals as stated above to advance the 100 compliance date for mid-size receivers from July 1, 2006, to March 1, 2006.

5. With regard to the 50 percent provision, we find that postponing application of the DTV tuner requirement to the 25–36″ receivers until March 1, the earliest date on which manufacturers state that they can meet the 100 percent requirement, would unacceptably delay the general availability of DTV reception capability in these products. While eliminating the 50 percent requirement for mid-size receivers until the 100 percent compliance requirement becomes effective might be more convenient for manufacturers and retailers, such an approach would also delay the wider dissemination of DTV tuners in products of this size range. It remains our intent that the implementation schedule aim for the most rapid introduction of DTV reception capability in this size range and indeed all new television receivers. Postponing the requirement for inclusion of DTV tuners in mid-size TV sets would be inconsistent with our efforts to advance the DTV transition as rapidly as possible. Our intent is to stem the flow of analog-only products as soon as possible for, every analog-only TV set sold is a blow to the DTV transition.

6. Initiating the DTV tuner requirement for mid-size receivers on March 1, 2006, the date that CEA–CERC

and manufacturers submit is the earliest feasible time by which manufacturers could meet the 100 percent compliance requirement, would undermine our goal of the most rapid introduction of DTV reception capability. The full eight months delay in which no mid-size TV sets would be required to include DTV tuners under that approach would miss the entire holiday and Super Bowl seasons this fall and next winter. Similarly, postponing the initiation of the 50 percent requirement until November 1, 2005 as suggested by CEA–CERC in their ex parte letter would miss the summer and most of the fall season and would also allow a large number of analog tuners to enter retailers' inventories for sale just before the holiday season. Moreover, consumers who purchase new receivers in the coming holiday and Super Bowl seasons would not likely return to the market again to purchase a new receiver for several years and so would be without a DTV tuner equipped device until they purchased a new set or until they obtained a separate set-top DTV tuner unit.

7. We recognize that there are DTV tuner-equipped mid-size TV receivers on the market now and that if we were to eliminate the 50 percent requirement in favor of a delayed 100 percent requirement there would still be DTV tuner equipped sets for consumers to acquire. Nonetheless, we expect that the quantity of DTV tuner equipped sets sold under that approach would be significantly lower than that under the 50 percent approach, given manufacturers' and retailers' description of the market. We also believe that it would further consumer awareness if manufacturers and retailers would provide point-of-sale and other marketing information to consumers and/or clearly label new television sets to indicate whether they can receive off-the-air DTV signals or only off-the-air analog signals. We believe that such efforts would result in more informed consumer choices about whether to buy DTV tuner equipped sets. We therefore encourage manufacturers and retailers to clearly label and identify the tuning capabilities of new TV sets and/or employ other means to disseminate to consumers information regarding whether or not specific models are able to receive off-the-air digital television signals.

8. With respect to the 100 percent compliance date, we conclude that it will ameliorate the concern of the consumer electronics manufacturers and retailers and further our goal of promoting DTV reception availability to advance the date on which 100 percent of 25–36″ receivers will be required to include a DTV tuner to March 1, 2006. Manufacturers have indicated that they will be able to equip 100 percent of new mid-size TV sets with DTV tuners by this date and both manufacturers and retailers support changing the 100 percent compliance date as a step to minimize the difficulties posed by the 50 percent requirement. We do not believe it would be feasible or practicable to advance the 100 percent requirement to a date earlier than that suggested by CEA–CERC. We recogniz manufacturers' arguments that the lead time associated with development of new products, and particularly the time needed to establish specifications, change manufacturing lines, and order parts, would not allow the industry generally to meet a 100 percent compliance requirement before March 1, 2006. It makes little sense to require products to be on the market before the general population of manufacturers can deliver them. As many commenting parties observe, if manufacturers were not able to meet our deadline, they might cease production of mid-range sets or switch to monitor products that do not include TV tuners. Such a result would be disruptive to our goal of ensuring that consumers are able to receive DTV signals and could serve to delay the DTV transition. Accordingly, we are maintaining the provision of the current rules requiring that 50 percent of 25–36″ television receivers include DTV tuners effective July 1, 2005, and advancing the date on which 100 percent of such receivers must include DTV tuners to March 1, 2006.

Final Regulatory Flexibility Analysis

9. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the *Notice of Proposed Rulemaking* (NPRM) in ET Docket No. 05–24. The Commission sought written public comment on the proposals on the NPRM concerning modification of the plan for applying the DTV tuner requirement to TV receivers with screen sizes 25–36″, including comment on the IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[2]

A. Need for and Objectives of the Rules

10. As described in the *NPRM,* the changes to the rules considered in this proceeding are intended to ensure a smooth transition of the nation's television system to digital television. Beginning in 1987, the Commission undertook to bring the most up-to-date technology to broadcast television.[3] That effort resulted in several Commission decisions, including those adopting a digital television (DTV) standard,[4] DTV service rules,[5] and a Table of DTV Allotments.[6] The Table of DTV Allotments provides each existing television broadcaster with a second channel on which to operate a DTV station for a transition period in which stations will operate both analog and digital TV service, after which analog service will cease and one of each station's two channels will revert to the government for use in other services. The transition deadline established by Congress is December 31, 2006.

11. Consistent with its efforts to promote the expeditious completion of the DTV transition, the Commission adopted a requirement that all new television receivers imported or shipped in interstate commerce after July 1, 2007, include the capability to receive DTV signals off-the-air. In order to minimize the impact of the DTV tuner requirement on both manufacturers and consumers, the Commission adopted a phase-in schedule that applies the DTV tuner requirement first to receivers with the screens and then to progressively smaller screen receivers and other TV receiving devices. The Consumer Electronics Association and the Consumer Electronics Retailers Coalition (CEA–CERC) submitted a petition for rule making requesting that the Commission eliminate the portion of the phase-in schedule requiring that 50 percent of TV receivers with screen sizes 25–36″ include DTV reception capability from July 1, 2005, to July 1, 2006, and instead advance the date for requiring all such receivers to include a DTV tuner to March 1, 2006, from July 1, 2006. CEA–CERC argued that the 50 percent requirement has proven to be disruptive to the market in the case of larger screen receivers. We are issuing this Report and Order to modify the portion of the DTV tuner requirement

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] *See* 5 U.S.C. 604.

[3] *See Notice of Inquiry* in MM Docket No. 87–268, 2 FCC Rcd 5125 (1987), 52 FR 34259, September 10, 1987; *see also Tentative Decision and Further Notice of Proposed Rulemaking* in MM Docket No. 87–268, 3 FCC Rcd 6520 (1988), 53 FR 38747, October 3, 1988.

[4] *See Fourth Report and Order* in MM Docket No. 87–268, 11 FCC Rcd 17771 (1996), 62 FR 14006, March 25, 1997.

[5] *See Fifth Report and Order* in MM Docket No. 87–268, 12 FCC Rcd 12809 (1997), 63 FR 13546, May 20, 1998.

[6] *See Sixth Report and Order* in MM Docket No. 87–268, 12 FCC Rcd 14588 (1997), 62 FR 2668, July 11, 1997.

phase-in plan that applies to receivers with screen sizes 24″ to 36″. Specifically, we are amending the rules to advance the date on which all 24–36″ receivers must include a DTV tuner to March 1, 2006, from the current date of July 1, 2006. Maintaining the 50 percent requirement for the period from July 1, 2005, to February 28, 2005, and advancing the 100 percent compliance date for mid-size receivers to March 1, 2006, will ameliorate the concerns of the consumer electronics manufacturers and retailers with respect to the 50 percent approach and further our goal of promoting DTV reception availability.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

12. No comments were filed in response to the IRFA.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

13. The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules.[7] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental entity.''.[8] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[9] 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).[10]

Electronics Equipment Manufacturers. Rules adopted in this proceeding will apply to manufacturers of DTV receiving equipment and other types of consumer electronics equipment. The SBA has developed definitions of small entity for manufacturers of audio and video equipment [11] as well as radio and television broadcasting and wireless communications equipment.[12] These categories both include all such companies employing 750 or fewer employees. The Commission has not developed a definition of small entities applicable to manufacturers of electronic equipment used by consumers, as compared to industrial use by television licensees and related businesses. Therefore, we will utilize the SBA definitions applicable to manufacturers of audio and visual equipment and radio and television broadcasting and wireless communications equipment, since these are the two closest NAICS Codes applicable to the consumer electronics equipment manufacturing industry. However, these NAICS categories are broad and specific figures are not available as to how many of these establishments manufacture consumer equipment. According to the SBA's regulations, an audio and visual equipment manufacturer must have 750 or fewer employees in order to qualify as a small business concern.[13] Census Bureau data indicates that there are 554 U.S. establishments that manufacture audio and visual equipment, and that 542 of these establishments have fewer than 500 employees and would be classified as small entities.[14] The remaining 12 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. Under the SBA's regulations, a radio and television broadcasting and wireless communications equipment manufacturer must also have 750 or fewer employees in order to qualify as a small business concern.[15] Census Bureau data indicates that there are 1,215 U.S. establishments that manufacture radio and television broadcasting and wireless communications equipment, and that 1,150 of these establishments have fewer than 500 employees and would be classified as small entities.[16] The remaining 65 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. We therefore conclude that there are no more than 542 small manufacturers of audio and visual electronics equipment and no more than 1,150 small manufacturers of radio and television broadcasting and wireless communications equipment for consumer/household use.

Computer Manufacturers. The Commission has not developed a definition of small entities applicable to computer manufacturers. Therefore, we will utilize the SBA definition of electronic computers manufacturing. According to SBA regulations, a computer manufacturer must have 1,000 or fewer employees in order to qualify as a small entity.[17] Census Bureau data indicates that there are 563 firms that manufacture electronic computers and of those, 544 have fewer than 1,000 employees and qualify as small entities.[18] The remaining 19 firms have 1,000 or more employees. We conclude that there are approximately 544 small computer manufacturers.

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

14. The rule changes adopted in the Report and Order impose no additional recordkeeping or recordkeeping requirements on manufacturers of television receiving equipment, large or small. While the modifications adopted therein may have a small impact on consumer electronics manufacturers, any such impact would be similar for both large and small entities.

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

15. 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 or reporting requirements or timetables that take into account the resources available to small

[7] 5 U.S.C. 603(b)(3).

[8] 5 U.S.C. 601(6).

[9] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[10] 15 U.S.C. 632.

[11] 13 CFR 121.201 (NAICS Code 334310).

[12] 13 CFR 121.201 (NAICS Code 334220).

[13] 13 CFR 121.201 (NAICS Code 334310).

[14] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Audio and Video Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

[15] 13 CFR 121.201 (NAICS Code 513220).

[16] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

[17] 13 CFR 121.201 (NAICS Code 334111).

[18] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Electronic Computer Manufacturing, Table 4 at 9 (1999).

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 any part thereof, for small entities.[19]

16. The modification of the provisions for implementing the DTV tuner requirement in TV receivers with screen sizes in the 25–36″ mid-size range set forth herein are intended to ameliorate certain market difficulties described by consumer electronics manufacturers and consumer electronics products retailers and to expedite the availability of DTV tuners in new mid-size television receivers that are offered to consumers. The revisions adopted preserve the requirement for DTV tuners in 50 percent of the new mid-size range of receivers for the period July 1, 2005, to February 28, 2005, in order to ensure that such receivers are available as soon as possible and particularly during the 2005 holiday season and 2006 Super Bowl season. The consumer electronics industry has indicated that it prefers the 100 percent requirement to become effective on March 1, 2006, rather than the original July 1, 2006, date. Advancing the date for 100 percent compliance by mid-size receivers will ameliorate the challenges of the 50 percent provision for manufacturers and retailers and will also serve to promote the availability of DTV tuner equipped TV sets to consumers.

17. Other approaches considered included various suggestions by broadcasters and others to advance the deadline for DTV tuners in 25–36″ sets to dates between November 1, 2005, and January 1, 2005. We rejected the options to advance the 100 percent requirement to a date earlier than March 1, 2006, on the basis that the 5 to 6 month lead-times available to manufacturers under those scenarios would be too short for manufacturers to meet with new products, especially given the lead-times associated with obtaining parts and components from suppliers. Extending the deadline beyond March 1, 2006, would be inconsistent with the need to expedite the DTV transition.

Report to Congress

18. The Commission will send a copy of the Report and Order, including this FRFA, in a report to Congress pursuant to the Congressional Review Act.[20] In addition, the Commission will send a copy of the Report and Order, including the FRFA, to the Chief Counsel for Advocacy of the SBA.[21]

Ordering Clauses

19. Pursuant to the authority contained in sections 2(a), 4(i) & (j), 7, 151 and 303 of the Communications Act of 1934 as amended, 47 U.S.C. 152(a), 154(i) & (j), 151, 157, and 303, this Report and Order *is adopted* and the Commission's rules *are hereby amended* as set forth in Rule Changes, and shall become effective August 5, 2005.

20. The Petition for Rulemaking submitted by the Consumer Electronics Association and the Consumer Electronics Retailers Association in this matter on November 5, 2004, *is denied* in part and *is granted* in part as indicated in the Report and Order.

21. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration,[22] to Congress and the General Accounting Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 15

Communications equipment, Radio.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

■ For the reasons set forth in the preamble, the Federal Communications Commission amends 47 CFR part 15 as follows:

PART 15—RADIO FREQUENCY DEVICES

■ 1. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302, 303, 304, 307, and 554A.

■ 2. Section 15.117 is amended by revising paragraph (i)(1) to read as follows:

§ 15.117 TV broadcast receivers.

* * * * *

(i) * * *

(1) Responsible parties, as defined in § 2.909 of this chapter, are required to equip new TV broadcast receivers that are shipped in interstate commerce or imported from any foreign country into the United States and for which they are responsible to comply with the provisions of this section in accordance with the following schedule:

(i) Receivers with screen sizes 36″ and above—50% of all of a responsible party's units must include DTV tuners effective July 1, 2004; 100% of such units must include DTV tuners effective July 1, 2005.

(ii) Receivers with screen sizes 25″ to less than 36″—50% of all of a responsible party's units must include DTV tuners effective July 1, 2005; 100% of such units must include DTV tuners effective March 1, 2006.

(iii) Receivers with screen sizes 13″ to less than 25″—100% of all such units must include DTV tuners effective July 1, 2007.

(iv) Other devices (videocassette recorders (VCRs), digital video disk and digital versatile disk (DVD) players/recorders, etc.) that receive television signals—100% of all such units must include DTV tuners effective July 1, 2007.

* * * * *

[FR Doc. 05–13027 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

[19] 5 U.S.C. 603.

[20] *See* 5 U.S.C. 801(a)(1)(A).

[21] *See* 5 U.S.C. 604(b).

[22] *See* 5 U.S.C. 603(a).

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 209, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 225, 228, 229, 230, 231, 232, 233, 234, 235, 236, 238, 239, 240, 241, and 244

[Docket No. FRA–2004–17529; Notice No. 4]

RIN 2130–AB66

Inflation Adjustment of the Ordinary Maximum Civil Monetary Penalty for a Violation of a Federal Railroad Safety Law or Federal Railroad Administration Safety Regulation

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule; withdrawal.

SUMMARY: FRA is withdrawing its final rule that adjusted from $11,000 to $15,000 the ordinary maximum civil penalty that applies when a civil penalty for a violation of railroad safety statutes and regulations is assessed under its authority, due to an error in the application of the rounding rules found in the applicable statute. The ordinary maximum civil penalty will remain at $11,000.

DATES: The final rule published on June 8, 2005, at 70 FR 33380 is withdrawn in its entirety as of July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Carolina Mirabal, Trial Attorney, Office

of Chief Counsel, FRA, 1120 Vermont Avenue, NW., Mail Stop 10, Washington, DC 20590 (telephone 202–493–6043), *carolina.mirabal@fra.dot.gov.*

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act of 1990 (Inflation Act) requires that an agency adjust by regulation each maximum civil monetary penalty (CMP), or range of minimum and maximum CMPs, within that agency's jurisdiction by October 23, 1996 and to adjust those penalty amounts once every four years thereafter to reflect inflation. Public Law 101–410, 104 Stat. 890, as amended by Section 31001(s) of the Debt Collection Improvement Act of 1996, Public Law 104–134, 110 Stat. 1321–373, April 26, 1996, 28 U.S.C. 2461, note. Congress recognized the important role that CMPs play in deterring violations of Federal law and regulations and realized that inflation has diminished the impact of these penalties. In the Inflation Act, Congress found a way to counter the effect that inflation has had on the CMPs by having the agencies charged with enforcement responsibility administratively adjust the CMPs.

Calculation of the Adjustment

Under the Inflation Act, the inflation adjustment is calculated by increasing the maximum CMP, or the range of minimum and maximum CMPs, by the percentage that the Consumer Price Index (CPI) for the month of June of the calendar year preceding the adjustment (here, June 2004) exceeds the CPI for the month of June of the last calendar year in which the amount of such penalty was last set or adjusted (here, June 1998 for the ordinary maximum). Section 5(a) of the Inflation Act also specifies that the amount of the adjustment must be rounded to the nearest multiple of $100 for a penalty between $100 and $1,000, or to the nearest multiple of $5,000 for a penalty of more than $10,000 and less than or equal to $100,000. The first adjustment may not exceed an increase of ten percent. FRA utilized Bureau of Labor Statistics data to calculate adjusted CMP amounts.

FRA is authorized as the delegate of the Secretary of Transportation to enforce the Federal railroad safety statutes and regulations, including the civil penalty provisions at 49 U.S.C. ch. 213. 49 CFR 1.49; 49 U.S.C. ch. 201–213. FRA currently has 27 regulations that contain provisions that reference its authority to impose civil penalties if a person violates any requirement in the pertinent portion of a statute or the Code of Federal Regulations. In this final rule, FRA is retracting its June 8, 2005 amendments to each of those separate regulatory provisions and the corresponding footnotes in each Schedule of Civil Penalties that raised the ordinary maximum CMP from $11,000 to $15,000. The ordinary maximum CMP should remain at $11,000, as shown below:

The June 2004 CPI of 568.2 divided by the June 1998 CPI of 488.2 equals an inflation factor of 1.164; $11,000 multiplied by 1.164 equals $12,804, or an increase of $1,804. The increase of $1,804 is then rounded to the nearest multiple of $5,000, which in this case is $0. Thus, the ordinary maximum will remain at $11,000. In the final rule, 70 FR 33380, FRA erroneously rounded to the nearest multiple of $5,000 the amount of $12,804, instead of the increased amount ($1,804) as required by the Inflation Act.

List of Subjects in 49 CFR Parts 209, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 225, 228, 229, 230, 231, 232, 233, 234, 235, 236, 238, 239, 240, 241, and 244

Penalties, Railroad safety.

The Final Rule

In consideration of the foregoing, the final rule published on June 8, 2005 at 70 FR 33380 is hereby withdrawn.

Issued in Washington, DC on June 28, 2005.

Joseph H. Boardman,

Administrator, Federal Railroad Administration.

[FR Doc. 05–13185 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 573 and 577

[Docket No. NHTSA–2004–18341; Notice No. 2]

RIN 2127–AJ48

Defect and Noncompliance Responsibility and Reports Defect and Noncompliance Notification

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final Rule; Response to Petitions for Reconsideration.

SUMMARY: This document responds to petitions for reconsideration of the June 23, 2004 dealer notification rule that amended several provisions of agency regulations on notifications by manufacturers of motor vehicles and motor vehicle equipment to dealers and distributors when they or NHTSA decide that vehicles or equipment contain a defect related to motor vehicle safety or do not comply with a Federal motor vehicle safety standard.

DATES: The amendments in this rule are effective on August 5, 2005.

Petitions: Petitions for reconsideration must be received by August 22, 2005 and should refer to this docket and the notice number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, you may contact Mr. George Person, Office of Defects Investigation, Room 5319, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590; Telephone: (202) 366–5210. For legal issues, you may contact Michael Goode, Office of Chief Counsel, Telephone: (202) 366–5263.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 1993, NHTSA published a Notice of Proposed Rulemaking (NPRM) proposing several amendments to its regulations (49 CFR parts 573 and 577) concerning manufacturers' obligations to provide notification and remedy for motor vehicles and items of motor vehicle equipment found to contain a defect related to motor vehicle safety or a noncompliance with a Federal motor vehicle safety standard (58 FR 50314). On April 5, 1995, we issued a final rule (60 FR 17254) addressing most aspects of that NPRM, and on January 4, 1996, we amended several provisions of that final rule in response to petitions for reconsideration of that rule (61 FR 274). However, the agency did not promulgate regulations on dealer notification in the 1995 or 1996 rulemakings because we had not resolved the issues raised by the comments submitted in response to the NPRM.

In the NPRM, we proposed to require manufacturers to notify their dealers and distributors [1] of safety-related

[1] 49 U.S.C. 30118, 30119, and 30120 refer to notification to ''dealers,'' without referring to ''distributors.'' However, under 49 U.S.C. 30116, manufacturers of motor vehicles and motor vehicle equipment have certain responsibilities toward their distributors after it is determined that a product contains a safety-related defect or a noncompliance. Therefore, the notification requirements apply to both dealers and distributors. However, throughout the remainder of this

Continued

defects and noncompliances in their motor vehicles and equipment within five days after notifying the agency of their determination of a safety defect or noncompliance pursuant to 49 CFR part 573, Defect and Noncompliance Reports. In a May 19, 1999 supplemental notice of proposed rulemaking (SNPRM), NHTSA proposed a different approach (64 FR 27227). Rather than specify a particular time period, we proposed to require manufacturers to notify dealers within a reasonable time in accordance with a schedule that is to be submitted to the agency with the manufacturer's defect or noncompliance information report required by 49 CFR § 573.6 (this section was codified as § 573.5 prior to August 9, 2002). NHTSA published the final rule on June 23, 2004 (69 FR 34954). It adopted the proposal in the SNPRM for dealer notification within a reasonable time after the manufacturer decides that a defect that relates to motor vehicle safety or a noncompliance exists. 49 CFR 577.7(c)(1). In addition, the final rule established that, if the agency were to find that the public interest requires dealers to be notified at an earlier date than that proposed by the manufacturer, the manufacturer would have to notify its dealers in accordance with the agency's directive. *Id.* Finally, the final rule adopted the proposal in the SNPRM requiring that the dealer notification contain certain information and described the manner in which such notification is to be accomplished. 49 CFR 577.7(c) and 577.13.

In response to the final rule, the agency received four petitions for reconsideration. Two joint petitions were received: Public Citizen (PC) and the Center for Auto Safety (CAS) (collectively PC/CAS) and Motor and Equipment Manufacturers Association (MEMA) and the Automotive Aftermarket Suppliers Association (AASA) (collectively MEMA/AASA). The Juvenile Products Manufacturers Association, Inc. (JPMA) and General Motors Corporation (GM) filed separate petitions.

PC/CAS objected to the provision allowing notification of dealers within a reasonable time and argued that the five-day period proposed in the NPRM should be instituted. GM asked the agency to clarify that manufacturers are required to verify that they sent the dealer notifications, rather than that the notifications were actually received by their dealers. MEMA/AASA, JPMA, and GM objected to the inclusion of a provision in the final rule on manufacturers' notification of offers to repurchase equipment in dealer inventory.

The issues raised by the petitioners are addressed below.

II. Discussion

A. Timing of Dealer Notification

Statutory and Regulatory Framework

Under 49 U.S.C. 30118(c), a manufacturer of motor vehicles or replacement equipment must notify NHTSA and owners, purchasers, and dealers of the vehicle or equipment as provided by 49 U.S.C. 30119(d) if the manufacturer learns that the vehicle or equipment contains a defect and decides in good faith that the defect is related to motor vehicle safety, or does not comply with an applicable federal motor vehicle safety standard. This notification must be accomplished within a reasonable time after the manufacturer first decides that a safety-related defect or noncompliance exists under 49 U.S.C. 30118(c). 49 U.S.C. 30119(c)(2). Similarly, if NHTSA decides, pursuant to 49 U.S.C. 30118(b), that the vehicle or equipment contains a safety-related defect or does not comply with an applicable standard, the Administrator is required to order the manufacturer to notify owners, purchasers, and dealers of vehicle or equipment of the defect or noncompliance. In these instances, notification is to be given within a reasonable time prescribed by NHTSA. 49 U.S.C. 30119(c)(1).

In addition to statutory requirements, NHTSA regulations delineate various aspects of manufacturers' notification obligations. For over 30 years, 49 CFR part 573, Defect and Noncompliance Responsibility and Reports, has set forth requirements for manufacturers' notification of NHTSA of a safety-related defect or noncompliance. In addition, 49 CFR part 577, Defect and Noncompliance Notification, has set out requirements for manufacturers' notification of owners of motor vehicles and motor vehicle equipment of a safety defect or noncompliance.

Dealer Notification in the 1993 NPRM

The September 1993 NPRM proposed that manufacturers conducting safety recalls provide their dealers with a document that contained the information set forth in the report submitted to the agency pursuant to 49 CFR part 573, within five working days after submitting the report to NHTSA.

A large number of parties commented on the dealer notification proposal in the NPRM, including manufacturer and dealer associations, individual manufacturers, and Advocates for Highway and Auto Safety. All manufacturing and dealer entities objected to the proposed five-day dealer notification requirement. Those objecting included Toyota Motor Corporate Services of North America, Inc. (Toyota), Volkswagen of America, Inc. (VWoA), Chrysler Corporation (Chrysler), American Automobile Manufacturers Association (AAMA), Association of International Automobile Manufacturers (AIAM), National Automobile Dealers Association (NADA), and five heavy truck manufacturers.

The manufacturer and dealer commenters explained the procedure for dealer notification in operation for almost two decades since the enactment of the 1974 Amendments to the National Traffic and Motor Vehicle Safety Act (Safety Act). 88 Stat. 1470 *et seq.* In essence, under the operating procedure, manufacturers provided notice to dealers within a reasonable time after deciding that there was a safety-related defect or noncompliance. As the commenters pointed out, this procedure was working well and there was no need for the proposed five-day dealer notification period. The heavy truck manufacturers maintained that manufacturers act responsibly without the five-day rule, citing as an example a steering gear recall, in which the affected manufacturers notified dealers within one day of the defect determination and advised drivers to park their trucks.

AAMA and NADA emphasized the statutory basis of dealer notification. They explained that section 153(b) of the Safety Act, as amended, (which has been recodified in 49 U.S.C. 30119(c)[2]) requires provision of notice of a safety-related defect to a dealer within a reasonable time after the determination of a defect. They argued that the reasonable time concept allows flexibility by taking into account the differing circumstances and complexities of any particular remedy program. Chrysler argued that circumstances requiring early notification can be taken care of in the present framework by the agency reviewing the issue with the manufacturer and resolving it based upon the reasonable time requirement.

preamble, we will refer to dealers and distributors as ''dealers,'' except where differentiation is required.

[2] The National Traffic and Motor Vehicle Safety Act, as amended, was repealed in the course of the 1994 recodification of various laws pertaining to the Department of Transportation and was reenacted and recodified without substantive change. Pub. L. 103–272, 108 Stat. 745, 941–973, 1379, 1385, 1388, 1397, 1399.

VWoA, Chrysler and Toyota addressed the practical implications of Section 2504 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102–240, 105 Stat. 1914, 2083–2084. Under that provision, which is now codified at 49 U.S.C. 30120(i), in essence, when a manufacturer has given notice to a dealer about a new vehicle or equipment in a dealer's possession that contains a defect related to motor vehicle safety or does not comply with an applicable standard, the dealer may sell the vehicle or equipment only if it is remedied before delivery under the sale. Toyota pointed out that this statutory stop sale provision does not require a stop sale of vehicles on the date of filing the defect report with NHTSA, but only after the manufacturer's notification to the dealer. In VWoA's and Chrysler's view, there was no need for the regulation to specify a specific time within which a manufacturer must notify its dealers because of the self-interest of the manufacturer once the defect has been determined. According to AAMA, this self-interest is most manifest in cases where there have been imminent safety defects in newly produced vehicles in dealer inventories. In such situations, manufacturers recognize that early notification of dealers, with the consequent embargo of products, is likely to provide a significant safety benefit, and they routinely act accordingly.

Conversely, in recall situations involving older vehicles, where few to no new vehicles would be in dealers' inventory, or where the defect does not pose an imminent safety risk, AAMA argued that there is no safety benefit from an early notification. AAMA called the proposed five-day dealer notification period ''unworkable, unnecessary, and in most cases, likely to be counterproductive.'' Likewise, Toyota commented that not all safety recalls are on the same level of importance. For example, where there is a minor labeling problem, it is both unreasonable and inconsistent for the manufacturer to stop sale of thousands of dollars of in-stock vehicles when in-use vehicles are being operated before the commencement of the recall. NADA emphasized that a stop sale where there is no safety risk puts an unfair burden on dealers because new vehicle inventory is a large portion of a dealer's overhead.

Similarly, VWoA maintained that where the defect is time or mileage dependent and is not going to arise immediately, there is no practical reason to notify dealers until the dealer has received the necessary diagnostic and repair training or parts to correct the defect. AAMA and Chrysler pointed out that publicity in situations where the remedy is not yet ready creates owner frustration and confusion, and results in a lower overall recall completion rate (the percentage of vehicles remedied). Thus, early notification is counterproductive.

Dealer Notification in the 1997 Notice

Pursuant to the Paperwork Reduction Act, the agency published a **Federal Register** notice requesting public comment on the potential paperwork burdens associated with the proposed rule. 62 FR 63598–63599 (Dec. 1, 1997). The notice referred to the agency's proposal to establish a time limit within which manufacturers must notify dealers and to a paperwork burden on manufacturers in writing letters to NHTSA to request a delay in providing dealer notification beyond the five days specified in the rule. 62 FR 63598.

Manufacturer trade associations and a motor vehicle dealer trade association submitted comments. AAMA again opposed the five-day notice proposal; AAMA's principal argument was that the statutory reasonable time standard controls timing issues. AAMA added that their position was underscored by the agency's retreat from a restrictive time requirement proposed in the same rulemaking effort to amend 49 CFR parts 573 and 577. In particular, in 1996, the agency changed a requirement that manufacturers provide a detailed schedule for any owner notification campaign in a recall that would not begin within 30 days of the filing of a defect and noncompliance information report under 49 CFR 573.5 (recodified at § 573.6 in 2002) (Part 573 Report) or end within 75 days of that report. AAMA quoted language from the **Federal Register** notice revising the rule wherein the agency stated that ''manufacturers will have flexibility to tailor the recall notification schedule [to owners] to the circumstances of the particular recall * * * while NHTSA will retain the ability, on a case-by-case basis, to ensure that the timing of recall notification is reasonable.'' 61 FR at 275. Ford opposed the five-day notification period, stating ''there is no evidence to support the need for a final rule on this [dealer notification] matter,'' and suggested that the agency terminate rulemaking action on dealer notification. Similarly, AIAM argued that there is no need for a five-day notice when the current procedure involving a reasonable time for notification has worked, and the agency has sufficient authority to require early notification when manufacturers do not act voluntarily. AIAM also asserted that there is no safety benefit in an early notice where there is no imminent safety risk; and the artificial sense of urgency results in a financial burden to dealers, market disruption, and confusion to consumers. NADA emphasized that the statute imposes a reasonable time standard rather than a five-day default period, and that the current system provides for the flexibility necessary in recall situations that are complex and variable.

The 1999 SNPRM

After considering the information presented in the comments on the 1993 proposed rule and the 1997 Paperwork Reduction Act notice, NHTSA published the SNPRM on May 19, 1999. 64 FR 27227. In the SNPRM, the agency proposed to require manufacturers to notify their dealers of safety defects and noncompliances in accordance with a schedule submitted to the agency with the manufacturer's Part 573 Report. The SNPRM stated that such a schedule will be reviewable by NHTSA to assure that the notification will be within a reasonable time.

In the SNPRM, the agency explained:

> This decision to permit greater flexibility than originally proposed is based on NHTSA's recognition that the process of dealer notification has worked well for over 20 years, notwithstanding the absence of formal regulatory requirements. In conformity with the statutory duty to notify dealers within a ''reasonable time'' (49 U.S.C. 30119(c)(2)), manufacturers have generally notified their dealers of defects and noncompliances in a manner that has allowed repairs to be performed promptly, with minimal disruption of the dealers' operations.
>
> Where manufacturers have concluded that a defect or noncompliance presented an immediate safety risk, they have notified their dealers as soon as the defect or noncompliance determination was made, and have directed the dealers to stop sales (and leases) until the problem is corrected. On occasion, however, NHTSA and a manufacturer have disagreed about when notification should occur or whether immediate notification and immediate cessation of sales is appropriate. For this reason, the agency needs to know the manufacturer's proposed schedule for dealer notification so it can assess the safety implications of that schedule. Therefore, NHTSA is proposing a new section 573.5(c)(8)(iii), which would require the manufacturer to include the estimated date of its dealer notification in its Part 573 defect or noncompliance report, in the same manner as section 573.5(c)(8)(ii) currently requires the submission of the manufacturer's proposed schedule for its owner notification and remedy campaign. In addition, to eliminate the possibility that any

disagreements between NHTSA and the manufacturers concerning the notification date of dealers, NHTSA is proposing a new section 577.7(c)(1), [which] requires manufacturers to comply with a NHTSA order to notify their dealers on a specific date, if the agency has found that notification at that time is in the public interest. In making such determinations, the agency will consider such factors as the severity of the safety risk; the likelihood of occurrence of the defect or noncompliance; availability of an interim remedial action by the owner; whether an initial dealer inspection would identify suspect vehicles or equipment items; the time frame in which the defect will manifest itself; whether there will be a delay in the availability of the remedy from the manufacturer; and, in those recalls where a delay is expected, the anticipated length of such delay. [64 FR at 27228]

In response to the SNPRM, twelve entities, including trade associations of the motor vehicle and motor vehicle equipment industries, and automobile dealers submitted comments. Comments by the Alliance and AIAM, TMA and NADA supported the proposal in the SNPRM for notification of dealers within a reasonable time. There were no objections to the proposed reasonable time standard. Petitioners Public Citizen and the Center for Auto Safety did not comment.

The June 2004 Final Rule

The June 2004 rule requires manufacturers to furnish dealers with notification of a safety-related defect or noncompliance in accordance with a schedule that manufacturers are to submit to the agency with their defect or noncompliance information report required by 49 CFR 573.6(c)(8)(ii). 49 CFR 577.7(c). The notification to dealers must be provided within ''a reasonable time'' after the manufacturer decides that a defect related to motor vehicle safety or noncompliance exists. If the agency finds that the public interest requires dealers to be notified at an earlier date than that proposed by the manufacturer, the manufacturer must provide the required notification in accordance with the agency's directive. *Id.* The rule included a number of factors that the agency may consider. *Id.* The rule also set forth the required content of the dealer notification and the manner in which such notification is to be accomplished. *Id;* § 577.13. In the preamble to the rule, NHTSA responded to comments on the SNPRM. Beyond that, it incorporated by reference the rationale in the SNPRM. 69 FR at 34955.

Petition for Reconsideration of the Reasonable Time Standard

One petition for reconsideration of the June 2004 rule, submitted by PC/CAS, objected to the provision requiring dealer notification within a reasonable time after the manufacturer decides that a defect that relates to motor vehicle safety or a noncompliance exists. The petition requested the agency to reverse the rule and adopt a requirement that manufacturers notify their dealers within five days of the manufacturer's notice to NHTSA as proposed in 1993. Following receipt of the notice, the dealer would be prohibited from delivering the vehicle under a sale until parts were available and repairs were made. 49 U.S.C. 30120(i). In PC/CAS's view, the simplest and safest step for consumers is if they are never sold a defective vehicle in the first place. Petition at 6. The petitioners assert that under a reasonable time standard, defective vehicles will be sold and remain unfixed for an indeterminate amount of time, thus exposing their owners to an otherwise avoidable safety risk.

PC/CAS contend that, as a matter of law, the Safety Act places significant restrictions on manufacturers and dealers in selling new vehicles with safety defects or a noncompliance, and implies real urgency in remedial action. *Id.* at 3. In their view, the rule is contrary to the ''intent'' of the Safety Act. *Id.* at 2, 8. Their argument does not address the central provision in the Safety Act, as amended and recodified, on the time for notification, 49 U.S.C. 30119(c). That provision states: ''[n]otification required under section 30118 of this title shall be given within a reasonable time—(1) prescribed by the Secretary, after the manufacturer receives notice of a final decision under section 30118(b); or (2) after the manufacturer first decides that a safety-related defect or noncompliance exists under section 30118(c) of this title.'' The petition pertains to the second clause, which applies to recalls initiated by manufacturers.[3] The language of this provision sets a standard of a reasonable time. The statute does not dictate a single period of time as the reasonable time period that would apply to manufacturers' notifications of dealers in all circumstances. Instead, as we interpret the Safety Act, as amended and recodified, a reasonable time means a time that is reasonable in the circumstances.[4]

Petitioners point to several subsections of the Act to support their view. For example, they cite 49 U.S.C. 30118(c), which requires manufacturers to notify owners, purchasers and dealers as provided by section 30119(d) if the manufacturer learns the vehicle contains a defect and decides in good faith that the defect is related to motor vehicle safety. Petitioners also refer to 49 U.S.C. 30116(a), which provides, in part, that if after a manufacturer sells a vehicle to a dealer and, before the dealer sells the vehicle, it is decided that the vehicle contains a safety-related defect or does not comply with an applicable motor vehicle safety standard, the manufacturer shall repurchase the vehicle or immediately give the dealer the part needed to make the vehicle comply with the standards or correct the defect. These subsections do not dictate a specific time for manufacturers' notifications to dealers.

Petitioners also refer to subsections that were added to the Safety Act, as amended. As discussed above, 49 U.S.C. 30120(i), provides that if the manufacturer has provided notice under section 30118 to a dealer about a new motor vehicle or replacement equipment in the dealer's possession at the time of notification that contains a safety-related defect or noncompliance, the dealer may sell the vehicle or equipment only if the defect is remedied before delivery under the sale. The second, 49 U.S.C. 30120(j), prohibits a person from selling any new or used motor vehicle equipment for installation on a motor vehicle that is the subject of a decision under 49 U.S.C. 30118(b) or a notice required under 49 U.S.C. 30118(c) in a condition that it may be reasonably be used for its original purpose unless the defect or noncompliance is remedied as required under section 30120 before delivery under the sale. These provisions preclude a dealer from delivering a vehicle or equipment under a sale after receiving notice of a safety-related defect or noncompliance from a manufacturer. But, they do not specify a particular time when the manufacturer must provide notice of the defect to a dealer.

PC/CAS also object to the provisions in the rule under which NHTSA could direct a manufacturer to provide notice to dealers. In the SNPRM, after stating that the manufacturer's proposed schedule may be reviewed by the Administrator, NHTSA proposed that the Administrator

[3] The first clause applies to recalls ordered by NHTSA's Administrator. Very few vehicle recalls have been ordered under 49 U.S.C. § 30118(b). Any such order would include a notification schedule.

[4] In the preamble to the 1996 rule, in the context of the manufacturer's provision to the NHTSA of estimated dates when they will first provide notice to owners of recalled vehicles, we noted that the agency may examine ''whether the manufacturer's time frame for the recall is reasonable under the circumstances.'' 61 FR at 275.

may order a manufacturer to send the notification to dealers on a specific date where the Administrator finds, after consideration of available information, that such notification is in the public interest. The factors that the Administrator may consider include, but are not limited to, the severity of the safety risk; the likelihood of occurrence of the defect or noncompliance; whether a dealer inspection would identify vehicles or equipment items that contain the defect or noncompliance; whether there will be a delay in the availability of the remedy from the manufacturer; and, in those recalls where a delay is expected, the anticipated length of such delay.

Proposed § 577.7(c)(1), 64 FR at 27231.

NHTSA received a number of comments on the proposal. Following the agency's consideration of the matter, NHTSA promulgated the final rule, which provides in part:

The Administrator may direct a manufacturer to send the notification to dealers on a specific date if the Administrator finds, after consideration of available information and the views of the manufacturer, that such notification is in the public interest. The factors that the Administrator may consider include, but are not limited to, the severity of the safety risk; the likelihood of occurrence of the defect or noncompliance; the time frame in which the defect or noncompliance may manifest itself; availability of an interim remedial action by the owner; whether a dealer inspection would identify vehicles or items of equipment that contain the defect or noncompliance; and the time frame in which the manufacturer plans to provide the notification and the remedy to its dealers. [§ 577.7(c)(1)]

In the preamble to the final rule, we noted that the final rule contained several changes to the proposal. 69 FR at 34956. We revised proposed paragraph (c) of § 577.7 to provide for consideration of the views of the manufacturer in ordering notification to dealers at a date earlier than that proposed by the manufacturer. We also indicated that we added two additional factors, namely, availability of an interim remedial action by the owner and the time frame in which the defect may manifest itself, that will be considered by the agency when deciding whether to require dealer notification on a specific date. These two factors had been discussed in the preamble to the SNPRM along with the other factors that became part of the regulatory text in the final rule.

PC/CAS criticize the three changes adopted in the final rule. Petition at 7. They assert that the ''views of the manufacturer'' is a catch-all for whatever the industry will say it means.'' PC/CAS's observation is not a fair characterization of the provision. As noted in the preamble to the final rule, NHTSA's defect and noncompliance notification rule contained a provision requiring that the manufacturers' notification of owners of recalled vehicles and equipment be furnished within a reasonable time after the manufacturer first decides that either a defect that relates to motor vehicle safety or a noncompliance exists (49 CFR 577.7(a)(1)). 69 FR at 34956. The rule further provided that NHTSA may direct a manufacturer to send the notification to owners on a specific date. § 577.7(c)(1); 69 FR at 34959. Under that provision on owner notification, the agency considers available information and the ''views of the manufacturer''. *Id.* The dealer notification provision parallels the related owner notification provision. Second, the provision on consideration of the views of the manufacturer is procedural. NHTSA need not adopt the views of the manufacturer. Third, it makes good sense for the agency to consider the views of the manufacturer before ordering it to provide notice to dealers on a specific date. Ordinarily, the agency's decision would be more informed if the agency considered the views of the regulated entity, as contrasted to ordering the entity to take an action on a specific date without first asking for its views. We would add that in other circumstances, formal or informal, NHTSA often considers the views of the manufacturer, which may possess pertinent information unknown to the agency. For instance, when determining whether to accelerate a manufacturer's remedy program the agency is required to consult with the manufacturer. See 49 CFR 573.14(c). Finally, PC/CAS's criticisms are not supported by any facts or analysis.

With regard to the second factor—availability of an interim remedy—PC/CAS comment that the agency did not explain why consumers should be burdened with addressing a safety defect. The point of this factor was not one of burdening consumers. When the recall remedy is not yet available, a common industry practice in appropriate cases has been for manufacturers to notify consumers to take some action, either to obtain whatever current repair may be available from a dealer or other authorized repair shop, or to take a precautionary action in operation of the vehicle. Similarly, this factor addresses any type of action (in vehicle operation or to the vehicle) that can be taken by the owner or performed at the owner's request by a dealer. For example, if there were an electrical defect in a non-essential accessory, the accessory could be unplugged from a wiring harness.

Third, PC/CAS argue that the factor on the time frame in which the defect will manifest itself is 180 degrees from the agency's initial position in 1993. Petition at 7. But the time in which the defect will manifest itself ordinarily is a valid consideration. If the defect will not manifest itself for a significant period of time, well beyond that in which the recall remedy will be available, a deferred notification to dealers is not problematic. PC/CAS's reference to language from the 1993 NPRM (58 FR 50317) that discussed the proposed requirement for manufacturers to provide justification in their defect report for any requests for delays of the recall or remedy does not dictate a different approach. The agency has rejected the approach proposed in the 1993 NPRM. In the 1996 notice responding to petitions, the agency deleted the extensive scheduling information required in the Part 573 Report under the 1995 rule. In addition, in the 1999 SNPRM, the agency explained its misgivings with the approach in the 1993 NPRM. The June 2004 rule implicitly rejected that approach.

More generally, PC/CAS assert that the agency's determination of what is a reasonable time for dealer notification will turn on factors pertaining to the availability of the remedy, rather than safety considerations. The agency disagrees. The regulation specifies a public interest test. Section 577.7(c)(1). One factor is the severity of the safety risk. Another is the likelihood of occurrence of the defect or noncompliance. A third is the time frame in which the defect or noncompliance may manifest itself. In any event, the factors set forth in section 577.7(c)(1), which employs the phrase ''include, but are not limited to'', are not all inclusive.

The rule addressed the range of circumstances encountered in vehicle and equipment recalls by employing the statutory phrase of notification ''within a reasonable time'' after the manufacturer decides that the defect or noncompliance exists. As both AAMA and NADA observed in their comments on earlier notices, the reasonable time standard permits the flexibility needed in the complex and variegated motor vehicle recall circumstances. The rule's approach is sufficiently flexible to consider the factual predicate for the recall and the wide range of circumstances giving rise to a recall.

In cases where the defect presents an immediate danger in new vehicles, we expect manufacturers, as they routinely

have done, to notify dealers within a short period of time after determining that a safety related defect exists. For example, recently Mitsubishi recalled its Model Year 2006 Eclipse vehicles. The vacuum brake booster may not have been crimped together and could come apart. If it does, the master cylinder will be disconnected and the vehicle will have complete brake failure. Mitsubishi promptly notified dealers. We believe that the regulation should be clarified to assure prompt notification in circumstances such as this. Thus, we are adding a provision to section 577.7(c)(1). The new provision states that in the case of defects or noncompliances that present an immediate and substantial threat to motor vehicle safety, the manufacturer shall transmit this notice to dealers and distributors within three business days of its transmittal of the Defect and Noncompliance Information Report under § 573.6 to NHTSA, except that when the manufacturer transmits the notice by other than electronic means, the manufacturer shall transmit this notice to dealers and distributors within five business days of its transmittal of the Defect and Noncompliance Information Report to NHTSA. Once the manufacturer has prepared the report to NHTSA, if it transmits the dealer notice electronically, it will be able to prepare and electronically transmit the dealer notice within three business days. Manufacturers with large dealer networks employ electronic communications with dealers. If the manufacturer uses a means other than electronic communication to dealers, we are allowing five business days.

We also believe that provisions on Defect and Noncompliance Information Reports should be modified slightly to improve our oversight. Currently, section 573.6(b) provides that each report shall be submitted not more than 5 working days after a defect in a vehicle or item of equipment has been determined to be safety related, or a noncompliance with a motor vehicle safety standard has been determined to exist. Required information that is not available within that period is to be submitted as it becomes available. *Id.* We are amending this section to provide that, at a minimum, information required by subparagraphs (1), (2) and (5) of paragraph (c) of this section shall be submitted in the initial report. The remainder of the information required by paragraph (c) that is not available within the five-day period shall be submitted as it becomes available. This would assure that we are provided timely information on the defect or noncompliance. Manufacturers have this information and commonly provide it in the initial report.

Some products contain potential or latent safety defects that do not manifest themselves for a considerable period of time. For example, vehicle manufacturers produce vehicles that are identical or almost identical in runs that last a number of model years. When a manufacturer identifies a defective part in a make and model of a vehicle, the manufacturer is required to include in its Part 573 Report all of the range of model years of that make and model of vehicle that contain the problematic part, even if failures have not been experienced in current model year vehicles. When the Part 573 Report covers current production vehicles, it does not mean that new vehicles on dealers' lots per se present an immediate safety risk. In fact, in some new vehicles, there is no present safety concern.

As noted in the SNPRM, in many recalls, the safety consequences of the defect are unlikely to arise until the vehicle has been in service for an extended period of time, such as where the problem is caused by corrosion or metal fatigue. 64 FR at 27228. The following examples further indicate some of the situations in which immediate notification of dealers would not be necessary, and support our view that the five-day rule sought by PC/CAS is not warranted.

A common type of progressive failure is accumulative wear of parts. In a new vehicle, the parts would not be worn. Over a period of many months or years, the parts could fail as a result of wear. An example where a component progressively wore and ultimately failed is ball joint failures in Toyota Tundra vehicles. In May 2005, Toyota initiated a recall covering vehicles with possible flaws in ball joints, which are parts in the suspension system of vehicles (Recall No. 05V225). The problem stemmed from scratches on the surface of some ball joints as newly manufactured. This could progress to wear and then to failures in which the ball joint could separate, which could result in a loss of control of the vehicle. The first ball joint separation occurred after 8 months and most occurred after tens of thousands of miles. The ball joints in new vehicles did not present safety issues.

In another instance, a part wore over time as a result of chafing. In September 1997 Ford recalled approximately 125,000 MY 1992–1993 Ford Thunderbird and Mercury Cougar vehicles to repair a fuel line leak (No. 97V159). The fuel line chafed against the floor pan at times when the vehicle was in motion, which eventually could create a pin hole fuel leak. The amount of chafing was mileage dependent and also increased under rough road conditions. Vehicles did not experience failures until they had been driven over 40,000 miles, except for one after 27,000 miles and another after 32,000 miles.

Corrosion may also cause slow, progressive failures. For example, in January 2005 Ford recalled 261,000 MY 2000—2002 Focus vehicles (No. 05V030). In that recall, dealers were instructed to conduct inspections and to replace rear door latches that do not latch properly. In a highly corrosive environment, some door latch assemblies corroded over an extended period of time, which prevented the proper engagement of the door latch ''catch'' to the latch striker on the vehicle body. Some owners experienced difficulty opening or closing the door, and eventually some doors did not latch properly. As revealed in the agency investigation, the failure condition did not manifest itself until the vehicles were in service for approximately two years or more, with the exception of two earlier failures, the earliest of which is unlikely to have been related to corrosion.

Similarly, in July 2004, Ford recalled 899,060 MY 1999–2001 Ford Taurus and Mercury Sable vehicles (No. 04V332) registered in the high corrosion states to repair front suspension coil springs, which may fracture and puncture the adjacent tire. The potential for corrosion causing a spring fracture increases with the number of miles and years in service. Data compiled during the agency investigation indicate that the vast majority of the failures occurred after the vehicles had been in service for two years. The earliest failure occurred after 7 months and the second after 10 months in service.

Some defects stem from materials degradation over time. For example, in August 1998, Chrysler Corporation notified the agency that it would be conducting a recall of 722,387 vehicles manufactured between 1992 and 1997 to replace several rubber o-ring seals in the fuel injection assembly that were prone to lose sealing capacity prematurely (No. 98V184). Prolonged exposure to high underhood temperatures and some aggressive automotive fuels caused the o-rings to experience compressive stress relaxation and lose their sealing force. The degradation of the defective o-rings took place over many months. Warranty data related to leakage in certain parts of the fuel rail assembly provided the first evidence of the problem over two years after the oldest vehicles were

built. Chrysler replaced the o-rings with seals made from a new material that was more resistant to high temperatures and aggressive fuels.

Plastics degradation led to a recall in November 1998 by Volkswagen of 6,217 MY 1992–1994 Corrado vehicles to address heat exchanger end cap ruptures (No. 98V295). The plastic cap degraded over time due to heat and some failed, resulting in a release of hot coolant. Warranty claims submitted by Volkswagen in the investigation show that the vehicles were at least three years old when the failures occurred, except for one that occurred after 9 months and another after two years. The majority of the failures occurred when the vehicles were four and five years old.

The alternative sought by PC/CAS—a rule requiring notice within a specific period of time in all cases—is excessive. It would provide an overbroad margin of safety in circumstances where it is not necessary to stop the sale of vehicles on dealers' lots. It would ground numerous vehicles that are not yet unsafe until parts could be produced, supplied, and installed. This approach, which would place an unnecessary and unjustified burden on those dealers who have large inventories of vehicles within the scope of a Part 573 Report, was proposed in the NPRM as a five-day notification period, and properly rejected.

PC/CAS do not challenge NHTSA's assessment that the process of dealer notification using the reasonable time standard has worked well for 20 years (64 FR at 27228; 69 FR at 34955 (incorporating SNPRM) and 34957), other than on theoretical grounds. Instead, they quibble with NHTSA's statement in the SNPRM that requiring 5 days notice in all cases could have perverse effects. NHTSA stated that a mandatory timeframe could encourage some manufacturers to delay making defect determinations to give them time to develop remedies and stockpile parts. PC/CAS argues that a delayed defect determination violates the Safety Act and subjects the manufacturer to civil penalties. While that is true, it does not resolve the central issue of the timing of dealer notification. As reflected in the examples above, in numerous circumstances there is no factual safety justification for requiring a manufacturer to provide notice to dealers within five days of the submission of their Part 573 Reports to NHTSA. The approach to dealer notification in the June 2004 rule should not be undone simply because a rigid regulation, such as that proposed in the NPRM, could be written to require early dealer notification in all cases and, under such a regime, an untimely notification could violate the Act or a rule.

PC/CAS also criticize the final rule for not requiring that the dealer notification schedule be a mandatory piece of information in the initial filing of the Part 573 defect report. Section 573.6(b) states that each Defect and Noncompliance Report shall be submitted by a manufacturer to NHTSA not more than 5 working days after a defect in a vehicle or item of equipment has been determined to be safety related or a noncompliance with a standard has been determined to exist. The information requirements for the report are set forth in § 573.6(c). Under the rule, including the amendment discussed above, certain information that is required by paragraph (c) that is not available within the five-day period is to be submitted as soon as it becomes available. § 573.6(b). The agency believes that requiring that the manufacturer's initial submission be complete, with all of the information specified in paragraph (c), is not sound. Indeed, it would delay the notification to NHTSA of the existence of a safety-related defect until all of the information is available. Such a delay is inconsistent with 49 U.S.C. 30118 and 30119, 49 CFR 573.6(b) (requirement of reporting within 5 days of determination of noncompliance or safety-related defect) and the agency's strong interest in receiving reports of defects as soon as possible. It is not uncommon that some information, such as a description of the manufacturer's program for remedying the defect or noncompliance (§ 573.6(c)(8)), is not available when the Part 573 Report is filed. 61 FR at 275. The formulation of the dealer notification schedule often is contingent on the availability of such information. At times, it is not known when the manufacturer submits the Part 573 defect report.

In addition, the petitioners argue that since the rate of remedying vehicles after sale is less than the 100 percent repairs achievable prior to sale of new vehicles on dealers' lots, a higher number of consumers will be at risk. Petition at 2. Their argument is theoretical. As noted above, the statutory ''reasonable time'' standard for dealer notification has been in place for three decades. Historically, the vast majority of vehicles covered by a safety recall have been remedied. In circumstances involving severe problems, manufacturers and dealers have embargoed the sale of new vehicles, particularly after the enactment of ISTEA. Today's amendment to 49 CFR 577.7(c)(1) provides further assurances that when the defect or noncompliance in a new motor vehicle presents and immediate and substantial risk to motor vehicle safety, the vehicle will not be sold until repaired. As to other vehicles, manufacturers and at times dealers provide notice of recalls to owners, the vast majority of which bring the vehicles to dealers for recall work. Also, owners commonly have vehicles serviced by dealers when the vehicles, such as those at issue, are under warranty. When vehicles are brought to dealers for warranty work, the dealers check the manufacturers' records on those vehicles and perform outstanding recall repairs.[5] In the end, the petition simply does not demonstrate with compelling real world evidence that the historical approach is fundamentally flawed.

PC/CAS also assert that a lack of public information about the defect does not allow the generation of any public pressure on manufacturers to develop a quick remedy. In particular, PC/CAS state that the public frequently will face a substantial delay in being informed of the defect because the agency does not routinely place Part 573 Reports on its Web site until weeks or months after the manufacturer's submission. Petition at 7. This is based on an incorrect understanding of agency practices. The Part 573 Reports are routinely placed on our website as soon as practicable, which currently is within a week of receipt.

B. Verification of Notice to Dealers

In the NPRM we had proposed that manufacturers maintain records to verify that they notified their dealers of the defect or noncompliance and that the dealers received the notification. Subsequently, as stated in the SNPRM: ''The agency has decided that it would be unduly burdensome, and perhaps impracticable, to require manufacturers to keep records reflecting that each dealer received the notification. The proposed new section 577.11(d) required that manufacturers be able to verify that it has sent the notification to its dealers and the date of such notification.''

The final rule essentially adopted the proposal in the SNPRM. In particular, proposed section 577.11(d) was moved to section 577.7(c)(2)(i) and illustrative language was added. The preamble to the final rule proceeded to say that:

[5] Of course, in general, far fewer than all the vehicles covered by a recall are defective. *See United States* v. *General Motors Corp.,* 581 F.2d 420, 438–439 (D.C. Cir. 1975).

> We are revising proposed § 577.7(c)(2)(i) to identify examples of what will be considered to be verifiable electronic means of notification, such as receipts or logs from electronic mail or satellite distribution systems. AAM/AIAM and MIC recommended this change in order to clarify the meaning of verifiable electronic means. However, the examples referenced are not the only types of verifiable electronic means that would be permissible, since other technology that provides comparable information may become available.

69 FR at 34956.

In its petition, GM points out that the preamble to the final rule appears to evert to the 1993 proposal to require proof of receipt by a dealer. In responding to a recommendation that manufacturers be allowed to send notifications by first class mail, we stated:

> While we have authorized the use of various means of notification, we have required that the manufacturer be able to verify that the notifications were sent to *and received by* each dealer. Since there is no way to verify receipt of first class mail, we have rejected this suggestion. [emphasis added]

69 FR at 34957. The phrase ''and received by'' was an inadvertent misstatement. We confirm that manufacturers are not required to verify that the notification was received by their dealers. There is no need for any clarification to the regulatory text of section 577.7(c)(2)(i). That section does not include language indicating that a manufacturer must prove receipt of the notification by its dealers. The meaning is confirmed by section 577.13(d), which states that ''[t]he manufacturer shall, upon the request of the Administrator, demonstrate that it sent the required notification to each of its known dealers and distributors and the date of such notification.''

C. Content of Dealer Notification—Requiring Manufacturers To Provide Notice Containing Offer To Repurchase Equipment

Section 30116 of the Safety Act, as amended, sets forth certain actions that manufacturers must take following a decision that a motor vehicle or an item of motor vehicle equipment is defective or noncompliant under 49 U.S.C. 30118. Section 30116(a) provides for the manufacturer's repurchase of the motor vehicle or equipment or, for vehicles, for the manufacturer's provision of parts or equipment needed to make the vehicle comply with the standards or correct the defect. In 49 U.S.C. 30116(c), Congress provided that the parties shall establish the value of the installation of the part and amount of reimbursement and, if they do not agree or the manufacturer does not comply with the statute, a Federal cause of action whereby the dealer may bring suit against the manufacturer.

In the final rule, section 577.13(c) required that for notifications of defects or noncompliances in items of motor vehicle equipment, the notification to dealers shall contain the manufacturer's offer to repurchase the items that remain in dealer or distributor inventory at a specified price, or as otherwise agreed to between the manufacturer and the dealer.

In its petition for reconsideration, JPMA asserts that equipment manufacturers have the statutory right to elect the remedy, that the final rule unreasonably interprets the Safety Act to preclude repair or replacement of equipment in dealer inventory, and that the final rule interferes with contractual relationships. JPMA observes that historically the agency has allowed such repair or replacement. GM asserts similar legal arguments and contends that there is no need for this type of regulation. It points out that items in dealer inventory are inspected and repaired as need be, as opposed to being repurchased. MEMA/AASA make legal arguments similar to those of JPMA and GM.

JPMA is correct that historically NHTSA has not opposed manufacturers' repair or replacement of items of equipment in dealer inventory that are the subject of a defect and noncompliance report under 49 CFR part 573. Indeed, we recognized that practice in the last clause of section 577.13(c), which in addition to a repurchase by the manufacturer recognized the appropriateness of arrangements as otherwise agreed to between the manufacturer and the dealer.

On reconsideration, we agree with GM and JPMA that section 577.13(c) is unnecessary and are deleting it. Manufacturers and equipment dealers have worked cooperatively in the past to satisfactorily handle inventory affected by a recall campaign. At this time, we do not see a safety need for additional notice requirements.

III. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

NHTSA has considered the impact of this rulemaking under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures, and for the following reasons has determined that it is not a ''significant regulatory action'' within the meaning of Sec. 3 of E.O. 12866 and is not ''significant'' within the meaning of the Department of Transportation's regulatory policies and procedures. This document was not reviewed by the Office of Management and Budget under E.O. 12866, ''Regulatory Planning and Review.''

For the following reasons, NHTSA concludes that this final rule will not have any quantifiable cost effect on motor vehicle manufacturers or motor vehicle equipment manufacturers. In response to petitions for reconsideration, this final rule requires that the information required in paragraphs (1), (2) and (5) of 49 CFR 573.6(c) be submitted in the manufacturer's initial Defect and Noncompliance Information Report that is submitted within 5 working days after a defect in a vehicle or item of equipment has been determined to be safety related, or a noncompliance with a motor vehicle safety standard has been determined to exist. These items of information are not new, are ordinarily submitted in the initial report and insofar as they are not it would not be burdensome to submit them in the initial report, as opposed to later. Second, while the rule retains the standard for notification of dealers within a reasonable time after the manufacturer decides that the defect or noncompliance exists that appears in the statute and the June 2004 final rule, it also adds a provision for prompt notice to dealers in circumstances where there is an immediate and

substantial risk to motor vehicle safety. This states the proper application of the reasonable time standard in the circumstances. Manufacturers have informed us and we have observed that under the reasonable time standard, they provide such prompt notice to dealers where the safety risks warrants it. Thus, this amendment does not add a real burden. Third, as made clear in the discussion above, manufacturers are not required to verify that their notifications were received by their dealers. Finally, this final rule eliminates an unnecessary paragraph in notices to equipment dealers. The section 577.13 notification to dealers and distributors need no longer include the manufacturer's offer to repurchase the items that remain in dealer or distributor inventory or as otherwise agreed to between the manufacturer and dealer.

Because the economic effects of this final rule are so minimal, no further regulatory evaluation is necessary.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBFEFA) of 1996), whenever an agency is required to publish a notice of proposed rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates primarily within the United States.'' (13 CFR 121.105(a)). No regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

The Administrator has considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The statement of the factual basis for the certification is that this final rule, formulated in response to petitions for reconsideration, does not change the information required by paragraphs (1), (2) and (5) of 49 CFR 573.6(c), but does require that it be submitted in the manufacturer's initial Defect and Noncompliance Information Report. These items of information are ordinarily submitted in the initial report and insofar as they are not it would not be burdensome to submit them in the initial report, as opposed to later. Second, within the existing standard for notification of dealers within a reasonable time after the manufacturer decides that the defect or noncompliance exists that appears in the statute and the June 2004 final rule, this rule adds a provision for prompt notice to dealers in circumstances where there is an immediate and substantial risk to motor vehicle safety. Manufacturers have informed us and we have observed that under the reasonable time standard, they provide such prompt notice to dealers where the safety risks warrants it. Under the statute and June, 2004 rule it would not have been appropriate for manufacturers to defer notice where the defect in a vehicle presented an immediate and substantial risk to motor vehicle safety. Thus, this amendment to the rule thus does not add a significant burden. Third, this final rule eliminates an unnecessary paragraph in notices to equipment dealers. It does not alter the underlying substantive provision of the statute or historical practice whereby manufacturers offer to repurchase the items that remain in dealer or distributor inventory or reach an alternative agreement.

For these reasons, and for the reasons described in our discussion on Executive Order 12866 and DOT Regulatory Policies and Procedures, NHTSA concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

C. National Environmental Policy Act

NHTSA has analyzed these amendments for the purposes of the National Environmental Policy Act and determined that they will not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA 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.'' The Executive Order defines ''policies that have federalism implications'' 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.'' Under Executive Order 13132, NHTSA may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local officials early in the process of developing the regulation. NHTSA also may not issue a regulation with Federalism implications and that preempts State law unless the agency consults with State and local officials early in the process of developing the regulation.

NHTSA has analyzed this rulemaking action in accordance with the principles and criteria set forth in Executive Order 13132. The agency has determined that this rule will not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. This rule will not have any substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. The reason is that this final rule applies to motor vehicle manufacturers and to motor vehicle equipment manufacturers, not to the States or local governments. Thus, the requirements of Section 6 of the Executive Order do not apply.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires federal agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). Before promulgating a rule for which a written assessment is needed, Section 205 of the UMRA generally requires NHTSA 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 NHTSA to adopt an alternative

other than the least costly, most cost-effective or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted.

This rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of more than $100 million annually. Accordingly, this rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

F. Executive Order 12988 (Civil Justice Reform)

Pursuant to Executive Order 12988 ''Civil Justice Reform,'' this agency has considered whether this final rule would have any retroactive effect. NHTSA concludes that this final rule will not have any retroactive effect. Judicial review of the rule may be obtainable under 5 U.S.C. 702. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

G. Paperwork Reduction Act

The Dealer Notification Rule, as published in June 2004 and as amended by this rule, involves an information collection under the Paperwork Reduction Act of 1995. NHTSA is in the process of obtaining clearance for requirements of the dealer notification rule. On May 6, 2005, NHTSA published notice that an information collection request has been forwarded to the Office of Management and Budget for review. 70 FR 24163. The comment period in the notice expired on June 6, 2005. NHTSA sought to revise a currently approved request, OMB No. 2127–0004.

H. Executive Order 13045

Executive Order 13045 applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental, health or safety risk that NHTSA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we 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 us.

This rulemaking does not involve any environmental, health or safety risks that disproportionately affect children.

I. Privacy Act

Anyone is able to search the electronic form of all submissions received into any of our dockets by the name of the individual submitting the comment or petition (or signing the comment or petition, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, section 12(d) (15 U.S.C. 272) directs NHTSA to use voluntary consensus standards in its regulatory activities unless doing 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, such as the Society of Automotive Engineers (SAE). The NTTAA directs the agency to provide Congress, through the OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

After conducting a search of available sources, we have concluded that there are no voluntary consensus standards applicable to this final rule.

K. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

List of Subjects

49 CFR Part 573

Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

49 CFR Part 577

Motor vehicle safety.

■ In consideration of the foregoing, Parts 573 and 577 of Chapter V of Title 49 of the Code of Federal Regulations are amended to read as follows:

PART 573—DEFECT AND NONCOMPLIANCE RESPONSIBILITY AND REPORTS

■ 1. The authority citation for Part 573 of Title 49 continues to read as follows:

Authority: 49 U.S.C. 30102, 30103, 30116–30121, 30166; delegation of authority at 49 CFR 1.50.

■ 2. Section 573.6 is amended by revising paragraph (b) to read as follows:

§ 573.6 Defect and noncompliance information report.

* * * * *

(b) Each report shall be submitted not more than 5 working days after a defect in a vehicle or item of equipment has been determined to be safety related, or a noncompliance with a motor vehicle safety standard has been determined to exist. At a minimum, information required by paragraphs (1), (2) and (5) of paragraph (c) of this section shall be submitted in the initial report. The remainder of the information required by paragraph (c) of this section that is not available within the five-day period shall be submitted as it becomes available. Each manufacturer submitting new information relative to a previously submitted report shall refer to the notification campaign number when a number has been assigned by the NHTSA.

* * * * *

PART 577—DEFECT AND NONCOMPLIANCE NOTIFICATION

■ 3. The authority citation for Part 577 of Title 49 continues to read as follows:

Authority: 49 U.S.C. 30102, 30103, 30116–30121, 30166; delegation of authority at 49 CFR 1.50.

■ 4. Section 577.7 is amended by revising paragraph (c)(1) as follows:

§ 577.7 Time and manner of notification.

* * * * *

(c) * * *

(1) Be furnished within a reasonable time after the manufacturer decides that a defect that relates to motor vehicle safety or a noncompliance exists. In the case of defects or noncompliances that present an immediate and substantial threat to motor vehicle safety, the manufacturer shall transmit this notice to dealers and distributors within three business days of its transmittal of the Defect and Noncompliance Information Report under 49 CFR 573.6 to NHTSA, except that when the manufacturer transmits the notice by other than electronic means, the manufacturer shall transmit this notice to dealers and distributors within five business days of its transmittal of the Defect and

Noncompliance Information Report to NHTSA. In all other cases, the notification shall be provided in accordance with the schedule submitted to the agency pursuant to § 573.6(c)(8)(ii), unless that schedule is modified by the Administrator. The Administrator may direct a manufacturer to send the notification to dealers on a specific date if the Administrator finds, after consideration of available information and the views of the manufacturer, that such notification is in the public interest. The factors that the Administrator may consider include, but are not limited to, the severity of the safety risk; the likelihood of occurrence of the defect or noncompliance; the time frame in which the defect or noncompliance may manifest itself; availability of an interim remedial action by the owner; whether a dealer inspection would identify vehicles or items of equipment that contain the defect or noncompliance; and the time frame in which the manufacturer plans to provide the notification and the remedy to its dealers.

* * * * *

§ 577.13 [Amended]

■ 5. Section 577.13 is amended by removing paragraph (c) and redesignating paragraph (d) as paragraph (c).

Issued: June 30, 2005.

Jeffrey W. Runge,

Administrator.

[FR Doc. 05–13249 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126332–5039–02; I.D. 062905A]

Fisheries of the Exclusive Economic Zone Off Alaska; ''Other Flatfish'' in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for ''other flatfish'' in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2005 ''other flatfish'' total allowable catch (TAC) in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 6, 2005, through 2400 hrs, A.l.t., December 31, 2005.

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

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

The 2005 ''other flatfish'' TAC in the BSAI is 4,375 metric tons (mt) as established by the 2005 and 2006 final harvest specifications for groundfish in the BSAI (70 FR 8979, February 24, 2005) and the apportionment from the non-specified reserve of groundfish to ''other flatfish'' in the BSAI, effective July 6, 2005, published in the Rules section of today's **Federal Register**.

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, has determined that the 2005 ''other flatfish'' TAC in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,375 mt, and is setting aside the remaining 1,000 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for ''other flatfish'' in the BSAI.

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

''Other flatfish'' consists of all flatfish species, except for Pacific halibut, flathead sole, Greenland turbot, rock sole, yellowfin sole, arrowtooth flounder, and Alaska plaice.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of ''other flatfish'' in the BSAI.

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

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

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

Dated: June 29, 2005.

Alan D. Risenhoover

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

[FR Doc. 05–13259 Filed 6–30–05; 12:42 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126332–5039–02; I.D. 062905B]

Fisheries of the Exclusive Economic Zone Off Alaska; ''Other Flatfish'' in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the non-specified reserve of groundfish to the ''other flatfish'' initial total allowable catch (ITAC) in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to allow the fishery to continue operating. It is intended to promote the goals and objectives of the fishery management plan for the BSAI.

DATES: Effective July 6, 2005 through 2400 hrs, Alaska local time (A.l.t.), December 31, 2005. Comments must be received at the following address no later than 4:30 p.m., A.l.t., July 15, 2005.

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

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

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

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2005 ITAC of ''other flatfish'' in the BSAI was established as 2,975 metric tons by the 2005 and 2006 final harvest specifications for groundfish in the BSAI (70 FR 8979, February 24, 2005). The Administrator, Alaska Region, NMFS, has determined that the ITAC for ''other flatfish'' in the BSAI needs to be supplemented from the non-specified reserve in order to continue operations.

Therefore, in accordance with § 679.20(b)(3), NMFS apportions 1,400 metric tons from the non-specified reserve of groundfish to the ''other flatfish'' ITAC in the BSAI. This apportionment is consistent with § 679.20(b)(1)(ii) and does not result in overfishing of a target species because the revised ITAC is equal to or less than the specification of the acceptable biological catch (70 FR 8979, February 24, 2005).

''Other flatfish'' consists of all flatfish species, except for Pacific halibut, flathead sole, Greenland turbot, rock sole, yellowfin sole, arrowtooth flounder, and Alaska plaice.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) and 679.20(b)(3)(iii)(A) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the apportionment of the non-specified reserves of groundfish to the ''other flatfish'' fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of June 16, 2005.

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

Under 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES**) until July 15, 2005.

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

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

Dated: June 29, 2005.

Alan D. Risenhoover,

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

[FR Doc. 05–13260 Filed 6–30–05; 12:42 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 70, No. 128
Wednesday, July 6, 2005

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21725; Directorate Identifier 2004–SW–45–AD]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Model 47D1, 47G, 47G–2, 47G–2A, 47G–2A–1, 47G–3, 47G–3B, 47G–3B–1, 47G–3B–2, 47G–3B–2A, 47G–4, 47G–4A, 47G–5, 47G–5A and Coastal Helicopters, Inc. Model OH–13H (Tomcat Mark 5A, 6B, 6C) Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes adopting a new airworthiness directive (AD) for Bell Helicopter Textron (Bell) Model 47D1, 47G, 47G–2, 47G–2A, 47G–2A–1, 47G–3, 47G–3B, 47G–3B–1, 47G–3B–2, 47G–3B–2A, 47G–4, 47G–4A, 47G–5, 47G–5A and Coastal Helicopters, Inc. Model OH–13H (Tomcat Mark 5A, 6B, 6C) helicopters that have a certain scissors assembly or weld assembly scissors bracket installed. The AD would require, within 60 days, determining and recording the total hours time-in-service (TIS) for each Parts Manufacturer Approval (PMA)-produced scissors assembly and weld assembly scissors bracket and would establish a life limit for each affected part. This proposal is prompted by the need to establish a life limit on scissors assemblies and weld assembly scissors brackets produced under PMA No. PQ808SW or installed per Supplemental Type Certificate (STC) No. SH2772SW. The actions specified by the proposed AD are intended to establish a life limit to prevent using a scissors assembly or weld assembly scissors bracket past its life limit, which could result in failure of the part and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before September 6, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically;
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically;
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590;
- Fax: 202–493–2251; or
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may get the service information identified in this proposed AD from Texas Helicopter Co., Inc., PO Box 177686, Irving, Texas 75017, phone (972) 399–1045, fax (972) 790–6397.

You may examine the comments to this proposed AD in the AD docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Marc Belhumeur, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76193–0170, telephone (817) 222–5177, fax (817) 222–5783.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any written data, views, or arguments regarding this proposed AD. Send your comments to the address listed under the caption **ADDRESSES.** Include the docket number ''FAA–2005–21725, Directorate Identifier 2004–SW–45–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed rulemaking. Using the search function of our docket web site, you can find and read the comments to any of our dockets, including the name of the individual who sent or signed the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov.*

Examining the Docket

You may examine the docket that contains the proposed AD, any comments, and other information in person at the Docket Management System (DMS) Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5227) is located at the plaza level of the Department of Transportation NASSIF Building in Room PL–401 at 400 Seventh Street, SW., Washington, DC. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

During FAA surveillance we discovered that an operator did not know the life limit for the weld assembly scissors bracket that was installed on his helicopter. The operator assumed that his assembly had the same life limit as the one built by the original equipment manufacturer; we discovered that when the PMA and STC were granted, the life limit was not established. We propose to correct that oversight by this AD action.

We have reviewed Texas Helicopter Co., Inc. (THC) Service Bulletin No. SB 003, dated December 1, 2002. THC holds STC No. SH2772SW and produces parts under PMA No. PQ808SW. That service bulletin was issued to clarify maintenance inspections and retirement schedules. The service bulletin specifies maintaining Bell Model 47 series and all other helicopters utilizing a 74–150–259–1M or 74–150–259–3M control installation per STC SH2772SW or 74–150–117–13M scissors bracket weld assembly as PMA replacement, in accordance with THC Instructions For Continued Airworthiness (ICA), Doc. No. THC 2002–22 Rev. 0, dated December 1, 2002. Those ICAs refer to STC SH2772SW and contain the mandatory retirement times for the scissors assembly and weld assembly

scissors bracket in the Airworthiness Limitations section.

An unsafe condition is likely to exist or develop on other helicopters of the same type design if the proposed life limits are not followed. Therefore, the proposed AD would require, within 60 days, determining and recording on the component service record or equivalent record the total hours TIS of each affected part. If the hours TIS cannot be determined, replacing the part with an airworthy part with known hours TIS would be required before further flight. The proposed AD would also establish a life limit for scissors assemblies and weld assembly scissors brackets produced by THC PMA No. PQ808SW or installed per THC STC No. SH2772SW.

Based on the manufacturer's production estimate, this proposed AD would affect 350 helicopters of U.S. registry. Determining and recording the initial hours TIS of each scissors assembly would take 1 hour, replacing a scissors assembly would take 2 hours, and replacing a weld assembly scissors bracket would take 8 hours. The average labor rate is $65 per work hour. Required parts would cost approximately $1,300 for the 2 scissors assemblies required per helicopter and $2,500 for each weld assembly scissors bracket required per helicopter. Based on these figures, the total cost impact of the proposed AD on U.S. operators would be $1,580,250, assuming all operators determine and record the hours TIS once, and replace the scissors assembly and weld assembly scissors bracket once.

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. Additionally, 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 draft economic analysis of the estimated costs to comply with this proposed AD. See the DMS to examine the draft economic analysis.

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.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

Bell Helicopter Textron (Bell) and Coastal Helicopters, Inc. (CCI) (formerly Continental Copters, Inc.; and Tom-Cat Helicopters, Inc.): Docket No. FAA–2005–21725; Directorate Identifier 2004–SW–45–AD.

Applicability: The following helicopter models with the referenced Texas Helicopter Co., Inc. (THC) scissors assembly part number (P/N) or weld assembly scissors bracket P/N installed as a Parts Manufacturer Approval (PMA) replacement part or as part of the modification in accordance with Supplemental Type Certificate (STC) No. SH2772SW, certificated in any category.

Model	With scissors assembly P/N	Or weld assembly scissors bracket P/N
(1) Bell Model 47D1, 47G, 47G–2, 47G–2A, 47G–2A–1, 47G–3, 47G–3B, 47G–3B–1, 47G–3B–2, 47G–3B–2A, 47G–4, 47G–4A, 47G–5, 47G–5A; and (2) CHI OH–13H (Tomcat Mark 5A, 6B, or 6C).	74–150–949–9 or 74–150–949–5 or 74–150–249–5M	74–150–117–13M

Compliance: Required as indicated, unless accomplished previously.

To prevent using a scissors assembly or weld assembly scissors bracket past it's life limit, which could result in failure of the part and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 60 days, determine and record on the service record or equivalent record the total hours time-in-service (TIS) of each affected part. If the TIS hours cannot be determined, replace the part with an airworthy part with known hours TIS before further flight.

(b) Thereafter, replace each affected part before it accumulates 5,000 hours TIS.

Note: Texas Helicopter Co., Inc. Service Bulletin No. SB 003, dated December 1, 2002, pertains to the subject of this AD.

(c) This AD establishes a life limit of 5,000 hours TIS for each affected PMA-produced scissors assembly and each affected PMA-produced weld assembly scissors bracket.

(d) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Rotorcraft Certification Office, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

Issued in Fort Worth, Texas, on June 24, 2005.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 05–13237 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21716; Directorate Identifier 2005–NM–080–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F Series Airplanes

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 Boeing Model 767–200, –300, and –300F series airplanes. This proposed AD would require replacing the aileron control override quadrant with a modified unit. This proposed AD is prompted by a report of the seizing of the input override mechanism bearings of the lateral central control actuator on affected airplanes. We are proposing this AD to prevent corrosion of the input override mechanism bearings of the lateral central control actuator, which, in the event of a subsequent jam in the pilot's aileron control system, could result in failure of the aileron override system and consequent reduced lateral controllability of the airplane.

DATES: We must receive comments on this proposed AD by August 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., 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 Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–21716; the directorate identifier for this docket is 2005–NM–080–AD.

FOR FURTHER INFORMATION CONTACT: Douglas Tsuji, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6487; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–21716; Directorate Identifier 2005–NM–080–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System (DMS) receives them.

Discussion

We have received a report of seized bearings in the input override mechanism of the lateral central control actuator on the affected airplanes. The seizing was discovered during an inspection, and it has been attributed to corrosion on the steel bearings in the override mechanism. A failed override system is a latent failure and does not affect normal operation. However, if the pilot's control system were to jam, seized override bearings could keep the aileron control override system from operating properly. This condition, if not corrected, could result in reduced lateral control of the airplane.

Other Relevant Rulemaking

We have previously issued AD 2003–15–03, amendment 39–13245 (68 FR 44197, July 28, 2003), applicable to Boeing Model 767–200, –300, and –300F series airplanes, line numbers (L/Ns) 1 through 836 inclusive. That AD requires replacement of the aileron control override quadrant with a modified unit. That AD prevents corrosion of the input override mechanism bearings of the lateral central control actuator, which, in the event of a subsequent jam in the pilot's aileron control system, could result in the failure of the aileron override system and consequent reduced lateral controllability of the airplane.

Since we issued that AD, we have determined that the same unsafe condition addressed in that AD may exist on certain additional Boeing Model 767–200, –300, and –300F series airplanes. We were advised that L/Ns 837 through 918 were omitted inadvertently from the applicability of AD 2003–15–03 because those airplanes had been excluded inadvertently from the effectivity of Section I.A. of Boeing Alert Service Bulletin 767–27A0175, dated October 25, 2001, which was cited as the appropriate source of service information for the actions in AD 2003–15–03. Therefore, these additional airplanes are also subject to the same unsafe condition addressed in AD 2003–15–03.

Relevant Service Information

We have reviewed Boeing Service Bulletin 767–27A0175, Revision 2, dated August 5, 2004. The procedures in Revision 2 of this service bulletin are essentially the same as the procedures in the original issue of Boeing Alert Service Bulletin 767–27A0175, dated October 25, 2001. These service bulletins describe procedures for replacing the aileron control override quadrant with a modified unit. The

modification involves replacing the existing steel bearings with corrosion-resistant steel bearings. Revision 2 includes an additional procedure for inspecting the cam follower bearing, and replacing it with a CRES bearing if necessary. Revision 2 also increases the applicability of the service bulletin. Accomplishment of the actions specified in Boeing Service Bulletin 767–27A0175, Revision 2, dated August 5, 2004 is intended to adequately address the identified unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in Revision 2 of the service bulletin described previously, except as discussed under ''Difference Between the Proposed AD and Revision 2 of the Service Bulletin.''

Since this proposed AD would expand the applicability of AD 2003–15–03, we have considered a number of factors in determining whether to issue a new AD or to supersede the ''old'' AD. We have considered the entire fleet size that would be affected by superseding AD 2003–15–03 and the consequent workload associated with revising maintenance record entries. In light of this, we have determined that a less burdensome approach is to issue a separate AD applicable only to the additional airplanes. This proposed AD would not supersede AD 2003–15–03; airplanes listed in the applicability of AD 2003–15–03 are required to continue to comply with the requirements of that AD. This proposed AD is a separate AD action, and is applicable only to Boeing Model 767–200, –300, and –300F series airplanes, L/N/s 837 through 918 inclusive; certificated in any category.

Difference Between the Proposed AD and Revision 2 of the Service Bulletin

Although Boeing Service Bulletin 767–27A0175, Revision 2, dated August 5, 2004, includes procedures for inspecting the cam follower bearing, and replacing it with a CRES bearing if necessary, this proposed AD would not include that action. Failure of the cam follower bearing would not prevent the operation of the aileron override mechanism and, therefore, does not pose a safety issue. Although a failed cam follower bearing would not rotate, the bearing would still be able to slide against the cam.

Costs of Compliance

There are about 127 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 45 airplanes of U.S. registry. The proposed actions would take about 10 work hours per airplane, at an average labor rate of $65 per work hour. Required parts would cost about $146 per airplane. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $35,820, or $796 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. 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 FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–21716; Directorate Identifier 2005–NM–080—AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by August 22, 2005.

Affected ADs

(b) This AD is related to AD 2003–15–03, amendment 39–13245 (68 FR 44197, July 28, 2003). AD 2003–15–03 is applicable to Boeing Model 767–200, –300, and –300F series airplanes, certificated in any category, line numbers (L/Ns) 1 through 836 inclusive.

Applicability

(c) This AD applies to Boeing Model 767–200, –300, and —300F series airplanes, certificated in any category, L/Ns 837 through 918 inclusive.

Unsafe Condition

(d) This AD was prompted by a report of the seizing of the input override mechanism bearings of the lateral central control actuator on affected airplanes. We are issuing this AD to prevent corrosion of the input override mechanism bearings of the lateral central control actuator, which, in the event of a subsequent jam in the pilot's aileron control system, could result in failure of the aileron override system and consequent reduced lateral controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 18 months after the effective date of this AD, replace the aileron control override quadrant with a modified unit, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–27A0175, Revision 2, dated August 5, 2004.

Note 1: This AD does not require accomplishing the actions specified by Step 5 of Figure 2 of Boeing Service Bulletin 767–27–A0175, Revision 2.

Part Installation

(g) As of the effective date of this AD, no person may install, on any airplane, an aileron control quadrant override assembly that has not been modified in accordance with the requirements of this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on June 27, 2005.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–13225 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21715; Directorate Identifier 2004–NM–277–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200 and –300 Series Airplanes

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 Boeing Model 767–200 and –300 series airplanes. This proposed AD would require measuring the turnbuckle gap of the inflation cylinder of the off-wing emergency escape slide; corrective action if necessary; and installing a safety device on the inflation cylinder of the off-wing emergency escape slide. This proposed AD is prompted by a report indicating that the inflation trigger cable may inadvertently disconnect from the inflation turnbuckle of the inflation cylinder of the off-wing emergency escape slide, due to incorrect spacing of the cable insertion gap; and additional reports indicating that the pull force increase mechanism on the off-wing charged cylinder assemblies of the escape slide may be inadvertently disengaged. We are proposing this AD to prevent failed deployment of the emergency escape slide during an emergency, which could impede an evacuation and result in injury to passengers or airplane crewmembers, or inadvertent inflation and loss of an emergency escape slide during flight, which could result in possible structural damage to the airplane.

DATES: We must receive comments on this proposed AD by August 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., 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 Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–21715; the directorate identifier for this docket is 2004–NM–277–AD.

FOR FURTHER INFORMATION CONTACT: Sue Rosanske, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6448; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–21715; Directorate Identifier 2004–NM–277–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report indicating that, during a pre-delivery slide deployment check, the inflation trigger cable inadvertently disconnected from the inflation trigger turnbuckle of the inflation cylinder of the off-wing emergency escape slide on a Boeing Model 767–300 series airplane. Further investigation revealed that the cable insertion gap in the turnbuckle (referred to as the ''turnbuckle gap'') of certain inflation cylinders was not crimped per the engineering drawing specification. The gap measured approximately 0.070-inch, instead of the 0.040-inch maximum allowable spacing.

We also received reports that operators have found the pull force increase mechanism (PFIM) on the inflation cylinder of the off-wing emergency escape slide incorrectly set to the ''DISENGAGED'' position on Boeing Model 767–200 and –300 series airplanes. If the PFIM retainer spring is not positioned in the ''ENGAGED'' position, airframe flexing could result in inadvertent actuation of the inflation cylinder and subsequent inflation of the off-wing emergency escape slide.

These conditions, if not corrected, could result in failed deployment of the emergency escape slide during an emergency, which could impede an evacuation and result in injury to passengers or airplane crewmembers, or

inadvertent inflation and loss of an emergency escape slide during flight, which could result in possible structural damage to the airplane.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 767–25–0358, dated September 18, 2003. The service bulletin describes procedures for measuring the turnbuckle gap on the inflation cylinder of the off-wing emergency escape slides (to ensure it meets the maximum allowable spacing limit), and performing corrective actions if necessary. The corrective actions include crimping the gap to the correct spacing, making sure the turnbuckle can rotate around the cable; and replacing the adjustable bottle cable assembly with a new assembly if the turnbuckle cannot rotate.

Special Attention Service Bulletin 767–25–0358 refers to Goodrich Service Bulletin 130104–25–342, dated July 23, 2003, as an additional source of service information.

We have also reviewed Boeing Special Attention Service Bulletin 767–25–0317, dated June 27, 2002. The service bulletin describes procedures for installing a safety device on the PFIM of the inflation cylinder of the off-wing emergency escape slide system and part-marking the inflation cylinder if applicable.

Special Attention Service Bulletin 767–25–0317 refers to Goodrich Service Bulletin 130104–25–328, Revision 1, dated July 23, 2003, as an additional source of service information.

Accomplishing the actions specified in the Boeing service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the Boeing service information described previously, except as discussed under ''Difference Between the Proposed AD and Boeing Service Information.''

Difference Between the Proposed AD and Boeing Service Information

The service bulletins recommend that the actions therein be accomplished ''at the next normally scheduled maintenance period when manpower, materials, and facilities are available.'' We find that such a non-specific compliance time may not ensure that the proposed actions are accomplished in a timely manner. In developing an appropriate compliance time for these actions, we considered the safety implications, operators' normal maintenance schedules, and the compliance time recommended by the airplane manufacturer. In consideration of these items, we have determined that 18 months represents an appropriate interval of time wherein the proposed actions can be accomplished during scheduled maintenance intervals for the majority of affected operators, and an acceptable level of safety can be maintained. This compliance time is consistent with the recommendation of the airplane manufacturer.

Clarification of ''Concurrent'' Service Information

The Boeing service bulletins specify concurrent accomplishment of the Goodrich service bulletins; however, this proposed AD refers to the Goodrich service bulletins as additional sources of service information.

Costs of Compliance

There are about 696 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 297 airplanes of U.S. registry.

The proposed inspection would take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed inspection for U.S. operators is $19,305, or $65 per airplane.

The proposed safety device installation would take about 3 work hours per airplane, at an average labor rate of $65 per work hour. Required parts cost would be minimal. Based on these figures, the estimated cost of the proposed installation for U.S. operators is $57,915, or $195 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. 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 FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–21715; Directorate Identifier 2004–NM–277–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by August 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–200 and –300 series airplanes; certificated in any category; equipped with off-wing

emergency escape slides; as identified in Boeing Special Attention Service Bulletin 767–25–0358, dated September 18, 2003; and Boeing Special Attention Service Bulletin 767–25–0317, dated June 27, 2002.

Unsafe Condition

(d) This AD was prompted by a report indicating that the inflation trigger cable may inadvertently disconnect from the inflation turnbuckle of the inflation cylinder of the off-wing emergency escape slide, due to incorrect spacing of the cable insertion gap; and additional reports indicating that the pull force increase mechanism (PFIM) on the off-wing charged cylinder assemblies of the escape slide may be inadvertently disengaged. We are issuing this AD to prevent failed deployment of the emergency escape slide during an emergency, which could impede an evacuation and result in injury to passengers or airplane crewmembers, or inadvertent inflation and loss of an emergency escape slide during flight, which could result in possible structural damage to the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Measurement/Corrective Action

(f) Within 18 months after the effective date of this AD: Accomplish the actions specified in paragraphs (f)(1) and (f)(2) of this AD.

(1) Measure the turnbuckle gap of the inflation cylinder of the off-wing emergency escape slides to ensure it meets the maximum allowable spacing limit and do applicable corrective actions by doing all the actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–25–0358, dated September 18, 2003. Accomplish any corrective action before further flight in accordance with the service bulletin.

(2) Install a safety device on the PFIM of the inflation cylinder of the off-wing emergency escape slides, and part-mark the inflation cylinder as applicable, by doing all the actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–25–0317, dated June 27, 2002.

Note 1: Goodrich Service Bulletins 130104–25–342, dated July 23, 2003; and 130104–25–328, Revision 1, dated July 23, 2003; may be used as additional sources of service information for accomplishing the actions.

Parts Installation

(g) As of the effective date of this AD, no person may install an inflation cylinder of the off-wing emergency escape slides on any airplane, unless it has been modified according to paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on June 24, 2005.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–13222 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19540; Directorate Identifier 2004–NM–110–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757 Airplanes

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

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: The FAA is revising an earlier proposed airworthiness directive (AD) for certain Boeing Model 757 airplanes. The original NPRM would have required inspections of certain wire bundles in the left and right engine-to-wing aft fairings for discrepancies, and related investigative and corrective actions if necessary. The original NPRM was prompted by a report indicating that a circuit breaker for the fuel shutoff valve tripped due to a wire that chafed against the structure in the flammable leakage zone of the aft fairing, causing a short circuit. This action revises the original NPRM by adding a new requirement for installing back-to-back p-clamps between the wire and hydraulic supply tube at the aft end of the right-hand strut only; and associated re-routing of the wire bundles, if necessary; and adding airplanes to the applicability. This action also clarifies the applicability specified in the original NPRM. We are proposing this supplemental NPRM to prevent chafing between the wire bundle and the structure of the aft fairing, which could result in electrical arcing and subsequent ignition of flammable vapors and possible uncontrollable fire.

DATES: We must receive comments on this supplemental NPRM by August 1, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this supplemental NPRM.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., 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 Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19540; the directorate identifier for this docket is 2004–NM–110–AD.

FOR FURTHER INFORMATION CONTACT: Thomas Thorson, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6508; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this supplemental NPRM. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19540; Directorate Identifier 2004–NM–110–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this supplemental NPRM. We will consider all comments received by the closing date and may amend this supplemental NPRM in light of those comments.

We will post all comments submitted, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this supplemental NPRM. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the

name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level in the Nassif Building at the DOT street address stated in **ADDRESSES.** Comments will be available in the AD docket shortly after the Docket Management System (DMS) receives them.

Discussion

We proposed to amend 14 CFR part 39 with a notice of proposed rulemaking (NPRM) for an AD (the ''original NPRM'') for certain Boeing Model 757 airplanes. The original NPRM was published in the **Federal Register** on November 5, 2004 (69 FR 64513). The original NPRM proposed to require inspections of certain wire bundles in the left and right engine-to-wing aft fairings for discrepancies, and related investigative and corrective actions if necessary. The original NPRM was prompted by a report indicating that a circuit breaker for the fuel shutoff valve tripped due to a wire that chafed against the structure in the flammable leakage zone of the aft fairing, causing a short circuit. Chafing between the wire bundle and the structure of the aft fairing could result in electrical arcing and subsequent ignition of flammable vapors and possible uncontrollable fire.

Comments

We have considered the following comments on the original NPRM.

Support for Original NPRM

One commenter states that it agrees with the actions specified in the original NPRM.

Request To Revise Service Information Referenced in the Original NPRM

Two commenters recommend that, due to additional findings by operators during accomplishment of the service bulletins referenced in the original NPRM, the service bulletins be revised with corrections to address certain discrepancies found in those bulletins. Subsequently Boeing revised the service bulletins. We have reviewed Boeing Alert Service Bulletins 757–28A0073 (for Model 757–200, –200CB, and –200PF series airplanes) and 757–28A0074 (For Model 757–300 series airplanes), both Revision 1, both dated February 24, 2005. (The original NPRM referenced Boeing Alert Service Bulletins 757–28A0073 and 757–28A0074, both dated November 20, 2003, as the appropriate sources of service information for accomplishing the proposed actions.) Revision 1 of the service bulletins adds provisions for installing back-to-back p-clamps between the wire and hydraulic supply tube at the aft end of the right-hand strut only; and performing associated re-routing of the wire bundles, if necessary. We have changed paragraphs (c) and (f) of this supplemental NPRM to reference Revision 1 of the service bulletins.

Request To Clarify Applicability

One commenter, the airplane manufacturer, asks that the applicability, specified in paragraph (c) of the original NPRM, be changed for clarification. The commenter states that the supplemental NPRM should apply only to Model 757 airplanes powered by Rolls-Royce engines, not Pratt & Whitney engines. The commenter adds that, for certain tasks, Revision 1 of the referenced service bulletins adds the last 13 airplanes to the applicability so that the entire 757 fleet powered by Rolls-Royce engines is included.

We agree with the commenter. The original NPRM refers to the effectivity identified in the referenced service bulletins; however, the applicability should be clarified to state that the supplemental NPRM is applicable only to airplanes with Rolls-Royce engines, as identified in Revision 1 of the referenced service bulletins. Paragraph (c) of this supplemental NPRM is changed accordingly. In addition, the total number of airplanes in the worldwide fleet specified in the original NPRM was incorrect. The original NPRM specified a total of 613 airplanes worldwide, but the airplane manufacturer has verified that the correct number of airplanes in the worldwide fleet should have been identified in the original NPRM as 605. Therefore, the correct number of airplanes for the supplemental NPRM is 618 worldwide and 342 of U.S. registry. We have changed those numbers in this supplemental NPRM.

Request To Add Repetitive Inspections of the Engine-to-Wing Aft Fairings

One commenter asks that operators be allowed to perform repetitive detailed visual inspections of the wire bundles in the engine-to-wing aft fairings instead of accomplishing the modification. The commenter supports its request by its inspection with minimal findings. The commenter adds that, in case of findings, the modification specified in the referenced service information should be performed as a terminating action. The commenter asks that the compliance time for the inspections be at intervals between 24 and 60 months. The commenter notes that the airplane manufacturer developed a maintenance schedule with repetitive inspections for its Model 757 special freighter airplanes at a C-check or 24 months, or 6,000 flight hours or 3,000 flight cycles.

We do not agree with the commenter. The configuration of several airplanes in the 757 fleet has been identified as having the potential to develop the unsafe condition specified in the original NPRM. The modification will ensure that the unsafe condition of chafing between the wire bundle and the structure of the aft fairing will not exist on additional airplanes in the fleet. However, under the provisions of paragraph (g) of this AD, affected operators may request approval of an alternative method of compliance (AMOC) for the relevant requirements. The request must include data substantiating that the AMOC would provide an acceptable level of safety. We have not changed the supplemental NPRM in this regard.

Request To Allow Compliance With Referenced Service Information

One commenter states that some pylon configurations already have the correct wire routing and need only a bracket with part number P/N 313N5033–134 installed in order to comply with the modification specified in the service information referenced in the original NPRM. The commenter does not provide any request.

We acknowledge the commenter's concern and offer the following response. The referenced service information is sufficiently comprehensive to allow completion of the corrective actions for all delivered airplane configurations, including the recommended provisional work instructions, which will reduce the quantity of AMOC approval requests by operators. We have approved Revision 1 of the service bulletins, as specified previously, and revised the original NPRM to refer to Revision 1. We hope this change will address the commenter's concern.

Request To Address Technical Disparity

The same commenter suggests that we address a technical disparity between the service information referenced in the original NPRM and aircraft drawings 288N3121 and 288N3122. The commenter notes that Step 3 of Figure 2 of the original issue of Service Bulletin 757–28A0073 specifies inspection and possible replacement of caterpillar grommet P/N BACG20Z–E on the pylon bulkhead at power plant station 278. The commenter adds that this pylon bulkhead is a flanged hole, and the drawings specify the use of caterpillar grommet P/N BACG20AD for the flanged holes. The commenter adds that it has verified that P/N BACG20Z–E will not fit on the pylon bulkhead at power plant station 278.

We acknowledge the commenter's concern. P/N BACG20Z–E has been verified by the manufacturer to be the P/N installed during production, and installation of this part per the referenced service bulletin has been validated in-service. The installation steps have been clarified in Revision 1 of the referenced service bulletin, and the manufacturer has verified that the Illustrated Parts Catalog reflects the same part number specified in the service bulletin. In addition, the referenced drawings authorize installation of either P/N BACG20Z–E or P/N BACG20AD by general note. We have received data substantiating that the commenter's issues have been addressed through coordination with the manufacturer. We have not changed the supplemental NPRM in this regard.

Request for Approval of Future Service Bulletin Revisions

One commenter asks that a statement be included in the supplemental NPRM allowing the use of later FAA-approved revisions of the referenced service information. The commenter states that this will allow operators to use FAA-approved revisions without requesting an AMOC.

We do not agree with the commenter. We cannot accept as-yet unpublished service documents for compliance with the requirements of an AD. Referring to an unavailable service bulletin in an AD to allow operators to use later revisions of the referenced documents (issued after publication of the AD) violates Office of the Federal Register regulations for approving materials that are incorporated by reference. It should be noted that when we approve AD-related service information, an AMOC is usually issued to the manufacturer to authorize use of the new bulletin, thus precluding the need for operators to submit AMOC requests. We have not changed the supplemental NPRM in this regard.

FAA's Determination and Proposed Requirements of the Supplemental NPRM

The changes discussed above expand the scope of the original NPRM; therefore, we have determined that it is necessary to reopen the comment period to provide additional opportunity for public comment on this supplemental NPRM.

Costs of Compliance

There are about 618 airplanes of the affected design in the worldwide fleet. This supplemental NPRM would affect about 342 airplanes of U.S. registry. The proposed actions would take between 16 and 44 work hours per airplane, depending on airplane configuration, at an average labor rate of $65 per work hour. Required parts would cost about $600 per airplane. Based on these figures, the estimated cost of this supplemental NPRM on U.S. operators is between $560,880 and $1,183,320, or between $1,640 and $3,460 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 supplemental NPRM. 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 FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19540; Directorate Identifier 2004–NM–110–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by August 1, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Model 757–200, –200PF, –200CB, and –300 series airplanes; certificated in any category; equipped with Rolls-Royce engines; as identified in Boeing Alert Service Bulletins 757–28A0073 and 757–28A0074, both Revision 1, both dated February 24, 2005.

Unsafe Condition

(d) This AD was prompted by a report indicating that a circuit breaker for the fuel shutoff valve tripped due to a wire that chafed against the structure in the flammable leakage zone of the aft fairing, causing a short circuit. We are issuing this AD to prevent chafing between the wire bundle and the structure of the aft fairing, which could result in electrical arcing and subsequent ignition of flammable vapors and possible uncontrollable fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

One-Time Inspections/Related Investigative and Corrective Actions

(f) Within 60 months after the effective date of this AD, do the actions required by paragraphs (f)(1) and (f)(2) of this AD.

(1) Accomplish the detailed inspections for discrepancies of the wire bundles in the left and right engine-to-wing aft fairings, and applicable and related investigative and corrective actions if necessary, as applicable, by doing all the actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletins 757–28A0073 (for Model 757–200, –200CB, and –200PF series airplanes) and 757–28A0074 (for Model 757–300 series airplanes), both dated November 20, 2003; or Revision 1, both dated February 24, 2005, as applicable. Accomplish any related investigative and corrective actions before further flight in accordance with the applicable service bulletin.

(2) Install back-to-back p-clamps between the wire and hydraulic supply tube at the aft end of the right-hand strut only; and re-route the wire bundles, if necessary, by doing all the applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 757–28A0073 or 757–28A0074, both Revision 1, both dated February 24, 2005; as applicable.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on June 27, 2005.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–20699; Airspace Docket No. 04–ASO–19]

RIN 2120–AA66

Proposed Establishment of Area Navigation Instrument Flight Rules Terminal Transition Routes (RITTR); Cincinnati, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish four Area Navigation Instrument Flight Rules Terminal Transition Routes (RITTR) in the Cincinnati, OH, terminal area. RITTRs are low altitude Air Traffic Service routes, based on area navigation (RNAV), for use by aircraft having instrument flight rules (IFR)-approved Global Positioning (GPS)/Global Navigation Satellite System (GNSS) equipment. The purpose of RITTR is to expedite the handling of IFR overflight aircraft through busy terminal airspace areas. The FAA is proposing this action to enhance the safe and efficient use of the navigable airspace in the Cincinnati, OH, terminal area.

DATES: Comments must be received on or before August 22, 2005.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify FAA Docket No. FAA–2005–20699 and Airspace Docket No. 04–ASO–19, at the beginning of your comments. You may also submit comments through the Internet at *http://dms.dot.gov.*

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2005–20699 and Airspace Docket No. 04–ASO–19) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://dms.dot.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2005–20699 and Airspace Docket No. 04–ASO–19.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the Internet at *http://dms.dot.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov,* or the **Federal Register**'s Web page at *http://www.gpoaccess.gov/fr/index.html.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337.

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

Background

In March 2000, the Aircraft Owners and Pilots Association (AOPA) requested that the FAA take action to develop and chart IFR RNAV airways for use by aircraft having IFR-approved GPS equipment. Due to the density of air traffic in some areas, en route aircraft are not always able to fly on the existing Federal airway structure when transiting congested terminal airspace. In such cases, air traffic control (ATC) is often required to provide radar vectors to reroute aircraft transitioning through the area to avoid the heavy flow of arriving and departing aircraft. AOPA stated that RNAV airways should facilitate more direct routings than are possible with the current Federal airway system and should provide pilots with easier access through terminal airspace. In addition, AOPA encouraged the expanded use of RNAV airways in the National Airspace System (NAS).

In response to the AOPA request, a cooperative effort was launched involving the FAA, AOPA, and the Government/Industry Aeronautical Charting Forum. This effort began with the development of RNAV routes to provide more direct routing for en route IFR aircraft to transition through busy terminal airspace areas. One step in this effort was the development of IFR transition routes to expedite the handling of IFR overflight traffic through the Cincinnati, OH, terminal area. Nine Cincinnati IFR transition routes are currently published in the East Central U.S. volume of the Airport/Facility Directory (A/FD). The RITTRs proposed in this notice would replace the nine Cincinnati transition routes currently published in the A/FD. The proposed RITTRs would be depicted on the appropriate low altitude IFR en route charts in lieu of publication in the A/FD.

RITTR Objective

The objective of the RITTR program is to enhance the expeditious movement of suitably equipped IFR aircraft around or through congested terminal airspace using IFR-approved RNAV equipment. RITTRs would enhance the ability of pilots to navigate through the area without reliance on ground-based navigation aids or ATC radar vectors. To facilitate this goal, and reduce ATC workload, RITTR routes would be designed based on the tracks routinely used by ATC to vector aircraft through or around the affected terminal area. Additionally, the routes begin and terminate at fixes or Navigational Aids located along existing VOR Federal airways in order to provide connectivity with the low-altitude en route structure. Initially, only GNSS-equipped aircraft capable of filing flight plan equipment suffix ''/G'' would be able to use RITTRs.

RITTR Identification and Charting

RITTRs are identified by the letter ''T'' prefix, followed by a three digit number. The ''T'' prefix is one of several International Civil Aviation Organization (ICAO) designators used to identify domestic RNAV routes. ICAO has allocated to the FAA the letter ''T'' prefix along with the number block 200 to 500 for this purpose.

RITTRs would be depicted in blue on the appropriate IFR en route low altitude chart(s). Each route depiction would include a GNSS Minimum Enroute Altitude (MEA) to ensure obstacle clearance and communications reception.

The FAA plans to publish information about the RITTR program in the Aeronautical Information Manual (AIM) and the Notices to Airmen Publication (NTAP). In addition, a Charting Notice would be issued by the FAA's National Aeronautical Charting Office to explain the charting changes associated with the RITTRs.

Related Rulemaking

On April 8, 2003, the FAA published a final rule, request for comment, entitled Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes, and Reporting Points, in the **Federal Register** (68 FR 16943). This rule adopted certain amendments proposed in Notice No. 02–20, RNAV and Miscellaneous Amendments. This rule revised and adopted several definitions in FAA regulations, including Air Traffic Service Routes, to be in concert with ICAO definitions. Additionally, the final rule reorganized the structure of FAA regulations concerning the designation of Class A, B, C, D, and E airspace areas, airways, routes, and reporting points. The rule was designed to facilitate the establishment of RNAV routes in the NAS for use by aircraft with advanced navigation system capabilities.

The Proposal

The FAA is proposing to amend Title 14 Code of Federal Regulations (14 CFR) part 71 to establish four RITTRs in the Cincinnati, OH, terminal area. The routes would be designated T–212, T–213, T–215, and T–217, and would be depicted on the appropriate IFR Enroute Low Altitude charts. RITTRs are low altitude Air Traffic Service routes, similar to VOR Federal airways, but based on GNSS navigation. RNAV-capable aircraft filing flight plan equipment suffix ''/G'' may file for these routes.

If approved, the RITTR routes proposed in this notice would replace the nine Cincinnati IFR Transition Routes that are currently published in the A/FD.

This proposed action would enhance safety, and facilitate more flexible and efficient use of the navigable airspace for en route IFR aircraft transitioning through the Cincinnati, OH, terminal area.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

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

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 6011—Area Navigation Routes

* * * * *

T–212 HEDEN, OH to Midwest, OH [New]

HEDEN, OH	WP	(Lat. 39°16′45″ N., long. 84°02′02″ W.)
Midwest, OH (MXQ)	VOR/DME	(Lat. 39°25′47″ N., long. 83°48′04″ W.)

* * * * * * *

T–213 Louisville, KY to Richmond, IN [New]

Louisville, KY (IIU)	VORTAC	(Lat. 38°06′13″ N., long. 85°34′39″ W.)
GAMKE, IN	WP	(Lat. 38°47′02″ N., long. 85°15′14″ W.)
MILAN, IN	WP	(Lat. 39°21′22″ N., long. 85°19′01″ W.)
Richmond, IN (RID)	VORTAC	(Lat. 39°45′18″ N., long. 84°50′20″ W.)

* * * * * * *

T–215 Lexington, KY to GAMKE, IN [New]

Lexington, KY (HYK)	VORTAC	(Lat. 37°57′59″ N., long. 84°28′21″ W.)
GAMKE, IN	WP	(Lat. 38°47′02″ N., long. 85°15′14″ W.)

* * * * * * *

T–217 Lexington, KY to Springfield, OH [New]

Lexington, KY (HYK)	VORTAC	(Lat. 37°57′59″ N., long. 84°28′21″ W.)
BOSTR, OH	WP	(Lat. 38°53′08″ N., long. 84°04′58″ W.)
HEDEN, OH	WP	(Lat. 39°16′45″ N., long. 84°02′02″ W.)
Springfield, OH (SGH)	VOR/DME	(Lat. 39°50′12″ N., long. 83°50′42″ W.)

* * * * *

Issued in Washington, DC, on June 28, 2005.

Edith V. Parish,

Acting Manager, Airspace and Rules.

[FR Doc. 05–13266 Filed 7–5–05; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

DEPARTMENT OF THE INTERIOR

15 CFR Part 303

[Docket No. 050613157–5157–01]

RIN 0625–AA68

Office of Insular Affairs; Changes in the Insular Possessions Watch, Watch Movement and Jewelry Programs

AGENCIES: Import Administration, International Trade Administration, Department of Commerce; Office of Insular Affairs, Department of the Interior.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Departments of Commerce and the Interior (the Departments) propose amending their regulations governing watch duty-exemption allocations and the watch and jewelry duty-refund benefits for producers in the United States insular possessions (the U.S. Virgin Islands, Guam, American Samoa and the Commonwealth of the Northern Mariana Islands). The proposed rule would amend the regulations by making technical changes required by passage of the Miscellaneous Trade and Technical Corrections Act of 2004; extending the duty refund benefits to include the value of usual and customary health insurance, life insurance and pension benefits; raising the ceiling on the amount of jewelry that qualifies for the duty refund benefit; allowing new insular jewelry producers to assemble jewelry and have such jewelry treated as an article of the insular possessions for up to 18 months after the jewelry company commences assembly operations; allowing duty refund certificate holders to secure a duty refund on any articles that are imported into the customs territory of the United States by the certificate holder duty paid; providing a more comprehensive definition of ''unit;'' adjusting the amount of watch repairs that are eligible for the duty refund; providing compensation to insular watch producers if tariffs on watches and watch movements are reduced; and clarifying which wages are eligible for purposes of determining the duty refund and identifying which records are needed for the audit.

DATES: Written comments must be received on or before August 5, 2005.

ADDRESSES: Address written comments to Faye Robinson, Acting Director, Statutory Import Programs Staff, FCB, Suite 4100W, U.S. Department of Commerce, 14th and Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Faye Robinson, (202) 482–3526, same address as above.

SUPPLEMENTARY INFORMATION: The insular possessions watch industry provision in Section 110 of Public Law 97–446 (96 Stat. 2331) (1983), as amended by Section 602 of Public Law 103–465 (108 Stat. 4991) (1994); additional U.S. Note 5 to chapter 91 of the Harmonized Tariff Schedule of the United States (''HTSUS''), as amended by Public Law 94–241 (90 Stat. 263) (1976) requires the Secretary of Commerce and the Secretary of the Interior (''the Secretaries''), acting jointly, to establish a limit on the quantity of watches and watch movements that may be entered free of duty during each calendar year. The law also requires the Secretaries to establish the shares of this limited quantity which may be entered from the Virgin Islands, Guam, American Samoa and the Commonwealth of the Northern Mariana Islands (''CNMI''). After the Departments have verified the data submitted on the annual application (Form ITA–334P), the producers' duty-exemption allocations are calculated from the territorial share in accordance with 15 CFR 303.14 and each producer is issued a duty-exemption license. The law further requires the Secretaries to issue duty-refund certificates to each territorial watch and watch movement producer based on the company's duty-free shipments and creditable wages paid during the previous calendar year.

Public Law 106–36 (113 Stat. 127) (1999) authorizes the issuance of a duty-

refund certificate to each territorial jewelry producer for any article of jewelry provided for in heading 7113 of the HTSUS which is the product of any such territory. The value of the certificate is based on creditable wages paid and duty-free units shipped into the United States during the previous calendar year. Although the law specifically mentions the U.S. Virgin Islands, Guam and American Samoa, the issuance of the duty-refund certificate would also apply to the CNMI due to the Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America (Pub. L. 94–241), which states that goods from the CNMI are entitled to the same tariff treatment as imports from Guam. *See also* 19 CFR 7.2(a). In order to be considered a product of such territories, the jewelry must meet the U.S. Customs Service substantial transformation requirements (the jewelry must become a new and different article of commerce as a result of production or manufacture performed in the territory). To receive duty-free treatment, the jewelry must also satisfy the requirements of General Note 3(a)(iv) of the HTSUS and applicable Customs Regulations (19 CFR 7.3).

Proposed Amendments

Section 1562 of Public Law 108–429 (2004) amended Public Law 97–446, Public Law 103–465 and Public Law 106–36. The proposed rule would make the necessary technical changes to reflect the new authority for the insular watch and jewelry programs. Changes would be made to Authority, 15 CFR 303.1(a), 303.2(a)(1), 303.12(c)(2), 303.15(a), and 303.16(a)(1).

Pursuant to Public Law 108–429, we propose changing the definitions of ''creditable wages'' by amending 15 CFR 303.2(a)(13) and 15 CFR 303.16(a)(9) to include the value of usual and customary health insurance, life insurance and pension benefits. We also propose changing the definition of creditable wages to include the difference between the duty rates for watches and watch movements that were in effect on January 1, 2001 and any new lower duty rates that takes place in the future. This provision in Public Law 108–429 would only be applicable if there were duty reductions on watches and watch movements. We further propose reapportioning the percentage of watch and watch movement repair wages that will be creditable towards the duty-refund. We propose raising the percentage of repairs that are eligible for benefits in response to a request we received which pointed out that repair work is very labor intensive and more time consuming than regular watch assembly. The producer requesting the change explained that there is a shortage of watchmakers in the United States and therefore companies are starting to send watches abroad to be repaired. The proposed change is intended to capture part of this market because there are currently experienced watchmakers in the U.S. Virgin Islands who are unemployed and looking for work. Increasing employment and providing meaningful work for permanent residents of the insular possessions is the cornerstone of the watch and jewelry programs.

In an effort to further clarify which wages are eligible for the duty refund, we propose adding a new Section 303.2(a)(14); redesignating the current Sections 303.2(a)(14) through (a)(16) as Sections 303.2(a)(15) through (a)(17), respectively; adding a new Section 303.16(a)(10); and redesignating current Sections 303.16(a)(10) and 303.16(a)(11) as Sections 303.16(a)(11) and 303.16(a)(12), respectively, to further clarify which wages are not creditable. We also propose, as requested by a producer, to clarify the term ''year'' in current Sections 303.2(a)(16) and 303.16(a)(11) to clear up any possible confusion.

We also propose amending Sections 303.2(b)(4), 303.2(b)(5), 303.12(c)(1), 303.16(b)(2), 303.16(b)(3), and 303.19(c)(1). These sections currently allow the duty refund certificate holder a refund of duties on watches, watch movements and parts therefor, except discrete watch cases and any article containing a material which is the product of a country to which column 2 rates of duty apply. Pursuant to Public Law 108–429, we propose allowing the refund of duties on any articles that are imported into the customs territory of the United States duty paid by the certificate holder unless the articles contain a material to which column 2 rates of duty apply.

Further, we propose amending Sections 303.20(b)(ii), (b)(iii) and (b)(iv) by raising the ceiling on the number of duty-free units of jewelry entering the United States each year that qualify for duty refund benefits under the program. Currently, a maximum of 750,000 units of jewelry a year qualifies for duty refund benefits. The proposed change, pursuant to Public Law 108–429, would allow a maximum of 10,000,000 units a year to qualify for the duty refund benefit as long as the limit on available program funds is not exceeded and all the units are entered free of duty in accordance with the regulations.

Another proposed change, pursuant to Public Law 108–429, would amend Section 303.20(a)(2) to allow new program jewelry producers up to an18 month exemption from meeting the substantial transformation requirements and the other provisions normally required for duty-free entry into the United States. Starting on the day the new producer commences jewelry manufacturing or jewelry assembly, the jewelry producer would have up to 18 months for any article of jewelry provided for in heading 7113, HTSUS, that is assembled in an insular possession, to be treated as a product of the insular possession. This proposed change is intended to allow a new producer adequate time to train employees in the skills necessary to meet the substantial transformation requirements.

The proposed rule would also amend Section 303.16(a)(7) by expanding the definition of a ''unit'' of jewelry so that the term unit more accurately represents the way some heading 7113, HTSUS, jewelry is sold in the industry.

The proposed rule would also amend Sections 303.5(b)(5) and 303.17(b)(4) to clarify that all records pertaining to shipment documents and proof of residency, as required, must be maintained and made available for the verification of data. We also propose adding new Sections 303.5(b)(8) and 303.17(b)(9) which would require the collection and maintenance of information pertaining to health insurance, life insurance and pension benefits for each employee in order that the benefit information can be verified and the duty refunds, based on the verified data, be issued in accordance with Public Law 108–429. Further, in accordance with Public Law 108–429, we proposed adding a new Section 303.5(b)(9) in the event that the HTSUS tariffs on watches and watch movements are reduced. If such tariffs were reduced, we would need records pertaining to the annual value and quantities of the duty-free shipments of watches and watch movements into the United States by individual HTSUS tariff numbers along with information about components contained in the watches and watch movements. This information would be collected on an annual basis.

Administrative Law Requirements

Regulatory Flexibility Act. In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Chief Counsel for Regulation at the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the

proposed rule, if promulgated as final, would not have a significant economic impact on a substantial number of small entities. There are currently four insular watch program companies and four insular program jewelry companies. All these companies would be considered small entities. The majority of proposed changes are being made to reflect the new statutory requirements contained in Public Law 108–429. The changes include extending the watch and jewelry programs to the year 2015; extending the duty refund benefit to include the value of usual and customary health insurance, life insurance and pension benefits; raising the ceiling on the number of units of jewelry that qualifies for the duty refund benefit; allowing new insular jewelry producers to assemble jewelry and have the jewelry be treated as an article of the insular possessions for up to 18 months after the jewelry company commences assembly operations; allowing duty refund certificate holders to secure a refund of duties on any articles that entered the customs territory of the United States with the duty having been paid by the certificate holder; providing a more comprehensive definition of ''unit;'' adjusting the amount of watch repairs that are eligible for the duty refund; providing compensation to insular watch producers if tariffs on watches and watch movements are reduced; and clarifying which wages are eligible for the duty refund and which records must be kept for audit purposes. Adoption of this proposed rule would afford producers greater flexibility in dealing with market realities, thereby giving them the ability to take further advantage of opportunities that are suited to their particular needs without losing the duty refund benefit. Also, increasing the ceiling on the amount of jewelry units eligible for the duty refund will be beneficial to the program because it will allow findings companies (re: companies that produce jewelry and jewelry components such as earring backs, links, etc.) to take advantage of the program, thereby increasing employment. Findings companies normally produce millions of units a year and without this ceiling increase, findings companies would not consider moving to the insular possessions. The proposed changes would have an overall positive economic benefit to watch and jewelry producers by providing greater program benefits which will be a further incentive for new companies to locate in the insular possessions. In addition, the proposed changes are intended to make companies more competitive with the expectation that this will result in increased sales and employment.

The proposed changes would require companies to provide information on their employees' health insurance, life insurance and pension benefits for the annual application (form ITA–334P) and have such information available for the annual audit. Also, if tariffs on watches and watch movements are reduced, then companies would have to provide annual aggregate information by individual HTSUS watch tariff numbers for the following components contained therein: The quantity and value of watch cases, the quantity of movements, the quantity and value of each type of strap, bracelet or band, and the quantity and value of batteries shipped free of duty into the United States. If discrete watch movements are shipped free of duty into the United States, then the companies would need to submit the annual aggregate quantity by individual HTSUS movement tariff numbers and the quantity and value of the batteries, if included in the movement. This information would normally be part of the each company's records. Consequently, a producer would merely need to provide the data on fringe benefits on the annual application and to retain the records for review during the audit. We estimate that the cost of supplying the documentation as needed would be no more than $40 a year. The reporting and recordkeeping requirements in this proposed rule would increase the total burden hours per company by approximately two hours a year to account for retrieval of the information for the audit and inclusion of the aggregate data on the annual application. Therefore, there would be little economic impact, because this information would be part of a company's normal recordkeeping.

This proposed rule would not have a significant economic impact on a substantial number of small entities. Although the rule effects a significant number of small entities, it would only impose minimal economic impact. The rule would only increase reporting or record keeping requirements by approximately 2 hours per year per company. Further, the proposed changes will not duplicate, overlap or conflict with other laws or regulations. Finally, the proposed changes would result in an overall positive economic benefit to the watch and jewelry producers. Consequently, these proposed changes are not expected to meet the RFA criteria of having a ''significant'' economic effect on a ''substantial number'' of small entities, as stated in 5 U.S.C. 603 *et seq.* Therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act. This proposed rulemaking contains revised collection of information requirements that have been submitted to the Office of Management and Budget (OMB) for review and approval. The rule would require further paperwork to be collected due to the passage of Public Law 108–429 which extends the duty refund benefit to include the value of usual and customary health insurance, life insurance and pension benefits and provides compensation to insular watch producers if tariffs on watches and watch movements are reduced. The documentation for the health insurance, life insurance and pension benefits, would be required for the annual audit of information and would be needed to complete the annual application, form ITA–334P, which will be revised. Also, if tariffs on watches and watch movements were reduced, then companies would have to provide annual aggregate information by individual HTSUS watch tariff numbers for the following components contained therein, *i.e.*, the quantity and value of watch cases, the quantity of movements, the quantity and value of each type of strap, bracelet or band, and the quantity and value of batteries shipped free of duty into the United States. If discrete watch movements are shipped free of duty into the United States, producers would have to provide the annual aggregate quantity of movements by individual HTSUS tariff numbers, and the value and quantity of the batteries, if included in the movement. This information would be required for the annual audit of information and would be needed to complete the annual application, form ITA–334P, if tariff on watches and watch movements were reduced. We estimate the burden to be no more than two hours a year to include the information on form ITA–334P and have it available for the audit. Collection activities are currently approved by the Office of Management and Budget under control numbers 0625–0040. Public comment is sought regarding: whether the proposed collection of information requirements are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and the ways to minimize the burden of the collection of information, including the use of automated collection techniques or other forms of

information technology. Send comments regarding the burden estimate or any other aspect of the collection of information to U.S. Department of Commerce, ITA Information Officer, Washington, DC 20230 and the Office of Information and Regulations Officer, Office of Management and Budget, Washington, DC 20503 (Att: OMB Desk Officer), or email *David_Rostker@omb.eop.gov.*

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with the collection of information unless it displays a currently valid OMB Control Number.

E.O. 12866. It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

List of Subjects in 15 CFR Part 303

Administrative practice and procedure, American Samoa, Customs duties and inspection, Guam, Imports, Marketing quotas, Northern Mariana Islands, Reporting and recordkeeping requirements, Virgin Islands, Watches and jewelry.

For reasons set forth above, the Departments propose to amend 15 CFR Part 303 as follows:

PART 303—WATCHES, WATCH MOVEMENTS AND JEWELRY PROGRAMS

1. The authority citation for 15 CFR Part 303 is revised to read as follows:

Authority: Pub. L. 97–446, 96 Stat. 2331 (19 U.S.C. 1202, note); Pub. L. 103–465, 108 Stat. 4991; Pub. L. 94–241, 90 Stat. 263 (48 U.S.C. 1681, note); Pub. L. 106–36, 113 Stat. 167; Pub. L. 108–429, 118 Stat. 2582.

2. The first sentence of § 303.1(a) is amended by removing ''and amended by Public Law 103–465, enacted 8 December 1994.'' and adding ''amended by Public Law 103–465, enacted 8 December 1994 and amended by Public Law 108–429 enacted 3 December 2004.'' in its place.

3. Section 303.2 is amended as follows:

A. Section 303.2(a)(1) is amended by removing ''.'' at the end of the sentence and adding '', Public Law 108–429, enacted on 3 December 2004, 118 Stat. 2582.'' in its place.

B. Section 303.2(a)(13) is revised as set forth below.

C. In Section 303.2, paragraphs (a)(14) through (a)(16) are redesignated as paragraphs (a)(15) through (a)(17), and a new paragraph (a)(14) is added as set forth below.

D. Newly designated paragraph (a)(17) is amended by removing ''(*i.e.*, be physically present for at least 183 days per year)'' and adding ''(*i.e.*, be physically present for at least 183 days within a continuous 365 day period)'' in its place.

E. The heading and the first sentence of paragraph (b)(4) are revised as set forth below.

F. The heading of paragraph (b)(5) is revised as set forth below.

§ 303.2 Definitions and forms.

(a) * * *

(13) Creditable wages, creditable fringe benefits and creditable duty differentials eligible for the duty refund benefit include, but are not limited to, the following:

(i) Wages up to an amount equal to 65 percent of the contribution and benefit base for Social Security, as defined in the Social Security Act for the year in which wages were earned, paid to permanent residents of the insular possessions employed in a firm's 91/5 watch and watch movement program.

(A) Wages paid for the repair of watches up to an amount equal to 85 percent of the firm's total creditable wages.

(B) Wages paid to watch and watch movement assembly workers involved in the complete assembly of watches and watch movements which have entered the United States duty-free and have complied with the laws and regulations governing the program.

(C) Wages paid to watch and watch movement assembly workers involved in the complete assembly of watches, excluding the movement, only in situations where the desired movement can not be purchased unassembled and the producer has documentation establishing this.

(D) Wages paid to those persons engaged in the day-to-day assembly operations on the premises of the company office, wages paid to administrative employees working on the premises of the company office, wages paid to security employees and wages paid to servicing and maintenance employees if these services are integral to the assembly and manufacturing operations and the employees are working on the premises of the company office.

(E) Wages paid to persons engaged in both creditable and non-creditable assembly and repair operations may be credited proportionally provided the firm maintains production, shipping and payroll records adequate for the Departments' verification of the creditable portion.

(F) Wages paid to new permanent residents who have met the requirements of permanent residency in accordance with the Departments' regulations, along with meeting all other creditable wage requirements of the regulations, which must be documented and verified to the satisfaction of the Secretaries.

(ii) The combined creditable amount of individual health and life insurance per year, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, may not exceed 100 percent of the ''weighted average'' yearly federal employee health insurance, which is calculated from the individual health plans weighted by the number of individual contracts in each plan. The yearly amount is calculated by the Office of Personnel Management and includes the ''weighted average'' of all individual health insurance costs for federal employees throughout the United States. The maximum life insurance allowed within this combined amount is $50,000 for each employee.

(A) The combined creditable amount of family health and life insurance per year, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, may not exceed 120 percent of the ''weighted average'' yearly federal employee health insurance, which is calculated from the family health plans weighted by the number of family contracts in each plan. The yearly amount is calculated by the Office of Personnel Management and includes the ''weighted average'' of all family health insurance costs for federal employees throughout the United States. The maximum life insurance allowed within this combined amount is $50,000 for each employee.

(B) The creditable pension benefit, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, is up to 3 percent of the employee's wages unless the employee's wages exceed the maximum annual creditable wage allowed under the program (*see* paragraph (a)(13)(i) of this section). An employee earning more than the maximum creditable wage allowed under the program will be eligible for only 3 percent of the maximum creditable wage.

(iii) If tariffs on watches and watch movements are reduced, then companies would be required to provide the annual aggregate data by individual HTSUS watch tariff numbers for the following components contained therein: The quantity and value of watch cases, the quantity of movements, the quantity and value of each type of strap, bracelet or band, and the quantity and value of batteries shipped free of

duty into the United States. If discrete watch movements are shipped free of duty into the United States, then the annual aggregate quantity by individual HTSUS movement tariff numbers would also be required along with the value of each battery if it is contained within. These data would be used to calculate the annual duty rate before each HTSUS tariff reduction, and the annual duty rate after the HTSUS tariff reduction. The amount of the difference would be creditable toward the duty refund. The tariff information would only be collected and used in the calculation of the annual duty-refund certificate and would not be used in the calculation of the mid-year duty-refund.

(14) Non-creditable wages and non-creditable fringe benefits. Wages ineligible for the duty refund benefit wages include, but are not limited to, the following:

(i) Wages over 65 percent of the contribution and benefit base for Social Security, as defined in the Social Security Act for the year in which wages were earned paid to permanent residents of the territories employed in a firm's 91/5 watch and watch movement program.

(A) Wages paid for the repair of watches in an amount over 85 percent of the firm's total creditable wages.

(B) Wages paid for the assembly of watches and watch movements which are shipped outside the customs territory of the United States; wages paid for the assembly of watches and watch movements that do not meet the regulatory assembly requirements; or wages paid for the assembly of watches or watch movements that contain HTSUS column 2 components.

(C) Wages paid for the complete assembly of watches, excluding the movement, when the desired movement can be purchased unassembled, if the producer does not have adequate documentation, demonstrating to the satisfaction of the Secretaries, that the movement could not be purchased unassembled whether or not it is entering the United States.

(D) Wages paid to persons not engaged in the day-to-day assembly operations on the premises of the company office; wages paid to any outside consultants; wages paid outside the office personnel, including but not limited to, lawyers, gardeners, construction workers, and accountants; wages paid to employees not working on the premises of the company office; and wages paid to employees who do not qualify as permanent residents in accordance with the Departments' regulations.

(E) Wages paid to persons engaged in both creditable and non-creditable assembly and repair operations if the producer does not maintain production, shipping and payroll records adequate for the Departments' verification of the creditable portion.

(ii) Any costs, for the year in which the wages were paid, of the combined creditable amount of individual health and life insurance for employees over 100 percent of the ''weighted average'' yearly individual health insurance costs for all federal employees. The cost of any life insurance over the $50,000 limit for each employee.

(A) Any costs, for the year in which the wages were paid, of the combined creditable amount of family health and life insurance for employees over 120 percent of the ''weighted average'' yearly family health insurance costs for all federal employee. The cost of any life insurance over the $50,000 limit for each employee.

(B) The cost of any pension benefit per employee over 3 percent of the employee's creditable wages unless the employee's wages exceed the maximum annual creditable annual maximum creditable wage allowed under the program (*see* paragraph (a)(13)(i) of this section). Employees earning over the maximum creditable wage allowed under the program would have a creditable annual pension benefit of up to 3 percent of the maximum creditable wage and wages over 3 percent of the maximum creditable wage would not be creditable.

* * * * *

(b) * * *

(4) ITA–360P ''Certificate of Entitlement to Secure the Refund of Duties on Articles that Entered the Customs Territory of The United State Duty Paid.'' This document authorizes an insular watch producer to request the refund of duties on imports of articles that entered the customs territory of the United States duty paid, up to the specified value of the certificate. * * *

(5) ITA–361P ''Request for Refund of Duties on Articles that Entered the Customs Territory of the United States Duty Paid.'' * * *

* * * * *

4. Section 303.5(b)(5) is revised to read as set forth below and paragraphs (b)(8) and (b)(9) are added to read as set forth below.

§ 303.5 Application for annual allocation of duty-exemptions.

* * * * *

(b) * * *

(5) Customs, bank, payroll, production records, and all shipping records including the importer of record number and proof of residency, as requested;

* * * * *

(8) All records pertaining to health insurance, life insurance and pension benefits for each employee; and

(9) If HTSUS tariffs on watches and watch movements are reduced, records of the annual aggregate data by individual HTSUS watch tariff numbers for the following components contained therein would be required: The quantity and value of watch cases; the quantity of movements; the quantity and value of each type of strap, bracelet or band; and the quantity and value of batteries shipped free of duty into the United States. In addition, if applicable, records of the annual aggregate quantity of discrete watch movements shipped free of duty into the United States by HTSUS tariff number.

* * * * *

5. Section 303.12 (c)(1) and (2) are revised to read as follows:

§ 303.12 Issuance and use of production incentive certificates.

* * * * *

(c) The use and transfer of certificate of entitlements. (1) Insular producers issued a certificate may request a refund by executing Form ITA–361P (*see* § 303.2(b)(5) and the instructions on the form). After authentication by the Department of Commerce, Form ITA–361P may be used to obtain duty refunds on articles that entered the customs territory of the United States duty paid except for any article containing a material which is the product of a country to which column 2 rates of duty apply. Articles for which duty refunds are claimed must have entered the customs territory of the United States during the two-year period prior to the issue date of the certificate or during the one-year period the certificate remains valid. Copies of the appropriate Customs entries must be provided with the refund request in order to establish a basis for issuing the claimed amounts. Certification regarding drawback claims and liquidated refunds relating to the presented entries is required from the claimant on the form.

(2) Regulations issued by the Bureau of Customs and Border Protection, U.S. Department of Homeland Security, govern the refund of duties under Public Law 97–446, as amended by Public Law 103–465 and Public Law 108–429. If the Departments receive information from the Bureau of Customs and Border Protection that a producer has made

unauthorized use of any official form, they shall cancel the affected certificate.

* * * * *

6. Section 303.15(a) is amended by removing ''.'' at the end of the sentence and adding '', and Public Law 108–429, enacted on 3 December 2004.'' in its place.

7. Section 303.16 is amended as follows:

A. Section 303.16(a)(1) is amended by removing ''.'' at the end of the last sentence and adding '', and Public Law 108–429, enacted on 3 December 2004.'' in its place.

B. Section 303.16(a)(7) is revised to read as set forth below.

C. Section 303.16(a)(9) is revised to read as set forth below.

D. Paragraphs (a)(10) and (a)(11) are redesignated as paragraphs (a)(11) and (12), and a new paragraph (a)(10) is added as set forth below.

E. Newly designated paragraph (a)(12) is amended by removing ''(*i.e.*, be physically present for at least 183 days per year)'' and adding ''(*i.e.*, be physically present for at least 183 days within a continuous 365 day period year)'' in its place.

F. Paragraph (b)(2) is revised to read as set forth below.

G. The heading of paragraph (b)(3) is revised to read as set forth below.

§ 303.16 Definitions and forms.

(a) * * *

(7) Unit of Jewelry means a single article (*e.g.,* ring, bracelet, necklace), pair (*e.g*, cufflinks), gram for links which are sold in grams and stocked in grams, and other subassemblies and components in the customary unit of measure they are stocked and sold within the industry.

* * * * *

(9) Creditable wages and creditable fringe benefits eligible for the duty refund benefit include, but are not limited to, the following:

(i) Wages up to an amount equal to 65 percent of the contribution and benefit base for Social Security, as defined in the Social Security Act for the year in which wages were earned, paid to permanent residents of the insular possessions employed in a firm's manufacture of HTSUS heading 7113 articles of jewelry which are a product of the insular possessions and have met the Bureau of Customs and Border Protection's criteria for duty-free entry into the United States, plus any wages paid for the repair of non-insular HTSUS heading 7113 jewelry up to an amount equal to 50 percent of the firm's total creditable wages.

(A) Wages paid to persons engaged in the day-to-day assembly operations at the company office, wages paid to administrative employees working on the premises of the company office, wages paid to security operations employees and wages paid to servicing and maintenance employees if these services are integral to the assembly and manufacturing operations and the employees are working on the premises of the company office.

(B) Wages paid to permanent residents who are employees of a new company involved in the jewelry assembly and jewelry manufacturing of HTSUS heading 7113 jewelry for up to 18 months after such jewelry company commences jewelry manufacturing or jewelry assembly operations in the insular possessions.

(C) Wages paid when a maximum of two producers work on a single piece of HTSUS heading 7113 jewelry which entered the United States free of duty under the program. Wages paid by the two producers will be credited proportionally provided both producers demonstrate to the satisfaction of the Secretaries that they worked on the same piece of jewelry, the jewelry received duty-free treatment into the customs territory of the United States, and the producers maintained production and payroll records sufficient for the Departments' verification of the creditable wage portion (*see* § 303.17(b)).

(D) Wages paid to persons engaged in both creditable and non-creditable assembly and repair operations may be credited proportionally provided the firm maintains production, shipping and payroll records adequate for the Departments' verification of the creditable portion.

(E) Wages paid to new permanent residents who have met the requirements of permanent residency in accordance with the Departments' regulations along with meeting all other creditable wage requirements of the regulations, which must be documented and verified to the satisfaction of the Secretaries.

(ii) The combined creditable amount of individual health and life insurance per year, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, may not exceed 100 percent of the ''weighted average'' yearly federal employee health insurance, which is calculated from the individual health plans weighted by the number of individual contracts in each plan. The yearly amount is calculated by the Office of Personnel Management and includes the ''weighted average'' of all individual health insurance costs for federal employees throughout the United States. The maximum life insurance allowed within this combined amount is $50,000 for each employee.

(A) The combined creditable amount of family health and life insurance per year, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, may not exceed 120 percent of the ''weighted average'' yearly federal employee health insurance, which is calculated from the family health plans weighted by the number of family contracts in each plan. The yearly amount is calculated by the Office of Personnel Management and includes the ''weighted average'' of all family health insurance costs for federal employees throughout the United States. The maximum life insurance allowed within this combined amount is $50,000 dollars for each employee.

(B) The creditable pension benefit, for each full-time permanent resident employee who works on the premises of the company office and whose wages qualify as creditable, is up to 3 percent of the employee's wages unless the employee's wages exceed the maximum annual creditable wage allowed under the program (*see* paragraph (a)(9)(i) of this section). An employee earning more than the maximum creditable wage allowed under the program will be eligible for only 3 percent of the maximum creditable wage.

(10) Non-creditable wages and non-creditable fringe benefits. Wages ineligible for the duty refund benefit include, but are not limited to, the following:

(i) Wages over 65 percent of the contribution and benefit base for Social Security, as defined in the Social Security Act for the year in which wages were earned, paid to permanent residents of the territories employed in a firm's 91/5 heading 7113, HTSUS, jewelry program.

(A) Wages paid for the repair of jewelry in an amount over 50 percent of the firm's total creditable wages.

(B) Wages paid to employees who are involved in assembling HTSUS heading 7113 jewelry beyond 18 months after such jewelry company commences jewelry manufacturing or jewelry assembly operations in the insular possessions if the jewelry does not meet the Bureau of Customs and Border Protection's substantial transformation requirements and other criteria for duty-free enter into the United States.

(C) Wages paid for the assembly and manufacturing of jewelry which is shipped to places outside the customs territory of the United States; wages paid for the assembly and manufacturing of jewelry that does not

meet the regulatory assembly requirements; or wages paid for the assembly and manufacture of jewelry that contain HTSUS column 2 components.

(D) Wages paid to those persons not engaged in the day-to-day assembly operations on the premises of the company office, wages paid to any outside consultants, wages paid to outside the office personnel, including but not limited to, lawyers, gardeners, construction workers and accountants; wages paid to employees not working on the premises of the company office and wages paid to employees who do not qualify as permanent residents in accordance with the Departments' regulations.

(E) Wages paid to persons engaged in both creditable and non-creditable assembly and repair operations if the producer does not maintain production, shipping and payroll records adequate for the Departments' verification of the creditable portion.

(ii) Any costs, for the year in which the wages were paid, of the combined creditable amount of individual health and life insurance for employees over 100 percent of the ''weighted average'' yearly individual health insurance costs for all federal employees. The cost of any life insurance over the $50,000 limit for each employee.

(A) Any costs, for the year in which the wages were paid, of the combined creditable amount of family health and life insurance for employees over 120 percent of the ''weighted average'' yearly family health insurance costs for all federal employee. The cost of any life insurance over the $50,000 limit for each employee.

(B) The cost of any pension benefit per employee over 3 percent of the employee's creditable wages unless the employee's wages exceed the maximum annual creditable annual maximum creditable wage allowed under the program (*see* paragraph (a)(9)(i) of this section). Employees earning over the maximum creditable wage allowed under the program would have a creditable annual pension benefit of up to 3 percent of the maximum creditable wage and wages over 3 percent of the maximum creditable wage would not be creditable.

* * * * *

(b) * * *

(2) ITA–360P ''Certificate of Entitlement to Secure the Refund of Duties on Articles that Entered the Customs Territory of The United State Duty Paid.'' This document authorizes an insular jewelry producer to request the refund of duties on imports of articles that entered the customs territory of the United States duty paid, with certain exceptions, up to the specified value of the certificate. Certificates may be used to obtain duty refunds only when presented with a properly executed Form ITA–361P.

(3) ITA–361P ''Request for Refund of Duties on Articles that Entered the Customs Territory of the United States Duty Paid.'' * * *

* * * * *

8.–9. Section 303.17 is amended by revising paragraph (b)(6); by redesignating paragraphs (b)(7) and (b)(8) as paragraphs (b)(8) and (b)(9); and by adding a new paragraph (b)(7) to read as follows:

§ 303.17 Annual jewelry application.

* * * * *

(b) * * *

(6) Customs, bank, payroll, production records, and all shipping records including the importer of record number and proof of residency, as requested;

(7) All records pertaining to health insurance, life insurance and pension benefits for each employee;

* * * * *

10. Section 303.19(c)(1) is revised to read as follows:

§ 303.19 Issuance and use of production incentive certificates.

* * * * *

(c) The use and transfer of certificate entitlements. (1) Insular producers issued a certificate may request a refund by executing Form ITA–361P (*see* § 303.16 (b)(3)) and the instruction on the form). After authentication by the Department of Commerce, Form ITA–361P may be used to obtain duty refunds on article that entered the customs territory of the United States duty paid. Duties on an article which is the product of a country with respect to column 2 rates of duty apply may not be refunded Articles for which duty refunds are claimed must have entered the customs territory of the United States during the two-year period prior to the issue date of the certificate or during the one-year period the certificate remains valid. Copies of the appropriate Customs entries must be provided with the refund request in order to establish a basis for issuing the claimed amounts. Certification regarding drawback claims and liquidated refunds relating to the presented entries is required from the claimant on the form.

* * * * *

10a. Section 303.20(a)(2) is revised to read as follows:

§ 303.20 Duty refund.

* * * * *

(a) * * *

(2) Eighteen month exemption. Any article of jewelry provided for in HTSUS heading 7113, assembled in the insular possessions by a new entrant jewelry manufacturer shall be treated as a product of the insular possessions if such article is entered into the customs territory of the United States no later than 18 months after such producer commences jewelry manufacturing or jewelry assembly operations in the insular possessions.

* * * * *

11. Section 303.20 is further amended as follows:

A. Paragraph (b)(1)(ii) is amended by removing ''450,000'' and adding ''3,533,334'' in its place.

B. Paragraph (b)(1)(iii) is amended by removing ''600,000'' and adding ''6,766,667'' in its place.

C. Paragraph (b)(1)(iv) is amended by removing ''750,000'' and adding ''10,000,000'' in its place.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration, Department of Commerce.

Nikolao I. Pula,

Director for Insular Affairs, Department of the Interior.

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FEDERAL TRADE COMMISSION

16 CFR Part 23

Guides for the Jewelry, Precious Metals, and Pewter Industries

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Request for public comment.

SUMMARY: The Commission is seeking comment on whether the platinum section of the FTC's Guides for the Jewelry, Precious Metals, and Pewter Industries, 16 CFR part 23, should be amended to provide guidance on how to mark or describe non-deceptively products containing between 500 and 850 parts per thousand pure platinum and no other platinum group metals.

DATES: Written comments must be received on or before September 28, 2005.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Jewelry Guides, Matter No. G711001'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text

and on the envelope, and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission/Office of the Secretary, Room 135–H (Annex Y), 600 Pennsylvania Avenue, NW., Washington, DC 20580. Because paper mail in the Washington area and at the Agency is subject to delay, please consider submitting your comments in electronic form, as prescribed below. Comments containing confidential material, however, must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with Commission Rule 4.9(c). 16 CFR 4.9(c) (2004).[1]

Comments filed in electronic form should be submitted by clicking on the following: *http://secure.commentworks.com/ftc-jewelry* and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the *http://secure.commentworks.com/ftc-jewelry.* You also may visit *http://www.regulations.gov* to read this request for comment, and may file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC website, to the extent practicable, at *http://www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

FOR FURTHER INFORMATION CONTACT: Neil Blickman, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3038.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Guides for the Jewelry, Precious Metals, and Pewter Industries (''Jewelry Guides'' or ''Guides''), 16 CFR part 23, address claims made about precious metals, diamonds, gemstones and pearl products. The Jewelry Guides provide guidance as to when claims about jewelry products may be deceptive and, for certain products, discuss when disclosures should be made to avoid unfair or deceptive trade practices. The Guides also provide examples of markings or descriptions that the Commission would not consider unfair or deceptive. The Commission is seeking public comment on Section 23.7 of the Guides, which addresses claims for products made of platinum.

Industry guides are administrative interpretations of the application of Section 5 of the FTC Act, 15 U.S.C. 45(a). The Commission issues industry guides to provide guidance for the public to conform with legal requirements. Guides provide the basis for voluntary and simultaneous abandonment of unlawful practices by members of industry. 16 CFR part 17. Failure to follow industry guides may result in corrective action under Section 5 of the FTC Act. In any such enforcement action, the Commission must prove that the act or practice at issue is unfair or deceptive.

Recently, several jewelry manufacturers informed Commission staff that they were seeking to market products that contain platinum, but differ in composition from traditional platinum products. Platinum products that have been marketed thus far typically contain over 85% pure platinum or contain a combination of pure platinum and platinum group metals (PGM) that total 95% PGM.[2] Some manufacturers propose to market products containing more than 50% but less than 85% pure platinum and no other PGM.[3] Subsequently, the staff responded to a request for a staff opinion regarding the application of the platinum section of the Guides to the marketing of a product containing 585 parts per thousand (ppt) pure platinum and no other PGM. The FTC staff opinion letter concludes that the Guides do not specifically address the marketing of such an alloy.[4] The letter also stated that the staff would recommend that the Commission publish a **Federal Register** Notice soliciting comments on whether the platinum section of the Jewelry Guides should be revised to address how to market non-deceptively products containing 500–850 ppt pure platinum and no other PGM.

II. Background

The platinum section of the Jewelry Guides contains a general prohibition against the deceptive use of the term ''platinum'' and specific examples where the Commission would consider use of the term ''platinum'' unfair or deceptive.[5] Section 7(a) of the Jewelry Guides states that it is ''unfair or deceptive to use the words 'platinum,' 'iridium,' 'palladium,' 'ruthenium,' 'rhodium,' and 'osmium,' or any abbreviation to mark or describe all or part of an industry product if such marking or description misrepresents the product's true composition.''[6] 16 CFR part 23.7(a).

Section 7(b) provides examples of markings or descriptions for products containing platinum that may be misleading:

(1) Use of the word ''Platinum'' or any abbreviation, without qualification, to describe all or part of any industry product that is not composed throughout of 950 parts per thousand pure Platinum.

(2) Use of the word ''Platinum'' or any abbreviation accompanied by a number indicating the parts per thousand of pure Platinum contained in the product without mention of the number of parts per thousand of other PGM contained in the product, to describe all or part of an industry product that is not composed throughout of at least 850 parts per thousand pure platinum, for example, ''600Plat.''

(3) Use of the word ''Platinum'' or any abbreviation therefor, to mark or describe any product that is not composed throughout of at least 500 parts per thousand pure Platinum.

16 CFR 23.7(b).

Section 7(c) includes four examples of markings and descriptions that are not considered deceptive. The first example lists the four and two-letter abbreviations for the PGM that would not be considered unfair or deceptive. The remaining three examples provide examples of descriptions for certain platinum products:

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

[2] The Platinum Group Metals include platinum, iridium, palladium, ruthenium, rhodium and osmium.

[3] The staff also is aware that other companies are selling similar products but marketing them under names other than ''platinum.''

[4] The request for a staff opinion and the staff's response to that request can be found at *www.ftc.gov/os/statutes/jewelry/letters/karatplatinum.pdf* and *http://www.ftc.gov/os/statutes/jewelry/letters/karatplatinum002.pdf* respectively.

[5] On April 8, 1997 (62 FR 16669), the Commission published the current platinum section of the Jewelry Guides. The section was revised as part of a comprehensive review of all of the provisions of the Guides.

[6] This section also lists the Platinum Group Metals.

(2) An industry product consisting of at least 950 parts per thousand pure platinum may be marked or described as ''Platinum.''

(3) An industry product consisting of 850 parts per thousand pure Platinum, 900 parts per thousand pure Platinum or 950 parts per thousand pure Platinum may be marked ''Platinum'' provided that the Platinum marking is preceded by a number indicating the amount in parts per thousand of pure Platinum * * * Thus, the following markings may be used: ''950Pt.,'' ''950Plat.,'' ''900Pt.,'' ''900Plat.,'' ''850Plat.,'' or ''850Pt.''

(4) An industry product consisting of at least 950 parts per thousand PGM, and of at least 500 parts per thousand pure Platinum, may be marked ''Platinum,'' provided that the mark of each PGM constituent is preceded by a number indicating the amount in parts per thousand of each PGM, as for example, ''600Pt.350Ir.,'' ''600Plat.350Irid.'' or ''550Pt.350Pd.50Ir.'' or ''550Plat.350Pall.50Irid.''

16 CFR 23.7(c).

Last year the staff received letters stating that several jewelry manufacturers were seeking to market products containing between 500 and 850 ppt pure platinum and no other PGM. On December 15, 2004, one manufacturer requested an opinion from the FTC staff regarding the application of the Jewelry Guides to a product that consists of 585 ppt pure platinum and 415 ppt non-precious metals. The request stated that the manufacturer's reading of the Guides indicated that the platinum section did not prohibit marking or describing the product as ''Platinum'' and that the Guides do not address how to mark or describe an alloy with this composition other than to require that any representation be truthful and not misrepresent the product's composition.

The staff posted this request on the FTC's website on December 17, 2004 to seek industry input. The staff notified several major jewelry trade associations that the request had been posted and invited the industry to provide comments by January 5, 2005, which the staff later extended until January 10, 2005. The staff received sixteen comments from jewelry trade associations and retailers.[7]

On February 2, 2005, the staff responded to the request for an opinion. The staff letter stated:

The Guides provide that, in order for a product to be marked or described as ''platinum,'' the product must contain a minimum of 500 ppt pure platinum. 16 CFR 23.7(b)(3). In addition, the Guides provide that, if a product contains 500 ppt pure platinum but less than 850 ppt pure platinum, the marketer must disclose the amount in ppt of the remaining PGM in the product. 16 CFR 23.7(b)(2).

In our opinion, a literal reading of the Guides indicates that they do not address the marketing of the Karat Platinum alloy, except to the extent that they require a minimum of 500 ppt pure platinum. The provisions of Section 23.7 that address misuse of the word ''platinum'' do not discuss how to mark or describe an alloy that contains over 500 ppt pure platinum but no other PGM.

The staff letter further explained that the marketing of the alloy would be subject to Section 23.1 of the Guides, which contains a general prohibition on deception, as well as Section 5 of the FTC Act.[8] The letter opined that the staff considers the alloy to be sufficiently different in composition from products consisting of platinum combined with other PGM as to require clear and conspicuous disclosure of the differences. The staff noted that it did not appear that simple stamping of the jewelry's content (*e.g.,* 585Plat., 0PGM) would be sufficient to alert consumers to the differences between the alloy and platinum products containing other PGM.

The staff letter provides general, but not specific, guidance for marketers seeking to mark or describe products that contain 50–85% pure platinum but no other PGM. Because of the public interest in this issue, the Commission is soliciting public comment as to whether the Guides should be revised to address specifically how to mark or describe such products.

Comments submitted previously stated that platinum alloys with no other PGM may present special issues that may require marketers to provide additional information. For example, commenters stated that it is unclear whether such products would possess certain qualities typically associated with traditional platinum products, such as being hypoallergenic. In addition, commenters questioned whether the presence of non-precious metals in the product might present unique issues in conjunction with jewelry repairs and other procedures, such as re-sizing. For instance, commenters asked whether a product with high copper content might require a bench jeweler to use atmosphere control equipment to avoid damaging the product. Accordingly, the Commission is soliciting public comment on whether the Guides should be amended to address products composed of 500–850 ppt pure platinum and no other PGM.

Staff also has received some inquiries regarding the application of the platinum section of the Guides to the marketing of platinum-clad or platinum-coated jewelry products. The platinum section of the Guides currently does not address platinum-clad, filled, plated or platinum-overlay products. Other sections of the Guides, however, address gold and silver-plated jewelry products.[9] These sections basically advise that the plating must be of a sufficient thickness to ensure reasonable durability. The Commission also seeks comment as to whether the Guides should provide guidance as to how to mark or describe non-deceptively products such as platinum-clad, filled, coated or platinum-overlay jewelry products.

III. Request for Public Comment

The Commission seeks public comment on whether the Jewelry Guides should be amended to discuss specifically how products that contain between 500 and 850 ppt pure platinum and no other PGM should be marked or described. In addition, the Commission seeks public comment on whether the Guides should be revised to provide guidance on how to mark or describe platinum-clad, filled, plated or platinum-overlay products. The Commission is particularly interested in comments addressing the following questions:

1. Should the platinum section of the Jewelry Guides be amended to address with particularity products that contain 500–850 ppt pure platinum and no other PGM?

2. Is there empirical evidence on what consumers generally expect in terms of performance or other objective qualities when purchasing a product marked or described as ''platinum''? What does that data show?

3. Are products containing 500–850 ppt pure platinum and no other PGM currently being marketed, and if so, how? Is there empirical evidence, *e.g.,* copy testing or other research, as to how consumers interpret the disclosures or marketing materials, or proposed disclosures and marketing materials, accompanying such products?

4. For products containing 500–850 ppt pure platinum and no other PGM what, if any, additional information, in addition to disclosure of the product

[7] Comments were received from the Jewelers Vigilance Committee, Platinum Guild International, Manufacturing Jewelers & Suppliers of America, American Gem Society, Jewelers of America, Sonny's On Fillmore, Kwiat, Inc., Cornell's Jewelers, Michael Bondanza, Inc., PMI, Traditional Jewelers, Standley Jewelers Gemologist, Davidson & Licht, Henne Jewelers, Johnson Matthey, MJ Christensen.

[8] Section 5 of the FTC Act prohibits deceptive acts or practices, in or affecting commerce. 15 U.S.C. 45(a).

[9] *See* 16 CFR 23.4 and 23.6 (addressing gold-plated, gold-filled, gold-overlay, gold-electroplated and silver-plated jewelry products).

composition, may be necessary to prevent deception under Section 5 of the FTC Act? How do these disclosures compare to disclosures already required for other jewelry products, for example, gold?

5. Are there significant differences between the 500–850 ppt pure platinum alloys with no PGMs and other platinum products in terms of durability, scratch resistance, tarnish, hypoallergenicity, ability to hold settings, or similar qualities? What evidence is there on these issues?

6. How would a product containing 500 ppt pure platinum and no other PGM be marked if it were being sold outside the United States? Is there an international standard that addresses a product with this composition?

7. Should the platinum section of the Jewelry Guides be amended to address other products that contain platinum, such as platinum-clad, platinum-filled, platinum-plated, platinum-coated or platinum overlay products, that are not currently addressed in the section? If so, why? What guidance is needed to ensure that consumers are not misled about the composition of such products and their performance, durability, value and special care requirements, if any? Are such products currently being marketed, and if so, how? How are such products marked if they are sold outside the United States? Are there any international standards that address such products?

All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before September 28, 2005.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 05–13285 Filed 7–5–05; 8:45 am]

BILLING CODE 6750–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RME No. R03–OAR–2004–MD–0002; FRL–7933–8]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Visible and Particulate Emissions From Glass Melting Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maryland. This revision consists of regulations for the control of particulate and visible emissions from glass melting facilities. This action is being taken under the Clean Air Act (CAA or the Act).

DATES: Written comments must be received on or before August 5, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2004–MD–0002 by one of the following methods:

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

Agency Web site: http://www.docket.epa.gov/rmepub/ RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

E-mail: campbell.dave@epa.gov.

Mail: R03–OAR–2004–MD–0002, David Campbell, Chief, Air Quality and Analysis Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

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

Instructions: Direct your comments to RME ID No. R03–OAR–2004–MD–0002. 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.docket.epa.gov/rmepub/,* including any personal information provided, unless the comment included information claimed to be Confidential Business Information (CBI) or other information whose disclose is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland, 21230, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Linda Miller, (215) 814–2068, or by e-mail at *miller.linda@epa.gov.*

SUPPLEMENTARY INFORMATION: On November 18, 2004, the State of Maryland submitted a formal revision to its State Implementation Plan (SIP). The SIP revision consists of regulations to control particulates and visible emissions from glass melting facilities.

The existing SIP requirements for particulates and visible emissions are found in Code of Maryland Regulations, Title 26, Subtitle 11 Air Quality, Chapter 06 General Emission Standards, Prohibitions, and Restrictions (COMAR 26.11.06). For air quality planning purposes, the State has been divided into planning areas (COMAR 26.11.01.03). This SIP revision affects requirements for the Baltimore and Washington planning areas. The entire State of Maryland is currently in attainment with the national ambient air quality standards (NAAQS) for particulate matter (PM_{10}). The Baltimore and Washington metropolitan areas have recently been designated nonattainment for fine particulate matter ($PM_{2.5}$). Requirements for the attainment of these areas will be submitted by the State of Maryland by April 5, 2008.

The State of Maryland identified a type of glass melting facility which required a different standard than the currently SIP-approved visible emissions and particulate matter (PM_{10}) requirements in the Baltimore and Washington areas. The State has revised its regulations to include amended visible and PM_{10} emission limits for glass melting facilities. These limits were promulgated in COMAR 26.11.16, subsequently recodified as COMAR 26.11.25. Currently, the State has identified one operating source in Baltimore which is subject to the revised requirements.

As required by CAA § 110(1), the State of Maryland performed air quality modeling using an EPA-approved protocol to demonstrate that revisions to the existing SIP requirements do not adversely affect the attainment or maintenance of the PM_{10} NAAQS. In addition, an analysis was completed to demonstrate that the changes did not exceed the maximum allowable increases level in CAA § 163.

II. Summary of SIP Revision

On November 18, 2004 the State submitted a SIP revision request which included COMAR 26.11.25 to be approved into the SIP. Supporting the request, the State provided a PM_{10} dispersion modeling analysis. Documentation of public participation was included in the submittal.

The regulations for glass melting facilities, COMAR 26.11.16 (Effective September 24, 1984), were recodified to COMAR 26.11.25 Control of Glass Melting Furnaces (Effective October 5, 1998). The regulation is applicable to certain types of glass melting furnaces in the Baltimore and Washington planning areas. MDE has identified one operating facility for which this regulation applies. The source is not a major source for PM_{10}.

According to MDE, it is not feasible for the specific type of glass melting furnaces referenced in this regulation to meet zero visible emissions as required in the Baltimore and Washington planning areas. Therefore, the regulation allows for this source category a standard permitting up to 20 percent opacity from the glass melting furnace and fugitive emissions standard allowing up to 20 percent opacity from a building containing forming and post-forming equipment.

The current particulate matter emissions standard for sources in these areas is 0.03 grains per standard dry cubic foot of dry exhaust gas (gr/SCFD). The submitted SIP revision includes a revised particulate matter emissions standard for glass melting furnace based on the following calculation:

(1) $E = 5 + 0.48\ (P)$

Where:

E = maximum weight discharged per hour (pounds)

P = process weight in tons per hour;

or

(2) $E = 2.27 + 0.24\ (P)$

Where:

E = maximum weight discharged per hour (kilograms)

P = process weight in megagrams per hour

The State of Maryland performed modeling analyses to demonstrate that the revised particulates standard in COMAR 26.11.25 would not adversely affect the national ambient air quality standards (NAAQS) for PM_{10}. EPA has reviewed the modeling analysis and agrees it demonstrates that the NAAQS for PM_{10} will not be exceeded by the proposed revision to the glass manufacturing emission limits.

The Maryland Department of the Environment provided public notice and opportunity for comment, including a public hearing, on the revision to the SIP. The regulation and the modeling demonstration were made available as part of this public notice. There were no comments on the proposal during the public hearing. No comments were received in the 30-day public comment period.

III. Proposed Action

EPA's review of this material indicates the revision will not cause or contribute to a violation of the NAAQS. EPA is proposing to approve the State of Maryland SIP revision for control of particulates and visible emissions from glass melting facilities as submitted on November 18, 2004. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). This action merely proposed to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to approve a state rule implementing a Federal requirements, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order

12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order.

This proposed rule to approve revisions to control of particulate emissions from glass melting facilities does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: June 15, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–13283 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RME–OAR–2005–MD–0006; FRL–7933–7]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Approval of Clarifications of Requirements for Fuel-Burning Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland for the purpose of approving clarifications to the applicability and compliance methods for particulate matter standards for fuel-burning equipment. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by August 5, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number RME–OAR–2005–MD–0006 by one of the following methods:

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

B. Agency Web site: *http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *Campbell.Dave@epa.gov.*

D. Mail: [RME ID Number], David Campbell, Chief, Air Quality Planning and Analysis, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

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

Instructions: Direct your comments to RME ID No. RME–OAR–2005–MD–0006. 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.docket.epa.gov/rmepub/*, 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov websites are 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 RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Linda Miller, (215) 814–2068, or by e-mail at *miller.linda@epa.gov*.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action on clarifications to the applicability and compliance methods for particulate matter standards for fuel-burning equipment, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: June 15, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–13282 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R06–OAR–2005–TX–0024; FRL–7928–5]

Approval and Promulgation of Implementation Plans; Texas; Transportation Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the Texas Commission on Environmental Quality (TCEQ) on May 22, 2003, and on May 17, 2005. These revisions serve to incorporate recent changes to the federal conformity rule into the state conformity SIP.

DATES: Comments must be received on or before August 5, 2005.

ADDRESSES: Comments may be mailed to Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas, 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Peggy Wade, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7247; fax number 214–665–7263; e-mail address *wade.peggy@epa.gov*.

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the state's submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of adverse comment.

For additional information, see the direct final rule that is located in the rules section of this **Federal Register**.

Dated: June 17, 2005.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 05–13280 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[OAR–2004–0091; FRL–7933–3]

Outer Continental Shelf Air Regulations Consistency Update for California

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

ACTION: Proposed rule—Consistency Update.

SUMMARY: EPA is proposing to update a portion of the Outer Continental Shelf (''OCS'') Air Regulations. Requirements applying to OCS sources located within 25 miles of States' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (''COA''), as mandated by section 328(a)(1) of the Clean Air Act, as amended in 1990 (''the Act''). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the Santa Barbara County Air Pollution Control District (Santa Barbara County APCD) and Ventura County Air Pollution Control District (Ventura County APCD) are the designated COAs. The intended effect of approving the OCS requirements for the above Districts is to regulate emissions from OCS sources in accordance with the requirements onshore. The change to the existing requirements discussed below is proposed to be incorporated by reference into the Code of Federal Regulations and is listed in the appendix to the OCS air regulations.

DATES: Comments on the proposed update must be received on or before August 5, 2005.

ADDRESSES: Submit comments, identified by docket number OAR–2004–0091, by one of the following methods:

1. Agency Web site: *http://docket.epa.gov/edocket/*. EPA prefers receiving comments through this electronic public docket and comment system. Follow the on-line instructions to submit comments.

2. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions.

3. E-mail: *steckel.andrew@epa.gov.*

4. Mail or deliver: Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket includes changes and may be made available online at *http://docket.epa.gov/edocket/*, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statue. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through the agency website, eRulemaking portal or e-mail. The agency website and eRulemaking portal are ''anonymous access'' systems, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. 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.

Docket: The index to the docket for this action is available electronically at *http://docket.epa.gov/edocket/* 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 publically available only at the hard copy location (*e.g.*, copyrighted material), and some may not be publically 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: Christine Vineyard, Air Division (Air-4), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4125, *vineyard.christine@epa.gov.*

I. Background Information

A. Why is EPA taking this action?

On September 4, 1992, EPA promulgated 40 CFR part 55,[1] which

[1] The reader may refer to the Notice of Proposed Rulemaking, December 5, 1991 (56 FR 63774), and the preamble to the final rule promulgated September 4, 1992 (57 FR 40792) for further

established requirements to control air pollution from OCS sources in order to attain and maintain federal and state ambient air quality standards and to comply with the provisions of part C of title I of the Act. Part 55 applies to all OCS sources offshore of the States except those located in the Gulf of Mexico west of 87.5 degrees longitude. Section 328 of the Act requires that for such sources located within 25 miles of a State's seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the COA. Because the OCS requirements are based on onshore requirements, and onshore requirements may change, section 328(a)(1) requires that EPA update the OCS requirements as necessary to maintain consistency with onshore requirements.

Pursuant to § 55.12 of the OCS rule, consistency reviews will occur (1) at least annually; (2) upon receipt of a Notice of Intent under § 55.4; or (3) when a state or local agency submits a rule to EPA to be considered for incorporation by reference in part 55. This proposed action is being taken in response to the submittal of rules by two local air pollution control agencies. Public comments received in writing within 30 days of publication of this document will be considered by EPA before publishing a final rule.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of States' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into part 55 as they exist onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the Act. Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. EPA's Evaluation

A. What criteria were used to evaluate rules submitted to update 40 CFR part 55?

In updating 40 CFR part 55, EPA reviewed the rules submitted for inclusion in part 55 to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure they are not arbitrary or capricious. 40 CFR 55.12 (e). In addition, EPA has excluded administrative or procedural rules,[2] and requirements that regulate toxics which are not related to the attainment and maintenance of federal and state ambient air quality standards.

B. What rule revisions and new rules were submitted to update 40 CFR part 55?

1. After review of the rules submitted by Santa Barbara County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to making the following rules applicable to OCS sources for which the Santa Barbara County APCD is designated as the COA:

Rule No.	Rule name	Adoption date
102	Definitions	1/20/05
202	Exemption to Rule 201	3/17/05
210	Fees	3/17/05

2. After review of the rules submitted by Ventura County APCD against the criteria set forth above and in 40 CFR part 55, EPA is proposing to make the following rules applicable to OCS sources for which the Ventura County APCD is designated as the COA:

Rule No.	Rule name	Adoption date
23	Exemptions from Permit	10/12/04
57	Incinerators	1/11/05
57.1	Particulate Matter Emissions from Fuel Burning Equipment	[1] 1/11/05
74.20	Adhesive and Sealants	1/11/05

[1] New.

III. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on

background and information on the OCS regulations.

[2] Each COA which has been delegated the authority to implement and enforce part 55, will use its administrative and procedural rules as onshore. However, in those instances where EPA has not delegated authority to implement and enforce part 55, EPA will use its own administrative and procedural requirements to implement the substantive requirements. 40 CFR 55.14(c)(4).

a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

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, as specified in Executive Order 13132, because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, 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 final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

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

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 rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

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

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of

the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2). This action will be effective August 5, 2005.

K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2005. Filing a petition for reconsideration by the Administrator of this final action 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 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: June 22, 2005.

Laura Yoshii,

Acting Regional Administrator, Region IX.

Title 40 Chapter I of the Code of Federal Regulations, is proposed to be amended as follows:

PART 55—[AMENDED]

1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401 *et seq.*) as amended by Public Law 101–549.

2. Section 55.14 is amended by revising paragraphs (e)(3)(ii)(F) and (H) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States' seaward boundaries, by State.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(F) *Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources*

* * * * *

(H) *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources.*

* * * * *

Appendix A to Part 55—[Amended]

3. Appendix A to CFR part 55 is amended by revising paragraphs (b)(6) and (b)(8) under the heading ''California'' to read as follows:

Appendix A to 40 CFR Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

California

* * * * *

(b) Local Requirements

* * * * *

(6) *The following requirements are contained in Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources:*

Rule 102 Definition (Adopted 1/20/05)
Rule 103 Severability (Adopted 10/23/78)
Rule 106 Notice to Comply for Minor Violations (Adopted 7/15/99)
Rule 107 Emergencies (Adopted 4/19/01)
Rule 201 Permits Required (Adopted 4/17/97)
Rule 202 Exemptions to Rule 201 (Adopted 3/17/05)
Rule 203 Transfer (Adopted 4/17/97)
Rule 204 Applications (Adopted 4/17/97)
Rule 205 Standards for Granting Applications (Adopted 4/17/97)
Rule 206 Conditional Approval of Authority to Construct or Permit to Operate (Adopted 10/15/91)
Rule 207 Denial of Application (Adopted 10/23/78)
Rule 210 Fees (Adopted 3/17/05)
Rule 212 Emission Statements (Adopted 10/20/92)
Rule 301 Circumvention (Adopted 10/23/78)
Rule 302 Visible Emissions (Adopted 10/23/78)
Rule 304 Particulate Matter-Northern Zone (Adopted 10/23/78)
Rule 305 Particulate Matter Concentration-Southern Zone (Adopted 10/23/78)
Rule 306 Dust and Fumes-Northern Zone (Adopted 10/23/78)
Rule 307 Particulate Matter Emission Weight Rate-Southern Zone (Adopted 10/23/78)
Rule 308 Incinerator Burning (Adopted 10/23/78)
Rule 309 Specific Contaminants (Adopted 10/23/78)
Rule 310 Odorous Organic Sulfides (Adopted 10/23/78)
Rule 311 Sulfur Content of Fuels (Adopted 10/23/78)
Rule 312 Open Fires (Adopted 10/2/90)
Rule 316 Storage and Transfer of Gasoline (Adopted 4/17/97)
Rule 317 Organic Solvents (Adopted 10/23/78)
Rule 318 Vacuum Producing Devices or Systems-Southern Zone (Adopted 10/23/78)
Rule 321 Solvent Cleaning Operations (Adopted 9/18/97)
Rule 322 Metal Surface Coating Thinner and Reducer(Adopted 10/23/78)
Rule 323 Architectural Coatings (Adopted 11/15/01)
Rule 324 Disposal and Evaporation of Solvents (Adopted 10/23/78)
Rule 325 Crude Oil Production and Separation (Adopted 7/19/01)
Rule 326 Storage of Reactive Organic Liquid Compounds (Adopted 1/18/01)
Rule 327 Organic Liquid Cargo Tank Vessel Loading (Adopted 12/16/85)
Rule 328 Continuous Emission Monitoring (Adopted 10/23/78)
Rule 330 Surface Coating of Miscellaneous Metal Parts and Products (Adopted 1/20/00)
Rule 331 Fugitive Emissions Inspection and Maintenance (Adopted 12/10/91)
Rule 332 Petroleum Refinery Vacuum Producing Systems, Wastewater Separators and Process Turnarounds (Adopted 6/11/79)
Rule 333 Control of Emissions from Reciprocating Internal Combustion Engines (Adopted 4/17/97)
Rule 342 Control of Oxides of Nitrogen (NO_X) from Boilers, Steam Generators and Process Heaters) (Adopted 4/17/97)
Rule 343 Petroleum Storage Tank Degassing (Adopted 12/14/93)
Rule 344 Petroleum Sumps, Pits, and Well Cellars (Adopted 11/10/94)
Rule 346 Loading of Organic Liquid Cargo Vessels (Adopted 01/18/01)
Rule 352 Natural Gas-Fired Fan-Type Central Furnaces and Residential Water Heaters (Adopted 9/16/99)
Rule 353 Adhesives and Sealants (Adopted 8/19/99)
Rule 359 Flares and Thermal Oxidizers (6/28/94)
Rule 360 Emissions of Oxides of Nitrogen from Large Water Heaters and Small Boilers (Adopted 10/17/02)
Rule 370 Potential to Emit—Limitations for Part 70 Sources (Adopted 6/15/95)
Rule 505 Breakdown Conditions Sections A., B.1., and D. only (Adopted 10/23/78)
Rule 603 Emergency Episode Plans (Adopted 6/15/81)
Rule 702 General Conformity (Adopted 10/20/94)
Rule 801 New Source Review (Adopted 4/17/97)
Rule 802 Nonattainment Review (Adopted 4/17/97)
Rule 803 Prevention of Significant Deterioration (Adopted 4/17/97)
Rule 804 Emission Offsets (Adopted 4/17/97)
Rule 805 Air Quality Impact Analysis and Modeling (Adopted 4/17/97)
Rule 808 New Source Review for Major Sources of Hazardous Air Pollutants (Adopted 5/20/99)
Rule 1301 Part 70 Operating Permits—General Information (Adopted 6/19/03)

Rule 1302 Part 70 Operating Permits—Permit Application (Adopted 11/09/93)
Rule 1303 Part 70 Operating Permits—Permits (Adopted 11/09/93)
Rule 1304 Part 70 Operating Permits—Issuance, Renewal, Modification and Reopening (Adopted 11/09/93)
Rule 1305 Part 70 Operating Permits—Enforcement (Adopted 11/09/93)

* * * * *

(8) The following requirements are contained in *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources:*

Rule 2 Definitions (Adopted 4/13/04)
Rule 5 Effective Date (Adopted 4/13/04)
Rule 6 Severability (Adopted 11/21/78)
Rule 7 Zone Boundaries (Adopted 6/14/77)
Rule 10 Permits Required (Adopted 4/13/04)
Rule 11 Definition for Regulation II (Adopted 6/13/95)
Rule 12 Application for Permits (Adopted 6/13/95)
Rule 13 Action on Applications for an Authority to Construct (Adopted 6/13/95)
Rule 14 Action on Applications for a Permit to Operate (Adopted 6/13/95)
Rule 15.1 Sampling and Testing Facilities (Adopted 10/12/93)
Rule 16 BACT Certification (Adopted 6/13/95)
Rule 19 Posting of Permits (Adopted 5/23/72)
Rule 20 Transfer of Permit (Adopted 5/23/72)
Rule 23 Exemptions from Permits (Revised 10/12/04)
Rule 24 Source Recordkeeping, Reporting, and Emission Statements (Adopted 9/15/92)
Rule 26 New Source Review (Adopted 10/22/91)
Rule 26.1 New Source Review—Definitions (Adopted 5/14/02)
Rule 26.2 New Source Review—Requirements (Adopted 5/14/02)
Rule 26.3 New Source Review—Exemptions (Adopted 5/14/02)
Rule 26.6 New Source Review—Calculations (Adopted 5/14/02)
Rule 26.8 New Source Review—Permit To Operate (Adopted 10/22/91)
Rule 26.10 New Source Review—PSD (Adopted 1/13/98)
Rule 26.11 New Source Review—ERC Evaluation At Time of Use (Adopted 5/14/02)
Rule 28 Revocation of Permits (Adopted 7/18/72)
Rule 29 Conditions on Permits (Adopted 10/22/91)
Rule 30 Permit Renewal (Adopted 4/13/04)
Rule 32 Breakdown Conditions: Emergency Variances, A., B.1., and D. only. (Adopted 2/20/79)
Rule 33 Part 70 Permits—General (Adopted 10/12/93)
Rule 33.1 Part 70 Permits—Definitions (Adopted 4/10/01)
Rule 33.2 Part 70 Permits—Application Contents (Adopted 4/10/01)
Rule 33.3 Part 70 Permits—Permit Content (Adopted 4/10/01)
Rule 33.4 Part 70 Permits—Operational Flexibility (Adopted 4/10/01)
Rule 33.5 Part 70 Permits—Time frames for Applications, Review and Issuance (Adopted 10/12/93)
Rule 33.6 Part 70 Permits—Permit Term and Permit Reissuance (Adopted 10/12/93)
Rule 33.7 Part 70 Permits—Notification (Adopted 4/10/01)
Rule 33.8 Part 70 Permits—Reopening of Permits (Adopted 10/12/93)
Rule 33.9 Part 70 Permits—Compliance Provisions (Adopted 4/10/01)
Rule 33.10 Part 70 Permits—General Part 70 Permits (Adopted 10/12/93)
Rule 34 Acid Deposition Control (Adopted 3/14/95)
Rule 35 Elective Emission Limits (Adopted 11/12/96)
Rule 36 New Source Review—Hazardous Air Pollutants (Adopted 10/6/98)
Rule 42 Permit Fees (Adopted 4/13/04)
Rule 44 Exemption Evaluation Fee (Adopted 9/10/96)
Rule 45 Plan Fees (Adopted 6/19/90)
Rule 45.2 Asbestos Removal Fees (Adopted 8/4/92)
Rule 47 Source Test, Emission Monitor, and Call-Back Fees (Adopted 6/22/99)
Rule 50 Opacity (Adopted 4/13/04)
Rule 52 Particulate Matter—Concentration (Adopted 4/13/04)
Rule 53 Particulate Matter—Process Weight (Adopted 4/13/04)
Rule 54 Sulfur Compounds (Adopted 6/14/94)
Rule 56 Open Burning (Revised 11/11/03)
Rule 57 Combustion Contaminants—Specific (Adopted 1/11/05)
Rule 57.1 Particulate Matter Emissions from Fuel Burning Equipment (Adopted 1/11/05)
Rule 62.7 Asbestos—Demolition and Renovation (Adopted 6/16/92)
Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
Rule 64 Sulfur Content of Fuels (Adopted 4/13/99)
Rule 67 Vacuum Producing Devices (Adopted 7/5/83)
Rule 68 Carbon Monoxide (Adopted 4/13/04)
Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
Rule 71.1 Crude Oil Production and Separation (Adopted 6/16/92)
Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 9/26/89)
Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 6/16/92)
Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 6/8/93)
Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
Rule 72 New Source Performance Standards (NSPS) (Adopted 4/10/01)
Rule 73 National Emission Standards for Hazardous Air Pollutants (NESHAPS (Adopted 04/10/01)
Rule 74 Specific Source Standards (Adopted 7/6/76)
Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
Rule 74.2 Architectural Coatings (Adopted 11/13/01)
Rule 74.6 Surface Cleaning and Degreasing (Revised 11/11/03—effective 7/1/04)
Rule 74.6.1 Batch Loaded Vapor Degreasers (Adopted 11/11/03—effective 7/1/04)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 7/5/83)
Rule 74.9 Stationary Internal Combustion Engines (Adopted 11/14/00)
Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 3/10/98)
Rule 74.11 Natural Gas-Fired Residential Water Heaters-Control of NO_X (Adopted 4/9/85)
Rule 74.11.1 Large Water Heaters and Small Boilers (Adopted 9/14/99)
Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 11/11/03)
Rule 74.15 Boilers, Steam Generators and Process Heaters (Adopted 11/8/94)
Rule 74.15.1 Boilers, Steam Generators and Process Heaters (Adopted 6/13/00)
Rule 74.16 Oil Field Drilling Operations (Adopted 1/8/91)
Rule 74.20 Adhesives and Sealants (Adopted 1/11/05)
Rule 74.23 Stationary Gas Turbines (Adopted 1/08/02)
Rule 74.24 Marine Coating Operations (Revised 11/11/03)
Rule 74.24.1 Pleasure Craft Coating and Commercial Boatyard Operations (Adopted 1/08/02)
Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.28 Asphalt Roofing Operations (Adopted 5/10/94)
Rule 74.30 Wood Products Coatings (Revised 11/11/03)
Rule 75 Circumvention (Adopted 11/27/78)
Rule 101 Sampling and Testing Facilities (Adopted 5/23/72)
Rule 102 Source Tests (Adopted 4/13/04)
Rule 103 Continuous Monitoring Systems (Adopted 2/9/99)
Rule 154 Stage 1 Episode Actions (Adopted 9/17/91)
Rule 155 Stage 2 Episode Actions (Adopted 9/17/91)
Rule 156 Stage 3 Episode Actions (Adopted 9/17/91)
Rule 158 Source Abatement Plans (Adopted 9/17/91)
Rule 159 Traffic Abatement Procedures (Adopted 9/17/91)
Rule 220 General Conformity (Adopted 5/9/95)
Rule 230 Notice to Comply (Adopted 11/9/99)

* * * * *

[FR Doc. 05–13276 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7933–1]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Fadrowski Drum Disposal Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is issuing a notice of intent to delete the Fadrowski Drum Disposal Superfund Site (Site) located in Franklin, Wisconsin, from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is found at appendix B of 40 CFR part 300 of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Wisconsin, through the Wisconsin Department of Natural Resources, have determined that all appropriate response actions under CERCLA, other than operation and maintenance and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final notice of deletion of the Fadrowski Drum Disposal Superfund Site without prior notice of intent to delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final deletion. If we receive no adverse comment(s) on this notice of intent to delete or the direct final notice of deletion, we will not take further action on this notice of intent to delete. If we receive adverse comment(s), we will withdraw the direct final notice of deletion and it will not take effect. We will, as appropriate, address all public comments in a subsequent final deletion notice based on this notice of intent to delete. We will not institute a second comment period on this notice of intent to delete. Any parties interested in commenting must do so at this time. For additional information, see the direct final notice of deletion which is located in the Rules section of this **Federal Register**.

DATES: Comments concerning this Site must be received by August 5, 2005.

ADDRESSES: Written comments should be addressed to: Briana Bill, Community Involvement Coordinator, U.S. EPA (P–19J), 77 W. Jackson Blvd., Chicago, IL 60604–3590, (312) 353–6646 or 1–800–621–8431.

FOR FURTHER INFORMATION CONTACT: Sheila Sullivan, Remedial Project Manager at (312) 886–5251 or Gladys Beard, State NPL Deletion Process Manager at (312) 886–7253 or 1–800–621–8431, Superfund Division, U.S. EPA (SR–6J), 77 W. Jackson Blvd., Chicago, IL 60604–3590.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final Notice of Deletion which is located in the Rules section of this **Federal Register**.

Information Repositories: Repositories have been established to provide detailed information concerning this decision at the following address: U.S. EPA Region 5 Library, 77 W. Jackson Blvd., Chicago, IL 60604–3590, (312) 353–5821, Monday through Friday 8 a.m. to 12 p.m.; Franklin Public Library, 9151 W. Loomis Rd., Franklin WI 53132, (414) 425–8214, Monday through Thursday 10 a.m. to 8:30 p.m., Friday through Saturday 10 a.m. through 5 p.m.; Franklin City Hall, City Clerk's Office, 9229 W. Loomis Rd., Franklin, WI 53132, (414) 275–7500, Monday through Friday 8:30 a.m. to 5 p.m.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: June 21, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

[FR Doc. 05–13171 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 05–24; FCC 05–121]

DTV Tuner Requirements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to advance the date on which all new television receiving equipment must include the capability to receive over-the-air DTV broadcast signals from July 1, 2007, to a date no later than December 31, 2006. This revision would require all television receivers to include DTV tuners on a schedule not later than the statutory target date for the end of the DTV transition, when analog television service is to end. This proposal is intended to apply the DTV tuner requirement to all TV receivers on an advanced schedule that will allow a more rapid completion of the DTV transition while providing manufacturers with adequate time to include DTV tuners in all their TV products.

DATES: Comments must be filed on or before July 27, 2005, and reply comments must be filed on or before August 10, 2005.

ADDRESSES: You may submit comments, identified by [ET Docket No. 05–24] by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Federal Communications Commission's Web Site: *http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Alan Stillwell, Office of Engineering and Technology, (202) 418–2925, e-mail: *Alan.Stillwell@fcc.gov*, TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Further Notice of Proposed Rule Making* (FNPRM), ET Docket No. 05–24, FCC 05–121, adopted June 9, 2005, and

released June 9, 2005. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov*. Alternate formats are available to persons with disabilities at TTY (202) 418–7365.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before July 27, 2005, and reply comments on or before August 10, 2005. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121, May 1, 1998. Comments filed through the ECFS can be sent as an electronic file via the Internet *to http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply. 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, commenters must submit two additional copies for each additional docket or rulemaking number.

All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

Summary of Further Notice of Proposed Rulemaking

1. Consistent with the need to promote a rapid end to the DTV transition, we now believe it would also be appropriate to advance the date on which all new television receiving equipment must include the capability to receive over-the-air broadcast DTV signals from July 1, 2007, to a date no later than December 31, 2006. This change would advance the date for all TV receivers to include a DTV tuner to a date not later than the statutory target date for the end of the transition. We specifically request suggestions for a date no later than December 31, 2006, that would be appropriate for requiring all new television receivers to include DTV reception capability. We believe that including DTV tuners in smaller screen and other traditionally low priced receiver products would not force substantial increases in the price of such products. The majority of all televisions are sets 25″ and larger. We believe that the economies of scale needed to support reductions on the incremental price of DTV tuner equipped products will therefore be achieved in the introduction of DTV tuners in these mid-size and large screen products, which will occur more than a year earlier. We therefore believe that the price increases for small screen and other receivers will be more modest. In this regard, we observe that Zoran Corporation has indicated to the Commission in an *ex parte* contact that it has developed a reference board that includes a low-cost DTV receiver. It states that this board could be used to manufacture a set-top box that provides DTV reception at the standard definition display level to allow analog-only receivers to display DTV signals for about $65. Zoran further states that the DTV tuning capability of this board could be incorporated into a TV receiver with display at this time for about a $80–100 retail price increase and that this price would decrease dramatically with increasing volume. We request comment on this proposal and suggestions for alternative approaches for including DTV reception capability in all TV receiving devices on a schedule reflective of the statutory target date for the end of the DTV transition.

2. We also seek comment on whether the requirement to include a DTV tuner in new receivers should be extended to receivers with screen sizes less than 13″ inches. We note that if such devices are to provide off-the-air reception of TV signals after the transition, they too must be able to receive DTV signals and that it is less likely that such products, and particularly handheld and similar portable devices, would be used with a separate device for receiving DTV signals.

3. In order to allow the Commission to conclude action in these proposals in an expeditious manner so as to afford manufacturers the maximum time to prepare to comply with new rules, we are limiting the comment and reply comment periods on these proposals to 21 days and 14 days respectively.

Initial Regulatory Flexibility Analysis

4. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] 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 Further Notice of Proposed Rulemaking (FNPRM) portion of this action.[2] 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 the FNPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.[3] In addition, the FNPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.[4]

A. *Need for and Objectives of the Proposed Rules.* As described in the FNPRM, the changes to the rules being considered in this proceeding are intended to ensure a smooth transition

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] *See* Report and Order and Further Notice of Proposed Rulemaking in ET Docket No. 05–24, FCC 05–121, released June 9, 2005.

[3] *See* 5 U.S.C. 603(a).

[4] *See id.*

of the nation's television system to digital television. Beginning in 1987, the Commission undertook to bring the most up-to-date technology to broadcast television.[5] That resulted in several Commission decisions, including those adopting a digital television (DTV) standard,[6] DTV service rules,[7] and a Table of DTV Allotments.[8] The Table of DTV Allotments provides each existing television broadcaster with a second channel on which to operate a DTV station for the transition period, after which one of its channels will revert to the government for use in other services. The transition deadline established by Congress is December 31, 2006.

5. Consistent with its efforts to promote the expeditious completion of the DTV transition, the Commission adopted a requirement that all new television receivers imported or shipped in interstate commerce after July 1, 2007 include the capability to receive DTV signals off-the-air. In order to minimize the impact of the DTV tuner requirement on both manufacturers and consumers, the Commission adopted a phase-in schedule that applies the DTV tuner requirement first to receivers with the screens and then to progressively smaller screen receivers and other TV receiving devices. Consistent with the need to promote a rapid end to the DTV transition, we now believe it would also be appropriate to advance the date on which all new television receiving equipment must include the capability to receive over-the-air broadcast DTV signals from July 1, 2007, to December 31, 2006. This change would move the date for all TV receivers to include a DTV tuner forward six months to coincide with the statutory end of the transition and also provide adequate time for manufacturers to modify their products to include DTV tuners in all new television sets.[9]

B. Legal Basis.

6. The authority for the action proposed in this rulemaking is contained in sections 4(i) & (j), 303, 307, 309 and 336 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) & (j), 303, 307, 309 and 336.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.

7. The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules.[10] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental entity.'' [11] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[12] 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).[13]

Electronics Equipment Manufacturers. Rules adopted in this proceeding would apply to manufacturers of DTV receiving equipment and other types of consumer electronics equipment. The SBA has developed definitions of small entity for manufacturers of audio and video equipment [14] as well as radio and television broadcasting and wireless communications equipment.[15] These categories both include all such companies employing 750 or fewer employees. The Commission has not developed a definition of small entities applicable to manufacturers of electronic equipment used by consumers, as compared to industrial use by television licensees and related businesses. Therefore, we will utilize the SBA definitions applicable to manufacturers of audio and visual equipment and radio and television broadcasting and wireless communications equipment, since these are the two closest NAICS Codes applicable to the consumer electronics equipment manufacturing industry. However, these NAICS categories are broad and specific figures are not available as to how many of these establishments manufacture consumer equipment. According to the SBA's regulations, an audio and visual equipment manufacturer must have 750 or fewer employees in order to qualify as a small business concern.[16] Census Bureau data indicates that there are 554 U.S. establishments that manufacture audio and visual equipment, and that 542 of these establishments have fewer than 500 employees and would be classified as small entities.[17] The remaining 12 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. Under the SBA's regulations, a radio and television broadcasting and wireless communications equipment manufacturer must also have 750 or fewer employees in order to qualify as a small business concern.[18] Census Bureau data indicates that there 1,215 U.S. establishments that manufacture radio and television broadcasting and wireless communications equipment, and that 1,150 of these establishments have fewer than 500 employees and would be classified as small entities.[19] The remaining 65 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. We therefore conclude that there are no more than 542 small manufacturers of audio and visual electronics equipment and no more than 1,150 small manufacturers of radio and television broadcasting and wireless communications equipment for consumer/household use.

Computer Manufacturers. The Commission has not developed a definition of small entities applicable to computer manufacturers. Therefore, we

[5] *See Notice of Inquiry* in MM Docket No. 87–268, 2 FCC Rcd 5125 (1987), 52 FR 34259, September 10, 1987; *see also Tentative Decision and Further Notice of Proposed Rulemaking* in MM Docket No. 87–268, 3 FCC Rcd 6520 (1988), 53 FR 38747, October 3, 1998.

[6] *See Fourth Report and Order* in MM Docket No. 87–268, 11 FCC Rcd 17771 (1996), 62 FR 14006, March 25, 1997.

[7] *See Fifth Report and Order* in MM Docket No. 87–268, 12 FCC Rcd 12809 (1997), 63 FR 13546, May 20, 1998.

[8] *See Sixth Report and Order* in MM Docket No. 87–268, 12 FCC Rcd 14588 (1997), 62 FR 2668, July 11, 1997.

[9] *See* 47 U.S.C. 309(j)(14)(A).

[10] 5 U.S.C. 603(b)(3).

[11] 5 U.S.C. 601(6).

[12] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[13] 15 U.S.C. 632.

[14] 13 CFR 121.201 (NAICS Code 334310).

[15] 13 CFR 121.201 (NAICS Code 334220).

[16] 13 CFR 121.201 (NAICS Code 334310).

[17] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Audio and Video Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

[18] 13 CFR 121.201 (NAICS Code 513220).

[19] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information.

will utilize the SBA definition of electronic computers manufacturing. According to SBA regulations, a computer manufacturer must have 1,000 or fewer employees in order to qualify as a small entity.[20] Census Bureau data indicates that there are 563 firms that manufacture electronic computers and of those, 544 have fewer than 1,000 employees and qualify as small entities.[21] The remaining 19 firms have 1,000 or more employees. We conclude that there are approximately 544 small computer manufacturers.

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

8. At this time, we do not expect that the rule changes being considered in this proceeding would impose any additional recordkeeping or recordkeeping requirements. While the modifications being considered in the NPRM could have an impact on consumer electronics manufacturers and broadcasters, we anticipate at this time that such impact would be similarly costly for both large and small entities. We seek comment on whether others perceive a need for recordkeeping under specific options for addressing the issues in the NPRM and, if so, whether the burden would fall on large and small entities differently.

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

9. 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 or 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 any part thereof, for small entities.[22]

10. The rule changes under consideration in this proceeding propose a revision in the schedule for implementation of the requirement that new television receivers include the capability for reception of broadcast DTV signals. We requested comment on a proposal that would advance to December 31, 2006 (from the current July 1, 2007), the date by which all television receivers with screen sizes 13″ and larger that are imported into the United States or shipped in interstate commerce must include the capability to receive over-the-air DTV broadcast signals. Because of our concern for advancing the full compliance date in a manner that would pose no unnecessary economic burden on smaller entities, we invited interested parties to submit alternative suggestions for revising and suggestions for alternative approaches for including DTV reception capability in all TV receivers on a schedule to coincide with statutory end of the DTV transition. We also invited comment on whether we should also extend the DTV tuner requirement to TV receivers with screen sizes less than 13″.

F. Federal Rules Which Duplicate, Overlap, or Conflict With the Commission's Proposals. None.

11. *Ordering Clauses.* Pursuant to the authority contained in sections 2(a), 4(i) & (j), 7, 151 and 303 of the Communications Act of 1934 as amended, 47 U.S.C. 152(a), 154(i) & (j), 157, and 303, this Notice of Proposed Rule Making *is adopted*.

12. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration, to Congress and the General Accounting Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).[23]

13. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration, in accordance with the Regulatory Flexibility Act.

List of Subjects in 47 CFR Part 15

Federal Communications equipment, Radio.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rule Changes

For the reasons set forth in the preamble, the Federal Communications Commission proposes to amends 47 CFR part 15 as follows:

PART 15—RADIO FREQUENCY DEVICES

1. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 303, 304, 307, and 554A.

2. Section 15.117 is amended by revising paragraph (i)(1) to read as follows:

§ 15.117 TV broadcast receivers.

* * * * *

(i) * * *

(1) Responsible parties, as defined in § 2.909 of this chapter, are required to equip new TV broadcast receivers that are shipped in interstate commerce or imported from any foreign country into the United States and for which they are responsible to comply with the provisions of this section in accordance with the following schedule:

(i) Receivers with screen sizes 36″ and above—50% of all of a responsible party's units must include DTV tuners effective July 1, 2004; 100% of such units must include DTV tuners effective July 1, 2005

(ii) Receivers with screen sizes 25″ to less than 36″—50% of all of a responsible party's units must include DTV tuners effective July 1, 2005; 100% of such units must include DTV tuners effective March 1, 2006

(iii) Receivers with screen sizes 13″ to less than 25″—100% of all such units must include DTV tuners effective December 31, 2006

(iv) Other devices (videocassette recorders (VCRs), digital video disk and digital versatile disk (DVD) players/recorders, etc.) that receive television signals—100% of all such units must include DTV tuners effective December 31, 2006.

* * * * *

[FR Doc. 05–13029 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MM Docket No. 92–264; DA 05–1723]

Cable Television Horizontal and Vertical Ownership Limits

AGENCY: Federal Communications Commission.

ACTION: Notice, extension of comment period.

SUMMARY: In this Order, the Media Bureau extends the comment and reply comment period in this proceeding, which seeks comment on the

[20] 13 CFR 121.201 (NAICS Code 334111).

[21] Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Electronic Computer Manufacturing, Table 4 at 9 (1999).

[22] 5 U.S.C. 603.

[23] *See* 5 U.S.C. 603(a).

Commission's horizontal and vertical cable ownership limits. The deadline to file comments is extended from July 8, 2005, to August 8, 2005, and the deadline to file reply comments is extended from July 25, 2005, to September 9, 2005. The action is taken in response to a Motion for Extension of Time.

DATES: Comments are due on or before August 8, 2005; and reply comments are due on or before September 9, 2005.

ADDRESSES: You may submit comments, identified by MM Docket No. 92–264, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Federal Communications Commission's Web site: *http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or telephone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Royce Sherlock, Industry Analysis Division, Media Bureau, (202) 418–2330 or *Royce.Sherlock@fcc.gov*; or Patrick Webre, Industry Analysis Division, Media Bureau, (202) 418–7953 or *Patrick.Webre@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Order in MM Docket No. 92–264, released June 22, 2005. The full text of the Order is available for inspection and copying Monday through Thursday from 8 a.m. to 4:30 p.m. and Friday from 8 a.m. to 11:30 a.m. in the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, Room CY–A257, Portals II, 445 12th Street, SW., Washington, DC 20554. The complete text is also available on the Commission's Internet Site at *http://www.fcc.gov*. To request materials in accessible formats for people with disabilities (electronic files, large print, audio format and Braille), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). The complete text of the Order may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 488–5300 or (800) 378–3160, e-mail *http://www.BCPIWEB.com*.

Synopsis of the Order

1. On May 17, 2005, the Commission released its Second Further Notice of Proposed Rulemaking (''Second Further Notice'') in the above-captioned proceeding.[1] The deadlines to file comments and reply comments were originally set as July 8, 2005, and July 25, 2005, respectively.

2. On June 10, 2005, the Media Access Project, filing on behalf of itself and other consumer groups, religious organizations and citizens groups (''MAP''), requested an extension of time until August 8, 2005, to file comments in response to the Second Further Notice, and until September 9, 2005, to file reply comments. MAP states that more time is needed because the Second Further Notice asks complex and detailed questions that would require extensive research and analysis to answer; public interest organizations have significant limits on their resources, preventing them from responding to such complex questions in a short period of time; and other conflicting commitments, including other proceedings, make the initial deadline impossible to meet for these groups.

3. It is the policy of the Commission that extensions of time are not routinely granted. However, there is good cause to extend the comment and reply comment deadlines. The Second Further Notice seeks comment on a broad range of proposals in the record, as well as recent developments in the industry, and the Commission has invited parties to undertake their own studies to further inform the record. In view of the complex and detailed questions and issues set forth in the Second Further Notice, and to assure the fullest possible public participation so that we can assemble a record that will help us to resolve the difficult issues in this proceeding, we find it appropriate to grant MAP's extension request and extend the deadlines for initial and reply comments to August 8, 2005, and September 9, 2005, respectively.

4. Accordingly, *it is ordered* that MAP's Request for Extension of Time to File Comments and Reply Comments in the above-captioned proceeding is granted.

5. *It is further ordered* that, pursuant to Sections 4(i), 4(j) and 5(c) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j) and 155(c), and Sections 0.61, 0.283, and 1.46 of the Commission's rules, 47 CFR 0.61, 0.283, and 1.46, the date for filing initial comments in MM Docket No. 92–264 is extended until August 8, 2005, and the date for filing reply comments is extended to September 9, 2005.

[1] 70 FR 33680 (rel. June 8, 2005).

List of Subjects in 47 CFR Part 76

Cable Television.

Federal Communications Commission.

Royce Sherlock,

Chief, Industry Analysis Division.

[FR Doc. 05–13148 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the American Eel as Threatened or Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of petition finding and initiation of status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 90-day administrative finding on a petition to list the American eel (*Anguilla rostrata*) under the Endangered Species Act of 1973, as amended (Act). We find the petition presents substantial information indicating that listing the American eel may be warranted. We are initiating a status review to determine if listing the species is warranted. To ensure that the review is comprehensive, we are soliciting information and data regarding this species.

DATES: The administrative finding announced in this document was made on July 6, 2005. To be considered in the 12-month finding for this petition, data, information, and comments should be submitted to us by September 6, 2005.

ADDRESSES: Data, comments, information, or questions concerning this petition should be sent to Martin Miller, Chief, Division of Endangered Species, Region 5, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035–9589; by facsimile to 413–253–8428; or by electronic mail to *AmericanEel@fws.gov*. The petition finding, supporting information, and comments are available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Heather Bell, at the above address (telephone 413–253–8645; facsimile 413–253–8428). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial information to indicate that the petitioned action may be warranted. To the maximum extent practicable, this finding is to be made within 90 days of receipt of the petition, and the finding is to be published promptly in the **Federal Register**.

This finding summarizes information included in the petition and information available to us at the time of the petition review. Our review of a 90-day finding under section 4(b)(3)(A) of the Act and section 424.14(b) of our regulations is limited to a determination of whether the information in the petition meets the ''substantial information'' threshold. Our standard for substantial information with regard to a 90-day listing petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)).

We have to satisfy the Act's requirement that we use the best available science to make our decisions. However, we do not conduct additional research at this point, nor do we subject the petition to rigorous critical review. Rather, at the 90-day finding stage, we accept the petitioner's sources and characterizations of the information, to the extent that they appear to be based on accepted scientific principles (such as citing published and peer reviewed articles, or studies done in accordance with valid methodologies), unless we have specific information to the contrary. Our finding considers whether the petition states a reasonable case for listing on its face. Thus, our 90-day finding expresses no view as to the ultimate issue of whether the species should be listed.

On November 18, 2004, the Service and the National Oceanic and Atmospheric Administration (NOAA Fisheries) received a petition, dated November 12, 2004, from Timothy A. Watts and Douglas H. Watts, requesting that the Service and NOAA Fisheries list the American eel as an endangered species under the Act. The petition contained detailed information on the natural history of the American eel, its cultural use, population status, and existing threats to the species. Threats discussed in the petition included destruction and modification of habitat, overutilization, inadequacy of existing regulatory mechanisms, and other natural and manmade factors such as contaminants and hydroelectric turbines. The petition did not address potential threats caused by disease or predation. In response to the petitioners' request to list the American eel, the Service, as administrative lead for the species, sent a letter to the petitioners dated December 13, 2004, explaining that the Service, in coordination with NOAA Fisheries, would review the petition and determine whether or not the petition presents substantial information indicating that listing the American eel may be warranted. Jurisdiction for the American eel is jointly held by the Service and NOAA Fisheries, with the Service having administrative lead for processing this petition and working closely with NOAA Fisheries during the process.

Accompanying the petition, and incorporated by reference into the petition, is the Atlantic States Marine Fisheries Commission's (ASMFC) Interstate Fishery Management Plan for American Eel (2000). The ASMFC is an Interstate Compact of the 15 Atlantic Coast States (Maine to Florida) charged with managing interstate fisheries resources of the Atlantic Coast. The Compact was approved by the Congress of the United States in 1942 in Public Law 77–539, and authority was further amended by Public Law 81–721 and the Atlantic Coastal Fisheries Cooperative Management Act (Pub. L. 103–206). The Interstate Fishery Management Plan for the American eel (Management Plan) was developed by ASMFC in response to declining stocks of American eel and had input from the public and commercial fishing industry, as well as considerable technical scrutiny from the scientific community. The Service and NOAA Fisheries were involved in producing the Management Plan for the American eel, as representatives to the ASMFC Eel Technical Committee charged with developing the Management Plan. State agencies and an academic institution were also involved in developing this document, and it was approved by the ASMFC board that consists of representatives from the 15 Atlantic Coast States.

The Management Plan provides a detailed description of the life history, habitat requirements, the commercial fishery, population status, and threats to the American eel. The goals of the Management Plan are to protect and enhance the abundance of American eels in both inland and territorial waters within ASMFC's jurisdiction, and to provide for sustainable commercial, subsistence, and recreational fisheries by preventing overharvest of any eel life stage.

For this finding, the Service utilized the petition and the Management Plan, which was incorporated into the petition by reference, and other petition appendices and references. Because of the rigor and integrity of the Management Plan, and the significance to the American eel of the geographic area covered by the Management Plan (the Gulf Stream transports the majority of larval American eel to the Atlantic Coast States), the Service relied on the petition and Management Plan in determining that the petitioned action may be warranted.

The ASMFC announced in March of 2004 that it is developing an amendment to the Management Plan to address continued stock declines. As part of the amendment process it committed to conduct a benchmark stock assessment in 2005, and requested that the Service and NOAA Fisheries conduct a status review of the American eel. Per this request, the Service agreed in September 2004, prior to receiving the petition, to conduct a rangewide status review of the American eel in coordination with NOAA Fisheries and the ASMFC.

Species Information

American eel are a migratory fish species with multiple life stages that migrate from freshwater to the ocean to spawn (a life history strategy known as ''catadromy''). American eels require various habitats over their long-lifespan, including open oceans, large coastal tributaries, small freshwater streams, and lakes and ponds. They are opportunistic feeders at every level of the food chain. The North Atlantic is home to two recognized species of catadromous eel: the American eel and the European eel (*A. anguilla*). The range of the American eel includes western Atlantic drainages from Greenland to northern portions of South America, including most Caribbean Islands, the eastern Gulf of Mexico, and inland areas of the Mississippi River and the Great Lakes drainages. The majority of the American eel population is along the Atlantic seaboard of the United States. There is U.S. and international commercial harvest, limited subsistence use by Native Americans, and limited recreational interest in the American eel fishery.

Life History Characteristics

Reproduction and Growth

American eel eggs hatch in the Sargasso Sea, in the western Atlantic Ocean (for further description of the Sargasso Sea, see Habitat section below). The required environmental conditions for reproduction and the incubation period for the American eel are unknown (ASMFC 2000). The resulting larvae (leptocephali) drift in the upper 300 meters of the Gulf Stream for up to one year before reaching the North American continent (Kleckner and McCleave 1985, as in ASMFC 2000). At sea, perhaps at the edge of the continental shelf (Hardy 1978, as in ASMFC), the shape of the larvae dramatically changes as they metamorphose into miniature transparent glass eels (ASMFC 2000). American eel larvae may only be capable of undergoing metamorphosis during a specific window beginning after 6–8 months and remain capable for only 4–6 additional months (McCleave 1987, 1993, as in Castonguay *et al.* 1994b).

Glass eels actively migrate toward freshwater and ascend rivers during the winter and spring by drifting on flooding tides, holding position near the bottom on ebb tides, and actively swimming along the shore in estuaries above tidal influence (Facey and Van Den Avyle 1987; Barbin and Krueger 1994, as in ASMFC 2000). Migration to freshwater occurs earlier in the southern portion of the range and later in the northern portion (Helfman *et al.* 1984, McCleave and Kleckner 1982, as in ASMFC 2000), possibly due to the increased distance of northern areas from the Sargasso Sea.

Anadromous fish (*e.g.*, salmon and shad) spawn in freshwater but spend most of their lives at sea. As they mature, these fish usually return to their river of origin to repeat the cycle. Return rates and abundance are driven by prior spawning success, at sea survival, and environmental conditions. American eels are also highly migratory, but in the opposite direction. Adult eels migrate from freshwater to the ocean to spawn (catadromy). Since they are not returning to a home river, dispersion of juvenile ''glass'' eels back into freshwater is more likely dependant on environmental conditions, such as ocean and nearshore currents, river discharge rates, and temperature, as well as timing of larval metamorphosis (R. StPierre pers. comm. 2005).

Glass eels become elvers when they ascend into brackish or fresh water and become pigmented (McCleave and Kleckner 1982, as in ASMFC 2000). Upstream migration may occur from May through October (Richkus and Whalen 1999, as in ASMFC 2000), peaking earlier in the southern and later in the northern portion of the range (Helfman *et al.* 1984, McCleave and Kleckner 1982, as in ASMFC 2000).

Elvers become yellow eels approximately 2 years after hatching and resemble the adult form. Yellow eels are usually yellow or green, and reach sizes up to about 11 in (28.0 cm) for males and 18 in (46 cm) for females (Hardy 1978, as in ASMFC 2000). The timing and duration of upstream migration is watershed specific, and upstream migration may occur in most months of the year (ASMFC 2000). The growth rates of yellow eels are variable, depending on latitudinal location (eels grow more slowly in the north than in the south) and habitat productivity (eels grow more slowly in freshwater than in estuarine areas because of the lack of productivity or nutrients in freshwater as compared to estuaries) (Richkus and Whalen 1999, as in ASMFC 2000).

The silver eel life stage, during which eels become sexually mature and begin their spawning migration, begins after 3, and up to 24 years as a yellow eel. Yellow eels, responding to some environmental or metabolic signal, begin to migrate downstream in the late summer or fall. As they proceed downstream, they transform into silver eels (Hardy 1978; Fahay 1978; Wenner 1973; Facey and Van Den Avyle 1987, as in ASMFC 2000). This transformation includes several physiological changes, including: (1) Silvering of the skin; (2) body fattening; (3) skin thickening; (4) eye enlargement and pigment change; (5) increased length of capillaries in the rete (a netlike structure) of the swim bladder; and (6) digestive tract degeneration (Facey and Van Den Avyle 1987).

Sex Ratio. There are several environmental variables that may influence age at sexual maturity, sexual determination, and the resulting ratios of females and males (juveniles are not sexually determined and at a certain stage may be hermaphroditic—being both sexes). In general, sexual differentiation does not occur until eels are about 8–10 in (20–25 cm) long (Dolan and Power 1977, as in Facey and Van Den Avyle 1987). Sexual maturity appears to occur at older ages and larger sizes in the northern portion of their range when compared with the southern portion, resulting in northern females being the most fecund and having a relatively long life span (Helfman *et al.* 1987, as in ASMFC 2000). Most sexually mature males are greater than 11 in (28 cm), and older than 3 years of age in the northern populations. Information from the northern stocks indicates that most sexually mature females are greater than 18 in (46 cm), and older than 4 years of age (Hardy 1978, Fahay 1978, as in ASMFC 2000).

It has been hypothesized that sex determination, and the resulting differences in ratios and distribution, may be due to a variety of factors, including: (1) Latitudinal differences (females more abundant in northern areas: McCleave 1996, as in ASMFC 2000), (2) differences in salinity (females more abundant in freshwater: Facey and LaBar 1981, as in ASMFC 2000), (3) density dependency (more females in areas of low density: Fahay 1978, as in Facey and Van Den Avyle 1987), (4) timing (males returning to spawn earlier than females, and therefore finding it beneficial to stay in southern latitudes), or (5) energy use (slower growth, such as that which would occur in typically less productive areas of northern or inland areas, leads to larger size, and for females a higher fecundity: Helfman *et al.* 1987, as in ASMFC 2000).

Spawning. American eel fecundity can range between 0.5 to 21.9 million eggs per female and can be predicted based on female size (Facey and Van Den Avyle 1987, McCleave and Oliveira 1998, as in ASMFC 2000). High fecundity of the eel is consistent with an r-selected strategy that assumes high mortality of larval and subadult stages (Wenner and Musick 1974, Barbin and McCleave 1997, as in ASMFC 2000).

Adult American eels from throughout their range are believed to synchronize their arrival at the spawning grounds; however, little is known about the oceanic portion of the spawning migration, or mechanisms for locating the spawning grounds (Miles 1968, as in ASMFC 2000). The American eel may use the geoelectrical fields generated by ocean currents for orientation (Rommel and Stasko 1973, as in ASMFC 2000). The depth at which American eels migrate in the ocean has been hypothesized to vary with light intensity and turbidity (Edel 1976, as in ASMFC 2000). Migration has been suggested to occur within the upper few hundred meters of the water column (Kleckner *et al.* 1983, McCleave and Kleckner 1985, as in ASMFC 2000). However, Robins *et al.* (1979, as in ASMFC 2000) photographed two *Anguillid* eels, possibly pre-spawning American eels, at depths of about 6,500 ft (2,000 m) on the floor of the Atlantic Ocean in the Bahamas.

Some feature of the surface water mass of the Sargasso Sea, such as thermal fronts, may serve as a cue for

adult American eels to cease migration and begin spawning. Eels are thought to spawn in the winter and early spring in the upper few hundred meters of the water column of the Sargasso Sea (Kleckner *et al.* 1983, McCleave and Kleckner 1985, as in ASMFC 2000). After spawning, the spent eel is assumed to die (Facey and Van Den Avyle 1987).

The American eel and the European eel, considered separate species, both spawn in the Sargasso Sea, but a mechanism for separation, possibly location, depth, or timing of spawning, is unknown, and an area of overlap in spawning habitat is likely. Leptocephali of both species have been captured in the same trawl (McCleave *et al.* 1986b, as in Facey and Van Den Avyle 1987). Morphologically, the adult American and European eel differ in the number of vertebrae or myomeres. Larvae with the ''American'' and ''European'' myomere counts have partially separate but overlapping spatial and temporal distributions in the Sargasso Sea (Schmidt 1922, Schoth 1982, Schoth and Tesch 1982, Boëatius and Harding 1985a, b, Mcleave *et al.* 1987, Kleckner and McCleave 1988, as in Avise 2003), indicating that spawning areas overlap to some degree. Both mitochondrial and nuclear gene evidence show that American and European eels belong to two largely separate gene pools (Avise 2003). Genetic data in conjunction with vertebral counts indicate that about 2 to 4 percent of the Icelandic eel are of American eel ancestry but do not appear to be strays, indicating a zone of hybridization between the two species (Avise 2003).

Genetic studies indicate that American eels are a single panmictic breeding population (Williams and Koehn 1984, as in ASMFC 2000), meaning that it is a single breeding population exhibiting random mating, and that offspring from any parents are capable of inhabiting any suitable habitat in any portion of the range. Recent analyses, however, may indicate genetic variation with latitude, suggesting that mating within the species is not panmictic in the strict sense and that dispersal of larvae is not entirely random with respect to where their parents resided in continental waters (Avise 2003).

Feeding Habits

American eels are carnivorous, and at various life stages and locations they feed on multiple trophic levels, such as zooplankton and phytoplankton as leptocephali, aquatic invertebrates as juveniles, and fish and crustaceans as adults (McCord 1977, Ogden 1970, Wenner and Musick 1975, as in ASMFC 2000).

Range, Distribution, and Habitat

The American eel occupies fresh, brackish, and coastal waters along the Atlantic Ocean from the southern tip of Greenland to northeastern South America, the inland waters near the Caribbean, the eastern Gulf of Mexico, and inland to the Mississippi River and Great Lakes drainages. Important aspects of American eel life history, including spawning, larval development, and migration, occur in the open ocean. Successful migration of leptocephali (and thus recruitment) depends on oceanic conditions being suitable to transport the larvae to continental areas during the window of metamorphosis from larvae into glass eel on the Continental Shelf (see the Reproduction and Growth section of this document). The mean circulation in the vicinity of the spawning area tends to transport larvae westward, and eventually into the Gulf Stream system, which carries them north and east along the coast of North America (*i.e.* Florida to Canada) (McCleave 1993, as in Castonguay *et al.* 1994). Other currents may transport larvae in smaller numbers to the more southerly areas of the range, but the conditions under which this happens are unclear.

Elver habitat likely includes soft, undisturbed bottom sediments (Facey and Van Den Avyle 1987) and river currents appropriate for upstream migration (Tesch 1977; Sorensen 1986; Sorensen and Bianchini 1986, as in ASMFC 2000). Feeding and growth of yellow eels occur in estuaries and fresh waters over a period of many years (including offshore, midwater, and bottom areas of lakes, estuaries, and large streams) (Adams and Hankinson 1928, Facey and LaBar 1981, GLFC 1996, Helfman *et al.* 1983, NYSDEC 1997a & b, as in ASMFC 2000; Facey and Van Den Avyle 1987).

When American eels metamorphose into silver eels and migrate seaward to their spawning ground, they travel downstream mostly at night (Bigelow and Schroeder 1953, as in ASMFC 2000) and may inhabit a broad range of depths throughout the water column.

As mentioned earlier, spawning occurs in the Sargasso Sea, an oval area in the middle of the Atlantic Ocean, between the West Indies and the Azores (between 20° to 35° North Latitude and 30° to 70° West Longitude), composed of a nearly 5.2 million km^2 area. Although the boundaries are not easily delineated, the Sea is identified as the ''eye'' of a large, slow, clockwise moving gyre of clear, deep blue colored, warm surface waters, with elevated salinity and low plankton production. The Gulf Stream provides the western boundary, which along with other ocean gyres (large circular currents in all the ocean basins), such as the North Equatorial Current, encircles the Sargasso Sea.

Knowledge of the specific spawning area for the American eel within the Sargasso Sea is based on the distribution of the smallest leptocephali, as adults have never been observed in the area. Miller (1995, as in ASMFC 2000) reported two major distribution patterns for leptocephali with the highest abundance in areas located near fronts in the west of the Subtropical Convergence Zone (STCZ) in the southwestern Atlantic. The smallest leptocephali were reported to have been collected near the Bahama Banks (the Bahamas) in the Florida Current and at stations close to the southerly fronts in the western STCZ.

Population Status

Historically, American eels were abundant in East Coast streams and estuaries, and thought to comprise more than 25 percent of the total fish biomass (Smith and Saunders 1955, Ogden 1970, as in ASMFC 2000). Although this species declined from the historic levels, the population remained relatively stable, some thought, until the 1970s (ASMFC 2000). Others, including the Southeastern Fishes Council Technical Advisory Committee, concluded, based on a review of 51 major drainages of the southern United States, that the regional stock of the American eel was stable (Warren *et al.* 2000) through the 1990s, and NatureServe, which utilizes occurrence data, listed many eel stocks in Atlantic States as stable in 2001 (NatureServe 2004).

According to the ASMFC (2000), the eel has lost much of its habitat along the eastern United States. As stated in the petition, the ASMFC states: ''By region, the potential habitat loss [for American eel] is greatest (91 percent) in North Atlantic region (Maine to Connecticut) where stream access is estimated to have been reduced from 111,482 kilometers to 10,349 kilometers of stream length. Stream habitat in the Mid Atlantic region (New York through Virginia) is estimated to have been reduced from 199,312 km to 24,534 km of unobstructed stream length (88 percent loss). The stream habitat in the South Atlantic region (North Carolina to Florida) is estimated to have decreased from 246,007 km to 55,872 km of unobstructed stream access, a 77 percent loss.''

Decreases have been noted in the commercial and recreational fisheries. Since the fisheries' peak in the mid 1970s at 3.5 million pounds, commercial landings have declined significantly to a near record low of 868,215 pounds in 2001. Recreational data concerning eel harvest also appears to indicate a decline in abundance. According to the National Marine Fisheries Service (now NOAA Fisheries) Marine Recreational Fisheries Statistics Survey, recreational harvest in 2001 was 10,805 eels, a significant decrease from the peak of 106,968 eels in 1982 (ASMFC 2000). Harvest data are often all that is available; however, taken alone without a measure of fishing effort, this type of data are not good indicators of eel abundance because harvest is dependent on demand, which can fluctuate dramatically (the number of commercial harvest permits issued per state can provide a surrogate for fishing effort, and understanding and adjusting for market fluctuations can provide a clearer picture of trends). Additionally, changes in year-class strength are not readily recognizable because most samples of eels include individuals of similar sizes, but from unknown year classes, and harvest of young yellow-phase eels for use as crab bait and as live bait for recreational fisheries frequently go unreported (Haro *et al.* 2000).

Richkus and Whalen (1999, as in ASMFC 2000) concluded that there is broad-based evidence for a decline of American eels from 1984 to 1995 based on a Mann-Kendall trend analysis of eel abundance time series on eel migration data, including data from the Moses-Saunders eel ladder. Their results indicate significant negative trends for yellow and/or silver eel abundance in Ontario, Quebec, New York, and Virginia. The authors found no trends for glass eel or elvers, but those data sets were generally not complete and may not have covered the years where the largest declines were observed in other data sets.

In Canada, different areas report seemingly opposing harvest data. Commercial landings in the Nova Scotia region of the Gulf of St. Lawrence and from Newfoundland show variability in yellow and silver eel landings, but no clear trend. By contrast, an upward trend is apparent in catches south of the Gulf of St. Lawrence, in the Canadian Atlantic/Bay of Fundy regions (threefold increase since the mid or late 1980s) (ICES 2000). According to Ontario's Ministry of Natural Resources, Lake Ontario, which had as many as 10 million eels two decades ago, now holds only tens of thousands. Ontario's commercial eel harvest peaked at more than 500,000 lbs (250 tn) in 1978. The 30,000 lbs (15 tn) harvest in 2003 was a fraction of the 1978 harvest (Dohne 2004, as in petition).

The St. Lawrence River in Canada, one of the largest rivers in North America, has seen little or no recruitment for the last 10 years, with an estimate of only 1 percent of the stocks remaining in this area. This observation is partially based on the age of eels (which appear to be getting older, indicating a failure in recruitment) and the monitoring of abundance at the eel ladder at the Moses-Saunders Dam. Annual numbers of juvenile eels climbing the Moses-Saunders Dam eel ladder decreased from a peak of 1,293,570 in 1983, to 935,170 in 1985, and went as low as 11,533 eels in 1992 (a 99 percent decline in recruitment to Lake Ontario). Electrofishing surveys and waterfall surveys of tributaries to the Gulf of St. Lawrence also point to an eel recruitment decline between 1981 and 1985 of approximately 80–90 percent (Castonguay *et al.* 1994a). Lake Ontario scientific trawl surveys from 1972–1999 (except 1989) indicated a downward trend with catches in the last five years an order of magnitude lower than in the first five years of the survey (ICES 2000). These observed declines may have significant impacts on the eel rangewide, as the stock in the St. Lawrence River is made up primarily of large spawning females. There is concern that if their numbers are down, it may affect recruitment to the entire Atlantic Coast. John Casselman, researcher for the Ontario Ministry of Natural Resources, Canada, and others, hypothesize that a substantial proportion of large female spawners for this panmictic species are from the St. Lawrence system (ASMFC 2004). As a consequence of the observed decline, the Ontario Ministry of Natural Resources issued a moratorium in 2004 on commercial eel harvest for Ontario waters, and a moratorium on recreational eel harvest is forthcoming (Casselman pers. comm. 2005).

Recent information indicates that a decline in U.S. harvest continues. Based on 2002 harvest reports collected by the ASMFC, the long-term average (52 year period) for landings is down 64 percent, the more recent average (past 20 years) for landings is down 44 percent, and the most recent average (past 5 years) for landings is down about 30 percent (Geer 2004).

The information provided by the petitioners indicates that American eel populations have generally declined and the species has lost much of its habitat. Declines in eel populations appear to be most dramatic in the Saint Lawrence, Lake Ontario, and northeastern states. In other areas, such as the southeast, declines may not be as severe and populations may be stable. Additionally, the American eel appears to have lost the majority of its stream habitat, ranging from 91 to 77 percent habitat loss in states bordering the Atlantic Ocean. Although much of the population trend information is based on harvest data without any measure of effort, we believe that the petitioner has provided substantial information indicating that the eel's population has declined on a regional basis, in addition to experiencing severe habitat loss.

Factors that may contribute to a possible population decline are habitat loss and degradation, overharvest, disease, structures impeding upstream and downstream passage, contaminants, and variable oceanic conditions (further discussed in Discussion of Listing Factors). Similar declines in the population of European and Japanese eels have been observed (Moriarty and Dekker 1997, Tatsukawa and Matsumiya 1999, as in Haro *et al.* 2000).

Discussion

In the following discussion, we respond to each of the major assertions made in the petition, organized by the Act's listing factors. Section 4 of the Act and its implementing regulations (50 CFR 424) set forth the procedures for adding species to the Federal list of endangered and threatened species. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. The five listing factors are: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; and (5) other natural or manmade factors affecting its continued existence.

The petition provided specific information on the life history of the American eel, use of American eels by humans, population status, obstacles to river passage, mortality by hydroelectric turbines, and the impacts of contaminants, habitat loss, and harvest, as well as a discussion of inadequacy of existing regulatory mechanisms. Incorporated into the petition by reference was the ASMFC Interstate Fishery Management Plan for American Eel (Management Plan) (ASMFC 2000), which summarizes peer reviewed papers on the status of the species and recent and historical trends and

provides extensive information on the life history and the threats and impacts affecting various life stages of the species, in the eastern United States. Participating in the development of the Management Plan were the Service; Maine Department of Marine Resources; New Jersey Division of Fish; Game and Wildlife; Delaware Division of Fish and Wildlife; South Carolina Department of Natural Resources; Maryland Department of Natural Resources; and East Carolina University. This document was also approved by the ASMFC board, which consists of representatives from 15 Atlantic Coast States.

This 90-day finding is not a status assessment and does not constitute a status review under the Act.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The petition, its appendices, and referenced documents discuss the following threats which we have grouped under Factor A: (1) Seaweed harvest; (2) benthic habitat degradation; (3) alterations in stream flow; (4) loss of wetland habitat; and (5) loss of upper tributary habitat.

Seaweed Harvest

Information provided in the petition. The petitioner did not provide specific information on the effects of seaweed harvest on American eels. However, the Management Plan incorporated by reference discussed seaweed harvest as a possible emerging threat to the ocean spawning habitat.

Reproduction of all American eels occurs in the Sargasso Sea. One species of *Sargassum,* a brown algae that is commonly found floating in the Sargasso Sea and drifting along the Atlantic Coast from Florida to Cape Cod, was harvested in U.S. waters primarily by one company. The harvesting of *Sargassum* began in 1976, but has only occurred in the Sargasso Sea since 1987 (ASMFC 2000).

Analysis of the information provided in the petition and information in our files. The Management Plan proposes that the harvest of *Sargassum* may affect American eels (ASMFC 2000). From 1976 through 1998, approximately 44,800 lbs (dry) of *Sargassum* have been harvested, 33,500 lbs of which were from the Sargasso Sea (ASMFC 1998). The ASMFC stated that the harvesting of *Sargassum* was to be eliminated in the South Atlantic Exclusive Economic Zone (EEZ) by January 2001; however, a Management Unit for *Sargassum* was established in 2002 throughout the South Atlantic EEZ and State Waters that did not eliminate harvest, but instituted timing restrictions and established specific areas where harvest is closed (ASMFC 2002). The remainder of the Sargasso Sea is outside of the EEZ and currently not subject to restriction.

It is conceivable that harvesting *Sargassum* would affect eggs and leptocephali, if harvest occurs where eggs and leptocephali are present. There is also the potential that migrating or spawning adults may be affected either directly or indirectly by the harvest of *Sargassum.* We agree that seaweed harvest may impact American eels. However, we are not aware of any analysis on the extent and impact of this activity on the American eel; therefore, we are unable to speak to whether seaweed harvest has caused or contributed to a decline in American eel.

Benthic Habitat Degradation

Information provided in the petition. The petitioner did not provide specific information on the effects of benthic habitat destruction on American eels. However, the Management Plan incorporated by reference discussed benthic habitat destruction as a possible threat within the Continental shelf habitat.

The Management Plan also explained that larval migration, feeding, and growth, and juvenile metamorphosis, migration, feeding, and growth all occur on the Continental Shelf. Glass eel growth, distribution, and abundance, according to the ASMFC, is probably impacted by a variety direct effects (*e.g.,* channel dredging and overboard spoil disposal) and indirect effects (*e.g.,* changes in salinity due to dredging) (ASMFC 2000).

Analysis of the information provided in the petition and information in our files. Glass eels and elvers burrow or rest in deep water during the day (Deelder 1958, as in ASMFC), and therefore may be susceptible to activities, such as dredging, that disturb those habitats. Channel dredging and overboard spoil disposal are common throughout the Atlantic coast. Changes in salinity as a result of dredging projects could alter the distribution of American eels. Additionally, dredging associated with whelk and other fisheries may damage benthic habitat for this species (ASMFC 2000). However, we are not aware of any analysis on the extent and impact of these activities on the American eel, and therefore, we are unable to speak to whether benthic habitat degradation has caused or contributed to a decline in the American eel.

Alterations of Stream Flow

Information provided by the petitioner. The petitioner did not provide specific information on the effects that alterations of stream flow have on American eels. However, the Management Plan incorporated by reference discussed alterations of stream flow as being a possible threat to their access to tributaries, which would limit upstream recruitment.

Elvers are small (4 in/10 cm or less in length) and are poor swimmers, initially utilizing tides when initiating upstream migration. Elvers orient to river currents for their upstream migration (Tesch 1977, as in ASMFC 2000). Their upstream migration is a slow process (Haro and Krueger 1988, as in Richkus and Whalen 1999, as in ASMFC, estimated upstream migration rates of 6 m/day), and if the current becomes too weak or too strong (changes in stream velocity), the eels may move into backwater areas, severely delaying upstream progress (Tesch 1977, as in ASMFC 2000). The onset of this active upstream migration appears to be influenced by several environmental variables (changes in water chemistry caused by intrusion of estuarine water, or changes in pH or salinity), or other environmental variables such as river current velocities, the odor of decomposing leaf detritus, or a temperature threshold (Facey and Van Den Avyle 1987, Sorensen and Bianchini 1986, as in ASMFC 2000).

Analysis of the information provided in the petition and information in our files. Altering stream flows, such as rapid changes in stream flow associated with hydroelectric project peaking operations and water storage facilities, may limit upstream recruitment according to ASMFC by affecting upstream migration (2000). However, we are not aware of any analysis on the extent and impact of alterations of stream flow on American eels, and therefore, we are unable to speak to whether alterations of stream flow have caused or contributed to a decline in the American eel.

Loss of Wetland Habitat

Information provided by the petitioner. The petitioner did not provide specific information on the effects of wetland habitat loss on American eels. However, the Management Plan incorporated by reference discussed loss of wetland habitat under decreased availability of important habitats.

Lost wetlands or access to wetlands have significantly decreased the availability of important habitats for

feeding and growth of American eel juveniles and subadults (ASMFC 2000). Ackerknecht *et al.* (1984, as in ASMFC 2000) reported in 1984 that over half (54 percent) of the coastal wetlands in the lower 48 states have been destroyed.

Analysis of the information provided in the petition and information in our files. Wetlands loss can be caused by filling and dredging, and coastal subsidence. Degradation of wetland habitat has occurred due to contaminants and the invasion of nonnative species. Although prior losses have been significant, regulations implemented in the 1970s have curbed declines by 42 percent. For example, all coastal States in the lower 48, except Texas, have enacted special laws to protect estuarine wetlands (Ackerknecht *et al.* 1984; Tiner 1991). The ASMFC (2000) reported that the historic loss of wetland habitat, along with loss of upper tributary habitat (discussed below), significantly decreased the availability of important habitats for the feeding and growth of American eels. However, the most significant loss of estuarine wetlands occurred before the decline in the American eel was reported. We agree that the loss of wetland habitat has likely impacted and may continue to impact American eels. However, because of the temporal discrepancy between the greatest wetland loss and the onset of a decline, we believe that the loss of wetland habitat is unlikely the single cause of the decline, but may have contributed to the decline in combination with other factors.

Loss of Upper Tributary Habitat

Information provided by the petitioner. The petitioners presented information on the decline of freshwater habitat available to American eels, stating that it has declined, having been destroyed, modified, or curtailed by at least 84 percent in the United States. This significant loss of habitat is due to blockage or restriction caused by dams.

In a Busch *et al.* (1998, as in ASMFC 2000) assessment, they determined that Atlantic coastal streams from Maine to Florida have 15,115 dams that can hinder or prevent upstream and downstream movement of eels, resulting in a restriction or loss of access to 84 percent of the stream habitat within the Atlantic Coastal historic range. This is a potential reduction from 345,359 miles (556,801 kilometers) to 56,393 miles (90,755 kilometers) of stream habitat available for species such as American eel. The greatest losses reported in Busch *et al.'s* study were in the North Atlantic region from Maine to Connecticut where potential habitat loss is estimated at 91 percent. The South Atlantic region of North Carolina to Florida is estimated to have experienced a 77 percent loss of habitat (Busch *et al.* 1998, as in ASMFC 2000). Although elvers will attempt to scale wetted substrates, such as small dam faces, for many of the migrants, dams probably limit their ability to pass these structures (Tesch 1977, as in ASMFC 2000).

In Canada, the construction of the Moses-Saunders Dam in 1954–58 impeded upstream (and downstream) migration on the St. Lawrence River, restricting access by migratory fish from the Atlantic Ocean to Lake Ontario and the Finger Lakes system in New York for 20 years. An eel ladder, constructed at the dam in 1974, improved upstream passage (ASMFC 2000).

Analysis of the information provided in the petition and information in our files. Castonguay *et al.* (1994a) reviewed major habitat modifications as a potential cause for the drastic decline of American eels in the Lake Ontario and Gulf of St. Lawrence ecosystems. Anthropogenic (human-caused) habitat modifications in the Lake Ontario/St. Lawrence River ecosystem (such as the Moses-Saunders Dam) occurred mostly before the 1960s, whereas the eel recruitment decline started only in the early to mid 1980s. The lack of temporal correspondence between permanent habitat modifications argues, according to Castonguay *et al.* (1994a), against their role in the decline. However, they provide caution to accepting this explanation, because of the American eel's strikingly different life histories (panmictic, longer lived, and ocean spawning as compared to anadromous fishes); catadromous fishes (such as eel) are likely to respond more slowly to these anthropogenic impacts compared with anadromous fish populations.

Although along the U.S. Atlantic Coast there remains some available upstream habitat, unlike anadromous species such as herring or shad, American eels have no particular homing instinct. The implication here is that although rivers remain that allow for upstream migration, even if an adult female successfully migrates down her resident stream and spawns, the resulting young eels will not necessarily return to that stream and could, due to currents, be delivered to an area with upstream blockage. Returning to a stream with blockage does not necessarily eliminate survival (as the young can remain in the lower reaches and likely become male), but it may present increased risks of predation (predation may be significant at the blockage where predatory fish may congregate).

Based on the information provided by the petitioner and an analysis of the information in our files, we agree with the petitioners' assertion that the decline in American eel may be in some part attributable to the loss of upper tributary habitat for female eel, and if not responsible for the decline initially, may well be a limiting factor as population numbers decrease.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Information provided by the petitioner. According to the petitioners, it is undisputed that overutilization through harvest of the American eel is occurring across the species' range in the United States and that along with habitat loss, harvest pressure is a primary cause of any possible historic and recent decline in abundance of the American eel (Castonguay *et al.* 1994a and 1994b, as in ASMFC 2000).

The U.S. commercial fishery has traditionally supplied American eels for the U.S. and European food markets, domestic trotline bait, bait for domestic sport fisheries, and (at times) the Asian food market. American eel fisheries exist in the United States, Canada, and to a lesser extent the Caribbean and Central America. American eel fisheries have fluctuated widely. For example, throughout the first half of the 20th century, the eel fishery was small; however, as European and Asian eel fisheries declined by the late 1960s, a strong market developed in the early 1970's for live American glass eel and elvers which range from 2–4 inches (Crawford 1996, as in ASMFC 2000). Eastern Asia has an intensive aquaculture industry (165,347 tn/150,000 t metric production) which is dependent upon and supported by wild-caught glass eel and elvers because artificial propagation of the species from fertilized egg to commercial size has not been successful (Moriarty and Dekker 1997, as in ASMFC 2000). Both glass and elver commercial eel fisheries are scattered throughout the American eel's range, with the present fishery concentrated in Maine (16,599 lbs landed in 1995; ASMFC 2000).

Yellow eel spend from 2 to 30 years in fresh and estuarine habitats before reaching sexual maturity and are harvested throughout that period. According to ASMFC (2000) they are thus susceptible to overharvest. Silver eels are sexually mature individuals and are harvested in freshwater and marine environments throughout their range.

During strong market periods, for instance in the 1970s and 1990's, legal shipment increases of over 153 and 230 percent, respectively, were recorded (ASMFC 2000). Annual harvest reported in the mid 1970's was in excess of 1,700 tons, and in the 1990's just under 14 tons. These harvests are likely less than the actual amount exported as underreporting has been an issue (underreporting has ranged from 3.6 to 261 percent) (ASMFC 2000). More recent information provided by the petitioner indicates that U.S. landings on the Atlantic Coast are down about 64 percent of the long-term average, possibly (Geer 2004).

Analysis of information provided in the petition and information in our files. Information in our files provides additional detail on the extent of the commercial and recreational American eel fishery. Few recreational anglers directly target eel, but eel are often purchased by recreational fishermen for use as bait for larger gamefish such as striped bass. From the Atlantic coast area surveyed, the estimated total annual catch of eel ranged from 212,690 eel in 1982 to 36,741 eel in 1997 (ASMFC 2000). Some recreational fishermen may catch eels for bait purposes directly, but not report such landings (ASMFC 2004).

Commercial exports of glass eels to Europe and Asia have led to enforcement problems due to high prices, low cost of entry to the fishery, and large numbers of participants. State agencies have focused enforcement efforts on take while federal efforts have been focused on foreign trade aspects of the fishery. A U.S. Fish and Wildlife Service, Division of Law Enforcement (USFWS–DLE) review of foreign trade of American eels from 1992 to 1996 revealed problems with reporting of catches and exports, with records for 1993 showing more than twice as many live American eels being exported as were reported caught in the U.S. Commercial eel harvest is reportedly one of the largest commercial fishing activities on the east coast due to the high economic incentives associated with glass eels. The commercial ''on-the-street'' price for glass eels from the Atlantic seaboard ranges from approximately $600 per pound in the early fishery to $100 per pound in the late fishery (USFWS–DLE pers. comm.).

Illegal take of glass eels and possibly other life stages were not recognized as a major problem until summer 1997. Numerous prosecutions for illegal fishing activity involving glass eels have taken place in state and federal courts since 1997. During the period March 1996 through March 1998, the Office of Law Enforcement expended a great deal of man hours and effort focused on the protection of American eels. This period saw a marked increase in illegal activity involving American eels that was directly attributable to the black market value of elvers. Service investigations revealed that during this period poachers could easily expect to command in the neighborhood of $350 per pound for eels, harvested at only about 2 to 4 inches long, that were then exported live to Asia and Europe (USFWS–DLE pers. comm.).

In 1999 the Office of Law Enforcement observed a nearly complete cessation of illegal activity involving American eels. This appears to be the result of a bottoming out of the black market value for elvers and not a reaction to previous enforcement activity. In 1999 commercial fisherman, who could legally harvest elvers in Maine, reported they were lucky to get $20–$22 a pound as compared to the $350 per pound seen the year before. This drop in value apparently was the result of the preference of Asian consumers for the taste of juvenile Asian eels over American eels and the availability of farmed raised Asian eels. During this three year period, the Office of Law Enforcement conducted three separate but related investigations intended to detect and prosecute subjects involved in illegal commercialization of elvers. Current regulatory requirements make it difficult to document the number of glass eels in the commercial trade. The Atlantic States Marine Fisheries Commission has recommended that the Fish and Wildlife Service proceed with listing the American eel in Appendix III of CITES to allow for better monitoring of glass eel harvest and commercialization. Recently the price for elvers has risen to $200 per pound (USFWS–DLE pers. comm.).

Shifts in population makeup are evident in the upper Chesapeake Bay in Maryland where harvest pressure is on larger eels. Weeder and Uphoff (2003) noted a shift in population makeup between the 1980s and 1990s toward younger, smaller eels being harvested. This is consistent with responses to increased size selective fishing pressure (i.e. large eels being exploited). Many exploited fish stocks decrease in size at maturity as a compensatory response (Trippel 1995, as cited in Weeder and Uphoff 2003). Harvest of large individuals unequally affects females. Eels below 40 cm in length are either male or female, but almost all eels greater than 40 cm are female. Additionally, suggests Weeder and Uphoff, smaller eels may be less reproductively successful. If there were sufficient reduction in the reproductive contribution from particular areas, overall egg production would likely be impacted. Because larval dispersal is random, a decline in larval production would impact the entire species range, including those areas from which the reproductive contribution of spawners was high. Weeder's more recent work in association with Hammond (in review), stated that strong fishing pressure, which removes thousands of pound of eels per day from the small tidal estuaries they studied, is likely to cause reduced densities consistent with the demographics they observed. Median catch-per-unit effort (CPUE) of eels sampled in a fishery-independent survey of Chesapeake Bay's Sassafras River, a heavily fished system, dropped from 9 to 0 eels per eel pot (between 1981 and 1998) and median total weight dropped from 2.5k kg/pot to 0 kg/pot. Conversely, an increase in eel size was observed after fishing ceased in the Wye River. They concluded that the lower fecundity and number of spawning adults may reduce the amount of spawner biomass to unsafe levels.

Along with the commercial fishery in the U.S., an active commercial fishery exists in Canada. Yellow and silver eel catches are reported from the Lake Ontario/St. Lawrence River ecosystem as well as from the Gulf of St. Lawrence and from Atlantic Nova Scotia and the Bay of Fundy (ICES 2000). The mean annual catches of St. Lawrence River were 788 tn (715 t) in 1984 and 592 tn (537 t) in 1991. The periodic reporting of ''river eel'' catches in the Caribbean and Central American countries are believed to be glass eels/elvers caught for export. Information has only been collected since 1975 and may very well be underreported. The catches have ranged from 1.1 tn (1 t) (1975 in Mexico, 1988 and 1989 in Dominican Republic, and 1989 in Cuba) to 54 tn (49 t) (Dominican Republic in 1994) (ICES 2000).

In analyzing the effect of harvest on American eel abundance, there are various reasons the magnitude of the threat is difficult to determine. Most of the data on eel numbers come from commercial harvest data (or landings) where fishing effort is not always available and may consist of different year-classes which are not differentiable simply based on eel size (ASMFC 2000). Harvest is market driven and therefore high harvest years may reflect high market demand rather than increased abundance (likewise, low harvest numbers may indicate a low market demand rather than a decrease in abundance). Harvest of highly valued

glass eels or elvers to meet foreign aquaculture demands are likely underreported, and there is evidence of substantial illegal harvest and sale of glass eels and elvers having occurred through the 1990s on the Atlantic Coast (R. St. Pierre, pers. comm. 2005).

The absence of fishing effort information was identified by Castonguay *et al.* (1994a) as a major weakness in their assessment of commercial fishing and declines in the American eel. They analyzed trends in commercial eel landings in Canada and the United States and compared them to the timing of the decline. They concluded that there was little evidence that commercial fishing caused the decline.

Ongoing research by Chesapeake Bay area scientists, however, suggests that eels appear to be overfished. Fishing mortality has been estimated at two to four times natural mortality (Weeder, J. and J. Uphoff. In in review). Although this does not point to the reason for the decline, it may indicate, at least in the Chesapeake Bay, an important area for American eels, current fishing pressure may be affecting future abundance.

There are several factors occurring on, and affecting the abundance of, multiple life stages (glass, elver, yellow, and silver) of American eel. These factors increase the risk that significant harvest pressure poses for the American eel population due to their life history. According to the ASMFC (2000), the following factors should be considered in any analysis of harvest effects: (1) American eels mature slowly, requiring 7 to 30+ years to attain sexual maturity (K. Oliveira, Univ. of Maine pers. comm., as in ASMFC 2000); (2) glass eels aggregate seasonally to migrate, making them more vulnerable to capture in large numbers (Haro and Krueger 1988, as in ASMFC 2000); (3) one year class of yellow eels are harvested over many years, resulting in high cumulative fishing mortality (Richkus and Whalen 1999, as in ASMFC 2000); (4) all harvest is pre-spawning (McCleave 1996, as in ASMFC 2000); and (5) changes in year class abundance are not readily recognizable, because harvest abundance data include eels of similar sizes but from a number of year classes (Ritter *et al.* 1997, as in ASMFC 2000), potentially masking declines.

In responding to the petitioners' assertion that commercial harvest is a threat to the American eel we were presented with differing analyses on whether and to what degree legal and illegal harvest is implicated in the decline, and complicating factors in determining harvest impacts. As part of our 12-month status review of the American eel, we will determine the implications of these factors on the role of harvest on the eel's decline. Information from the Chesapeake studies suggests that not only numbers, but eel size may well be important in determining the impacts of harvest, as have already been noted in the Chesapeake Bay. Because the petitioner and the ASMFC indicated that commercial harvest is a possible reason for the decline of the American eel and that at the 90-day finding stage we accept the petitioner's sources and characterizations of the information, to the extent that they appear to be based on accepted scientific principles, we conclude that commercial harvest likely effects American eel abundance, although it may not be solely responsible for its decline, and we conclude that commercial harvest is likely to impact the American eel in the future.

C. Disease or Predation

Information provided in the petition: The petition did not specifically provide information on disease and predation: however, the Management Plan incorporated by reference provided the information below.

Disease

American eels are afflicted by disease like any other species; however, one disease was specifically discussed by ASMFC as a potential threat to the overall health of the American eel. The non-indigenous eel swimbladder nematode (*Anguillicola crassus*) is a parasite native to marine and freshwater areas of eastern Asia, from Japan and China to Vietnam. Its native host is the Japanese eel (*Anguilla japonica*). The nematode has been documented to have significant negative impacts on European eels, and on American eels in Texas and South Carolina.

Analysis of information provided in the petition and information in our files. The swimbladder nematode was found in American eels (Barse and Secor 1999, as in ICES 2000) in 1997, but may have been present earlier. The nematode has been implicated with acute mortality in eels, as well as internal injury and growth impairment. Part of its life cycle occurs in the eel's swim bladder, and its departure through the swim bladder wall can cause injury and scarring. These effects on the swim bladder could impact a silver eel's ability to travel to the Sargasso Sea spawning grounds and thus its reproductive success (ICES 2000).

Although there is evidence that the parasite *Anguillicola crassus* causes negative impacts to *Anguilla* spp, according to the International Council for the Exploration of the Sea (ICES) (2000), it is unlikely that there are substantial effects from the parasite on American eel abundance (because of the lack of temporal correspondence between the appearance of the parasite and American eel declines).

Predation

American eel juveniles and adults are a seasonal food item of various finfish, and data are available that indicate eels are preyed on by fish-eating birds and mammals such as mink (Sinha and Jones 1967, Seymour 1974, as in ASMFC 2000). Younger life stages may also provide a food source.

Analysis of information provided in the petition and information in our files. Under conditions of abundance, impacts from predation would not be of concern; however, when populations are declining, or particular life stages are experiencing heavy predation, the impact of what were typical stresses may be magnified. The information provided and available in our files is, however, insufficient to determine the role of predation in the decline of the American eel.

D. The Inadequacy of Existing Regulatory Mechanisms

The petition stated that State and Federal agencies have not adequately regulated (1) fish passage, or (2) harvest and trade, leading to a decline in population numbers and range of the American eel.

Fish Passage

Information provided by the petitioner. The petitioners stated that under the authority of the Federal Power Act, the Federal Energy Regulatory Commission (FERC) can immediately stop the killing of adult female American eels in hydroelectric turbines in the United States, but have failed to do so. They also state that the Service and NOAA Fisheries, pursuant to Section 18 of the Federal Power Act, have the legal authority to require the licensees of private hydroelectric dams to provide safe and efficient upstream and downstream passage for American eels. The petitioners allege that, to date, neither agency has exercised this legal authority. Additionally, the petitioners state that pursuant to the Federal Clean Water Act, the Environmental Protection Agency (EPA) has the legal authority to require the licensees of private hydroelectric dams to provide safe and efficient upstream and downstream passage for American eels. Allegedly, to date, the EPA has declined to exercise this legal authority. Finally,

the petitioners were not aware of any instance in Maine or Massachusetts where these States have required by law the safe and efficient passage of American eels at non-hydroelectric dams, despite fish passage statutes which allow the States to make such requirements. Also, the petitioners questioned whether other States had statutes requiring safe and efficient passage of juvenile American eels at non-hydroelectric dams and whether such statutes were being enforced.

Analysis of information provided in the petition and information in our files. Safe upstream and downstream passage, which the petitioner alleges lacks adequate regulatory mechanisms, is standard when special licenses are required. For example, dams for hydropower production and navigation provide opportunities for fish passage when required by the resource management agencies, such as the Service. The Service takes every opportunity available to insure that safe upstream and downstream passage is prescribed for American eels under the Federal Power Act during relicensing of hydroelectric power facilities that are under the purview of FERC. NOAA Fisheries has exercised its legal authority under the Federal Power Act to prescribe fishways for eels at select projects. However, not all hydroelectric power facilities are currently equipped with structures that ensure safe upstream and downstream passage. Of the 15,570 dams on the Atlantic Coast only 1,100 dams were identified for hydropower production and 50 for navigation. Therefore, over 90 percent of the dams in the range of the American eel, including those for water-level control, water supply, and recreation, do not necessarily have Federal licensing requirements (ASMFC 2000), but not all these structures would be considered barriers.

To the extent that we find safe upstream passage (Factor A. Access to upper tributary habitat) and downstream passage (Factor E. Hydropower turbines) may be responsible in part for the decline of the American eel, we concur with the petitioners that the existing regulations for facilities preventing safe up and downstream passage may be inadequate or not exist because the vast majority of these dams do not have Federal licensing requirement, and therefore, may be partly responsible for the decline of the American eel.

Harvest and Trade

Information provided by the petitioner. The petitioners stated that under the authority of the Magnuson-Stevens Fisheries Conservation and Management Act, the ASMFC can immediately prohibit the harvest of American eels in the waters of the United States from Maine to Florida, and asserted that they have not exercised this authority.

Analysis of information provided in the petition and information in our files. The Magnuson Stevens Fisheries Conservation and Management Act does not apply as indicated by the petitioner. The Atlantic Coastal Fisheries Cooperative Management Act does allow for emergency actions to be taken by the ASMFC and obligates States to implement the emergency actions (*e.g.,* harvest restrictions). To address concerns regarding coastwide declines in American eel abundance, the ASMFC's American Eel Management Board authorized development in March 2004, of an Amendment to the Interstate Fishery Management Plan for American eel, which may include changes in harvest restrictions for recreational and commercial fisheries. However, these are not currently in place, and a large number of eel use areas/habitats are outside the jurisdictional boundaries of the State agencies within the purview of the ASMFC. These include watersheds in the Canadian Atlantic Provinces of Quebec and Ontario, upstream freshwater reaches managed by inland fish and wildlife agencies, regional institutions such as the Gulf States Marine Fisheries Commission and Great Lakes Fishery Commission, and those waters within Native American Reservations where Tribal Governments have jurisdiction. To date, of these other jurisdictions, only the Province of Ontario, Canada, has placed a moratorium on the harvest of American eels.

Currently, Atlantic Coast states differ in their eel harvest regulations, such as variations in the minimum size of harvestable eel, dates of harvest, and fishing gear. Few states have defined fishing seasons and limited management over the eel fishery (ASMFC 2000).

The ASMFC also recommended in the Management Plan that the Secretary of Commerce address and initiate controls over harvest and use of American eels in Federal waters (3–200 nautical miles offshore) that are not landed in States' waters. Specifically, the ASMFC recommended that the Secretary of Commerce ban harvests of American eels at any life stage in the EEZ, but permit the possession of up to 50 eel per person as bait. NOAA Fisheries does not now have a fishery management plan for eels and does not manage the fishery in the EEZ.

In summary, although individual jurisdictions have taken some action in response to the decline of the American eel (Canada's moratorium on commercial harvest in Ontario) or are considering changes (ASMFC Amendment 1), there are both gaps in the ability of current regulations to address threats (varied state regulations), and as the petitioners pointed out, limited implementation of existing regulatory mechanisms (limited and varying state restrictions on eel harvest, harvest within the EEZ). To the extent we find that commercial harvest (Factor B. Overutilization for commercial, recreational, scientific, or educational purposes) may be responsible in part for the decline of the American eel, the existing regulations may be inadequate or nonexistent and therefore partly responsible for the decline of the American eel.

E. Other Natural or Manmade Factors Affecting Continued Existence

The petition, its appendices, and referenced documents discuss the following threats which we have grouped under Factor E: (1) Hydropower turbines; (2) displacement by or competition with nonnative species: (3) contaminants; and (4) changes in oceanographic conditions.

Hydropower Turbines

Information provided by the petitioners. According to the petitioners, radio tagging studies of migrating female American eels conducted by the Maine Department of Marine Resources (MDMR) at two hydroelectric dams in Maine indicate nearly 100 percent of adult female eels entering project turbines are killed or severely injured, and therefore unable to complete their spawning migration (MDMR 2002, as in petition). Additionally, the Petitioner's state, "Radio-tracking of adult American eels by Maine Department of Marine Resources just above the Lockwood hydro-electoric project on the Kennebec River during fall 2002 indicates that 40 percent or more of the adult American eel attempting to migrate past the Lockwood Project each fall are entrained and killed in the Lockwood Dam turbines, despite the availability of the project spillway for passage (MDMR 2003). According to the petitioner, the entrainment and death of eels in the turbine is not a recent issue. The petitioners' state that records of severe kills of female American eels by the turbines of hydro-mechanical and hydroelectric dams exist since as early as the 1880s.

Downstream passage of silver eels is stated by ASMFC (2000) as a problem in

streams with hydropower turbines. According to Ritter *et al.* (1997, as in ASMFC), the 1,100 hydropower dams on the eastern seaboard of the United States may represent a major source of mortality to pre-spawning adults and represent approximately 7 percent of the dams on the eastern seaboard. According to the petitioners, virtually none of these hydropower facilities provide safe passage for migrating female American eels. As a result, downstream passage by female American eels at these facilities is via the project turbines, which results in the death of female eels attempting to migrate. According to Hadderingh (1990, as in ASMFC) and McCleave (pers. comm., as in ASMFC), if eels have to pass through turbines in their downstream migration, mortality rates range from 5 to 60 percent depending on the flow through the turbines and the length of the individual.

Analysis of information provided in the petition and information in our files. We agree with the petitioners' assertions that rivers with hydropower turbines are a documented threat to female American eels as they leave the rivers to spawn and may be a threat to the species as a whole. Although hydropower turbines are on less than 7 percent of the rivers, this mortality may be playing a larger role as the population declines (because as the population declines, gravid females become a vital resource and a high percentage of these individuals are lost to hydropower turbines). Additionally, not all hydroelectric power facilities are currently equipped with structures that ensure safe upstream and downstream passage. There is particular concern that the St. Lawrence River/Lake Ontario stock, a significant (possibly 19 percent of total female spawners) source of old, large, fecund female spawners (Castonguay *et al.* 1994a), is impacted by turbines at the Moses-Saunders and Beauhrnois-Les Cédres hydroelectric complex on the St. Lawrence River.

Displacement by or Competition With Nonnative Species

Information provided by the petitioners. The petitioner did not provide information on the impact of displacement by or competition with nonnative species. Rather, what is presented below is recent information from a petition reference on a potentially emerging threat.

Two nonnative species may be impacting American eels, the flathead catfish (*Pylodictis olivaris*) and the blue catfish (*Ictalurus furcatus*), both native to the Mississippi River watershed. These two species, according to the minutes from the 2004 ASMFC meeting, have exploded in certain areas, having been introduced as recently as the early 1980s in some systems. They have displaced some of the indigenous catfish species. There has been speculation from some research done at Virginia Commonwealth University that they have a large impact on the shad population and potentially on the American eel population as well (ASMFC 2004). Because no additional information was presented or available in our files at this time, we are unable to analyze further the impact of displacement by or competition with nonnative species on American eels.

Contaminants

Information provided by the petitioners. As the petitioners state, American eels are benthic, long-lived, and lipid (fat) rich (bioaccumulation of many toxins occurs in the fat of the fish). Therefore, American eels can accumulate high concentrations of contaminants, potentially causing an increased incidence of disease and reproductive impairment than is found in other fish species (Couillard *et al.* 1997, as in ASMFC). Studies have shown bioaccumulation of mercury and other heavy metals, dioxin and chlordane, polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichloroethane (DDT) in American eels.

An analysis of the contaminants in migrating silver eels in the St. Lawrence River showed that the highest concentrations of chemicals were in the gonads. Concentrations of PCB and DDT were found to be 17 percent and 28 percent higher in the gonads than in the carcasses. The chemical levels in the eggs could exceed the thresholds of toxicity for larvae. Also, since the migrating females are not feeding, the chemical levels in the eggs could be even higher at hatching, increasing the likelihood of toxicity to the larvae (Hodson *et al.* 1994, as in ASMFC 2000). According to ASMFC (2000), in the St. Lawrence River migrating silver eels, vertebral malformations and basophilic foci (lesions) in the liver were found to be most common in contaminated eels (Couillard *et al.* 1997, as in ASMFC 2000).

Aside from bioaccumulation, ASMFC expressed concern over accidental spills and mosquito abatement practices and their effect on eels. Accidental release of toxins into the Rhine River in 1986 killed hundreds of thousands of European eels (Facey and Van Den Avyle 1987, as in ASMFC 2000). Toxicity studies of aquaculture chemical effects on various life stages of the American eel suggest increased tolerance with size and age (Hinton and Eversole 1978, 1979, 1980, as in ASMFC 2000). A relatively new, specific area of concern deals with coastal wetlands and the potential impact caused by spraying insecticides for mosquito control at the time glass eels enter these areas (ASMFC 2000).

Analysis of information provided in the petition and information in our files. Contaminants clearly accumulate in American eels at high levels. Some evidence indicates that contaminant levels may be high enough to be toxic to larvae and possibly affect the health of adult migrating eels. However, we were not presented with information, nor did we have information in our files, on the level of risk to the species from different contaminants. Declines in recruitment in the St. Lawrence River (and in Europe), according to Castonguay *et al.,* do not coincide with periods of maximum contamination by organochlorine compounds (Castonguay *et al.* 1994a; Knights 1996, as in ICES 2000), and ICES stated that spawners would still be available from uncontaminated areas (ICES 2000). Therefore, in responding to the petitioners' assertion that contaminants are a threat to the American eel, we can agree that individual American eel and their young are likely at risk from certain contaminants: however, the petitioners did not provide substantial information nor do we have any in our files supporting this assertion. Therefore we are unable to support, at this time, the assertion that contaminants are a threat to the species at a population level.

Changes in Oceanographic Conditions

Information provided by the petitioner. The petition did not specifically provide information on the effects that changes in oceanographic conditions are having on American eel abundance and distribution, but the Management Plan incorporated by reference provided the information below.

The ASMFC lists changes in oceanographic conditions as a concern to the ocean habitat of the American eel. The spatial and temporal distribution of leptocephali is a result of oceanic circulation patterns and the drifting behavior of the larvae, and therefore potential changes in oceanographic conditions that influence the transport of leptocephali may have an impact on juvenile recruitment to coastal tributaries, potentially impacting an overall year class (McCleave 1998; Castonguay *et al.* 1994b, as in ASMFC 2000). Castonguay *et al.* (1994a, as in

ASMFC 2000) suggests that a weak, slow Gulf Stream would cause larvae to miss the optimum period for metamorphosis and be lost to the population. Castonguay *et al.* (1994a, as in ASMFC 2000) also suggests that recent cooling events and oceanographic changes in the northwest Atlantic may have altered the currents or other processes that carry glass eel to the continent.

Analysis of information provided in the petition and information in our files. Eels are expected to be even more affected by North Atlantic climatic changes than most marine species as the relative strength and position of the Gulf Stream is vital for their dispersal and successful migration, and the species consists of a single spawning population which may depend on the strength or location of thermal ocean fronts to trigger spawning. Evidence of historic population contractions is presented for both the American eel and the European eel. Most of these events probably occurred during the Wisconsinan glaciation 20,000 years ago, which changed ocean circulation, thereby reducing the speed of the Gulf Stream (Duplessy 1999, Lynch-Stieglitz *et al.* 1999, as in Wirth and Bernatchez 2003), and moved the gyre boundary and associated currents further to the south (Keffer *et al.* 1988, as in Wirth and Bernatchez 2003).

However, the degree to which recent (within the last 30–40 years) oceanic changes have contributed to the American eel population decline is still being debated. Castonguay *et al.* (1994a) evaluated the role of oceanic variations in the decline of both the American and European eel, and although they could not test the hypothesis of reduced recruitment directly, they found the most important result of their analysis to be the similarity between North America and Europe in both the rate of decline of these two eel species and the year in which the decline began. That such declines could be due to simultaneous and equivalent habitat, pollution, or fishing pressures, they say, is unlikely. Rather they conclude that the most probable cause is an oceanic factor acting simultaneously on both species.

We would concur with the ASMFC that changes in oceanographic conditions (*i.e.* changes in the strength and direction of ocean currents ''in particular the Gulf Stream) may have an impact on juvenile recruitment to coastal tributaries, particularly those on the Atlantic seaboard. Also, because of the lack of information in our files to the contrary, we concur that changes in oceanic conditions may be a reason for a decline in the American eel abundance and their distribution, whether taken singly or in combination with other factors discussed above.

Summary

It is reasonable to infer, as the petitioners proposed and scientifically supported, that the American eel is experiencing a decline. The petitioner also provided information on possible reasons for this decline which are generally not refuted, but more often are validated by the information in our files, which suggests that the listing action may be warranted. Our review of the ASMFC 2000 Management Plan (which the petitioner incorporated by reference and which the Service and NOAA Fisheries, State representatives, and academics were involved with writing), with regards to the life history of the species, potential threats to the various life stages of this species, and the habitats it utilizes, provided us with a range of potential causes for the decline and the likely effects to the species. These potential threats and effects provided by the petitioner were supported by scientific research with gaps in information acknowledged.

The complex life history and the incompleteness of historical data (abundance, stock composition, life stage mortality rates, and exploitation rates) make it challenging at this time to understand the potential influence of the numerous individual threats, and threats acting in a cumulative fashion or synergistically. Individual and cumulative effects of these threats upon the American eel may be magnified as the species' abundance declines, and as proposed by Wirth and Bernatchez (2003), there may be a synergistic effect of the short- and long-term threats faced by the species because of its peculiar life history.

Further analysis of oceanic variations is necessary particularly in light of the scant direct evidence and the potential for oceanic variations to be compounding or confounding the impact of other threats. Commercial harvest, habitat loss and degradation (primarily the loss of wetlands and upper tributary habitat), hydropower turbine mortality, and inadequacy of existing regulatory mechanisms, may also have caused or contributed to the decline of the American eel. Other potential threats, such as seaweed harvest, benthic habitat destruction, alterations of stream flow, disease, predation, and contaminants, could not be fully addressed or supported.

Finding

On the basis of our review, we find that the petition presents substantial scientific and commercial information indicating that listing the American eel may be warranted. The main threats to the species presented by the petitioner and supported by the information they provided appear to be commercial harvest, habitat loss and degradation due to loss of wetlands and upper tributary habitat, hydropower turbine mortality, changes in oceanic conditions, and inadequacy of existing regulatory mechanisms.

Public Information Solicited

When we make a finding that substantial information is presented to indicate that listing a species may be warranted, we are required to promptly commence a review of the status of the species. To ensure that the status review is complete and based on the best available scientific and commercial data, we are soliciting information on the American eel. We request any additional data, comments, and suggestions from the public, other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning the status of the American eel. We are seeking information regarding the species' historical and current status and distribution, its biology and ecology, ongoing conservation measures for the species and its habitat, and threats to the species and its habitat.

Finally, if we determine that listing the American eel is warranted, it is our intent to propose critical habitat to the maximum extent prudent and determinable at the time we would propose to list the species. Therefore, we request data and information on what may constitute physical or biological features essential to the conservation of the species, where these features are currently found and whether any of these areas are in need of special management, and whether there are areas not containing these features which might of themselves be essential to the conservation of the species. Please provide specific comments as to what, if any, critical habitat should be proposed for designation, if the species is proposed for listing and why that proposed habitat meets the requirements of the Act.

If you wish to comment or provide information, you may submit your comments and materials concerning this finding to the Division of Endangered Species (*see* **ADDRESSES** section).

Our practice is to make comments and materials provided, including names and home addresses of respondents, available for public review during regular business hours. Respondents may request that we withhold a respondent's identity, to the extent allowable by law. If you wish us to withhold your name or address, you must state this request prominently at the beginning of your submission. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the address listed above under **ADDRESSES.**

Literature Cited

A complete list of all references cited herein is available, upon request, from the Hadley, Massachusetts, Regional Office (see **ADDRESSES** section above).

Author

The primary author of this notice is Heather Bell, Hadley, Massachusetts, Regional Office (*see* **ADDRESSES** section above).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 21, 2005.

Matt Hogan,

Acting Director, Fish and Wildlife Service.

[FR Doc. 05–12971 Filed 7–5–05; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 050323081–5081–01; I.D. 031505C]

RIN 0648–AT02

Endangered and Threatened Species: Extension of Public Comment Period on Proposed Listing Determination for the Southern Distinct Population Segment of North American Green Sturgeon

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

ACTION: Proposed rule; extension of public comment period.

SUMMARY: In April 2005, NMFS proposed to list the Southern Distinct Population Segment (DPS) of the North American green sturgeon (*Acipenser medirostris*; hereafter ''green sturgeon'') as threatened under the Endangered Species Act. NMFS is extending the public comment period on the proposed listing determination until July 27, 2005.

DATES: The due date for written comments is extended to July 27, 2005.

ADDRESSES: You may submit comments on the proposed rule by any of the following methods:

- E-mail: *GreenSturgeon.Comments@noaa.gov*.
- Federal e-Rulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Submit written comments to Chief, Protected Resources Division, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA, 90802–4213.
- Fax: 562–980–4027.

The updated green sturgeon status review and other reference materials related to the proposed rule can be obtained via the Internet at: *http://www.swr.noaa.gov*. The updated status review and list of references are also available by submitting a request to the Assistant Regional Administrator, Protected Resources Division, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213, or the Assistant Regional Administrator, Protected Resources Division, Northwest Region, NMFS, 1201 NE Lloyd Avenue, Suite 1100, Portland, OR 97232.

FOR FURTHER INFORMATION CONTACT: Melissa Neuman, NMFS, Southwest Region (562) 980–4115; Scott Rumsey, NMFS, Northwest Region (503) 872–2791; or Lisa Manning, NMFS, Office of Protected Resources (301) 713–1401.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2005, NMFS published a proposed ESA listing determination for the Southern DPS of green sturgeon (70 FR 17386). The proposed rule was based on: information showing that spawning adults are concentrated into one spawning river (i.e., Sacramento River), thus, increasing the risk of extirpation due to catastrophic events; threats that remain severe and have not been adequately addressed by conservation measures currently in place; fishery-independent data exhibiting a negative trend in juvenile green sturgeon abundance; and information showing evidence of lost spawning habitat in the upper Sacramento and Feather Rivers. With the publication of the proposed listing determination, NMFS announced a 90–day public comment period ending on July 5, 2005. On June 20, NMFS announced that it would hold a public hearing (70 FR 35391) on July 6 in Sacramento, CA, and extended the public comment period to July 6 to coincide with the public hearing.

Extension of Public Comment Period

NMFS has received a request from a U.S. Department of the Interior to extend the public comment period by 2 weeks. In this notice NMFS is extending the public comment period by three weeks, and now comments will be accepted until July 27, 2005.

References

Copies of the **Federal Register** notices and related materials cited in this document are available on the Internet at http://swr.noaa.gov, or upon request (see **ADDRESSES**).

Authority: 16 U.S.C. 1531 *et seq.*

Dated: June 30, 2005.

Wanda L. Cain,

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

[FR Doc. 05–13264 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 70, No. 128

Wednesday, July 6, 2005

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 29, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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.

Agricultural Marketing Service

Title: Grain News Reports and Molasses Market News.

OMB Control Number: 0581–0005.

Summary of Collection: The Agricultural Marketing Act of 1046 (7 U.S.C. 1621) Section 203(g), directs and authorizes the collection and dissemination of marketing information including adequate outlook information, on a market area basis, for the purpose of anticipating and meeting consumer requirements aiding in the maintenance of farm income and to bring about a balance between production and utilization. Livestock and Grain News provides a timely exchange of accurate and unbiased information on current marketing conditions (supply, demand, prices, trends, movement, and other information) affecting trade in livestock, meats, grain, and wool. Administered by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS), this nationwide market news program is conducted in cooperation with approximately 30 state departments of agriculture. The up-to-the-minute reports collected and disseminated by professional market reporters are intended to provide both buyers and sellers with the information necessary for making intelligent, informed marketing decisions, thus putting everyone in the marketing system in an equal bargaining position. AMS will collect information using market new reports.

Need and Use of the Information: AMS will collect information on various aspects of the grain and feed industry in determining available supplies and current pricing. Industry traders use market news information to make marketing decisions on when and where to buy and sell. In addition, the reports are used by other Government agencies to evaluate market conditions and calculate price levels used for the Farmer-owned Reserve Program. The reports must be collected and disseminated by an impartial third party. Since the Government is a large holder of grain, some type of system would have to be established to monitor the collection and reporting data.

Description of Respondents: Business or other for-profit; Individuals or households; Farms; Federal Government.

Number of Respondents: 202.

Frequency of Responses: Reporting: On occasion; Weekly; Monthly.

Total Burden Hours: 129.

Agricultural Marketing Service

Title: Plan for Estimating Daily Livestock Slaughter Under Federal Inspection.

OMB Control Number: 0581–0050.

Summary of Collection: The Agriculture Marketing Act of 1946 (7 U.S.C. 1621) Section 203(g), directs and authorizes the collection and dissemination of marketing information including adequate outlook information, on a market area basis, for the purpose of anticipating and meeting consumer requirements aiding in the maintenance of farm income and to bring about a balance between production and utilization. Livestock and Grain news provides a timely exchange of accurate and unbiased information on current marketing conditions (supply, demand, prices, trends, movement, and other information) affecting trade in livestock, meats, grain, and wool. Administered by the U.S. Department of Agriculture's Agricultural marketing Service (AMS), this nationwide market news program is conducted in cooperation with approximately 30 State departments of agriculture. The up-to-the minute reports collected and disseminated by professional market reporters are intended to provide both buyers and sellers with the information necessary for making intelligent, informed marketing decisions, thus putting everyone in the marketing system in an equal bargaining position.

Need and Use of the Information: AMS will collect information on estimation of the current day's slaughter at their plant(s) and the actual slaughter of the previous day. The report is used to make market outlook projections and maintain statistical data. The information must be collected and disseminated by an impartial third party. Since the government is a large purchaser of meat, a system to monitor the collection and reporting of data is needed. Collecting this information less frequently would hinder the timely use of this data.

Description of Respondents: Business or other for-profit; Individuals or households; Farms; Federal Government; State, local or tribal government.

Number of Respondents: 72.

Frequency of Responses: Reporting; Weekly; Other: Daily.

Total Burden Hours: 624.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–13189 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 30, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA&_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Warehouse Regulations Under the United States Warehouse Act.

OMB Control Number: 05160–0120.

Summary of Collection: The United States Warehouse Act (USWA) (7 U.S.C. 244) authorizes the Secretary of Agriculture to license public warehouse operators that are in the business of storing agricultural products; to examine such federally-licensed warehouses; and to license qualified persons to sample, inspect, weigh, and grade agricultural products. The USWA licenses over 50 percent of all commercial grain and cotton warehouse capacities in the United States. USWA activities are administered by the Farm Service Agency (FSA) and also encompass examination of warehouses operated under the Standards for Approval of Warehouses Under the Commodity Credit Corporation (CCC) Charter Act. Although there are several types of warehouses covered by USWA and CCC functions, the reporting requirements for a particular type of warehouse are essentially the same. With some exceptions, the same forms are used for both USWA licensing and CCC. The forms are furnished to interested warehouse operators or used by the warehouse examiners employed by FSA to secure and record information about the warehouse operators and the warehouse. FSA will collect information using several forms.

Need and Use of the Information: FSA will collection information (1) to determine whether or not the warehouse and the warehouse operator making application for licensing and/or approval meets applicable standards; (2) to issue such license or approvals; (3) to determine, once licensed or approved, that the licensee or warehouse operator continues to meet such standards and is conforming to regulatory or contractual obligations, (4) to determine that the stored commodity is in good condition and (5) to determine that the licensee or warehouse operator is storing the commodity for which licensed or approved in a safe and prudent manner.

Description of Respondents: Business or other for-profit.

Number of Respondents: 4,000.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Other (daily record).

Total Burden Hours: 10,626.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–13296 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–05–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 05–031–1]

Notice of Request for Extension of Approval of an Information Collection; Importation of Gypsy Moth Host Material From Canada

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection in support of regulations to prevent the introduction of gypsy moth into noninfested areas of the United States from Canada.

DATES: We will consider all comments that we receive on or before September 6, 2005.

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

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 05–031–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 05–031–1.

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: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information on the regulations regarding importation of gypsy moth host material from Canada, contact Mr. Weyman Fussell, Program Manager, Pest Detection and Management Program, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–5705. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION:

Title: Importation of Gypsy Moth Host Material from Canada.

OMB Number: 0579–0142.

Type of Request: Extension of approval of an information collection.

Abstract: As authorized by the Plant Protection Act (PPA, 7 U.S.C. 7701–7772) the Secretary of Agriculture may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, means of conveyance, or other article if the Secretary determines that the prohibition or restriction is necessary to prevent a plant pest or noxious weed from being introduced into or disseminated within the United States. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS), which administers regulations to implement the PPA. Regulations governing the importation of gypsy moth host material into the United States from Canada are contained in 7 CFR 319.77 through 319.77–5.

These regulations are intended to prevent the introduction of gypsy moth into noninfested areas of the United States by placing certain inspection and documentation requirements on gypsy moth host material (*i.e.,* regulated articles) from Canada. These regulated articles are: Trees without roots (*e.g.,* Christmas trees), trees with roots, shrubs with roots and persistent woody stems, logs and pulpwood with back attached, outdoor household articles, and mobile homes and their associated equipment. Under the regulations, phytosanitary certificates, certificates of origin, or signed homeowner statements will be required for some of these regulated articles, depending on their place of origin in Canada and their destination in the United States. These requirements necessitate the use of information collection activities.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.03632 hours per response.

Respondents: Canadian plant health authorities; growers, exporters, shippers of Christmas trees, shrubs, logs, pulpwood, and other articles from gypsy moth-infested Provinces in Canada; private individuals entering the United States with mobile homes or outdoor household articles.

Estimated annual number of respondents: 147.

Estimated annual number of responses per respondent: 15.17007.

Estimated annual number of responses: 2,230.

Estimated total annual burden on respondents: 81 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 29th day of June 2005.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–13298 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Angeles National Forest, CA, Littlerock Reservoir Sediment Removal Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: Notice is hereby given that the USDA, Forest Service, Angeles National Forest (ANF) and the Palmdale Water District (District) will prepare a joint Environmental Impact Statement (EIS) and Environmental Impact Report (EIR), referred to as an EIR/EIS, that will evaluate the proposed project and alternatives to the proposed project. As the project proponent, the District proposes to excavate sediment from the Littlerock Reservoir and construct a grade control structure (proposed project) located on Littlerock Creek, in Los Angeles County, California. The proposed grade control structure would be located at, or just downstream of, River Station 4,235 (also know as Rocky Point). the proposed project would:

- Remove excess Reservoir sediment that has accumulated over time
- Restore the water storage and flood control capacity of the Reservoir; and
- Prevent sediment loss and headcutting of the stream channel upstream of Rocky Point to prevent the incidental ''take'' of arroyo toad (*Bufo californicus*), a federally endangered species.

The proposed project would entail the initial removal of between 270,000 and 540,000 cubic yards of sediment from Littlerock Reservoir from below Rocky Point to just upstream of Littlerock Dam. Thereafter, the District would annually remove approximately 54,000 cubic yards of sediment to balance sediment deposition and maintain water storage capacity in the Reservoir. Sediment would be mechanically removed from the Reservoir by the use of heavy equipment. The ANF and the District invite written comments on the scope of this proposed project. In addition, the agencies give notice of this analysis so that interested and affected individuals are aware of how they may participate and contribute to the final decision.

DATES: Comments concerning the scope of the analysis must be received by July 30, 2005. A public information and scoping meeting will be held July 13, 2005. The draft EIR/EIS is expected December 2005 and the Final EIR/EIS is expected March 2006.

ADDRESSES: Send written comments to Mr. Matt Knudson, Engineering Supervisor, Palmdale Water District, 2029 East Avenue Q, Palmdale, CA 93550, *mknudson@palmdalewater.org*, (661) 947–4111, ext. 118.

For further information, mail correspondence to Mr. Rich Robertson, USDA Forest Service, Angeles National Forest, Santa Clara Mojave Rivers

Ranger District, 30800 Bouquet Canyon Road, Saugus, CA 91390, *rrobertson01@fs.fed.us*, (661) 296–9710, ext. 223. A public information and scoping meeting is scheduled at the following time and location: Palmdale Water District, Board Room, 2029 East Avenue Q, Palmdale, CA 93550, July 13, 2005, 7 p.m.

All project-related documents are available for review at the Palmdale Water District address stated above.

FOR FURTHER INFORMATION CONTACT: For additional information related to the proposed on National Forest System land, contact Mr. Rich Robertson, U.S. Forest Service, Angeles National Forest, Santa Clara Mojave Rivers Ranger District, (*see* address above). For additional information related to the project on non-National Forest System land, contact Mr. Matt Knudson, Engineering Supervisor, Palmdale Water District, (*see* address above).

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The underlying need of the project is to restore the water storage and flood control capacity of the Littlerock Reservoir. The Littlerock Dam and Reservoir are located on Littlerock Creek below the confluence of Santiago Canyon on National Forest System land (managed by the Angeles National Forest). The District operates the Littlerock Reservoir as a local surface water impoundment, and water is conveyed from the Reservoir to a water treatment facility located at Palmdale Lake. Inflow into the Reservoir is seasonal and varies widely depending on stream flows and snowmelt within the watershed. The Littlerock Reservoir was constructed in 1924 with an initial design capacity of 4,300 acre-feet. This capacity has been substantially reduced over time by the deposition of sediment behind the Dam. Preliminary calculations conducted by the District indicated that the Reservoir capacity is further reduced at a rate of approximately 30 to 40 acre-feet per year.

Proposed Action

The Angeles National Forest Supervisor proposes to authorize and issue a special use permit to the District to excavate sediment from the Littlerock Reservoir and construct a grade control structure at, or just downstream of, River Station, 4,235, also known as Rocky Point. The proposed project would entail the excavation of approximately between 270,000 and 540,000 cubic yards of material from the Reservoir, followed by excavation of approximately 54,000 cubic yards annually. Initial excavation would commence just upstream of the Dam and extend to River Station 3,037. The grade control structure, which would be constructed at or just downstream of River Station 4,235 (the Rocky Point Area), would be constructed of soil cement or concrete and span approximately 250 feet of the channel. The structure would be buried, with the top at, or slightly below, the existing channel surface. Maximum depth of the structure would be approximately 70 feet. Construction of the structure would result in a temporary disturbance to a section of the channel and adjacent bank approximately 300 feet wide in width and 500 feet wide in the direction parallel to flow.

The proposed project involves lands managed by the Santa Clara/Mojave Rivers Ranger District, Angeles National Forest within Township 5 North, Range 11 West, and Section 34.

Possible Alternatives

For the purpose of this analysis, the ANF and the District have identified preliminary action alternatives for consideration in the scoping process. The alternatives currently under consideration are:

- No Project/No Action Alternative: Under the No Action Alternative, sediment removal would not occur and sediment would continue to accumulate upstream of Littlerock Dam. In addition, no grade control structure would be built.
- Alternative 1—Initial excavation of approximately 270,000 cubic yards of material from the Reservoir, followed by yearly excavation of approximately 54,000 cubic yards. Initial excavation to commence just upstream of the Dam and extend to River Station 1,390: Under this alternative, the District would excavate a trapezoidal section of the Reservoir with an approximate 80-foot bottom width and 5:1 side slopes. All excavation would occur in Reach 1 and maximum excavation would be approximately 43 feet in depth.
- Alternative 2—Initial excavation of approximately 270,000 cubic yards of material from the Reservoir, followed by yearly excavation of approximately 54,000 cubic yards. Initial excavation to commence just upstream of the Dam and extend to River Station 4,235: Under this alternative, the District would excavate a trapezoidal section of the Reservoir with an approximate 200-foot bottom width and 5:1 side slopes. All excavation would occur in Reach 1 and 2, and maximum excavation would occur near River Station 2,210 and would be approximately 10 feet in depth.
- Alternative 3—Initial excavation of approximately 540,000 cubic yards of material from the Reservoir, followed by excavation of approximately 270,000 cubic yards every five years. Initial excavation to commence just upstream of the Dam and extend to River Station 3,037: Under this alternative, the District would excavate a trapezoidal section of the Reservoir with an approximate 80-foot bottom width and 5:1 side slopes. All excavation would occur in Reach 1 and 2, and maximum excavation would be approximately 43 feet in depth.
- Alternative 4—Initial excavation of approximately 540,000 cubic yards of material from the Reservoir, followed by excavation of approximately 270,000 cubic yards every five years. Initial excavation to commence just upstream of the Dam and extend to River Station 4,235: Under this alternative, excavation depths would be 20 feet, and would occur in Reach 1 and 2. The maximum top width excavation would begin approximately 370 feet from the dam and would remain consistent to River Station 2,815, at which point the top width would taper to zero at Station 4,235.

Lead and Cooperating Agencies

The Forest Service is the lead agency under the National Environmental Policy Act (NEPA) in accordance with 40 CFR 1501.5(b). Palmdale Water District is the lead agency under the California Environmental Quality Act (CEQA) in accordance with California Code of Regulations, Title 14, Chapter 3, Article 4, § 15050.

Responsible Official

The responsible official for the preparation of the EIR/EIS is Jody Noiron, Forest Supervisor, Angeles National Forest, 701 N. Santa Anita Avenue, Arcadia, CA 91006.

Nature of Decision To Be Made

The Angeles National Forest Supervisor will decide whether to permit the proposed sediment removal from behind Littlerock Dam and construction of the grade control structure within National Forest System lands. The authorization will include removal of sediment from National Forest System lands needed to restore the Littlerock Reservoir's capacity, and construction of a grade control structure to maintain the Reservoir capacity. If this alternative is approved, the Forest Supervisor will also decide what mitigation measures and monitoring will be required. The Forest Supervisor

will only make a decision regarding impacts on National Forest System lands.

Scoping Process

Public participation will be especially important at several stages during the analysis. The purpose of scoping is to help ensure that a comprehensive and focused EIR/EIS will be prepared that provides a firm basis for the decision-making process. Members of the public, affected Federal, State, and local agencies, interested groups, and other interested parties may participate in the scoping process for this project by providing written and verbal comments or recommendations concerning the issues to be analyzed in the EIR/EIS. Comments can be given verbally by attending the scheduled scoping meeting at: Palmdale Water District, July 13, 2005, 7 p.m., 2029 East Avenue Q, Palmdale, CA 93550, (661) 947–4111.

Attendees requiring language interpretation services at the Scoping Meeting must call (818) 597–3407, ext. 338 by July 6, 2005. The meeting location is wheelchair accessible.

Preliminary Issues

The EIR/EIS will present the analysis of the environmental impacts of the proposed project and comparative environmental effects of the alternatives, and will identify mitigation measures for potentially significant impacts. The EIR/EIS will address all issue areas for which potential significant impacts are anticipated. These issue areas include: Air quality; biological resources; cultural resources; geology and soils; hazardous materials; land use and public recreation; noise; socioeconomics and environmental justice; traffic; utilities and service system; visual resources; and water resources.

Permits or Licenses Required

The Regional Director of Natural Resource Management of the Forest Service would issue a Special Use Permit for construction of the grade control structure and maintenance of the Reservoir capacity through sediment removal. Additional permits that may be required for the proposed project could include: A Permit to Operate issued by the Antelope Valley air Quality Management District, a National Pollutant Discharge Elimination system General Construction Permit issued by California's Regional Water quality Control Board, a Section 404 Permit (per Section 404 of the Clean Water Act) issued by the U.S. Army Corps of Engineers, and a Streambed Alteration Agreement (per Section 1601 of the California Fish and Game Code) issued by the California Department of fish and Game.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the EIR/EIS. The Forest Service is seeking public and agency comment on the proposed project to identify major issues to be analyzed in depth and assistance in identifying potential alternatives to be evaluated. Comments received on this notice, including the names and addresses of those who comment, will be considered as part of the public record on this proposed project, and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR Part 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality. Where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted, without names and addresses, within a specified number of days.

Early Notice of Importance of Public Participation in Subsequent Environmental Review: A Draft EIR/EIS will be prepared for comment. The comment period on the draft EIR/EIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of the Draft EIR/EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the Draft EIR/EIS stage but that are not raised until after completion of the Final EIR/EIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day EIR/EIS comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the Final EIR/EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft EIR/EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the Draft EIR/EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: June 28, 2005.

Susan Swinson,

Acting Forest Supervisor.

[FR Doc. 05–13243 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta-Trinity National Forest, California; Turntable Bay Marina Master Development Plan

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Shasta-Trinity National Forest proposes to authorize a 30-year term permit to Seven Resorts, Inc. to build and operate a resort marina at Turntable Bay located in section 22 & 27, T34N, R4W, MDBM on Shasta Lake. In conjunction with this authorization, Seven Resorts, Inc. (Project Proponent) will relinquish the existing permit for the operation of Digger Bay Marina located in section 12 and 13, T33N,

R5W, MDBM on Shasta Lake. The proposed Turntable Bay Marina and associated land-based development will be designed for water-based recreational use on a year-around basis. Proposed water-based facilities include a retail store, public moorage facilities, boat rentals, and service docks (fuel, septic waste, and refuse collection). Proposed land-based improvements include off-ramp lighting, paved access road, paved parking, launch ramp, public restrooms, water supply, sanitary waste disposal system, and power and communications utilities.

In addition, a non-significant amendment to the Shasta-Trinity National Forest Land and Resource Management Plan to amend management prescription IV, ''Roaded, High Density Recreation,'' to include the proposed site of the Turntable Bay Marina is proposed. The proposal is within the Shasta Unit of the Whiskeytown-Shasta-Trinity National Recreation Area.

DATES: Comments concerning the scope of the analysis should be received no later than 30 days after publication of this notice in the **Federal Register**. The draft environmental impact statement is expected in November 2005 and the final environmental impact statement is expected during the spring of 2006.

ADDRESSES: Send written comments to District Ranger Kristy Cottini, Shasta-Trinity National Forest, National Recreation Area Ranger Station, 14225 Holiday Road, Redding, CA 96003.

FOR FURTHER INFORMATION CONTACT: Project Manager Lee Simons, Shasta-Trinity National Forest, National Recreation Area Ranger Station, 14225 Holiday Road, Redding, CA 96003.

SUPPLEMENTARY INFORMATION: Turntable Bay was identified by the Shasta-Trinity National Forest, as the most viable site for a new marina on Shasta Lake. Turntable Bay offers direct access from Interstate 5, limited impact from lake level fluctuations, and an area well suited for a variety of recreational activities both on and off the water. Shasta Lake is the largest lake in the Whiskeytown-Shasta-Trinity National Recreation Area (NRA), and is managed by the Shasta-Trinity National Forest to provide quality recreational experiences to the public.

In May 2002, the Shasta-Trinity National Forest issued a prospectus offering the opportunity to relocate an existing marina's operation on Shasta Lake to Turntable Bay. The Project Proponent submitted a proposal in response to the prospectus and was awarded the opportunity to prepare a conceptual Turntable Bay Marina Master Development Plan. This plan has been accepted by the Shasta-Trinity National Forest for environmental analysis under the National Environmental Policy Act (NEPA).

Purpose and Need for Action

There is a need for the Forest Service, Shasta-Trinity National Forest, to take action (provide response) on the application submitted by the Project Proponent requesting a special use authorization. The proposed use is construction and operation of a full service marina at Turntable Bay on Shasta Lake within the NRA. The purpose of the proposed project is to provide a high-quality recreational opportunity at Turntable Bay. The current Management Guide (NRA Guide) for the Shasta and Trinity Units of the NRA identifies Turntable Bay as the most feasible new location for a resort/marina operation.

The Shasta-Trinity National Forest manages the Shasta Unit of the NRA to be a showcase recreational area that supports the enjoyment and use of the natural environment. The combination of water and land surface provides the opportunity to enjoy many types of outdoor recreation; however, environmental factors such as a hot climate, steep terrain, and sparse forest cover favor water-oriented recreation. On the Shasta Unit, the key attraction or recreation resource is the available water surface of Shasta Lake. Recreational boating on Shasta Lake is dependent upon access to the water via shoreline facilities such as marinas, docks, and launch ramps.

Fluctuations in the water levels, however, have effects on the provision of and access to water-based recreational services. With regard to the marinas on Shasta Lake, some facilities are located in areas (shallow water ports) that require them to move their docks substantial distances from their land-based facilities and/or close their boat ramps during low water periods. This decreases the consistency, efficiency, and overall quality of services provided. Deepwater ports are more efficient locations for marinas.

To allow existing marinas, which are restricted by their locations, to improve the quality of the services they provide, the NRA Guide contains the following recommendation.

''Upon approval by the Forest Service, resort/marinas may merge, or consolidate to one location, or a resort/marina may move to a new location based on the following criteria:

- Maintains or improves dispersion of services around the lake.
- Accommodates low water conditions.
- Removes or eliminates the threat for threatened and/or endangered species.
- The site can adequately support both land and water based facilities and services.
- Road access is feasible and reasonable (location and cost).
- Utilities (electricity and telephone) are reasonably available to the location.
- Compatibility with existing commercial resort/marina locations.
- Compatibility with natural resources, such as preservation of watershed or fish habitat values.
- Compatibility with public recreation sites or facilities.''

Based on these criteria, Turntable Bay was determined to be the most viable location for a new marina on Shasta Lake. Turntable Bay possesses many site characteristics which would contribute to efficient and consistent marina operation, including direct access from a major interstate, deep water moorage with limited effects from lake fluctuations, access to utilities, and an area well suited for a variety of recreational activities, both on and off the water. Therefore, the proposed project offers an opportunity to improve the location and quality of facilities/services currently provided by Digger Bay Marina (an existing marina operated by the Project Proponent) through relocation to Turntable Bay.

In comparison, the facility at Digger Bay is located approximately 6 miles form Interstate 5. Access is via Shasta Dam Boulevard, through the City of Shasta Lake, and then north on Digger Bay Road. Digger Bay Road is a low-standard, narrow, and winding road about 3.5-mile long, making it poorly suited for trailer carrying boats.

The boat launch ramp at Digger Bay Marina ends at a depth of 60 feet below full lake level. When the lake surface drops below this level, boasts can no longer be launched at the site. From 60 to 100 feet below full lake level, access to marina facilities on the water is constrained by a winding asphalt road. This road is difficult to negotiate with vehicles and requires frequent repositioning of the docks as water levels change. Below 100 feet from full lake level, marina facilities cannot be accessed form the land at all.

Proposed Action

The proposed action to issue a 30 year term permit for the development and operation of Turntable Bay Resort Marina would include the following actions:

- All land-based developments are proposed to occur above 1090 feet elevation, to avoid conflicts with a potential increase of 20 feet in the height of Shasta Dam.

• Land-based developments will include placement of safety lighting at the north-bound and south-bound ramps of Interstate Highway 5 (Turntable Bay exit).
• Reconstruction and construction of a two-land paved access road.
• Construction of paved parking areas.
• Construction of a four land (60 feet wide) boat-launching ramp.
• Construction of public restrooms, water supply, and septic disposal systems.
• Construction of disposal area for excess excavation materials.
• Revegetation and slope protection measures emphasizing native vegetation.
• Construction of power and communication utilities.
• Water-based facilities will include a retail store, boat rentals, public moorage docks, and systems for selling fuel, septic pump out, and refuse management.

The proposed permit area includes 79 acres above the current high water level of Shasta Lake (1070 feet above mean sea level). This area is currently undeveloped, with the exception of an access road that terminates at the back (west end) of Turntable Bay, immediately east of northbound Interstate 5. The proposed marina and land-based development will be designed to provide recreational opportunities consisting of varied boating and other water-based activities as well as pubic access to park-like areas on land including a day-use picnic area, walking trails, and public restrooms. The development design provides compliance with the Americans with Disabilities Act (ADA) and appropriate public law. The proposed marina site includes waters of Shasta Lake within Turntable Bay, the area between Interstate Highway 5 and Shasta Lake north of the Turntable Bay exit, a portion of the existing access road, and an area to the north of Turntable Bay that will be used to place excess excavation material.

The shoreline of Shasta Lake in the project area is rugged. The development of roads and parking areas will require grading (estimated 94,000 cubic yards of net excess material). The proposed design has been developed to minimize the total disturbed area and retain as much of the area in an undisturbed condition as possible. The design of appropriate cuts and fills to minimize grading is planned.

As designed, the proposed project will minimize impacts to native vegetation and will implement a vegetation management plan that emphasizes native vegetation in the project design. This plan will also use revegetation strategies to address other potential resource impacts (*e.g.,* visuals, erosion, water quality, and noxious weeds).

Upon authorization and construction of Turntable Bay Marina, SCR will relinquish its permit to operate Digger Bay Marina. This will result in abandoning the current land-side operations and relocating the water-side improvements to Turntable Bay. When the Resort/Marina Term Special Use Permit for the Digger Bay location is relinquished, some land-side improvements at the existing Digger Bay site, including paved access roads, parking areas, launch ramp, and utilities (water and septic) will remain intact for possible future use to be determined though subsequent planning by the Forest Service.

Possible Alternatives

Any action alternatives would be developed based on significant issues to the proposed action following the public scoping process.

Lead and Cooperating Agencies

USDA Forest Service is the lead agency for this environmental impact statement. Other Federal, state, or local agencies may have discretionary approvals and authorities.

Responsible Official

J. Sharon Heywood, Forest Supervisor, Shasta-Trinity Forest, 3644 Avtech Parkway, Redding, CA 96002.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to implement the proposed action, take an alternative action that meets the purpose and need, to take no action.

Scoping Process

The project is included in the Shasta-Trinity National Forest's quarterly schedule of proposed actions (SOPA). Information describing the proposed action will also be posted on the Web site, *http://www.fs.fed.us/r5/shastatrinity/projects*, and advertised in the Redding Record Searchlight. This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. Comments submitted during this scoping process should be in writing and should be specific to the proposed action. The comments should describe as clearly and completely as possible any issues the commenter has with the proposal. The scoping process includes:

(a) Identifying potential issues.
(b) Identifying issues to be analyzed in depth.
(c) Eliminating non-significant issues or those previously covered by a relevant previous environmental analysis.
(d) Exploring additional alternatives.
(e) Identifying potential environmental effects of the proposed action and alternatives.

Preliminary Issues

No preliminary issues have been identified.

Permits or Licenses Required

By definition, the Forest Service has identified the proposed Turntable Bay Marina as a water-dependent project that will be subject to the requirements of the Clean Water Act. Under the Act, the U.S. Army Corp of Engineers has the responsibility to ensure that the waters of the U.S. are protected. The location and types of activities associated with proposed action will require issuance of a 404 Permit prior to Forest Service authorization of the Special Use Permit to construct and operate the proposed Turntable Bay Marina.

The California Regional Water Quality Control Board, Central Valley Region, is the agency authorized to issue the 401 certification under the Clean Water Act. Due to the nature of some of the proposed land-based development (*i.e.,* water and sanitation facilities), this agency is also responsible for preparing waste discharge requirements prior to Forest Service authorization of the Special use Permit to construct and operate the proposed Turntable Bay Marina.

The California Department of Transportation maintains a right-of-way associated with Interstate 5. Some land-based components of the proposed Turntable Bay Marina may encroach on this right-of-way and require the issuance of a California Department of Transportation encroachment permit prior to Forest Service authorization of the Special Use Permit to construct and operate the proposed Turntable Bay Marina.

Comments Requested

This notice of intent initiates the scoping process which guides development of the environmental impact statement.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be

45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register.**

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *Court of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp, 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 211.)

Dated: June 16, 2005.

J. Sharon Heywood,

Forest Supervisor.

[FR Doc. 05–13242 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Craig Ranger District, Tongass National Forest; Alaska; Scratchings Timber Sale EIS

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The USDA Forest Service, Craig Ranger District will prepare an Environmental Impact Statement (EIS) to consider a proposal to harvest timber from Suemez Island, located on the Craig Ranger District, Tongass National Forest in southeastern Alaska. The proposed action would harvest up to 40 MMBF of timber from approximately 5,000 acres. Approximately 16.5 miles of road construction is planned. About 3.5 miles of this road would be temporary construction.

DATES: Comments concerning the scope of the analysis should be received within 45 days from the date of this notice. The draft environmental impact statement is expected to be completed by October 31, 2005 and the final environmental impact statement is expected to be completed by March 31, 2006.

ADDRESSES: Send written comments to Planning Staff, Thorne Bay Ranger District, Attn: Scratchings Scoping; P.O. Box 19001; Thorne Bay, AK 99919–0001. Comments can also be faxed to 907–828–3309 or e-mailed to *comments-alaska-tongass-thorne-bay@fs.fed.us,* subject line: Scratchings scoping EIS comments.

FOR FURTHER INFORMATION CONTACT: Mail correspondence to Planning Staff, Thorne Bay Ranger District, Attn: Scratchings Scoping; P.O. Box 19001; Thorne Bay, AK 99919–0001. The Craig and Thorne Bay Ranger Districts are served by a single, zoned Planning Staff.

SUPPLEMENTARY INFORMATION: The proposed timber sale would occur on Suemez Island in southeastern Alaska. Suemez Island is located west of Prince of Wales Island and southwest of Craig, Alaska. The proposed project lies within Tongass National Forest Value Comparison Units 633, 634, 635, 636 and 637. Land Use Designations (LUD), for the project area, include Timber Production, Modified Landscape, Old-growth Habitat and Special Interest Areas. A few potential sale units may be located within the Inventoried Roadless Area #502. No timber harvest is planned in Old-growth Habitat or within the Special Interest Area.

Purpose and Need for Action

The purpose of and need for the Scratchings Timber Sale project is to provide timber harvest opportunities suitable for large and possibly small timber purchasers, mill operators and the value-added wood product industries in southeast Alaska in accordance with Forest Plan direction. The Forest Supervisor will decide whether or not to harvest timber from the Scratching Timber Sale project area, and if so, how this timber will be harvested. The decision will be based on the information that is disclosed in the Environmental Impact Statement. The responsible official will consider comments, responses, the disclosure of environmental consequences, as well as applicable laws, regulations, and policies in making the decision and will state that rationale in the Record of Decision. The Scratching Timber Sale would move the project area toward the desired condition described in the Tongass Land and Resource Management Plan (TLMP) or Forest Plan). The following Forest-wide goals and objectives as applied to the Scratchings Timber Sale project area include:

(1) Improve timber growth and productivity on suitable timber lands made abailable for timber harvest, and manage these lands for long-term sustained yield of timber.

(2) Contribute to a timber supply from the Tongass National Forest that seeks to meet annual and Forest Plan planning cycle market demand.

(3) Provide opportunities for local employment in the wood products industry that would in turn contribute to the local and regional economies of southeast Alaska.

Proposed Action

The Craig Ranger District is considering a proposal to harvest 25 to 40 million board-feet (MMBF) of timber from approximately 5,000 acres resulting in a variety of large and small timber sales. A combination of harvest methods may be used. Harvest prescriptions would be written to meet Forest Plan Standards and Guidelines. This will result in units with smaller openings and more partial-cut harvesting than has historically occurred within the Project Area. Approximately 16.5 miles of road construction is planned. About 3.5 miles of road would be temporary construction.

Public Participation

Public participation is an important part of the analysis process and will

continue to be especially important at several points during the analysis. The USDA Forest Service will be seeking additional information. A legal notice for this project will be published in the newspaper of record in addition to this Notice of Intent. Publication is expected in the newspaper of record, The Juneau Empire, July 7, 2005. Written scoping comments are being solicited through the scoping letters that are anticipated to be mailed to individual and organizations on the Craig Ranger District public involvement list July 7, 2005. The scoping process includes the following: identification of potential issues; identification of issues to be analyzed in depth; and elimination of non-significant issues or those which have been covered by a previous environmental review. Alternatives including ''No-Action'' alternative will be developed for the Draft Environmental Impact Statement based on the results of scoping and resource capabilities within the project area. Subsistence hearings, as provided for in Title VIII, Section 810 of the Alaska National Interest Lands Conservation Act (ANILCA), are planned during the comment period on the Draft EIS. The comment period on the Draft Environmental Impact Statement will be 45 days from the date the Environmental Protection Agency published the notice of availability in the **Federal Register**.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the environmental impact statement. The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the Final Environmental Impact Statement. A Draft Environmental Impact Statement will be prepared for comment. To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft Environmental Impact Statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the Draft Environmental Impact Statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points. Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision pursuant to 36 CFR parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may require the agency to withhold submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Requesters should be aware that under FOIA confidentiality maybe granted in only very limited circumstances; for example, to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request of confidentiality. The agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within seven days, should the request be is denied. To be more helpful and timely, scoping comments should be received within 45 days of the publication of this Notice of Intent.

Preliminary Issues

Based on preliminary analysis, we have developed two initial significant issues to be analyzed in the EIS: (1) Designing an economically viable timber sale that would benefit local communities in the form of additional employment opportunities and income; and (2) addressing cumulative impacts in the Port Dolores watershed from road building and timber harvest.

Possible Alternatives

In addition to a No Action alternative, three preliminary action alternatives have been developed. The three preliminary alternatives are (1) Timber harvest of approximately 40 MMBF from approximately 5,000 acres, maximizing harvest within TLMP Standards and Guidelines; (2) timber harvest of approximately 24 MMBF from approximately 931 acres, emphasizing development of economically viable timber sales; and (3) timber harvest of approximately 24 MMBF from approximately 983 acres, addressing cumulative impact to the Dolores watershed resulting from past harvest and road construction. The Old Growth (OGR) strategy will be considered in the various action alternatives.

Permits or Licenses Required

Permits required for implementation may include the following:

1. U.S. Army Corp of Engineers.

— Approval of discharge of dredged or fill material into the waters of the United States under Section 404 of the Clean Water Act.

— Approval of the construction of structures or work in navigable waters of the United States under Section 10 of the Rivers and Harbor Act of 1899.

2. Environmental Protection Agency.

— General National Pollutant Discharge Elimination System Permit for Log Transfer Facilities in Alaska.

— Spill Prevention Control and Countermeasure Plan.

3. State of Alaska, Department of Environmental Conservation.

— Tideland and Permit and Lease or Easement.

— Certification of Compliance with Alaska Water Quality Standards (401 Certification) Chapter 20.

4. Office of Project Management & Permitting (DNR).

— Coastal Zone Consistency Determination concurrence.

Responsible Official

Forest Cole, Forest Supervisor, Tongass National Forest; 648 Mission St., Federal Building; Ketchikan, AK 99901–6591 is the responsible official.

Nature of Decision To Be Made

The Forest Supervisor will decide whether or not to harvest timber from this area, and if so, how this timber would be harvested. The decision will be based on the information disclosed in the EIS, and the goals, objectives and desired future conditions as stated in the Forest Plan. The responsible official will consider the comments; response; disclosure of environmental

consequences; and applicable laws, regulations and policies; in making the decision and stating the rational in the Record of Decision. Alternatives would be developed to meet the objectives and criteria for small old-growth reserves. Four of the five VCUs in the project area requires small old-growth reserves. The effect of past and future harvest activities, along with existing and planned transportation routes would be studies.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21.)

Dated: June 24, 2005.

Forrest Cole,

Forest Supervisor.

[FR Doc. 05–13218 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Opal Creek Scenic Recreation Area (SRA) Advisory Council

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Opal Creek Scenic Recreation Area Advisory Council is participating in a field tour on July 23, 2005. The field trip is scheduled to begin at 10 a.m., and will conclude at approximately 3:30 p.m. Participants will meet at Oregon Department of Forestry Office (ODF) located on N. Fork Road and Highway 22 in Mehema, Oregon. Attendance by the public must be arranged one week in advance with the Designated Federal Official listed below.

The Opal Creek Wilderness and Opal Creek Scenic Recreation Area Act of 1996 (Opal Creek Act) (Pub. L. 104–208) directed the Secretary of Agriculture to establish the Opal Creek Scenic Recreation Area Advisory Council. The Advisory Council is comprised of thirteen members representing state, county and city governments, and representatives of various organizations, which include mining industry, environmental organizations, inholders in Opal Creek Scenic Recreation Area, economic development, Indian tribes, adjacent landowners and recreation interests. The council provides advice to the Secretary of Agriculture on preparation of a comprehensive Opal Creek Management Plan for the SRA, and consults on a periodic and regular basis on the management of the area. Tentative itinerary includes visiting and discussing current issues at Pearl Creek Guard Station about restoration, popular dispersed sites and Three Pools about use issues, and SRA entrance about transportation planning and signing.

A public comment period is tentatively scheduled to begin at 3 p.m. at the ODF office. Time allotted for individual presentations will be limited to 3 minutes. Written comments are encouraged, particularly if the material cannot be presented within the time limits of the comment period. Written comments may be submitted prior to the July 23rd by sending them to Designated Federal Official Paul Matter at the address given below.

FOR FURTHER INFORMATION CONTACT: For more information regarding this meeting, contact Designated Federal Official Paul Matter; Willamette National Forest, Detroit Ranger District, HC 73 Box 320, Mill City, OR 97360; (503) 854–3366.

Dated: June 29, 2005.

Dallas J. Emch,

Forest Supervisor

[FR Doc. 05–13220 Filed 7–5–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–274–804]

Notice of Final Results of Antidumping Duty Changed Circumstances Review: Carbon and Certain Alloy Steel Wire Rod from Trinidad and Tobago

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department has determined that Mittal Steel Point Lisas Limited (Mittal) is the successor–in-interest to Carribbean Ispat Limited (CIL) and, as a result, should be accorded the same treatment previously accorded to CIL in regard to the antidumping order on steel wire rod from Trinidad and Tobago as of the date of publication of this notice in the **Federal Register**.

EFFECTIVE DATE: July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Dennis McClure or Victoria Cho, at (202) 482–5973 or (202) 482–5075, respectively; AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On March 21, 2005, the petitioners[1] requested that the Department determine whether Mittal had become the successor–in-interest of CIL, pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216 and 351.221(c)(3). On April 6, 2005, CIL requested that the Department initiate and conduct an expedited changed circumstances review to determine whether Mittal is the successor–in-interest to CIL.

On May 2, 2005, the Department initiated this review and made its preliminary determination that Mittal is the successor–in-interest to CIL and should be treated as such for antidumping cash deposit purposes. *See Notice of Initiation and Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Trinidad and Tobago*, 70 FR 22634 (May 2, 2005) (*Preliminary Results*). In the *Preliminary Results*, we stated that interested parties could request a hearing or submit case briefs and/or written comments to the Department no later than 30 days after publication of the *Preliminary Results* notice in the **Federal Register**, and submit rebuttal briefs, limited to the issues raised in those case briefs, seven days subsequent to the case briefs due date. We did not receive any hearing requests or comments on the *Preliminary Results*.

Scope of the Order

The merchandise subject to this order is certain hot–rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above–noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (HTSUS) definitions for (a) stainless steel; (b) tool steel; c) high nickel steel; (d) ball bearing steel; and (e) concrete reinforcing bars and rods. Also excluded are (f) free machining steel products (i.e., products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod

[1] ISG Georgetown Inc., Gerdau Ameristeel US Inc., Keystone Consolidated Industries Inc., and North Star Steel Texas Inc.

and 1080 grade tire bead quality wire rod. This grade 1080 tire cord quality rod is defined as: (i) grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton, and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

This grade 1080 tire bead quality rod is defined as: (i) grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

For purposes of the grade 1080 tire cord quality wire rod and the grade 1080 tire bead quality wire rod, an inclusion will be considered to be deformable if its ratio of length (measured along the axis - that is, the direction of rolling - of the rod) over thickness (measured on the same inclusion in a direction perpendicular to the axis of the rod) is equal to or greater than three. The size of an inclusion for purposes of the 20 microns and 35 microns limitations is the measurement of the largest dimension observed on a longitudinal section measured in a direction perpendicular to the axis of the rod. This measurement methodology applies only to inclusions on certain grade 1080 tire cord quality wire rod and certain grade 1080 tire bead quality wire rod that are entered, or withdrawn from warehouse, for consumption on or after July 24, 2003. *Carbon and Certain Alloy Steel Wire Rod from Brazil, Canada, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine: Final Results of Changed Circumstances Review*, 68 FR 64079 (November 12, 2003).

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end–use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under the order are currently classifiable under subheadings 7213.91.3010, 7213.91.3090, 7213.91.4510, 7213.91.4590, 7213.91.6010, 7213.91.6090, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0010, 7227.20.0020, 7227.20.0090, 7227.20.0095, 7227.90.6051, 7227.90.6053, 7227.90.6058, and 7227.90.6059 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Final Results of Changed Circumstances Review

Based on the information provided by Mittal, and the fact that the Department did not receive any comments during the comment period following the preliminary results of this review, the Department hereby determines Mittal is the successor–in-interest to CIL for antidumping duty cash deposit purposes.

Instructions to U.S. Customs and Border Protection

The Department will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all shipments of the subject merchandise produced and exported by Mittal entered, or withdrawn from warehouse, for consumption, on or after the publication date of this notice at 3.61 percent (*i.e.* CIL's cash deposit rate). This deposit rate shall remain in effect until publication of the final results of the ongoing administrative review, in which Mittal/CIL is participating.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.306. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is in accordance with sections 751(b) and 777(i)(1) of the Act, and section 351.216(e) of the Department's regulations.

Dated: June 29, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–3548 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–475–703, A–588–707)

Granular Polytetrafluoroethylene Resin from Italy and Japan; Five-year (''Sunset'') Reviews of Antidumping Duty Orders; Final Results

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 1, 2004, the Department of Commerce (''the Department'') initiated a sunset review

of the antidumping duty orders on Granular Polytetrafluoroethylene Resin (''PTFE Resin'') from Italy and Japan, pursuant to section 751(c) of the Tariff Act of 1930, as amended, (''the Act''). On the basis of the notice of intent to participate and adequate substantive responses filed on behalf of the domestic interested parties and inadequate responses from respondent interested parties, the Department conducted expedited sunset reviews. As a result of these sunset reviews, the Department finds that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping at the levels listed below in the section entitled ''Final Results of Reviews.''

EFFECTIVE DATE: July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Martha V. Douthit or Dana Mermelstein, Office 6, Antidumping/Countervailing Duty Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC, 20230; telephone: (202) 482–5050 or (202) 482–1391.

SUPPLEMENTARY INFORMATION:

Background

On December 1, 2004, the Department initiated sunset reviews of the antidumping duty orders on PTFE Resin from Italy and Japan pursuant to section 751(c) of the Act. *See Initiation of Five-year (''Sunset'') Reviews*, 69 FR 69891 (December 1, 2004). The Department received notices of intent to participate from a domestic interested party, E.I. DuPont de Nemours & Company (''DuPont''), within the deadline specified in section 351.218(d)(1)(i) of the Department's regulations. DuPont claimed interested party status under section 771(9)(C) of the Act as a U.S. producer of a domestic like product. We received a complete substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). However, we did not receive responses from any respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted expedited sunset reviews of these orders.

On April 7, 2005, the Department extended the time limit for final results of these sunset reviews to not later than June 29, 2005. *See Carbon Steel Butt–Weld Pipe Fittings From Brazil, Japan, the People's Republic of China, Taiwan, and Thailand, and Granular Polytetrafluoroethylene Resin From Italy and Japan; Extension of Time Limit for the Final Results of Sunset Reviews of Antidumping Duty Orders*, 70 FR 17647 (April 7, 2005).

Scope of the Orders

Italy

The merchandise covered by this order is PTFE Resin, filled or unfilled, from Italy. The antidumping duty order also covers PTFE Resin wet raw polymer exported from Italy to the United States. See Granular Polytetrafluoroethylene Resin From Italy; Final Determination of Circumvention of Antidumping Duty Order, 58 FR 26100 (April 30, 1993). This order excludes PTFE dispersions in water and fine powders. The subject merchandise is classified under subheading 3904.61.00 of the Harmonized Tariff Schedule of the United States (''HTS'').

Japan

The merchandise covered by this order is PTFE Resin, filled or unfilled, from Japan. PTFE Resin dispersions in water and PTFE Resin fine powders are excluded from the order. The merchandise covered by this antidumping duty order is currently classifiable under subheading 3904.61.00 of the HTS.

Analysis of Comments Received

All issues raised in these cases are addressed in the ''Issues and Decision Memorandum'' from Barbara E. Tillman, Acting Deputy Assistant Secretary for Import Administration, to Joseph A. Spetrini, Acting Assistant Secretary for Import Administration, dated June 29, 2005 (''Decision Memorandum''), which is hereby adopted by this notice. The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margin likely to prevail if the orders were revoked. Parties can find a complete discussion of all issues raised in these sunset reviews and the corresponding recommendations in this public memorandum, which is on file in room B–099 of the main Department building.

In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at http://ia.ita.doc.gov, under the heading ''July 2005''. The paper copy and electronic version of the Decision Memorandum are identical in content.

Final Results of Reviews

We determine that revocation of the antidumping duty orders on PTFE Resin from Italy and Japan would likely lead to continuation or recurrence of dumping at the following percentage weighted–average margins:

Manufacturers/Exporters/Producers	Weighted–Average Margin (Percent)
Italy.	
Montefluos S.p.A./Ausimont U.S.A	46.46[1]
All Others	46.46
Japan.	
Daikin Industries, Inc.	103.00
Asahi Fluoropolymers, Inc.	51.45
All Others	91.74

[1] Solvay Solexis S.p.A. and Solvay Solexis, Inc., are the successors–in-interest to Ausimont S.p.A. and Ausimont U.S.A., Inc.

This notice also serves as the only reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department's regulations. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: June 29, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–3550 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–863]

Honey from the People's Republic of China: Final Results and Final Rescission, In Part, of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 27, 2004, the Department published the *Preliminary Results* of the second administrative review of the antidumping duty order on honey from the People's Republic of China (''PRC'') (69 FR 77184). This review covers nine exporters or producer/exporters: (1) Zhejiang Native Produce and Animal By–Products Import & Export Group Corp. (''Zhejiang''); (2) Shanghai Eswell

Enterprise Co., Ltd. (''Eswell''); (3) Wuhan Bee Healthy Company, Ltd. (''Wuhan Bee''); (4) Jinfu Trading Co., Ltd. (''Jinfu''); (5) Sichuan–Dujiangyan Dubao Bee Industrial Co., Ltd. (''Dubao''); (6) Inner Mongolia Autonomous Region Native Produce and Animal By–Products Import & Export Corp. (''Inner Mongolia''); (7) Shanghai Xiuwei International Trading Co., Ltd. (''Shanghai Xiuwei''); (8) Shanghai Shinomiel International Trade Corporation (''Shanghai Shinomiel''); and (9) Kunshan Foreign Trade Company (''Kunshan''), and exports of the subject merchandise to the United States during the period December 1, 2002 through November 30, 2003.

Based on our analysis of the record, including factual information obtained since the *Preliminary Results*, we have made changes to the margin calculations for Zhejiang, Eswell, Wuhan Bee, and Jinfu. Based on Dubao's non–cooperation after the *Preliminary Results*, we have applied total adverse facts available to all of Dubao's sales during the POR. Therefore, the final results differ from the *Preliminary Results*. *See* ''Final Results of Review'' section below

EFFECTIVE DATE: July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Anya Naschak or Kristina Boughton at (202) 482–6375 or (202) 482–8173, respectively; AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

We published in the **Federal Register** the *Preliminary Results* of the second administrative review on December 27, 2004. *See Honey from the People's Republic of China: Preliminary Results, Partial Rescission, and Extension of Final Results of Second Antidumping Duty Administrative Review*, 69 FR 77184 (December 27, 2004) (''*Preliminary Results*''). The period of review (''POR'') is December 1, 2002 through November 30, 2003.

Since the *Preliminary Results* the following events have occurred:

On January 10, 2005, Dubao informed the Department that it wished to withdraw from this administrative review. On January 12, 2005, the Department issued a letter informing Dubao that the request to withdraw from the review was well after the deadline for submitting such requests, and petitioners in this case had not withdrawn their request for review. The Department also informed Dubao that, because of Dubao's failure to respond to three outstanding supplemental questionnaires and the Department's inability to conduct verification of information submitted by Dubao, the Department may find Dubao to have failed to cooperate to the best of its ability pursuant to section 776(b) of the Tariff Act of 1930, as amended (''the Act''), and provided Dubao with an additional opportunity to submit the requested information. The Department received no response from Dubao.

From February 28, 2005 through March 4, 2005, the Department conducted verification of Wuhan Bee's sales and factors of production information at Wuhan Bee's facility in Wuhan. *See* Memorandum to the File from Case Analysts: Verification of U.S. Sales and Factors of Production for Respondent Wuhan Bee Healthy Co., Ltd., dated April 14, 2005 (''Wuhan Bee HM Verification Report'').

From March 7, 2005 through March 11, 2005, the Department conducted verification of Shanghai Eswell's sales and factors of production information at Shanghai Eswell's facility in Shanghai, and at Shanghai Eswell's unaffiliated producer, Nanjing Lishui Changli Bees Product Co., Ltd.'s (''Nanjing Changli''). *See* Memorandum to the File from Case Analysts: Verification of Sales of Shanghai Eswell Enterprise Co., Ltd. and of Factors of Production for Nanjing Lishui Changli Bees Product Co., Ltd.'s in the Antidumping Duty Administrative Review of Honey from the People's Republic of China, dated April 15, 2005 (''Eswell HM Verification Report''). From March 24, 2005 to March 25, 2005, the Department conducted verification of Shanghai Eswell's and Eswell America, Inc.'s (''Eswell America'') (collectively ''Eswell'') sales information at Shanghai Eswell's claimed U.S. affiliate, Eswell America, in Los Angeles. *See* Memorandum to the File from Case Analysts: Verification of Sales of Eswell America, Inc. in the Antidumping Duty Administrative Review of Honey from the People's Republic of China, dated April 15, 2005 (''Eswell US Verification Report'').

From April 27, 2005 through April 29, 2005, the Department conducted verification of Wuhan Bee's claimed U.S. affiliate in Wisconsin. *See* Memorandum to the File from Carrie Blozy and Kristina Boughton: Verification of U.S. Sales and Further Manufacturing Expenses for Respondent Wuhan Bee Healthy Co., Ltd (Wuhan Bee), as reported by Presstek Inc., Pure Sweet Honey Farm Inc., and Pure Food Ingredients, dated May 6, 2005 (''Wuhan Bee U.S. Verification Report'').

We invited parties to comment on our *Preliminary Results*. We received a case brief from respondents Zhejiang, Eswell, Wuhan Bee, and Jinfu on May 4, 2005. We also received a case brief from the American Honey Producers Association and the Sioux Honey Association (collectively, ''petitioners''), on May 4, 2005. The Department rejected respondents' case brief on May 5, 2005, and May 9, 2005, because the brief contained untimely submitted new information. Respondents refilled their case brief on May 10, 2005. We received a rebuttal brief from petitioners on May 13, 2005. The Department also requested comment on a number of issues, including the verification of Wuhan Bee's claimed U.S. affiliate, the methodology for constructing an export price (''EP'') database for Wuhan Bee and Shanghai Eswell, additional information with respect to the surrogate value of raw honey, and on calculating a per–unit assessment and cash deposit rate for the final results. We received comments from parties on each of these issues.

On June 3, 2005, we held a public hearing in this review. On June X, 2005, the Department submitted a letter to respondents and petitioners requesting comments on its proposed redaction of certain sur–rebuttal comments made by respondents in the public hearing. We received comments from parties on these proposed redactions on June 20, 2005.

Scope of the Order

The products covered by this order are natural honey, artificial honey containing more than 50 percent natural honey by weight, preparations of natural honey containing more than 50 percent natural honey by weight, and flavored honey. The subject merchandise includes all grades and colors of honey whether in liquid, creamed, comb, cut comb, or chunk form, and whether packaged for retail or in bulk form.

The merchandise subject to this order is currently classifiable under subheadings 0409.00.00, 1702.90.90, and 2106.90.99 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise under order is dispositive.

Partial Rescission of Administrative Review

In the *Preliminary Results*, the Department issued a notice of intent to rescind this administrative review with

respect to Kunshan, as we found that there were no entries of subject merchandise during the POR. *See Preliminary Results*, 69 FR at 77186. The Department received no comments on this issue. Therefore, the Department is rescinding this administrative review with respect to Kunshan.

Separate Rates

Zhejiang, Eswell, Wuhan Bee, Jinfu, and Dubao have requested separate, company–specific antidumping duty rates. In our *Preliminary Results*, we found that Zhejiang, Eswell, Wuhan Bee, Jinfu, and Dubao had met the criteria for the application of a separate antidumping duty rate. *See Preliminary Results*. Also in the *Preliminary Results*, we found that Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel did not respond in a complete and timely manner to the Department's requests for information, and hence do not qualify for a separate rate. The Department did not receive comments on this issue prior to these final results. *See* also ''The PRC–Wide Rate and Application of Facts Otherwise Available'' section below.

Since the *Preliminary Results*, the Department requested additional information from Dubao and stated its intent to complete a verification of Dubao. *See Preliminary Results*, 69 FR 77186. The Department was unable to verify the information submitted by Dubao because Dubao withdrew from this administrative review, and therefore Dubao is subject to adverse facts available and shall be deemed to be part of the PRC–wide entity. *See* The PRC–Wide Rate and Application of Adverse Facts Available section below.

We have not received any information since the *Preliminary Results* with respect to Zhejiang, Eswell, Wuhan Bee, and Jinfu which would warrant reconsideration of our separate–rates determination with respect to these companies. Therefore, we have assigned individual dumping margins to Zhejiang, Eswell, Wuhan Bee, and Jinfu for this review period.

Analysis of Comments Received

All issues raised in the briefs are addressed in the Issues and Decision Memorandum for the Final Results in the 2002/2003 Administrative Review of Honey from the People's Republic of China from Barbara E. Tillman, Acting Deputy Assistant Secretary to Joseph A. Spetrini, Acting Assistant Secretary, dated June 27, 2005 (''Issues and Decision Memorandum''), which is hereby adopted by this notice. A list of the issues raised, all of which are in the Issues and Decision Memorandum, is attached to this notice as Appendix I. Parties can find a complete discussion of all issues raised in the briefs and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit (''CRU''), room B–099 of the Herbert H. Hoover Building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at http://ia.ita.doc.gov/frn/index.html. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Shipments by Wuhan Bee

During the POR, the Department discovered a discrepancy between Wuhan Bee's reported U.S. sales database quantity and value and U.S. Customs and Border Protection (''CBP'') information. *See* Supplemental Questionnaire to Wuhan Bee from the Department of Commerce, dated January 6, 2005, and two memorandums to the file, dated January 6, 2005, and May 11, 2005. The CBP information indicated that Wuhan Bee appeared to have entries of subject merchandise into the United States during the POR that were not accounted for in its reported U.S sales database.

The Department took several steps with regard to this issue. First, the Department requested the entry documents associated with these sales from CBP and noted discrepancies between these invoices and Wuhan Bee's invoices. *See* ''Memorandum to the File: Wuhan Bee Healthy Co., Ltd. (Wuhan Bee) Invoices,'' dated June 10, 2005. Next, the Department conducted extensive completeness tests during Wuhan Bee's verification in China, in addition to standard verification procedures. In addition to conducting a reconciliation of Wuhan Bee's total reported sales value and quantity during the POR to its financial records, the Department also reconciled the reported sales values and total volume of shipments reported to the Department to all bills of lading, VAT receipts, raw material withdrawals, raw material inputs, and payment deposits. The Department did not find any evidence, based on these exhaustive completeness tests, that the additional sales had been made by Wuhan Bee.

Finally, the Department extensively interviewed company officials, at the verifications in both China and Wisconsin, regarding the discrepancy and the steps Wuhan Bee had taken regarding this matter. Company officials claimed that they reported these sales to CBP as fraudulent entries, and that they did not produce or ship these entries. They also outlined the steps they took with the U.S. Food and Drug Administration (''FDA'') and CBP regarding the matter, *e.g.*, providing a list of all of Wuhan Bee's legitimate entries during a certain time period at FDA's behest, meeting with FDA personnel, and hiring a law firm to handle the matter with the CBP. Company officials said that, to their knowledge, however, there had yet to be a resolution to this matter.[1]

The Department was unable to find any evidence that Wuhan Bee or its claimed affiliates, Presstek Inc. (''Presstek''), Pure Sweet Honey Farm Inc. (''PSH''), and Pure Food Ingredients (''PFI''), produced, shipped, invoiced, or received payment for these additional entries. Therefore, for these final results, the Department finds that these sales were not in fact Wuhan Bee sales and will instruct the CBP to liquidate these entries at the PRC–wide rate.

Changes Since the Preliminary Results

Based on the comments received from the interested parties, we have made changes to the margin calculation for Zhejiang, Eswell, Wuhan Bee, and Jinfu. For a discussion of these changes, *See* the Issues and Decision Memorandum. For the final results, we have updated our selection of a surrogate value for raw honey, based on new information placed on the record following the *Preliminary Results*. *See* the Issues and Decision Memorandum at Comment 1.

For the final results, we revised our calculation of surrogate financial ratios for factory overhead, selling, general and administrative expenses (''SG&A''), and profit, to use the more contemporaneous 2003/2004 annual report from the Mahabaleshwar Honey Producers Cooperative (''MHPC''), and applied these new ratios in our margin calculations. *See* the Issues and Decision Memorandum at Comment 2 and 3.

We revised our calculation of surrogate home market brokerage and handling expenses to be consistent with recent Department determinations. *See* the Issues and Decision Memorandum at Comment 4.

We revised our calculation of CEP profit for Zhejiang, and Shanghai Eswell to use the surrogate profit ratio from MHPC's financial statements in accordance with the Department's practice. *See, e.g.*, the Issues and Decision Memorandum at Comment 5.

We revised our classification of certain of Wuhan Bee's sales to Presstek from constructed export price (''CEP'') to export price (''EP''). *See* the Issues

[1] *See* Wuhan Bee U.S. Verification Report.

and Decision Memorandum at Comment 11, and below under ''Wuhan Bee Affiliation.'' For the remaining CEP sales by Wuhan Bee to Presstek, the Department has applied adverse facts available. *See* the Issues and Decision Memorandum at Comment 13, and ''The PRC–Wide Rate and Application of Facts Otherwise Available'' section, below.

Affiliation

With respect to Wuhan Bee, the Department has reversed its finding in the *Preliminary Results* that Wuhan Bee and its U.S. reseller were affiliated parties for the entire POR. Wuhan Bee has claimed that it is affiliated with Presstek, PSH, and PFI within the meaning of section 771(33) of the Act. Section 771(33) of the Act states that affiliated persons include: (A) members of a family, including brothers and sisters (whether by the whole or half blood), spouse, ancestors, and lineal descendants, (B) any officer or director of an organization and such organization, (C) partners, (D) employer and employee, (E) any person directly or indirectly owning, controlling, or holding with power to vote, five percent or more of the outstanding voting stock or shares of any organization and such organization, (F) two or more persons directly or indirectly controlling, controlled by, or under common control with, any person, (G) any person who controls any other person and such other person. For purposes of this paragraph, a person shall be considered to control another person if the person is legally or operationally in a position to exercise restraint or direction over the other person. To find affiliation between companies, the Department must find that at least one of the criteria listed above is applicable to the respondents.

Although no party in this case is questioning whether or not Wuhan Bee was in fact affiliated with Presstek, PSH, and PFI at some point during the POR within the meaning of Section 771(33), we note that the effective date of this affiliation is in question, and is significant to this proceeding for purposes of determining whether Wuhan Bee's U.S. sales made on various dates should be treated as ''export price'' sales or ''constructed export price'' sales. Wuhan Bee claims that it was affiliated with Presstek, PSH, and PFI throughout the entire POR, such that all of its POR sales should be treated as CEP sales. In support of this contention, Wuhan Bee has provided documentation it claims establishes that it had a close supplier relationship with Presstek, PSH, and PFI during the entire POR and that this close supplier relationship is sufficient to find affiliation between the parties. Petitioners claim that, if the Department were to find Wuhan Bee and Presstek, PSH, and PFI affiliated at any point during the POR, then the date of affiliation should be September 30, 2003, when Wuhan Bee recorded the ownership interest purchase by Presstek, PSH, and PFI's president in its normal books and records.

In considering for purposes of these final results whether Wuhan Bee was affiliated with Presstek, PSH, and PFI under section 771(33) of the Act, we analyzed all information on the record regarding the possible affiliations between PSH and Presstek, between Wuhan Bee and Presstek, and between Wuhan Bee and PSH. In particular, we considered whether Wuhan Bee and Presstek were affiliated from the beginning of the POR and whether the investment of the individual who was the president of Presstek, PSH, and PFI which led to that individual's board membership in Wuhan Bee resulted in a common control relationship between the parties at any time during the POR. *See* ''Memorandum to James C. Doyle: Administrative Review of the Antidumping Duty Order on Honey from the People's Republic of China (PRC): Analysis of the Relationship and Treatment of Sales between Wuhan Bee Healthy Co., Ltd. and Presstek Inc., Pure Sweet Honey Farm Inc., and Pure Foods Ingredients, Inc.'' (June 27, 2005) (''Wuhan Bee Affiliation Memo'') and accompanying Issue and Decision Memo at Comment 11.

Based on an analysis of the information on the record, the Department has determined that Wuhan Bee and Presstek, PSH, and PFI were not ''affiliated'' within the meaning of sections 771(33)(E) or (G) during the POR, and that they only became affiliated within the meaning of section 771(33)(F) of the Act when the Wuhan Bee board membership of the president of Presstek, PSH, and PFI became effective on July 20, 2003. At that point, Wuhan Bee, Presstek, PSH, and PFI came under the common control of that individual, and thus became affiliated with each other. Therefore, the Department has determined that, for purposes of these final results, all sales between Wuhan Bee and Presstek prior to July 20, 2003, will be examined on an EP basis, while all sales on or after this date will be examined on a CEP basis. *See* ''The PRC–Wide Rate and Application of Facts Otherwise Available'' section of this notice and accompanying Issue and Decision Memo at Comment 11 and 12 for further discussion.

The PRC–Wide Rate and Application of Facts Otherwise Available

As explained above, Eswell, Jinfu, Wuhan Bee, and Zhejiang (collectively ''separate rate companies'') each have obtained a separate rate. The PRC–wide rate applies to all entries of subject merchandise except for entries from PRC producers/exporters that have their own calculated rate. *See* ''Separate Rates'' section above.

Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel:

The Department did not receive comments on its preliminary determination to apply adverse facts available (''AFA'') to the PRC–wide entity (including Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel). Therefore, we have not altered our decision to apply total AFA to the PRC–wide entity (including Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel) for these final results, in accordance with sections 776(a)(2)(A) and (B), as well as section 776(b) of the Tariff Act of 1930, as amended (''the Act''). For a complete discussion of the Department's decision to apply total AFA for Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel, *See Preliminary Results*, 69 FR at 77188–77190. Furthermore, as stated in the *Preliminary Results*, the Department determined that, because Inner Mongolia, Shanghai Xiuwei, and Shanghai Shinomiel did not respond to our requests for information regarding separate rates, these companies do not merit separate rates. *See* Separate Rates section, above.

Facts Available:

Section 776(a)(2) of the Act provides that, if an interested party or any other person: (A) withholds information that has been requested by the administering authority; (B) fails to provide such information by the deadlines for the submission of the information or in the form and manner requested, subject to subsections (c)(1) and (e) of section 782; (C) significantly impedes a proceeding under this title; or (D) provides such information but the information cannot be verified as provided in section 782(i), the Department shall, subject to section 782(d) of the Act, use the facts otherwise available in reaching the applicable determination under this title. Where the Department determines that a response to a request for information does not comply with the request, section 782(d) of the Act provides that the Department shall promptly inform the party submitting the response of the nature of the

deficiency and shall, to the extent practicable, provide that party with an opportunity to remedy or explain the deficiency. Section 782(d) further states that, if the party submits further information that is unsatisfactory or untimely, the administering authority may, subject to subsection (e), disregard all or part of the original and subsequent responses. Section 782(e) of the Act provides that the Department shall not decline to consider information that is submitted by an interested party and is necessary to the determination but does not meet all the applicable requirements established by the administering authority if (1) the information is submitted by the deadline established for its submission, (2) the information can be verified, (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination, (4) the interested party has demonstrated that it acted to the best of its ability in providing the information and meeting the requirements established by the administering authority with respect to the information, and (5) the information can be used without undue difficulties.

Wuhan Bee:

Wuhan Bee responded to the Department's original questionnaire and several supplemental questionnaires, reporting its sales on a CEP basis, and the Department calculated a margin using CEP methodology for Wuhan Bee in the *Preliminary Results*, based on Wuhan Bee's claimed affiliation with Presstek, PSH, and PFI. However, based on the findings discussed above under ''Affiliation,'' in the Wuhan Affiliation Memo, and the Issues and Decision Memorandum at Comment 11, the Department has determined for these final results that Wuhan Bee did not become affiliated with Presstek and PSH until July 20, 2003, eight months into the POR. Based on these findings, the Department has classified all of Wuhan Bee's entered sales prior to the date of affiliation (July 20, 2003) as EP transactions. The Department has continued to classify all Wuhan Bee invoiced sales dated between July 20, 2003, and November 30, 2003, (the end of the POR) as CEP transactions.

Because Wuhan Bee provided a CEP sales database in response to the Department's questionnaire, however, the record does not contain an EP sales database that can be used in calculating a margin for the sales now classified as EP sales. Therefore, the Department finds that it is necessary to use facts available in determining the margin for these sales, in accordance with section 776(a)(1) of the Act. Moreover, because the Department made its determination that the sales should be accorded EP treatment after the *Preliminary Results*, it was not practicable for the Department to request that Wuhan Bee provide an EP sales database so late in the review and after verification; thus, section 782(d) of the Act does not apply.

As noted above, section 782(e) of the Act provides that the Department shall not decline to consider information that is submitted by an interested party and is necessary to the determination but does not meet all the applicable requirements established by the administering authority if (1) the information is submitted by the deadline established for its submission, (2) the information can be verified, (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination, (4) the interested party has demonstrated that it acted to the best of its ability in providing the information and meeting the requirements established by the administering authority with respect to the information, and (5) the information can be used without undue difficulties. During its verification of Wuhan Bee, the Department collected information on invoices for all entries of subject merchandise made by Wuhan Bee into the United States during the POR. *See* Wuhan Bee HM Verification Report. Therefore, as facts otherwise available, and in accordance with section 782(e) of the Act, as a proxy for an EP U.S. sales database, the Department has determined to use the fully verified invoice price and quantity data for sales from Wuhan Bee to Presstek based on the invoice list collected at verification. Interested parties in this review commented on this methodology as discussed in the Issues and Decision Memorandum at Comment 12, and agree with the Department's proposed methodology. *See also*, Wuhan Bee Final Analysis Memo.

The invoiced sales dated on or after affiliation began are appropriately classified as CEP sales. However, the Department has determined that it cannot rely on Wuhan Bee's reported CEP sales databases for the period after July 20, 2003, because it was unable to verify significant portions of the CEP data submitted by Wuhan Bee. Therefore, pursuant to section 776(a)(2)(D) of the Act, the Department has determined to use the facts otherwise available in determining the margins for Wuhan Bee's CEP sales.

At the verification of Presstek, PSH, and PFI in Wisconsin, the Department was unable to verify the quantity of subject merchandise sold by PSH to unaffiliated parties because of pervasive errors in Wuhan Bee's reported blend ratios. *See* The Issues and Decision Memorandum at Comment 13 for a further discussion of the Department's verification findings. The blend ratios represent the percentage of Chinese honey in the total honey blend that was sold to PSH's U.S. customers. Wuhan Bee relied on its blend ratios to determine whether an invoice line item represented a sale of subject merchandise. Wuhan Bee itself notes in its December 3, 2004, submission that ''1 MT of Chinese honey may be imported and then split into 5 portions of 20% Chinese honey, blended with non–subject merchandise, and resold under 5 invoices.'' Wuhan Bee further explains that, in this example, ''1 MT of Chinese honey is blended into 5 batches at a 20% blend prior to resale {and} only 20% of the honey that was sold was Chinese.'' *See* Comments on *Preliminary Results* Calculation Methodology for Wuhan Bee, dated December 3, 2004. Therefore, without accurate blend ratios, the Department has no way of determining the quantity of subject merchandise included in a given sale. Respondent admitted for the first time at the CEP verification that the underlying assumptions it used to report PSH's sales of subject merchandise were faulty, and that contrary to its statements prior to verification it was never able to report ''a one–to-one ratio relationship'' between the quantity of subject merchandise blended to produce each product listed as a separate line item on the PSH invoice and the quantity of subject merchandise sold under that line item. *See* Respondent's Refiling of Wuhan Bee's Case Brief, dated May 24, 2005, at 18. The Department gave Wuhan Bee ample opportunity prior to verification to modify its blend ratios or explain any problems it had with these data (issuing supplemental questionnaires on the CEP sales and further manufacturing expenses associated with the blending operations on October 20, 2004, and accepting Wuhan Bee's comments regarding the blend ratios on March 15, 2005), but Wuhan Bee did not approach the Department with these concerns prior to verification. Moreover, as detailed in the Issues and Decision Memo at Comment 13, the Department was also unable to verify other portions of Wuhan Bee's sales database during the CEP verification. *See* The Issues and Decision Memorandum at Comment 13 for further discussion of this issue.

Pursuant to section 776(a)(2)(D) of the Act, the Department may use facts

otherwise available when a party submits information that cannot be verified as provided in section 782(i). In addition, in accordance with section 782(d), the Department gave Wuhan Bee several opportunities to address problems it may have had in substantiating its blend ratios based on the books and records maintained in its normal course of business (as discussed in detail in the Issues and Decision Memo at Comment 13). The Department therefore finds, pursuant to section 776(a)(2)(C) of the Act, that Wuhan Bee has significantly impeded the Department's ability to conduct this proceeding with respect to Wuhan Bee's CEP sales by failing to submit accurate data. Therefore, the application of facts available is warranted with respect to Wuhan Bee's reported CEP sales.

Dubao:

Dubao responded to the Department's original questionnaire and several supplemental questionnaires, and the Department calculated a company–specific margin for Dubao in the *Preliminary Results*. In the *Preliminary Results* the Department stated its intent to verify the information submitted by Dubao. *See Preliminary Results* 69 FR at 77186. In addition, as stated in the ''Background'' section of this notice, the Department requested additional information from Dubao on January 3, 2005, due to ''concerns regarding the status of Dubao's relationship with its customers, the status of its customers as legitimate importers of record, and when and how Dubao received payment for its sales,'' as noted in the *Preliminary Results, Id.* at 77191 and in the Proprietary Analysis Memorandum to the File from Anya Naschak, Case Analyst, dated December 15, 2004. This supplemental questionnaire included four questions regarding returns of Dubao's merchandise, how and from whom Dubao received payment from its customers, and inconsistencies contained in Dubao's response with respect to its customers. This information was critical to the Department's analysis of the accuracy and veracity of Dubao's responses for the final results this administrative review, and was required to be submitted to the Department prior to its verification of Dubao's responses at its facilities in Baoji and Dujiangyan, PRC. In addition, this supplemental questionnaire included questions that the Department requested Dubao forward to its bank regarding the disposition of funds related to Dubao's sales. The Department also issued questionnaires to Dubao's customers, containing seventeen questions related to their purchases of subject merchandise from Dubao.

Despite providing Dubao with ample time to collect the requested information, the Department did not receive any of the requested information from Dubao. After the issuance of these questionnaires, the Department received a letter from Dubao withdrawing from this administrative review. *See* Letter from Dubao dated January 10, 2005 (''Dubao Withdrawal Letter''). The Department issued a letter to Dubao on January 12, 2005, in which it provided Dubao with an additional opportunity to respond to the Department's request for information, informing Dubao that, because its request to withdraw from the review had come in well after the deadline for making such requests, and because petitioners had not withdrawn their request for an administrative review, the Department would be proceeding with this administrative review with respect to Dubao. *See* Letter from James C. Doyle, Office Director, to Dubao, dated January 12, 2005. In this letter the Department noted that, because of Dubao's failure to respond to the Department's supplemental questionnaire and the Department's inability to conduct verification of the information submitted by Dubao to date pursuant to section 782(i)(2) of the Act, the Department might find Dubao to have failed to cooperate by not acting to the best of its ability, pursuant to section 776(b) of the Act.

The Department provided Dubao with another opportunity to provide the requested information, which was critical to the Department's analysis for these final results. Dubao again failed to provide the information requested, and did not respond to the Department's January 12, 2005, letter. Although the Department supplied Dubao with numerous opportunities to respond to the Department's additional requests for information, Dubao refused to submit any information in response to these supplemental questionnaires, did not permit verification, and withdrew from this administrative review. The Department therefore finds, pursuant to section 776(a)(2)(A), (B), (C), and (D) of the Act, that Dubao has repeatedly withheld information requested by the Department, failed to timely provide requested information, significantly impeded the Department's ability to conduct this proceeding, and, by withdrawing from the review, prevented the verification of the information it had earlier provided. Therefore, the application of facts available is warranted with respect to Dubao.

Application of an Adverse Inference:

Section 776(b) of the Act provides that, in selecting from among the facts available, the Department may use an inference that is adverse to the interests of the respondent if it determines that a party has failed to cooperate to the best of its ability. Adverse inferences are appropriate ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See Statement of Administrative Action* (''SAA'') accompanying the URAA, H. Doc. No. 316, 103d Cong., 2d Session at 870 (1994). In determining whether a respondent has failed to cooperate to the best of its ability, the Department need not make a determination regarding the willfulness of a respondent's conduct. *See Nippon Steel Corp. v. United States*, 337 F. 3d 1373, 1382–1393 (Fed. Cir. 2003) (''*Nippon Steel*''). Furthermore, ''an affirmative finding of bad faith on the part of the respondent is not required before the Department may make an adverse inference.'' *Antidumping Duties; Countervailing Duties: Final Rule*, 62 FR 27296, 27340 (May 19, 1997). Instead, the courts have made clear that the Department must articulate its reasons for concluding that a party failed to cooperate to the best of its ability, and explain why the missing information is significant to the review. *Id.*

In determining whether a party failed to cooperate to the best of its ability, the Department considers whether a party could comply with the request for information, and whether a party paid insufficient attention to its statutory duties. *See Tung Mung Dev. Co. v. United States*, 223 F. Supp. 2d 1336, 1342 (August 6, 2002). Furthermore, the Department also considers the accuracy and completeness of submitted information, and whether the respondent has hindered the calculation of accurate dumping margins. *See Certain Welded Carbon Steel Pipes and Tubes from Thailand: Final Results of Antidumping Duty Administrative Review*, 62 FR 53808, 53819–53820 (October 16, 1997).

The United States Court of Appeals has held that, if a respondent ''fails to provide {requested} information by the deadlines for submission,'' Commerce shall fill in the gaps with ''facts otherwise available.'' The focus of section 776(a) of the Act is respondent's failure to provide information. The reason for the failure is of no moment. As a separate matter, section 776(b) of the Act permits Commerce to ''use an inference that is adverse to the interests of {a respondent} in selecting from

among the facts otherwise available,'' only if Commerce makes the separate determination that the respondent ''has failed to cooperate by not acting to the best of its ability to comply.'' The focus of 776(b) of the Act is respondent's failure to cooperate to the best of its ability, not its failure to provide requested information. *See Nippon Steel*, 337 F. 3d at 1382.

In *Nippon Steel*, the Federal Circuit held that ''the statutory mandate that a respondent act to the 'best of its ability' requires the respondent to do the maximum it is able to do.'' *See Nippon Steel*, 337 F.3d at 1382.

An adverse inference may include reliance on information derived from the petition, the final determination in the investigation, any previous review, or any other information placed on the record. *See* section 776(b) of the Act. It is the Department's practice to assign the highest rate from any segment of a proceeding as total adverse facts available when a respondent fails to cooperate to the best of its ability. *See, e.g., Stainless Steel Plate in Coils from Taiwan; Preliminary Results and Rescission in Part of Antidumping Duty Administrative Review*, 67 FR 5789 (February 7, 2002) (''Consistent with Department practice in cases where a respondent fails to cooperate to the best of its ability, and in keeping with section 776(b)(3) of the Act, as adverse facts available, we have applied a margin based on the highest margin from any prior segment of the proceeding.'').

Wuhan Bee

Pursuant to Section 776(b), the Department finds that Wuhan Bee has failed to cooperate to the best of its ability with regard to its reported CEP data. The court has consistently found that it is a respondent's responsibility to build an accurate record, as the information necessary to calculate accurate margins is in the sole possession of respondents. *See Mannesmanrohren–Werke AG v. United States*, 120 F. Supp. 2d 1075 (CIT 2000). In addition, in *Nippon Steel*, 337 F. 3d at 1382, the court stated that ''an adverse inference may not be drawn merely from a failure to respond, but only under circumstances in which it is reasonable for Commerce to expect that more forthcoming responses should have been made.'' In the instant case, Wuhan Bee had ample opportunity to inform the Department of problems it may have encountered in reporting accurate blend ratios. Moreover, as late into the proceeding as March 15, 2005, it claimed that the reported ratios were accurate and reported based on Presstek/PSH's books and records, and thus Wuhan Bee impeded the Department's ability to assist Wuhan Bee in finding a means to report accurate blend ratio data.

At verification, the Department discovered that the blend ratios could not be verified using data maintained in their normal books and records, and only then did respondent admit that it had reported inaccurate blend ratios. The blend ratios are essential to the calculation of a dumping margin because the blend ratios determine whether a particular sale of honey is of subject or non–subject merchandise. Without confidence in these data, we cannot accurately say whether all U.S. sales of subject merchandise were reported and, within individual sales, whether the correct quantity of subject merchandise was reported.

Wuhan Bee could have informed the Department at the onset of this administrative review that it was having difficulty constructing a complete, accurate database based on the books and records of Presstek/PSH. Wuhan Bee failed to do so at any point in this proceeding, prior to the Department's discoveries at verification. Wuhan Bee therefore failed to do the maximum it was able to do, consistent with *Nippon Steel*.

Therefore, pursuant to section 776(b) of the Act, we find that Wuhan Bee failed to act to the best of its ability with respect to its CEP sales; we therefore find it appropriate to use an inference that is adverse to the interests of Wuhan Bee in selecting from among the facts otherwise available with respect to the valuation of those CEP sales. By doing so, we ensure that the companies that fail to cooperate will not obtain a more favorable result by failing to cooperate than had they cooperated fully in this review. In accordance with the Department's practice, we have assigned the rate of 183.80 percent, as adverse facts available, to the portion of Wuhan Bee's entries during the POR that were entered and sold on a CEP basis through PSH. Because we cannot rely on the reported CEP sales quantity (since we have found the quantity data to be unreliable), we have used the quantity of honey invoiced from Wuhan Bee to Presstek from July 17, 2003 through November 30, 2003, as a proxy for the total quantity of subject merchandise sold by Presstek to unaffiliated customers during this period. *See* below for a discussion of the probative value of the 183.80 percent rate.

Dubao/PRC–Wide Entity

As discussed above, Dubao is appropriately considered to be part of the PRC–wide entity because its separate rate eligibility could not be verified. Furthermore, because the PRC–wide entity did not provide information necessary to the instant proceeding, it is necessary that we review the PRC–wide entity. In doing so, we note that Section 776(a)(1) of the Act mandates that the Department use the facts available if necessary information is not available on the record of an antidumping proceeding. In addition, we find that an element of the PRC–wide entity (Dubao) did not respond to our requests for information, the necessary information was not provided, that the information that was provided was unable to be verified, and an element of the PRC–wide entity (Dubao) has failed to act to the best of its ability in providing the requested information. Therefore, we find it necessary, under section 776(a)(2) of the Act, to continue to use facts otherwise available as the basis for the final results of this review for the PRC–wide entity.

Pursuant to section 776(b) of the Act, we find that the PRC–wide entity failed to cooperate by not acting to the best of its ability to comply with requests for information. As noted above, an element of the PRC–wide entity (Dubao) informed the Department that it would not participate further in this review, and did not provide any of the requested information, despite repeated requests that it do so. This information was in the sole possession of the respondents, and could not be obtained otherwise. Thus, because the PRC–wide entity refused to participate fully in this proceeding, we find it appropriate to use an inference that is adverse to the interests of the PRC–wide entity in selecting from among the facts otherwise available. By doing so, we ensure that the companies that are part of the PRC–wide entity will not obtain a more favorable result by failing to cooperate than had they cooperated fully in this review.

As above stated, the PRC–wide entity (including Dubao, Shanghai Xiuwei, Inner Mongolia, and Shanghai Shinomiel) did not respond to our requests for information or otherwise submitted unreliable information. Because the PRC–wide entity did not respond to our request for information or otherwise submitted unreliable information, we find it necessary, under sections 776(a)(2) and 776(b) of the Act, to use adverse facts available as the basis for these final results of review for the PRC–wide entity. In accordance with the Department's practice, we have assigned to the PRC–wide entity (including Dubao, Inner Mongolia, Shanghai Xiuwei, Shanghai Shinomiel,

and Dubao) the rate of 183.80 percent as AFA. *See, e.g., Rescission of Second New Shipper Review and Final Results and Partial Rescission of First Antidumping Duty Administrative Review: Brake Rotors from the People's Republic of China*, 64 FR 61581, 61584 (November 12, 1999). In selecting a rate for adverse facts available, the Department selects a rate that is sufficiently adverse ''as to effectuate the purpose of the facts available rule to induce respondents to provide the Department with complete and accurate information in a timely manner.'' *See Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors from Taiwan*, 63 FR 8909, 8932 (February 23, 1998). This rate is the highest dumping margin from any segment of this proceeding and was established in the less–than-fair–value investigation based on information contained in the petition, and corroborated in the final results of the first administrative review. *See e.g., Notice of Final Determination of Sales at Less Than Fair Value; Honey from the PRC*, 66 FR 50608 (October 4, 2001); *Honey from the People's Republic of China: Preliminary Results of First Antidumping Duty Administrative Review*, 68 FR 69988 (December 16, 2003); and reinforced in Honey from the People's Republic of China: Final Results of First Antidumping Duty Administrative Review, 69 FR 24128 (May 3, 2004). For the reasons stated in the *Preliminary Results*, 69 FR 77190, the Department continues to find this rate to be both reliable and relevant, and, therefore, to have probative value in accordance with the *Statement of Administrative Action*, H.R. Doc. 103–316 (''*SAA*''). *See SAA* at 870. The Department received no comments on the Department's preliminary analysis of this rate for purposes of these final results. Therefore, the Department determines that the PRC–wide rate of 183.80 is still reliable, relevant, and has probative value within the meaning of section 776(c) of the Act.

Final Results of Review

We determine that the following antidumping duty margins exist:

Exporter	Margin (percent)
Zhejiang Native Produce and Animal By–Products Import & Export Group Corp. ...	45.54%
Shanghai Eswell Enterprise Co., Ltd.	38.60 %
Jinfu Trading Co., Ltd. ..	72.02%
Wuhan Bee Healthy Company, Ltd.	101.51%
PRC–Wide Rate[2]	183.80%

[2] Including Sichuan-Dujiangyan Dubao Bee Industrial Co., Ltd., Shanghai Xiuwei International Trading Co., Ltd., Inner Mongolia Autonomous Region Native Produce and Animal By-Products Import & Export Corp., and Shanghai Shinomiel International Trade Corporation.

For details on the calculation of the antidumping duty weighted–average margin for each company, *see* the respective company's Analysis Memorandum for the Final Results of the Second Administrative Review of the Antidumping Duty Order on Honey from the People's Republic of China, dated June 27, 2005. Public Versions of these memoranda are on file in the CRU.

Assessment of Antidumping Duties

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of the final results of this review. For assessment purposes, where possible, we calculated importer–specific assessment rates for honey from the PRC on a per–unit basis.[3] Specifically, we divided the total dumping margins (calculated as the difference between normal value and export price or constructed export price) for each importer by the total quantity of subject merchandise sold to that importer during the POR to calculate a per–unit assessment amount. In this and future reviews, we will direct CBP to assess importer–specific assessment rates based on the resulting per–unit (*i.e.*, per–kilogram) rates by the weight in kilograms of each entry of the subject merchandise during the POR.

Cash Deposits

For this and all subsequent review segments, we will establish and collect a per–kilogram cash deposit amount which will be equivalent to the company–specific dumping margin published in this and all future reviews. The following cash–deposit requirements will be effective upon publication of these final results for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) for subject merchandise exported by Shanghai Eswell, Jinfu, Wuhan Bee, and Zhejiang, we will establish a per–kilogram cash deposit rate which will be equivalent to the company–specific cash deposit established in this review; (2) the cash deposit rate for PRC exporters who received a separate rate in a prior segment of the proceeding will continue to be the rate assigned in that segment of the proceeding (except for Dubao, Inner Mongolia, and Shanghai Xiuwei, whose cash–deposit rates have changed in this review to the PRC–wide entity rate, as noted below); (3) for all other PRC exporters of subject merchandise which have not been found to be entitled to a separate rate (including Dubao, Shanghai Xiuwei, Inner Mongolia, and Shanghai Shinomiel), the cash–deposit rate will be the PRC–wide rate of 183.80 percent; (4) for all non–PRC exporters of subject merchandise, the cash–deposit rate will be the rate applicable to the PRC supplier of that exporter.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

Notification to Interested Parties

This notice also serves as the final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and in the subsequent assessment of double antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Failure to comply is a violation of the APO.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 27, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

Appendix I

List of Issues

General Issues

Comment 1: Appropriate Surrogate Value for Honey

[3] In our *Preliminary Results*, for those respondents who reported an entered value, we divided the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each applicable importer to calculate an *ad valorem* assessment rate.

Comment 2: Appropriate Surrogate Value for Financial Ratios
Comment 3: Calculation of the MHPC Financial Ratios
Comment 4: Brokerage and Handling Expenses
Comment 5: Recalculation of Constructed Export Price (''CEP'') Profit
Comment 6: Calculation of the Surrogate Wage Rate
Comment 7: Calculation of Assessment and Cash Deposit Rate

Company–Specific Issues

Jinfu–Related Issue:

Comment 8: Classification of Jinfu's U.S. Sales

Shanghai Eswell–Related Issues

Comment 9: Calculation of the Assessment Rates for Shanghai Eswell
Comment 10: Classification of Shanghai Eswell's U.S. Sales

Wuhan Bee–Related Issues

Comment 11: Classification of Wuhan Bee's U.S. Sales
Comment 12: Use of EP sales for Wuhan Bee
Comment 13: Application of Adverse Facts Available to Wuhan Bee

[FR Doc. E5–3547 Filed 7–5–05; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty–Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW, Washington, D.C.

Docket Number: 05–023. Applicant: Dartmouth College, Procurement and Auxiliary Services, Caller ι10,001, Hanover, NH 03755. Instrument: Electron Microscope, Model Technai G² 20 U-TWIN with XL30 ESEM FEG. Manufacturer: FEI Co, The Netherlands. Intended Use: The instrument is intended to be used to study:

1. Nanophase and nanocrystalline magnetic intermagnetic alloys

2. Monolayer–protected metal nanoparticle clusters

3. Protein crystals with infused inorganic nanoparticles. The instrument will also be use in graduate and undergraduate studies. Application accepted by Commissioner of Customs: June 9, 2005.

Docket Number: 05–027. Applicant: Beckman Research Institute of the City of Hope National Medical Center, 1450 East Duarte Road, Duarte, CA 91010. Instrument: Scanning Electron Microscope, Model Quanta 200 ESEM. Manufacturer: FEI Company, The Netherlands. Intended Use: The instrument is intended to be used in various research projects of the Institute including:

1. Studies of cell–cell interactions, such as occurs in cell-mediated immunity, or the arrangement of cells in tissues

2. Studies of cell surface structures, such as those that may be important in pathogens gaining a foothold in immune compromised and healthy patients

3. The examination of nanodevices used in mass spectrometers and other instrumentation for the study of small quantities of proteins and nucleic acid. Application accepted by Commissioner of Customs: June 21, 2005.

Docket Number: 05–028. Applicant: University of Wisconsin, Madison, Department of Biochemistry, 433 Babcock Drive, Madison, WI 53706–1544. Instrument: Electron Microscope, Model Technai 12 TWIN. Manufacturer: FEI Company, Czech Republic. Intended Use: The instrument is intended to be used for research by investigators at the University. Studies involve electron microscopy of animal cells, isolated proteins, DNA molecules, viruses, etc. All of the materials are biological in origin and the objective is to explore either the structure and/or the mechanism of action of these biological materials. Application accepted by Commissioner of Customs: June 23, 2005.

Gerald A. Zerdy,

Program Manager Statutory Import Programs Staff.

[FR Doc. E5–3549 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Opportunity To Apply for Membership on the U.S. Travel and Tourism Advisory Board

AGENCY: International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce is currently seeking applications for membership on the U.S. Travel and Tourism Advisory Board (''Board''). The purpose of the Board is to recommend to the Secretary of Commerce the appropriate coordinated activities with regards to funding for the U.S. Travel and Tourism Promotional Campaign (''Campaign''). Pursuant to Public Law 108–7, Division B, Section 210, the Secretary of Commerce shall in consultation with the Board design, develop and implement an international promotional campaign, which seeks to encourage foreign individuals to travel to the United States for the purposes of engaging in tourism related activities. Also, pursuant to 15 U.S.C. 1512 which provides the Department of Commerce the province and duty to foster, promote, and develop foreign and domestic commerce, the Board shall advise the Secretary of Commerce on the development, creation and implementation of a national tourism strategy and shall provide a means of ensuring regular contact between the government and the travel and tourism sector. The Board shall advise the Secretary on government policies and programs that affect the United States travel and tourism industry and provide a forum for discussing and proposing solutions to industry-related problems.

SUPPLEMENTARY INFORMATION: The Office of the Advisory Committees is accepting applications for Board members. Members shall serve until the Board's charter expires on August 1, 2007. Members will be selected based on our judgement of the candidates' proven experience in promoting, developing, and implementing advertising and marketing programs for travel-related or tourism-related industries; or the candidates' proven abilities to manage tourism-related or other service-related organizations. Also, members will be selected based on our judgement of the candidates' ability to represent the travel and tourism industry in the development, creation and implementation of a national tourism strategy.

Each Board member shall serve as the representative of a tourism-related ''U.S.

entity.'' However, for the purposes of eligibility, a U.S. entity shall be defined as a firm incorporated in the United States (or an unincorporated firm with its principal place of business in the United States) that is controlled by U.S. citizens or by another U.S. entity. An entity is not a U.S. entity if 50 percent plus one share of its stock (if a corporation, or a similar ownership interest of an unincorporated entity) is controlled, directly or indirectly, by non-U.S. citizens or non-U.S. entities. Priority may be given to chief executive officers or a similarly-situated officer of a tourism-related entity. Priority may also be given to individuals with international tourism marketing experience.

Officers or employees of state and regional tourism marketing entities are also eligible for consideration for Board membership. A state and regional tourism marketing entity, may include, but is not limited to, state government tourism office, state and/or local government supported tourism marketing entities, or multi-state tourism marketing entities. Again, priority may be given to chief executive officers or a similarly-situated officer.

Secondary selection criteria will ensure that the board has a balanced representation of the tourism-related industry in terms of point of view, demographics, geography and company size. The Board members will be selected on the basis of their experience and knowledge of the tourism industry. Members will serve at the discretion of the Secretary of Commerce.

Board members shall serve in a representative capacity presenting the views and interests of the particular tourism-related sector in which they operate. Board members are not special government employees, and will receive no compensation for their participation in Board activities. Members participating in Board meetings and events will be responsible for their travel, living and other personal expenses. Meetings will be held regularly, usually in Washington, DC.

To be considered for membership, please provide the following: 1. Name and title of the individual requesting consideration. 2. A letter containing a brief statement of why the applicant should be considered for membership on the Board. This letter should include the applicant's tourism-related experience. 3. The applicant's personal resume. 4. An affirmative statement that the applicant is not required to register as a foreign agent under the Foreign Agents Registration Act of 1938, as amended. 5. If a state or regional tourism marketing entity, the functions and responsibilities of the entity. 6. The company's size and ownership, product or service line and major markets in which the company operates.

ADDRESSES: Submit application information to Lindsey Dickinson, Director, Office of Advisory Committees, U.S. Department of Commerce, Room 4043, Washington, DC 20230.

Deadline: All applications must be received by the Office of Advisory Committees, by close of business on July 29, 2005.

FOR FURTHER INFORMATION CONTACT: Lindsey Dickinson, (202) 482–0087.

Dated: June 30, 2005.

Lindsey Dickinson,

Director, Office of Advisory Committees.

[FR Doc. E5–3552 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement (NAFTA), Article 1904 Binational Panel Reviews

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of decision of panel.

SUMMARY: On June 24, 2005 the binational panel issued its decision in the review of the five year review made by the International Trade Commission, respecting Gray Portland Cement and Clinker from Mexico, NAFTA Secretariat File Number USA–MEX–2000–1904–10. The binational panel affirmed in part and remanded in part the International Trade Commission's determination. Copies of the panel decision are available from the U.S. Section of the NAFTA Secretariat.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686). The panel review in this matter has been conducted in accordance with these Rules.

Panel Decision: The panel affirmed in part and remanded in part the International Trade Commission's determination respecting Gray Portland Cement and Clinker from Mexico. The panel remanded on the following issues:

1. On remand the Commission is to apply the ''probable'' or ''more likely than not'' standard announced by the CIT in *Siderca* when making its determination regarding likely volume, likely price effects, and likely impact on the industry.

2. With regard to the likely volume of subject imports if the antidumping duty order is revoked, the Commission is to (a) explain how it is probable that subject imports would increase if the antidumping duty order is revoked, and (b) render a complete analysis of how the various third-country antidumping duty orders would affect the likely volume of subject imports to the United States.

3. With regard to the likely price effects of subject imports on the industry if the order is revoked, the Commission is to (a) explain the price implications of revocation of the antidumping duty order with sufficient clarity to show how the record supports the Commission findings that revocation of the order would be likely to lead to significant negative price effects on the domestic industry, (b) explain how revocation of the antidumping duty order would be likely to lead to significant price underselling by subject imports of the domestic product, and (c) explain how subject imports are likely to enter the United States at prices that otherwise would have a significant price depressing or suppressing effect on the domestic product.

4. With regard to the likely impact on the domestic industry if the antidumping duty order is revoked, the Commission is to (a) explain how it reached the conclusion that the order should remain in place in order to protect the highly-profitable, regional industry, given the continuing solid demand in the region and a substantial increase in non-Mexican cement

imports; (b) explain how it reached the conclusion that the regional industry would be likely to suffer material injury, having found that the regional industry is not in a vulnerable states; and (c) explain how the decreasing market share of the regional industry, due to a substantial increase in demand, was not attributed to imports of non-Mexican cement.

5. With regard to the Commission's conclusion that the producers of all or almost all of the production in the Southern Tier region would likely suffer material injury be reason of the dumped imports if the order is revoked, the Commission is to (a) explain why producers of all or almost all of the production in the Southern Tier region would likely be materially injured if the order is revoked, (b) explain what percentage of regional production would likely suffer material injury, and (c) explain what its aggregate and individual plant analyses consisted of and what anomalies, if any, the individual plant analysis revealed.

6. The Commission is to fully evaluate the information concerning the proposed Southdown acquisition.

The Commission was directed to issue it's determination on remand within 60 days of the issuance of the panel decision or not later than August 23, 2005.

The Panel affirmed the Commission's determination in all other respects.

Dated: June 30, 2005.

Caratina L. Alston,

U.S. Secretary, NAFTA Secretariat.

[FR Doc. E5–3551 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that the Judges Panel of the Malcolm Baldrige National Quality Award will meet Thursday, July 28, 2005. The Judges Panel is composed of ten members prominent in the field of quality management and appointed by the Secretary of Commerce. The purpose of this meeting is to review the stage 1 process, consideration for moving applicants forward, review of stage 1 data and selection of applicants for consensus, pre-site visit conference call with team leaders, review of Stage 3 process documentation, update on revisions to Judges' survey, and summary of Improvements Day. The applications under review contain trade secrets and proprietary commercial information submitted to the Government in confidence. All visitors to the National Institute of Standards and Technology site will have to pre-register to be admitted. Anyone wishing to attend this meeting must register 48 hours in advance in order to be admitted. Please submit your name, time of arrival, e-mail address and phone number to Virginia Davis no later than Friday, July 22, 2005, and she will provide you with instructions for admittance. Ms. Davis' e-mail address is *virginia.davis@nist.gov* and her phone number is 301/975–2361.

DATES: The meeting will convene July 28, 2005, at 9 a.m. and adjourn at 4:30 p.m. on July 28, 2005. The entire meeting will be closed.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Administration Building, Lecture Room A, Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Harry Hertz, Director, National Quality Program, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975–2361.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on December 20, 2004, that the meeting of the Judges Panel will be closed pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, as amended by section 5(c) of the Government in the Sunshine Act, Pub. L. 94–409. The meeting, which involves examination of Award applicant data from U.S. companies and a discussion of this data as compared to the Award criteria in order to recommend Award recipients, may be closed to the public in accordance with section 552b(c)(4) of title 5, United States Code, because the meetings are likely to disclose trade secrets and commercial or financial information obtained from a person which is privileged or confidential.

Dated: June 27, 2005.

Hratch G. Semerjian,

Acting Director.

[FR Doc. 05–13261 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062805A]

Marine Mammals; File No. 932–1489

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

ACTION: Issuance of permit amendment.

SUMMARY: Notice is hereby given that the Marine Mammal Health and Stranding and Response Program (MMHSRP), National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD, has been issued an amendment to Permit No. 932–1489 to continue stranding response activities for marine mammal species under NMFS jurisdiction.

DATES: Written, telefaxed, or e-mail comments must be received on or before August 5, 2005.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment: See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Ruth Johnson or Amy Sloan, (301)713–2289.

SUPPLEMENTARY INFORMATION: Permit No. 932–1489–00 was issued on July 2, 1999 (64 FR 37933). The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (MMPA; 50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The permit has been amended to extend the expiration date of the permit by two years; allow aerial surveys as a method for finding injured or entangled marine mammals or to survey the extent of a disease outbreak or die-off of marine mammals; allow harassment of marine mammals on land incidental to other MMHSRP activities authorized by the permit; and allow development and maintenance of marine mammal cell lines for diagnostic testing. The objectives of the permit amendment remain the same as the original permit: to implement the Marine Mammal Health and Stranding Response Program

in accordance with Title IV of the MMPA (16 U.S.C. 1421 *et seq.*).

Pursuant to the provisions of Section 104(c)(3)(A) of the MMPA and implementing regulations at 50 CFR 216.33(e)(6), NMFS has issued this permit amendment without making the application available for a 30–day public comment period. Specifically, these provisions allow NMFS to waive the comment period in a situation where the health and life of an ESA-listed marine mammal is threatened and no reasonable alternative is available. Whereas the MMPA provides authorization for federal, state, and local government officials to take marine mammals in a humane manner if such taking is for the protection or welfare of the mammal, there are no comparable provisions under the ESA. Without this permit amendment, there would be no permit allowing for proper response to imperiled ESA-listed marine mammals. NMFS therefore determined that there was a compelling reason for waiving the 30–day public review and comment period on the application.

Issuance of this permit, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Documents may be reviewed in the following locations:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 427–2521;

Northwest Region, NMFS, 7600 Sand Point Way NE., BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206) 526–6150; fax (206) 526–6426;

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586–7221; fax (907) 586–7249;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Rm 1110, Honolulu, HI 96814–4700; phone (808) 973–2935; fax (808) 973–2941;

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978) 281–9200; fax (978) 281–9371; and

Southeast Region, NMFS, 263 13th Avenue South, St. Petersburg, FL 33702–2432; phone (727) 824–5312; fax (727) 824–5517.

Dated: June 29, 2005.

Patrick Opay,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–13265 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062805E]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Summer Flounder Monitoring Committee, Scup Monitoring Committee, Black Sea Bass Monitoring Committee, and Bluefish Monitoring Committee will hold a public meeting.

DATES: The meeting will be held on Thursday, July 28, 2005, beginning at 9 a.m.

ADDRESSES: The meeting will be held at the Renaissance Philadelphia Airport, 500 Stevens Drive, Philadelphia, PA 19113; telephone: 1–610–521–5900.

Council address: Mid-Atlantic Fishery Management Council, Room 2115, 300 S. New Street, Dover, DE 19904.

FOR FURTHER INFORMATION CONTACT: Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council; telephone: 302–674–2331, ext. 19.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to recommend the 2006 commercial management measures, commercial quotas, and recreational harvest limits for summer flounder, scup, and black sea bass. The Bluefish Monitoring Committee will meet to recommend commercial management measures, recreational management measures, and a commercial quota for bluefish for 2006.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Collins (302) 674–2331 ext: 10 at the Council Office at least 5 days prior to the meeting date.

Dated: June 29, 2005.

Emily Menashes,

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

[FR Doc. E5–3545 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 062805D]

Fisheries of the South Atlantic, Gulf of Mexico, and Caribbean; Southeastern Data, Assessment, and Review (SEDAR) Steering Committee Meeting.

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

ACTION: Notice of SEDAR Steering Committee Meeting.

SUMMARY: The SEDAR Steering Committee will meet to discuss the SEDAR process, assessment scheduling, and management coordination.

DATES: The SEDAR Steering Committee meeting will be held on August 2 and August 3, 2005. The Committee will meet from 10 a.m. to 5 p.m. on August 2, 2005 and 9 a.m. to 4 p.m. on August 3, 2005.

ADDRESSES: The SEDAR Steering Committee will meet at the Southeast Regional Office (SERO), 263 13th Avenue South, St. Petersburg, FL 33702; telephone: (305) 824–5301.

Council address: South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407.

FOR FURTHER INFORMATION CONTACT: John Carmichael, SEDAR Coordinator, SEDAR/SAFMC, One Southpark Circle, Suite 306, Charleston, SC 29407; telephone: (843) 571–4366, (866) SAFMC–10; fax: (843) 769–4520; *email: John.Carmichael@safmc.net.*

SUPPLEMENTARY INFORMATION: The South Atlantic, Gulf of Mexico, and Caribbean Fishery Management Councils in

conjunction with NOAA Fisheries, the Atlantic States Marine Fisheries Commission, and the Gulf States Marine Fisheries Commission implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks. SEDAR activities are conducted through committees established by the Councils under their 302(g) authority.

The SEDAR Steering Committee is composed of the Executive Directors and Chairs of the 3 Caribbean, Gulf, and South Atlantic Fishery Management Councils, the Executive Directors of the Gulf States and Atlantic States Marine Fisheries Commissions, the Southeast Regional Administrator, and the Southeast Fisheries Science Center Director. The Steering Committee provides coordination and integration of the management, assessment, and research activities in the Southeast Region.

The SEDAR Steering Committee will meet to review the SEDAR process, develop assessment priorities for 2009–10, review research and monitoring priorities, review scheduled regional management activities, and develop an appropriate work plan.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the South Atlantic Fishery Management Council office or the Southeast Regional Office at the addresses listed above at least 10 business days prior to the meeting.

Dated: June 29, 2005.

Emily Menashes,

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

[FR Doc. E5–3546 Filed 7–5–05; 8:45 am]

BILLING CODE 3510–22–S

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 05–C0009]

Rose Art Industries, Inc., a Corporation, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the **Federal Register** in accordance with the terms of 16 CFR § 1118.20(e). Published below is a provisionally-accepted Settlement Agreement with Rose Art Industries, Inc., a corporation, containing a civil penalty of $300,000.00.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by July 21, 2005.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 05–C0009, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT: Ronald G. Yelnik, Trial Attorney, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7582.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: June 30, 2005.

Todd A. Stevenson,

Secretary.

Settlement Agreement and Order

1. This Settlement Agreement is made by and between the staff (the ''staff'') of the U.S. Consumer Product Safety Commission (the ''Commission'') and Rose Art Industries, Inc. (''Rose Art'' or ''Respondent''), a corporation, in accordance with 16 CFR section 1118.20 of the Commission's procedures for Investigations, Inspections, and Inquiries under the Consumer Product Safety Act (''CPSA''). This Settlement Agreement and the incorporated attached Order settle the staff's allegations set forth below.

The Parties

2. The Commission is an independent federal regulatory agency responsible for the enforcement of the Consumer Product Safety Act, 15 U.S.C. sections 2051–2084.

3. Rose Art is a corporation organized and existing under the laws of the State of New Jersey with its principal corporate offices located in Livingston, New Jersey. Respondent manufactures are materials, toys and stationery products.

Staff Allegations

4. Between August 1997 and December 2001, Rose Art manufactured and sold nationwide approximately 124,000 Glamour Gear Soap Making Kits, models 4054 and 4121 (the ''Kit(s)'' or the ''product(s)''. Each Kit includes bars of soap, molds, and a plastic cup to melt soap chunks. These Kits are intended for use by children eight years of age and older.

5. The Kits are ''consumer products'' and Respondent is a ''manufacturer'' of ''consumer products,'' which were ''distributed in commerce'' as those terms are defined in sections 3(a)(1), (4), (11) and (12) of the CPSA, 15 U.S.C. 2052(a)(1), (4), (11), and (12).

6. The Kits are defective because the plastic cup used to heat the soap in a microwave oven may become deformed or develop a hole in the bottom, causing the hot soap contained therein to leak from the cup. If this occurs, young children and others may sustain serious burn injuries.

7. Between January 1998 and January 2002, Rose Art received reports of 10 children who were burned by hot soap while removing the plastic cup from a microwave oven. The majority of these children sustained second and third degree burns.

8. Despite being aware of the aforementioned reports, Rose Art did not inform the Commission about this information until February 14, 2002, when it submitted both a section 15 and a section 37 report.

9. Although Rose Art had obtained sufficient information to reasonably support the conclusion that the Kits contained a defect which could create a substantial product hazard, or created an unreasonable risk of serious injury or death, long before February 14, 2002, it failed to immediately inform the Commission of such defect or risk as required by sections 15(b)(2) and (3) of the CPSA, 15 U.S.C. 2064(b)(2) and (3). By failing to do so, Rose Art violated section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4).

10. Respondent committed this failure to immediately inform the Commission of the subject defect or risk ''knowingly'' as the term ''knowingly'' is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d), and pursuant to section 20 of

the CPSA, 15 U.S.C. 2069, Respondent is subject to civil penalties.

Response of Rose Art

11. Rose Art denies the allegations of the staff that the Kits contain a defect which could create a substantial product hazard, or create an unreasonable risk of serious injury or death, and denies that it violated the reporting requirements of section 15(b) of the CPSA, 15 U.S.C. 2064(b). Respondent also denies that the products when maintained and used properly create a substantial product hazard or an unreasonable risk of serious injury or death under section 15(b) of the CPSA, 15 U.S.C. 2064(b). Respondent asserts that it did not ''knowingly'' violate any reporting requirements under the CPSA. Respondent further asserts that any injury associated with the use of its products was attributable to unreasonable consumer misuse of the products contrary to instructions and without adequate adult supervision.

12. Notwithstanding its denial that the Kits contain a defect which could create a substantial product hazard, or create an unreasonable risk of serious injury or death, Respondent nevertheless, cooperated with the staff in recalling the products.

Agreement of The Parties

13. The Commission has jurisdiction over this matter and over Rose Art Under the CPSA, 15 U.S.C. 2051–2084.

14. In settlement of the staff's allegations, Rose Art agrees to pay a civil penalty of three hundred thousand dollars ($300,000.00) in two installments. The first installment of one hundred fifty thousand dollars ($150,000.00) shall be paid within twenty (20) calendar days of service of the Final Order of the Commission accepting this Settlement Agreement. The second installment of one hundred fifty thousand dollars ($150.000.00) shall be paid on or before January 31, 2006. These payments shall be made by check payable to the order of the United States Treasury.

15. The parties enter into this Settlement Agreement for settlement purposes only. The Settlement Agreement does not constitute an admission by Rose Art, or a determination by the Commission that Rose Art has violated the CPSA's reporting requirements.

16. Upon provisional acceptance of this Settlement Agreement and Order by the Commission, the Commission shall place this Agreement and Order on the public record and shall publish it in the **Federal Register** in accordance with he procedure set forth in 16 C.F.R. 1118.20(e). If the Commission does not receive any written request not to accept the Settlement Agreement and Order within 15 days, the Agreement and Order shall be deemed finally accepted on the 16th day after the date it is published in the **Federal Register**

17. Upon final acceptance of this Settlement Agreement by the Commission and issuance of the Final Order, Rose Art knowingly, voluntarily and completely waives any rights it may have in this matter to the following: (i) An administrative or judicial hearing; (ii) judicial review or other challenge or contest of the validity of the Commission's actions; (iii) a determination by the Commission as to whether Respondent failed to comply with the CPSA and its underlying regulations; (iv) a statement of findings of fact and conclusions of law; and (v) any claims under the Equal Access to Justice Act.

18. The Commission may publicize the terms of the Settlement Agreement and Order.

19. This Settlement Agreement and Order shall apply to, and be binding upon Respondent and each of its successors and assigns.

20. The Commission's Order in this matter is issued under the provisions of the CPSA, 15 U.S.C. 2051–2084, and a violation of the Order may subject Respondent to appropriate legal action.

21. This Settlement Agreement may be used in interpreting the Order. Agreements, understandings, representations, or interpretations made outside of this Settlement Agreement and Order may not be used to vary or to contradict its terms.

22. The Settlement Agreement and Order shall not be waived, changed, amended, modified, or otherwise altered, except in writing executed by the party against whom such amendment, modification, alteration, or waiver is sought to be enforced, and approved by the Commission.

23. If, after the effective date hereof, any provision of this Settlement Agreement and Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Settlement Agreement and Order shall remain in full effect, unless the Commission and Respondent determine that severing the provision materially impacts the purpose of the Settlement Agreement and Order.

Rose Art Industries, Inc.
Dated: April 25, 2005
Jeffrey Rosen,
Chief Operating Officer, Rose Art Industries, Inc., 6 Regent Street, Livingston, NJ 07039.

Frederick B. Locker, Esq.,
Locker, Brainin & Greenberg, 420 Fifth Avenue, New York, NY 10018, Counsel for Rose Art Industries, Inc.

U.S. Consumer Product Safety Commission.

John Gibson Mullan,
Director, Office of Compliance.

Eric L. Stone, Director,
Legal Division, Office of Compliance.

Dated: April 27, 2005.
Ronald G. Yelenik,
Senior Attorney, M. Reza Malihi, Trial Attorney, Legal Division, Office of Compliance.

Order

Upon consideration of the Settlement Agreement entered into between Rose Art Industries, Inc. (''Rose Art'') and the staff of the U.S. Consumer Product Safety Commission (the ''Commission''), and the Commission having jurisdiction over the subject matter and over Rose Art, and it appearing that the Settlement Agreement is in the public interest, it is

Ordered, that the Settlement Agreement be, and hereby is, accepted; and it is

Further Ordered, that Rose Art shall pay a civil penalty of three hundred thousand dollars ($300,000.00) in two installments. The first installment of one hundred fifty thousand dollars ($150,000.00) shall be paid within twenty (20) calendar days of service of the Final Order of the Commission accepting the Settlement Agreement. The second installment of one hundred fifty thousand dollars ($150,000.00) shall be paid on or before January 31, 2006. These payments shall be made by check payable to the order of the United States Treasury. Upon the failure of Rose Art to make a payment or upon the making of a late payment, (i) the entire amount of the civil penalty shall become due and payable, and (ii) interest on the outstanding balance shall accrue and be paid at the federal legal rate of interest under the provisions of 28 U.S.C. 1961(a) and (b).

Provisionally accepted and Provisional Order issued on the 30th day of June, 2005.

By Order of the Commission,
Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 05–13288 Filed 7–5–05; 8:45 am]
BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB review; comment request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by August 5, 2005.

Title and OMB Number: Commissary Evaluation and Utility Surveys—Generic; OMB Number 0704–0407.

Type of Request: Extension.

Number of Respondents: 6,633.

Responses Per Respondent: 1.

Annual Responses: 6,633.

Average Burden Per Response: 1.34 minutes (average).

Annual Burden Hours: 148.

Needs and Uses: The Defense Commissary Agency (DeCA) will conduct a variety of one-time surveys to include customer satisfaction and preference surveys on various services and processes within the commissary system. The survey population will include, but is not limited to, persons eligible to use the commissary throughout the world. The information collected will be used to support or assess: (1) Commissary renovation and new construction, (2) commissary site decisions, (3) impact to commissaries that are near a closing commissary or a commissary that is undergoing some other kind of transformation, (4) processes within the commissaries, (5) commissary patrons perception of savings compared to local commercial supermarkets, and (6) demographic mark-up of commissary users.

Affected Public: Individuals or households; business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Lewis Oleinick. Written comments and recommendations on the proposed information collection should be sent to Mr. Oleinick at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Patricia Toppings. Written requests for copies of the information collection proposal should be sent to Ms. Toppings, WHS/ESD/Information Management Division, 1225 South Clark Street, Suite 504, Arlington, VA 22202–4326.

Dated: June 27, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 05–13191 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by August 5, 2005.

Title, Form, and OMB Number: Application for Uniformed Services Identification Card—DEERS Enrollment; DD Form 1172; OMB Number 0704–0020.

Type of Request: Revision.

Number of Respondents: 1,146,898.

Responses Per Respondent: 1.

Annual Responses: 1,146,898.

Average Burden Per Response: 5 minutes.

Annual Burden Hours: 95,575.

Needs and Uses: This information collection requirement is needed to obtain the necessary information to authorize members of the Uniformed Services, their spouses and dependents, and other authorized individuals certain benefits and privileges. These privileges include health care, use of commissary, base exchange, and morale, welfare, and recreation facilities. This information collection is needed to obtain the necessary data to determine eligibility, to provide eligible individuals with an identification care for benefits and privileges administered by the Uniformed Services, and maintain a centralized database of eligible individuals.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Mr. Lewis Oleinick.

Written comments and recommendations on the proposed information collection should be sent to Mr. Oleinick at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings, WHS/ESD/Information Management Division, 1225 South Clark Street, Suite 504, Arlington, VA 22202–4326.

Dated: June 27, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13192 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

New Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary of Defense (Health Affairs) announces the new collection of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the new 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 6, 2005.

ADDRESSES: Written comments and recommendations on the information collection will be sent to Office of the Assistant Secretary of Defense (Health Affairs) TRICARE Management Activity, Contracting Office, 16401 East Centretech Parkway, Aurora Colorado 80011–9088—Attn: Mr. Bruce Mitterer or Mr. Marty Blomberg.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection, please write to the above address or contact one of the following: Mr. Bruce Mitterer, TRICARE Management Activity, Contracting Officer, or Mr. Marty Blomberg, 16401 East Centretech Parkway, Aurora, Colorado 80011–9088, 1–303–676–3575.

Title; Associated Form; and OMB Number: TRIWEST/TRICARE Provider Satisfaction Survey.

Needs and Uses: The data will be used to improve the services and

relationship between providers and TriWest to ensure that TriWest is delivering upon the commitment to provide ''Beneficiary satifaction at the highest possible level''.

Affected Public: Individuals or household.

Annual Burden Hours: 145 hours.

Number of Respondents: 850.

Responses Per Respondent: 1.

Average Burden Per Response: .17 hours.

Frequency: Annually.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The TriWest Healthcare Alliance is a Phoenix-based corporation that partners with the Department of Defense (DoD) to provide access to cost-effective, high quality health care for our nation's active and retired uniformed services members and their families. These individuals are eligible for the DoD's regionally managed health care program for the military, called TRICARE. TriWest is under contract with the DoD to manage and administer TRICARE throughout the 21-state TRICARE West Region.

In addition to supporting military families through the TRICARE program, TriWest has developed relationships with organizations such as the USO, Fisher House, the Women in Military Service for America Memorial Foundation and other military relief and support associations to strengthen America's military community locally and nationally.

TRICARE West includes the following states:

- Alaska
- Arizona
- California
- Colorado
- Hawaii
- Idaho
- Iowa
- Kansas
- Minnesota
- Missouri (except the St. Louis area)
- Montana
- Nebraska
- Nevada
- New Mexico
- North Dakota
- Oregon
- South Dakota
- Texas (El Paso area only)
- Utah
- Washington
- Wyoming

Dated: June 27, 2005.

Patricia Toppings,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13193 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Healthy Choices for Life Initiatives Demonstration Projects for TRICARE Prime Beneficiaries

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Notice of Healthy Choices for Life Initiatives Demonstration Projects for TRICARE Prime Beneficiaries.

SUMMARY: This notice is to advise interested parties of demonstration projects that the Department of Defense Military Health System proposes to implement and evaluate under the Healthy Choices for Life Initiatives: A Tobacco Cessation Quitline Demonstration project and a Weight Management Demonstration project. The Tobacco Cessation Demonstration project is being done to measure the effectiveness of a toll-free telephone Tobacco Quitline alone, or when used in conjunction with prescription pharmacotherapy in curtailing or stopping the use of tobacco products by demonstration participants. This portion of the Demonstration will enable DoD to evaluate these selected interventions in a DoD beneficiary population and gather data for health care costs and utilization. The Demonstration will occur in four states: Colorado, Kansas, Missouri and Minnesota. The Tobacco Cessation Demonstration project will provide information that will enable DoD to determine whether behavior modification, either alone or with pharmacotherapy, should be added to the TRICARE Prime benefit for the treatment of patients who use or are dependent upon tobacco.

The Weight Management Demonstration project will allow the DoD to determine the efficacy and acceptability of distance behavioral interventions and pharmacotherapy in producing and maintaining clinically significant weight loss in at-risk overweight or obese individuals. The Weight Management Demonstration project will occur in four states: Indiana, Illinois, Michigan, and Ohio. The Weight Management Demonstration project will provide information that will enable DoD to determine whether to seek a change in statute to authorize, as part of the TRICARE benefit, behavior modification either alone or with pharmacotherapy for the treatment of patients that are overweight or obese.

Certain preventive care services not normally provided as part of basic program benefits under TRICARE are covered benefits when provided to TRICARE Prime enrollees. Tobacco cessation and weight loss programs, along with pharmacotherapy, are currently not benefits under either the TRICARE basic program or under TRICARE Prime. This demonstration will evaluate whether these services should be extended to Prime beneficiaries as additional preventive care benefits. These Demonstration projects are being conducted under the authority of 10 U.S.C. 1092.

EFFECTIVE DATE: October 1, 2005.

FOR FURTHER INFORMATION CONTACT: LCDR Robert Fry, Office of the Chief Medical Officer, TRICARE Management Activity (TMA), 5111 Leesburg Pike, Skyline Five, Suite 810, Falls Church, VA 22041–3206, telephone (703) 681–0064.

SUPPLEMENTARY INFORMATION:

A. Background

By law, under 10 U.S.C. 1079(a)(13), TRICARE may cost share only medically or psychologically necessary care under the Basic Program. Under TRICARE Prime, TRICARE may also provide additional preventive health care benefits. One of the major priorities of the Assistant Secretary of Defense for Health Affairs is the Healthy Choices for Life Initiatives for a fit and ready force and healthy beneficiary population. Preventive health measures are an integral part of Healthy Choices for Life. Currently, uniform tobacco cessation and weight management programs for TRICARE Prime enrollees in the Military Health System (MHS) have not been established as a preventive benefit.

Tobacco Cessation

Tobacco use is the leading cause of preventable death in the United States. It is responsible for 440,000 deaths annually nationwide, including 14,000 in the Department of Defense (DoD). The case for an expanded and comprehensive approach to tobacco cessation in the DoD is compelling. With estimated medical costs from tobacco use that exceed $1.6 billion per year and the observation of an alarming increase in smoking prevalence among young active duty service members, the need for a global and effective DoD strategy has never been greater. Research indicates tobacco use has a negative impact on readiness during wartime (for example, 20–50 percent reduction in night vision for smokers; deleterious effects of rapid nicotine withdrawal on cognitive function and visual acuity; significant decrement in tracking ability; and increased reaction times). Tobacco use also (1) puts

individuals at greater risk for pneumonia, asthma, and lung disease; (2) results in more hospitalization and lost work in young active duty; (3) degrades performance on physical fitness tests; and (4) increases likelihood of sustaining musculoskeletal injuries.

The purpose of this demonstration is to determine that pharmacotherapy, proactive telephone Quitlines, and counseling are effective interventions in achieving tobacco cessation for the TRICARE eligible population. According to the Centers for Disease Control and Prevention (CDC), smokers are more likely to utilize telephone counseling than group or individual counseling, and high intensity interventions are more effective than lower intensity ones.

TRICARE does not cover behavioral counseling for tobacco cessation, or medications used to facilitate tobacco cessation. Treatment of tobacco use/dependence is excluded by 32 CFR 199.4(g). The Tobacco Cessation Demonstration project will provide the opportunity to test the effectiveness of selected interventions in the DoD population before these interventions are considered for inclusion in the TRICARE Prime benefit.

Weight Management

Obesity is a leading cause of preventable death in the United States, contributing to more than 112,000 deaths annually. All segments of the DoD population demonstrate upward weight trends with approximately 13 percent of active duty members, 34 percent of non-active duty adults, and 19 percent of dependent DoD adolescents classified as obese according to National Institutes of Health criteria. Many high volume, high cost medical conditions, including diabetes, heart disease, back and joint pain, asthma, some cancers, and sleep apnea are related to obesity, and costs will increase as the DoD population ages.

In 2004, the Centers for Medicare and Medicaid Services deleted policy language indicating that obesity is not a disease. Blue Cross/Blue Shield of North Carolina recently decided to offer coverage of physician visits and nutritional counseling for weight loss. According to an America's Health Insurance Plans survey, 76 percent of surveyed U.S. health insurers covered nutritional counseling as part of their preventive services benefit.

According to the 1998 National Heart Lung and Blood Institute (NHLBI) Guideline for the Identification, Evaluation and Treatment of Overweight and Obesity in Adults, a reduction in body weight of 10 percent is an appropriate initial goal with six months cited as a reasonable period of time in which to achieve this goal (weight loss of 1–2 pounds/week). Weight loss in the 5–10 percent range has been shown to produce health benefits for obese patients. Greater weight loss does not improve health outcomes and rapid weight loss is more likely to be followed by weight gain.

After six months of successful weight loss the rate of weight loss usually declines or plateaus. Successful weight maintenance is defined as a regain of weight less than 6.6 pounds (3 kilograms) in 2 years.

TRICARE does not cover nutritional counseling, behavioral counseling, or medication for weight loss. Treatment of obesity as a sole medical condition is excluded by statute (10 U.S.C. 1079(a)(11)) with the exception of bariatric surgery for morbid obesity when conditions for coverage under 32 CFR 199.4(e)(15) are met. Bariatric surgical procedures performed in the purchased care network have increased from 954 in 2001 to 3,415 in 2004. Facility costs associated with bariatric surgery made the top ten list for most expensive DoD Diagnosis Related Groups for the first time in fiscal year 2004, with $26 million in actual government costs. This does not include associated professional fees or the value of approximately 500 additional procedures performed annually in the direct care system.

Each military service offers behavioral and educational interventions to active duty service members exceeding body fat standards. These interventions are sometimes, but not universally, available to non-active duty beneficiaries depending on the resources of the Military Treatment Facility (MTF) or the local health promotion activity.

B. Description of Demonstration Project and Costs

For the Tobacco Cessation Quitline Demonstration project, based upon information from DoD and CDC surveys, of the 101,000 Prime enrollees in the four states, we estimate that about 22,000 (or 21.8 percent) are smokers. Treatment protocol costs are estimated at approximately $1.8 million. For the Weight Management Demonstration project, based upon information from DoD and CDC surveys in the four states, we estimate that about 45,000 Prime enrollees meet the definition (Body Mass Index greater than or equal to 25) for overweight or obese. Treatment protocol costs are estimated at approximately $3 million.

These demonstration projects are anticipated to start in the first quarter of fiscal year 2006 and continue for three years.

Tobacco Cessation Demonstration

Location: The Tobacco Cessation Demonstration project will include four states—Colorado, Minnesota, Missouri, and Kansas—which have large numbers of Prime beneficiaries who are greater than 40 miles from an inpatient MTF within the same TRICARE Region. The Demonstration participants will be TRICARE eligible beneficiaries enrolled in TRICARE Prime, TRICARE Prime Remote (TPR), or TPR for Active Duty Family Members (TPR–ADFM), are between18–64 years of age, who are not entitled to Medicare on the basis of age, disability, or end-stage renal-disease, and reside in the identified zip code areas of the demonstration. Beneficiaries enrolled in other special programs (for example, Extended Care Health Options (ECHO)) available through TRICARE are not eligible for enrollment in this demonstration. Eligible beneficiaries in the four state demonstration areas will receive a letter from the Tobacco Cessation Demonstration service provider explaining program elements, participation criteria, and how to enroll in the demonstration.

Scope: The scope of services available through the program will include: (1) The availability of a proactive toll-free telephone Quitline; (2) the availability of a web-based tobacco cessation information resource; (3) prescription pharmacotherapy and physician visits with normal cost-shares; and (4) unlimited numbers of quit attempts.

Key elements of the Tobacco Cessation Demonstration project include enrollment of participants and utilization of a Quitline plus access to scheduled telephone counseling. Additionally, the website will also provide links to DoD, Federal, and State resources for tobacco cessation. E-mail support will be available for questions and comments.

Pharmacotherapy will be made available in all four states only through the TRICARE Mail Order Pharmacy (TMOP). Uniform formulary TMOP cost-shares will apply. To access pharmacotherapy, Prime enrolled beneficiaries in the four-state area must be enrolled in the demonstration program, see a provider, and obtain a prescription for appropriate tobacco cessation pharmacotherapy, and submit it to the TMOP.

It will be necessary for Quitline personnel to make follow-up contact to program participants to evaluate the effectiveness of the program and to

determine tobacco-use status after program participation. This will require the Quitline personnel to obtain basic contact information on participants to allow for follow-up.

There will be no limit on the number of times an eligible beneficiary will be allowed to participate in the program if they fail to stop using tobacco products or obtain a prescription for appropriate tobacco cessation pharmacotherapy during the demonstration period.

Weight Management

Location: The Weight Management Demonstration will include Prime enrollees residing in Indiana, Illinois, Michigan and Ohio. These states have been selected in part on the basis of high prevalence of obesity and overweight in these areas, according to the CDC. The Demonstration participants will be TRICARE eligible beneficiaries enrolled in TRICARE Prime, TRICARE Prime Remote (TPR), or TPR for Active Duty Family Members (TPR–ADFM), are between18–64 years of age, who are not entitled to Medicare on the basis of age, disability, or end-stage renal-disease, and reside in the identified zip code areas of the demonstration. Beneficiaries enrolled in other special programs (for example, ECHO) available through TRICARE are not eligible for enrollment in this demonstration. Eligible beneficiaries in the four state demonstration areas will receive a letter from the Weight Management Demonstration service provider explaining program elements, participation criteria, and how to enroll in the demonstration.

Scope: The scope of services available through the program will include: (1) Telephone and web-based counseling for weight management, and (2) prescription pharmacotherapy and physician visits with normal cost-shares. The physician visits are to evaluate the patient to insure patients who may be at cardiovascular risk or metabolic risk approve patient's participation in diet and exercise changes. Physician visits may also be used to manage medication in event titration is needed, or there are side effects.

To access pharmacotherapy, Prime enrolled beneficiaries must see a provider, have a Body Mass Index ≥30 or ≥27 with other risk factors or diseases, and obtain a prescription for appropriate weight loss pharmacotherapy. Pharmacotherapy will be made available through TMOP only. Uniform formulary TMOP cost-shares will apply.

Dated: June 29, 2005.

Jeanette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13196 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0091]

Federal Acquisition Regulation; Submission for OMB Review; Anti-Kickback Procedures

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning anti-kickback procedures. A request for public comments was published in the **Federal Register** at 70 FR 22650, on May 2, 2005. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before August 5, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405. Please cite OMB Control No.9000–0091, Anti-Kickback Procedures, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Ernest Woodson, Contract Policy Division, GSA (202) 501–3775.

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal Acquisition Regulation (FAR) 52.203–7, Anti-Kickback Procedures, requires that all contractors have in place and follow reasonable procedures designed to prevent and detect in its own operations and direct business relationships, violations of section 3 of the Anti-Kickback Act of 1986 (41 U.S.C. 51–58). Whenever prime contractors or subcontractors have reasonable grounds to believe that a violation of section 3 of the Act may have occurred, they are required to report the possible violation in writing to the contracting agency or the Department of Justice. The information is used to determine if any violations of section 3 of the Act have occurred.

B. Annual Reporting Burden

Respondents: 100.
Responses Per Respondent: 1.
Annual Responses: 100.
Hours Per Response: 1.
Total Burden Hours: 100.
Obtaining Copies of Proposals: Requesters may obtain copies of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0091, Anti-Kickback Procedures, in all correspondence.

Dated: June 27, 2005

Julia B. Wise

Director, Contract Policy Division.

[FR Doc. 05–13252 Filed 7–5–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Cancellation for the July 7–8, 2005 Meeting of the Independent Review Panel To Study the Relationships Between Military Department General Counsels and Judge Advocates General

AGENCY: Department of Defense.

ACTION: Notice; Cancellation for the July 7–8, 2005 Meeting of the Independent Review Panel to Study the Relationships between Military Department General Counsels and Judge Advocates General.

SUMMARY: The Department of Defense published a document in the **Federal Register** on June 23, 2005, concerning a meeting on July 7–8, 2005 of the Independent Review Panel to Study the Relationships between Military Department General Counsels and Judge Advocates General. The Panel has decided to cancel the meetings scheduled for July 7 and 8.

DATES: July 7–8, 2005; 8:30 a.m.–11:30 a.m., and 1 p.m.–4 p.m. (Cancelled).

Location: Hilton Crystal City, 2399 Jefferson Davis Highway, Arlington, Virginia 22202 (Cancelled).

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information concerning this notice or wishing to submit written comments may contact: Mr. James R. Schwenk, Designated Federal Official, Department of Defense Office of the General Counsel, 1600 Defense Pentagon, Arlington, Virginia 20301–1600, Telephone: (703) 697–9343, Fax: (703) 693–7616, *schwenkj@dodgc.osd.mil.*

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13197 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Proposed Collection; Comment Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army, (OAA–RPA), DoD.

ACTION: Notice.

In compliance with Section 350(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 6, 2005.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Department of the Army, Military Surface Deployment and Distribution Command, (SDDC), 661 Sheppard Place, Ft. Eustis, Virginia 23604. ATTN: (Ken Morrison, Fort Eustis, 757–878–8503). Consideration will be given to all comments received within 60 days of the day of publication of this notice.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Department of the Army Reports Clearance Officer at (703) 602–0636.

Title, Associated Form, and OMB Number: Department of Defense Standards Tender of Freight, SDDC Form 364, OMB Control No. 0704–0261.

Type of Request: Extension.

Number of Respondents: 434

Responses per Respondent: 50.

Annual Responses: 21,563.

Average Burden Per Response: 15 minutes.

Annual Burden Hours: 5,391.

Need and Uses: The information derived from the DOD tenders on file with the Military Surface Deployment and Distribution Command (SDDC) is used by SDDC subordinate commands and D0D shippers to select the best value carriers to transport surface freight shipments. Freight carriers furnish information in a uniform format so that the Government can determine the cost of transportation, accessorial, and security services, and select the best value carriers for 1.1 million Bill of Lading shipments annually. The DoD tender rate and other pertinent tender data are noted on the Bill of Lading at the time of shipment. The DoD tender is the source document for the General Services Administration post-shipment audit of carrier freight bills.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondents Obligation: Required to obtain or retain benefits.

SUPPLEMENTARY INFORMATION: The DoD tender format was developed to take advantage of improved information collection technology and to connect with ongoing initiatives to implement automated systems to file tenders, select carriers, quote rates, and audits. The disciplined data fields of the tenders will facilitate the Electronic Data Interchange of tender data between carriers and SDDC, also between SDDC subordinates commands and DoD shippers. This initiative ultimately will permit electronic filing of the tender and eliminate mailing paper documents, which are manually processed.

Dated: June 27, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13194 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of Army

Proposed Collection; Common Request

AGENCY: Office of the Administrative Assistant to the Secretary of the Army, (OAA–RPA), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 6, 2005.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Department of the Army, Surface Deployment and Distribution Command, 661 Sheppard Place, Fort Eustis, Virginia, 23604 ATTN: SDDC–SDG3–GD–CS (Pamela Mainor). Consideration will be given to all comments received within 60 days of the publication of this notice.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address, or call Department of the Army Reports Clearance Officer at (703) 602–0636.

Title, Associated Form, and OMB Number: Transportation Discrepancy

Report; DD Form X513; OMB Control Number 0702–TBD.

Type of Request: New.

Number of Respondents: 1434.

Responses Per Respondent: 1.

Annual Responses: 1434.

Annual Burden Per Response: 1 hour.

Annual Burden Hours: 1434.

Needs and Uses: DD Form X513 is essential for documenting any loss, damage, or other discrepancy, which may result from the movement of Government freight by commercial transportation companies (carriers). The form is ordinarily completed by the Federal agencies for which the transportation service is provided. However, in a small minority of cases (Approximately 9%), contractor personnel acting for the government may be required to complete this form.

Affected Public: Business or other for-profit; Federal Government.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION: As insurers of goods transported under the bill of lading contract, carriers are responsible, to the extent provided by law, for the delivery of goods as tendered by or for the Government.

Dated: June 27, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13195 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Defense Information Systems Agency

Privacy Act of 1974; System of Records

AGENCY: Defense Information Systems Agency, DoD.

ACTION: Notice to amend a system of records; K890.08 Recall Roster/Locator Records.

SUMMARY: The Defense Information Systems Agency is amending a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on August 5, 2005 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the Defense Information Systems Agency, ATTN: Records Manager (SPI21), P.O. Box 4520, Arlington, VA 22204–4502.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanette Jenkins at (703) 681–2103.

SUPPLEMENTARY INFORMATION: The Defense Information Systems Agency systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the record system being amended are set forth below followed by the notice, as amended, published in its entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: June 29, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

K890.08

SYSTEM NAME:

Recall Roster/Locator Records (May 23, 2005, 70 FR 29487).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with: 'DISA Civilian employees, Military personnel assigned or detailed to DISA, including DISA field activities.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with: 'Individual's name, duty title, grade, social security number, home address, work/home/cellular telephone numbers, work and home electronic mail addresses, facsimile number, pager number (if applicable).'

* * * * *

K890.08

SYSTEM NAME:

Recall Roster/Locator Records.

SYSTEM LOCATION:

Defense Information Systems Agency (DISA), ATTN: SPI21, P.O. Box 4502, Arlington, VA 22204–4502 and DISA organizations elements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DISA Civilian employees, Military personnel assigned or detailed to DISA, including DISA field activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, duty title, grade, social security number, home address, work/home/cellular telephone numbers, work and home electronic mail addresses, facsimile number, pager number (if applicable).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulation; 10 U.S.C. chp 8; DoD Directive 5105.19, Defense Information Systems Agency (DISA); E.O. 9397 (SSN).

PURPOSE(S):

Information is collected and maintained to ensure that DISA has the capability to recall personnel to their place of duty when required for operational reasons. Sure emergency notification may be required when necessary to perform relevant functions/requirements/actions consistent with the DISA mission.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' set forth at the beginning of the DISA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are maintained in file folders, index cards, Rolodex-type files, loose-leaf and bound notebooks. Computer files are maintained on magnetic tape, diskette, or other machine-readable media.

RETRIEVABILITY:

Records are retrieved by Social Security Number and/or name of individual.

SAFEGUARDS:

Buildings are secured by guards during non-duty hours. Access to records is controlled by management personnel, who are responsible for maintaining the confidentiality of the records and using the information contained therein only for official purposes related to emergency notification. Access to computerized data is restricted by passwords.

RETENTION AND DISPOSAL:

Records are continuously updated. Records that are no longer current are destroyed by tearing into pieces, shredding, pulping, or burning. Obsolete computer records are erased or overwritten.

SYSTEM MANAGER(S) AND ADDRESS:

Records Manager, SPI21, Defense Information Systems Agency, P.O. Box 4520, Arlington, VA 22204–4502.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to Records Manager, SPI21, Defense Information Systems Agency, P.O. Box 4520, Arlington, VA 22204–4502.

The individual should make reference to the office where he/she is/was assigned or affiliated and include address and telephone number applicable to the period during which the record was maintained. Social Security Number should be included in the inquiry for positive identification.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to Records Manager, SPI21, Defense Information Systems Agency, P.O. Box 4520, Arlington, VA 22204–4502.

The individual should make reference to the office where he/she is/was assigned or affiliated and include address and telephone number applicable to the period during which the record was maintained. Social Security Number should be included in the inquiry for positive identification.

CONTESTING RECORD PROCEDURES:

DISA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DISA Instruction 210–225–2 at 32 CFR part 316 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13204 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Privacy Act of 1974; Systems of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to add a system of records; S600.50 DLA Workplace Lactation Program Records.

SUMMARY: The Defense Logistics Agency proposes to add a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on August 5, 2005 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Headquarters, Defense Logistics Agency, ATTN: DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Salus at (703) 767–6183.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 27, 2005 to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 29, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

S600.50

SYSTEM NAME:

DLA Workplace Lactation Program Records.

SYSTEM LOCATION:

Staff Director, Environment, Safety and Occupational Health, Headquarters Defense Logistics Agency, ATTN: DES–E, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221, and the Defense Logistics Agency Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian, military, and contractor personnel assigned to Defense Logistics Agency (DLA) facilities who have asked to participate in the DLA Workplace Lactation Program. The system may also cover individuals of other agencies who receive services from DLA under an administrative support agreement.

CATEGORIES OF RECORDS IN THE SYSTEM:

Participant's name, employing office and office symbol, work and home telephone numbers, signed agreement forms, dates and times of lactation room use, and physician's approval slips and forms (if applicable).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; and Section 631 of Pub. L. 107–67, Treasury and General Government Appropriations Act, 2002.

PURPOSE(S):

The records are maintained and used by program coordinators to administer the DLA Workplace Lactation Program and to schedule and track room use. Records may also be used to ensure compliance with program rules and restrictions on room use. Statistical data with all personal identifiers removed may be used by management for program audit or effectiveness reviews, adequacy of facility size and amenities, or other administrative purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD ''Blanket Routine Uses'' set forth at the beginning of DLA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in paper and electronic form.

RETRIEVABILITY:

Records are retrieved by participant's name.

SAFEGUARDS:

Access is limited to those individual who require the records in the performance of their official duties. Access is further restricted by the use of passwords which are changed periodically. Physical entry is restricted by the use of locks, guards, and administrative procedures. Employees are periodically briefed on the consequences of improperly accessing restricted data.

RETENTION AND DISPOSAL:

Disposition pending. Until the National Archives and Records Administration has approved the retention and disposal of these records, treat as permanent.

SYSTEM MANAGER AND ADDRESS:

Staff Director, Environment, Safety and Occupational Health, Headquarters Defense Logistics Agency, ATTN: DES–E, 8725 John J. Kingman Road, Stop 6220, Fort Belvoir, VA 22060–6221; and the Heads of the Environment, Safety, and Occupational Health offices of the Defense Logistics Agency Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Privacy Act Officer, Defense Logistics Agency, ATTN: DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221, or the Privacy Act Officer of the DLA Field Activity where employed or assigned. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Privacy Act Officer, Defense Logistics Agency, ATTN: DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221, or the Privacy Act Officer of the DLA Field Activity where employed or assigned. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the Privacy Act Officer, Headquarters, Defense Logistics Agency, ATTN: DP, 8725 John J. Kingman Road, Stop 2533, Fort Belvoir, VA 22060–6221.

RECORD SOURCE CATEGORIES:

Data is provided by the record subject, by the subject's personal physician, and by the lactation room coordinator.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13205 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

National Security Agency/Central Security Service

Privacy Act of 1974; System of Records

AGENCY: National Security Agency/Central Security Service.

ACTION: Notice to add a system of records; GNSA21 NSA/CSS Morale, Welfare, and Recreation (MWR) and Non-appropriated Fund Instrumentality (NAFI) Files.

SUMMARY: The National Security Agency/Central Security Service proposes to add a system of records notice to its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective without further notice on August 5, 2005 unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to the National Security Agency/Central Security Service, Office of Policy, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Hill at (301) 688–6527.

SUPPLEMENTARY INFORMATION: The National Security Agency's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on June 27, 2005, to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 29, 2005.

Jeanette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

GNSA21

SYSTEM NAME:

NSA/CSS Morale, Welfare, and Recreation (MWR) and Non-appropriated Fund Instrumentality (NAFI) Files.

SYSTEM LOCATION:

National Security Agency/Central Security Service, Office of Policy, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian DoD employees, non-appropriated fund instrumentality employees, employees of other Federal agencies or military departments, contractor employees, and dependents of these individuals, and personnel authorized to use DoD-sponsored MWR services and participate in NAFI sponsored activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include information on members, participants, patrons, and other authorized users to include name, address, phone number, social security number, organization, and other pertinent information; correspondence; membership applications; special activity applications; accounts receivable records; loan information; dishonored check listings; and investigatory reports involving abuse of facilities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Security Agency Act of 1959 as amended, 50 U.S.C. 402 note (Pub. L. 86–36); 5 U.S.C. 301, Departmental Regulations; E.O. 9397, (SSN); DoD Directive 1015.2, Military Morale, Welfare, and Recreation (MWR); DoD Directive 1015.8, DoD Civilian Employee Morale, Welfare, and Recreation (MWR) Activities and Supporting Non-appropriated Fund Instrumentalities (NAFIs); DoD Directive 1015.14, Establishment, Management, and Control of Non-appropriated Fund Instrumentalities and Financial management of Supporting Resources; DoD Regulation 1015.8–R, DoD Civilian Employee Morale, Welfare, and Recreation (MWR) Activities and Supporting Non-appropriated Fund Instrumentalities (NAFIs) Regulation; and NSA/CSS Policy Number 4–2.

PURPOSE:

To develop MWR programs and NAFI to promote and provide a centrally managed, well-rounded MWR program to help ensure the mental and physical well being of its civilian and military personnel and to provide programs and resources through financial support from both appropriated and non-appropriated funds. Information will be used to maintain records necessary for the administration of MWR programs and NAFI.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD Blanket Routine Uses set forth at the beginning of the NSA/CSS's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper files and on electronic media.

RETRIEVABILITY:

By name, organization (or affiliation), Social Security Number, home address and phone number, subject matter, and form category.

SAFEGUARDS:

The NSA/CSS Fort Meade facility is secured by a series of guarded pedestrian gates and checkpoints. Access to the facility is limited to security cleared personnel and escorted visitors only. Within the facility itself, access to paper and computer printouts is controlled by limited-access facilities and lockable containers. Access to electronic mediums is controlled by computer password protection.

Access to information is limited to those individuals specifically authorized and granted access by NSA/CSS regulations. For records on the computer system, access is controlled by passwords and limited to authorized personnel only.

RETENTION AND DISPOSAL:

Records are maintained for 6 years and 3 months, and then destroyed. Destruction is by pulping, burning, shredding, or erasure of magnetic media.

SYSTEM MANAGER AND ADDRESS:

Director of Policy, National Security Agency/Central Security Service, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if records about themselves are contained in this record system should address written inquiries to the Director of Policy, National Security Agency/Central Security Service, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

Written inquires should include requester's full name, address, and Social Security Number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Director of Policy, National Security Agency/Central Security Service, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248.

Written inquires should include requester's full name, address, and Social Security Number.

CONTESTING RECORD PROCEDURES:

The NSA/CSS rules for contesting contents and appealing initial determinations are published at 32 CFR part 322 or may be obtained by written request addressed to the Director of Policy, National Security Agency/Central Security Service, Ft. George G. Meade, MD 20755–6000.

RECORD SOURCE CATEGORIES:

Individual patrons/users of a service, and activity records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13203 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy.

ACTION: Notice to add systems of records; N07220–1 Navy Standard Integrated Personnel System (NSIPS).

SUMMARY: The Department of the Navy proposes to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on August 5, 2005, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available: from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on June 27, 2005, to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: June 29, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

N07220–1

SYSTEM NAME:

Navy Standard Integrated Personnel System (NSIPS).

SYSTEM LOCATION:

Primary location: Space and Naval Warfare Systems Center New Orleans (SSC NOLA), 2251 Lakeshore Drive, New Orleans, LA 70145–0001 for records of all active duty and reserve members.

Secondary locations: Personnel Offices and Personnel Support Detachments providing administrative support for the local activity where the individual is assigned. Official mailing addresses are published in the Standard Navy Distribution List available at *http://neds.daps.dla.mil/sndl.htm.*

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Navy military members.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number (SSN), date of birth, education, training and qualifications, professional history, assignments, performance, promotions, leave and pay entitlements and deductions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy and E.O. 9397 (SSN).

PURPOSE(S):

The purpose of this system is to provide secure worldwide personnel and pay support for Navy members and their commands. To allow authorized Navy personnel and pay specialists to collect, process, modify, transmit, and store unclassified personnel and pay data. To support management of leave and pay entitlements and deductions so

that this information can be provided to the Defense Finance and Accounting Service (DFAS) for payroll processing and preparation of the Leave and Earnings Statements (LES).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Records are retrieved by name and Social Security Number (SSN).

SAFEGUARDS:

Password controlled system, file, and element access based on predefined need-to-know. Physical access to terminals, terminal rooms, buildings and activities' grounds are controlled by locked terminals and rooms, guards, personnel screening and visitor registers.

RETENTION AND DISPOSAL:

Records shall be destroyed when no longer needed.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: NSIPS Program Management Office, 2251 Lakeshore Drive, New Orleans, LA 70145–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Personnel Office or Personnel Support Detachment providing administrative support for the local activity where they are assigned. Official mailing addresses are published in the Standard Navy Distribution List available at *http://neds.daps.dla. mil/sndl.htm.*

The request should include full name, Social Security Number, and address of the individual concerned and should be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Personnel Office or Personnel Support Detachment providing administrative support for the local activity where they are assigned. Official mailing addresses are published in the Standard Navy Distribution List available at *http://neds.daps.dla. mil/sndl.htm.*

The request should include full name, Social Security Number, and address of the individual concerned and should be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Enlisted Personnel Management Center; Navy Enlisted System; Navy Manpower and Personnel Distribution System; Navy Personnel Database; Reserve Headquarters System; Navy Training Reservation System; Officer Personnel Information System; Officer Promotion Administrative System; Total Force Manpower Management System; Reserve Automated Medical Interim System; Standard Training Administration Support System (STASS); Recruit Training Module; Defense Manpower Data Center; Defense Joint Military Pay System—Active Component; and, Defense Joint Military Pay System—Reserve Component.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13198 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy.

ACTION: Notice to add systems of records; NM01500–9 Integrated Learning Environment (ILE) Classes.

SUMMARY: The Department of the Navy proposes to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The proposed action will be effective on August 5, 2005, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available: from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on June 27, 2005, to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (February 20, 1996, 61 FR 6427).

Dated: June 29, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

NM01500–9

SYSTEM NAME:

Integrated Learning Environment (ILE) Classes.

SYSTEM LOCATION:

Naval Education Training Professional Development Technology Center (NETPDTC), Saufley Field, FL 32509–5337.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

U.S. Navy Sailors (active duty and reserve); active duty and reserve members of the U.S. Marine Corps; Department of the Navy civilian personnel; delayed entry personnel; Naval Academy Midshipmen; retired U.S. Navy Sailors and Marine Corps personnel; and members of the United States Coast Guard. Non-Appropriated Fund personnel are granted limited access for job performance requirements, and Foreign Nationals are granted limited access as required when attending a designated formal military school or institution.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, home address, Social Security Number (SSN), date of birth, individualized training plan, and course progress of individuals who register to take classes offered under Navy Knowledge On-Line.0

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; 14 U.S.C. 93, Commandant, U.S. Coast Guard General Powers; and E.O. 9397 (SSN).

PURPOSE(S):

The purpose of this system is to identify individuals who enroll and take computerized training courses offered through the Navy's Integrated Learning Environment (ILE). Each user will be able to create an individualized training plan, complete web-based training courses and track their course progress.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic storage media.

RETRIEVABILITY:

Records are retrieved by name, Social Security Number (SSN) and date of birth.

SAFEGUARDS:

Access is provided on a 'need-to-know' basis and to authorized authenticated personnel only. Records are maintained in controlled access rooms or areas. Data is limited to personnel training information. Computer terminal access is controlled by terminal identification and the password or similar system. Terminal identification is positive and maintained by control points. Physical access to terminals is restricted to specifically authorized individuals. Password authorization, assignment and monitoring are the responsibility of the functional managers.

RETENTION AND DISPOSAL:

Records are maintained permanently.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Naval Education and Training Command,250 Dallas Street, Pensacola, FL 32508–5220.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves system of records should address written inquiries to the Commander, Naval Education and Training Command (ATTN: ILE Program Manager), 250 Dallas Street, Pensacola, FL 32508–5220.

Requests should contain full name, address, Social Security Number (SSN) and be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Commander, Naval Education and Training Command (ATTN: ILE Program Manager), 250 Dallas Street, Pensacola, FL 32508.

Requests should contain full name, address, Social Security Number (SSN) and be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is obtained from Individual; Navy Knowledge On-Line clearance; schools and educational institutions; Navy Personnel Command; and Naval Education and Training Command.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13199 Filed 7–5–05; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to alter a system of records; NM05512–1 Vehicle Control System (May 17, 2004, 69 FR 27898).

SUMMARY: The Department of the Navy proposes to alter a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on August 5, 2005, unless comments are received which result in a contrary determination.

ADDRESSES: Send comments to Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations, (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system reports, as required by 5 U.S.C. 552a(r), of the Privacy Act of 1974, as amended, were submitted June 27, 2005, to the House Committee on Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: June 29, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

NM05512–1

SYSTEM NAME:

Vehicle Control System (May 17, 2004, 69 FR 27898).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Vehicle Parking Permit and License Control System

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with: ''Individuals who apply for parking or who have registered their vehicles, boats, or trailers at a Navy, Marine Corps, Pacific Command, or Joint Forces Command installation; individuals who have applied for a Government Motor Vehicle Operator's license; and individuals who possess a Government Motor Vehicle Operator's license with authority to operate government vehicles.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete first sentence and replace with: ''File contains records of each

individual who has registered a vehicle on the installation concerned to include parking permit information, decal data, insurance information, state of registration and identification.''

* * * * *

PURPOSE(S):

Delete entry and replace with: ''To track the issuance of parking permits and to provide a record of each individual who has registered a vehicle at an installation to include a record on individuals authorized to operate official government vehicles.''

NM05512–1

SYSTEM NAME:

Vehicle Parking Permit and License Control System

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.daps.mil/sndl.htm.*

Commander, U.S. Joint Forces Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488.

Commander, U.S. Pacific Command, P.O. Box 64028, Camp H.M. Smith, HI 96861–4028.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who apply for parking or who have registered their vehicles, boats, or trailers at a Navy, Marine Corps, Pacific Command, or Joint Forces Command installation; individuals who have applied for a Government Motor Vehicle Operator's license; and individuals who possess a Government Motor Vehicle Operator's license with authority to operate government vehicles.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains records of each individual who has registered a vehicle on the installation concerned to include parking permit information, decal data, insurance information, state of registration and identification. Applications may contain such information as name, date of birth, Social Security Number, Driver's license information (*i.e.*, height, weight, hair and eye color), place of employment, driving record, Military I.D. information, etc. File also contains records/notations of traffic violations, citations, suspensions, applications for government vehicle operator's I.D. card, operator qualifications and record licensing examination and performance, record of failures to qualify for a Government Motor Vehicle Operator's permit, record of government motor vehicle and other vehicle's accidents, and information on student driver training.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).

PURPOSE(S):

To track the issuance of parking permits and to provide a record of each individual who has registered a vehicle at an installation to include a record on individuals authorized to operate official government vehicles.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Individual's name, Social Security Number, state license plate number, case number, and organization.

SAFEGUARDS:

Limited access provided on a need-to-know basis only. Information maintained on computers is password protected. Files maintained in locked and/or guarded office.

RETENTION AND DISPOSAL:

Records are maintained for one year after transfer or separation from the installation concerned. Paper records are then destroyed and records on magnetic tapes erased.

SYSTEM MANAGER(S) AND ADDRESS:

Commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.daps.mil/sndl.htm.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Commanding Officer or head of the activity where assigned. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.daps.mil/sndl.htm.*

Written requests should contain the individual's full name, Social Security Number, and the request must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Commanding Officer or head of the activity where assigned. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.daps.mil/sndl.htm.*

Written requests should contain the individual's full name, Social Security Number, and the request must be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual concerned, driving record, insurance papers, activity correspondence, investigators reports, and witness statements.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 05–13202 Filed 7–5–05; 8:45 am]

BILLING CODE 5000–06–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EMSSAB), Savannah River. 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: Monday, July 25, 2005, 1 p.m.–6 p.m.; Tuesday, July 26, 2005, 8:30 a.m.–4 p.m.

ADDRESSES: Newberry Hall, 151 Bee Lane, Aiken, SC 29803.

FOR FURTHER INFORMATION CONTACT: Gerri Flemming, Closure Project Office,

Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, SC, 29802; phone: (803) 952–7886.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Monday, July 25, 2005

1 p.m.—Combined Committee Session.
5:15 p.m.—Adjourn.
5:15 p.m.—Executive Committee Meeting.
6 p.m.—Adjourn.

Tuesday, July 26, 2005

8:30 a.m.—Approval of Minutes, Agency Updates.
9:15 a.m.—Public Comment Session.
9:30 a.m.—Chair and Facilitator Update.
10 a.m.—Waste Management Committee Report.
11:30 a.m.—Administrative Committee Report.
11:50 a.m.—Public Comments.
12 p.m.—Lunch Break.
1 p.m.—Nuclear Materials Committee Report.
2 p.m.—Facilities Disposition & Site Remediation Committee Report.
3 p.m.—Strategic and Legacy Management Committee Report.
3:50 p.m.—Public Comments.
4 p.m.—Adjourn.

If needed, time will be allotted after public comments for items added to the agenda, and administrative details. A final agenda will be available at the meeting Monday, July 25, 2005.

Public Participation: The meeting is open to the public. 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 Gerri Flemming's office at the address or telephone 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 business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Department of Energy's Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Minutes will also be available by writing to Gerri Flemming, Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, SC 29802, or by calling her at (803) 952–7886.

Issued in Washington, DC on June 29, 2005.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 05–13227 Filed 7–5–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho National Engineering Laboratory

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EMSSAB), Idaho National Engineering Laboratory. 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: Tuesday, July 19, 2005, 8 a.m.–6 p.m.; Wednesday, July 20, 2005, 8 a.m.–5 p.m.

Opportunities for public participation will be held Tuesday, July 19, from 12:15 to 12:30 p.m. and 5:45 to 6 p.m.; and on Wednesday, July 20, from 11:45 a.m. to 12 p.m. and 4 to 4:15 p.m. Additional time may be made available for public comment during the presentations.

These times are subject to change as the meeting progresses, depending on the extent of comment offered. Please check with the meeting facilitator to confirm these times.

ADDRESSES: Ameritel Inn, 645 Lindsay Boulevard, Idaho Falls, ID 83402.

FOR FURTHER INFORMATION CONTACT: Shannon A. Brennan, Federal Coordinator, Department of Energy, NE–ID Idaho Operations Office, 1955 Fremont Avenue, MS–1216, Idaho Falls, ID 83401. Phone (208) 526–3993; Fax (208) 526–1926 or e-mail: *Shannon.Brennan@nuclear.energy.gov* or visit the Board's Internet home page at: *http://www.ida.net/users/cab.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Topics (agenda topics may change up to the day of the meeting; please contact Shannon A. Brennan for the most current agenda):

- Decontamination and decommissioning of nuclear reactors and other complex facilities.
- Review of the independent risk assessments developed by the Consortium for Risk.
- Evaluation with Stakeholder Participation.
- Long-term stewardship at the Idaho National Engineering Laboratory.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Shannon A. Brennan at the address or telephone number listed above. The request 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 comment will be provided a maximum of five minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Department of Energy's Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Minutes will also be available by writing to Shannon A. Brennan, Federal Coordinator, at the address and phone number listed above.

Issued in Washington, DC on June 29, 2005.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 05–13228 Filed 7–5–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Fernald

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EMSSAB), Fernald. 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, July 14, 2005, 6:30 p.m.–9 p.m.

ADDRESSES: Ross Township Firehouse, 2565 Cincinnati-Brookville Road, Ross Township, Ohio 45061.

FOR FURTHER INFORMATION CONTACT: Doug Sarno, The Perspectives Group, Inc., 1055 North Fairfax Street, Suite 204, Alexandria, VA 22314, at (703) 837–1197, or e-mail; *djsarno@theperspectivesgroup.com.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

Goals:

—Determine next steps on Fernald Citizens' Advisory Board History Project.
—Discuss Impressions of the Fernald History Roundtable.
—Discuss Plans for Fernald Citizens' Advisory Board Retreat in September.

6:30 p.m.—Call to Order.

6:35 p.m.—Updates and Announcements.

—Projects Updates.
—Ex-Officio Updates.
—Silos Projects Status.
—Site Transition Update.

7:30 p.m.—Fernald Citizens' Advisory Board Retreat and Upcoming Meetings Schedule.

7:50 p.m.—Break.

8 p.m.—History Project Next Steps.

8:20 p.m.—Impressions of History Roundtable.

8:50 p.m.—Public Comment.

9 p.m.—Adjourn.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board chair either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Board chair at the address or telephone number listed below. Requests must be received five days prior to the meeting and reasonable provisions 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 comment will be provided a maximum of five minutes to present their comments. This notice is being published less than 15 days before the date of the meeting due to programmatic issues that had to be resolved.

Minutes: The minutes of this meeting will be available for public review and copying at the Department of Energy's Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to the Fernald Citizens' Advisory Board, Phoenix Environmental Corporation, MS–76, Post Office Box 538704, Cincinnati, OH 43253–8704, or by calling the Advisory Board at (513) 648–6478.

Issued in Washington, DC on June 29, 2005.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 05–13229 Filed 7–5–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EMSSAB), Paducah. 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, July 21, 2005, 5:30 p.m.–9:30 p.m.

ADDRESSES: 111 Memorial Drive, Barkley Centre, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: William E. Murphie, Deputy Designated Federal Officer, Department of Energy Portsmouth/Paducah Project Office, 1017 Majestic Drive, Suite 200, Lexington, Kentucky 40513, (859) 219–4001.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management and related activities.

Tentative Agenda:

5:30 p.m.—Informal Discussion.

6 p.m.—Call to Order.

Introductions.

Review of Agenda.

Approval of May Minutes.

Approval of June Minutes.

6:05 p.m.—Deputy Designated Federal Officer's Comments.

6:25 p.m.—Federal Coordinator's Comments.

6:30 p.m.—Ex-officios' Comments.

6:40 p.m.—Public Comments and Questions.

6:50 p.m.—Task Forces/Presentations.

- Waste Disposition Task Force.

—3 D Model Presentation.
—Burial Grounds Remedial Investigation/Feasibility Study (RI/FS) Review.

- Water Quality Task Force.
- Long Range Strategy/Stewardship Task Force.

—Depleted Uranium Hexafluoride (DUF6) Project Overview.

- Community Outreach Task Force.

7:50 p.m.—Public Comments and Questions.

8 p.m.—Break.

8:10 p.m.—Administrative Issues.

- Review of Workplan.
- Review of Next Agenda.

8:20 p.m.—Review of Action Items.

8:25 p.m.—Subcommittee Reports.

- Executive Committee.

—Chairs Meeting Recap.

8:40 p.m.—Final Comments.

9:30 p.m.—Adjourn.

Public Participation: The meeting is open to the public. 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 David Dollins at the address listed below or by telephone at (270) 441–6819. 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 comment will be provided a maximum of five minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Department of Energy's Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information Center and Reading Room at 115 Memorial Drive, Barkley Centre, Paducah, Kentucky between 8 a.m. and 5 p.m., on Monday thru Friday or by writing to David Dollins, Department of Energy, Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001 or by calling him at (270) 441–6819.

Issued in Washington, DC on June 29, 2005.

R. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 05–13230 Filed 7–5–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Hearings and Appeals; Proposed Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals; Department of Energy.

ACTION: Notice of Proposed Implementation of Special Refund Procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy (DOE) announces the proposed procedures for the disbursement of $1,585,576.76, plus accrued interest, in crude oil overcharges obtained by the DOE concerning BPM Ltd., Case No. TEF–0001, Honeymon Drilling Co., Case No. TEF–0002, Intercontinental Oil, Case No. TEF–0003, Knox Oil, Case No. TEF–0004, Pescar Trading, Case No. TEF–0005, Shepherd Oil, Inc., Case No. TEF–0006, Sierra Petroleum Co., Case No. TEF–0007, Thriftway Co., Case No. TEF–0008, and Western Refining Co. (Robert J. Martin), Case No. TEF–0011.

DATES: Comments must be filed in duplicate within 30 days of publication of this notice in the **Federal Register**

ADDRESSES: Comments should be addressed to the Office of Hearings and Appeals, Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585–1615. All comments should display a reference to Case No. TEF–0001.

FOR FURTHER INFORMATION CONTACT: Richard A. Cronin, Jr., Assistant Director, Office of Hearings and Appeals, 1000 Independence Ave., SW., Washington, DC 20585–1615 (202) 287–1589, *richard.cronin@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 205.282(b), notice is hereby given of the issuance of the Proposed Decision and Order set out below. The Proposed Decision sets forth the procedures that the DOE has tentatively formulated to distribute to eligible claimants $1,585,576.76, plus accrued interest, obtained by the DOE from BPM Ltd., Honeymon Drilling Co., Intercontinental Oil, Knox Oil, Pescar Trading, Shepherd Oil, Inc., Sierra Petroleum Co., Thriftway Co., and Western Refining Co. (Robert J. Martin).

The OHA has proposed to distribute these funds in the currently-existing crude oil refund proceeding described in the Proposed Decision and Order. Because the deadline for filing crude oil refund applications has passed, no new applications for refund for the alleged (or established) crude oil pricing violations of the listed firms will be accepted for these funds.

Any member of the public may submit written comments regarding the proposed refund procedures. Commenting parties are requested to forward two copies of their submission, within 30 days of the publication of this notice in the **Federal Register**, to the address set forth at the beginning of this notice. Comments so received will be made available for public inspection between the hours of 1:30 p.m. and 4 p.m., Monday through Friday, except Federal Holidays, in Room 7132 (the public reference room), 950 L'Enfant Plaza, Washington, DC.

Dated: June 29, 2005.

Fred L. Brown,

Acting Deputy Director, Office of Hearings and Appeals.

Proposed Decision and Order

Names of Firms: BPM Ltd., Honeymon Drilling Co., Intercontinental Oil, Knox Oil, Pescar Trading, Shepherd Oil, Inc., Sierra Petroleum Co., Thriftway Co., and Western Refining Co. (Robert J. Martin).

Date of Filing: June 21, 2005.

Case Numbers: TEF–0001, TEF–0002, TEF–0003, TEF–0004, TEF–0005, TEF–0006, TEF–0007, TEF–0008, and TEF–0009.

I. Background

The Office of General Counsel (OGC) of the Department of Energy (DOE) filed a Petition requesting that the Office of Hearings and Appeals (OHA) formulate and implement subpart V special refund proceedings. Under the procedural regulations of the DOE, special refund proceedings may be implemented to refund monies to persons injured by violations of the DOE petroleum price regulations, provided DOE is unable to readily identify such persons or to ascertain the amount of any refund. 10 CFR 205.280. We have considered OGC's request to formulate refund procedures for the disbursement of monies remitted by the following firms pursuant to administrative or judicial decisions or in settlement of the DOE allegations that the firms had violated the DOE petroleum price control and allocation regulations:

BPM Ltd., Honeymon Drilling Co., Intercontinental Oil, Knox Oil, Pescar Trading, Shepherd Oil, Inc., Sierra Petroleum Co., Thriftway Co., and Western Refining Co. (Robert J. Martin).

We have determined that the refund procedures requested by OGC are appropriate.

A total of $1,585,576.76 has been remitted to DOE by these firms to remedy violations that occurred during the relevant audit periods. These funds are being held in an escrow account established with the United States Treasury pending a determination of their proper distribution. This Decision sets forth OHA's proposed plan to distribute those funds.

II. Jurisdiction and Authority

The general guidelines that govern OHA's ability to formulate and implement a plan to distribute refunds are set forth at 10 CFR Part 205, subpart V. These procedures apply in situations where the DOE cannot readily identify the persons who were injured as a result of actual or alleged violations of the regulations or ascertain the amount of the refund each person should receive. For a more detailed discussion of subpart V and the authority of the OHA to fashion procedures to distribute refunds, *see* Office of Enforcement, 9 DOE ¶ 82,508 (1981) and Office of Enforcement, 8 DOE ¶ 82,597 (1981).

III. Refund Procedures

A. Allocation of Remitted Funds

The alleged violations by the above-named firms all concerned the sale of crude oil. Under these circumstances, we propose that all of the funds remitted be allocated for restitution for parties injured by the firms' alleged violations of the crude oil regulations.

B. Refund Procedures for Crude Oil Violations

We propose that the funds should be distributed in accordance with the DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases, (MSRP), *see* 51 FR 27899 (August 4, 1986). Pursuant to the MSRP, OHA may reserve up to 20 percent of those funds for direct refunds to applicants who claim that they were injured by the crude oil violations. The remaining funds would be distributed to the states and federal government for indirect restitution. We propose to distribute the funds obtained from the two firms in accordance with the MSRP, which was issued as a result of the Settlement Agreement approved by the court in The Department of Energy Stripper Well Exemption Litigation, 653 F. Supp. 108 (D. Kan. 1986). Shortly after the issuance of the MSRP, the OHA issued an Order that announced that this policy would be applied in all subpart V proceedings involving alleged crude

oil violations. *See* Order Implementing the MSRP, 51 FR 29,689 (August 20, 1986) (the August 1986 Order).

Under the MSRP, 40 percent of crude oil overcharge funds will be disbursed to the federal government, another 40 percent to the states, and up to 20 percent may initially be reserved for the payment of claims to injured parties. The MSRP also specified that any funds remaining after all valid claims by injured purchasers are paid will be disbursed to the federal government and the states in equal amounts.

In April 1987, the OHA issued a Notice analyzing the numerous comments received in response to the August 1986 Order. 52 FR 11737 (April 10, 1987) (April 10 Notice). This Notice provided guidance to claimants that anticipated filing refund applications for crude oil monies under the Subpart V regulations. In general, we stated that all claimants would be required to (1) document their purchase volumes of petroleum products during the August 19, 1973 through January 27, 1981 crude oil price control period, and (2) prove that they were injured by the alleged crude oil overcharges. Applicants who were end-users or ultimate consumers of petroleum products, whose businesses are unrelated to the petroleum industry, and who were not subject to the DOE price regulations would be presumed to have been injured by any alleged crude oil overcharges. In order to receive a refund, end-users would not need to submit any further evidence of injury beyond the volume of petroleum products purchased during the period of price controls. See City of Columbus Georgia, 16 DOE ¶ 85,550 (1987).

1. Individual Refund Claims

The amount of money obtained from the listed firms intended for restitution of crude oil violations is $1,585,576.76 plus accrued interest. In accordance with the MSRP, we shall initially reserve 20 percent of those funds ($317,115 plus accrued interest) for direct refunds to applicants who claim that they were injured by crude oil overcharges. We shall base refunds on a volumetric amount which has been calculated in accordance with the methodology described in the April 10 Notice. That volumetric refund amount is currently $0.0016 per gallon. *See* 57 FR 15562 (March 24, 1995). On May 13, 2004, we announced final procedures for the distribution of the remaining crude oil overcharge funds held by DOE, and estimated that the remaining funds would result in an additional volumetric refund amount of $0.00072 per gallon. *See* 69 FR 29300 (May 21, 2004).

The filing deadline for refund applications in the crude oil refund proceeding was June 30, 1994. This was subsequently changed to June 30, 1995. *See* Filing Deadline Notice, 60 FR 19914 (April 20, 1995); see also DMLP PDO, 60 FR 32004, 32007 (June 19, 1995). Because the June 30, 1995, deadline for crude oil refund applications has passed, no new applications for restitution from purchasers of refined petroleum products based on the alleged (or established) crude oil pricing violations will be accepted for these funds. Instead, these funds will be added to the general crude oil overcharge pool used for direct restitution.

2. Payments to the States and Federal Government

Under the terms of the MSRP, the remaining 80 percent of the crude oil violation amounts subject to this Decision, or $1,268,461 plus accrued interest, should be disbursed in equal shares to the states and federal government, for indirect restitution. Refunds to the states will be in proportion to the consumption of petroleum products in each state during the period of price controls. The share or ratio of the funds which each state will receive is contained in Exhibit H of the Stripper Well Settlement Agreement. When disbursed, these funds will be subject to the same limitations and reporting requirements as all other crude oil monies received by the states under the Stripper Well Agreement.

Accordingly, we will direct the DOE's Office of the Controller to transfer one-half of that amount, or $634,230 plus interest, into an interest bearing subaccount for the states, and one-half or $634,230 plus interest, into an interest bearing subaccount for the federal government.

It is therefore ordered that: The payments remitted to the Department of Energy by BPM Ltd., Honeymon Drilling Co., Intercontinental Oil, Knox Oil, Pescar Trading, Shepherd Oil, Inc., Sierra Petroleum Co., Thriftway Co., and Western Refining Co. (Robert J. Martin) will be distributed in accordance with the forgoing Decision.

[FR Doc. 05–13231 Filed 7–5–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–905–000, ER01–1064–000, ER01–1064–001]

Celerity Energy Partners San Diego LLC; Celerity Energy of New Mexico LLC; Notice of Issuance of Order

June 27, 2005.

Celerity Energy Partners San Diego LLC (Celerity-SD) filed an application for market-based rate authority, with an accompanying rate tariff. The proposed rate tariff provides for the sales of capacity, energy, and ancillary services at market-based rates. Celerity-SD also requested waiver of various Commission regulations. In particular, Celerity-SD requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Celerity-SD.

On June 23, 2005, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—South, granted the request for blanket approval under part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Celerity-SD should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is July 27, 2005.

Absent a request to be heard in opposition by the deadline above, Celerity-SD is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Celerity-SD, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Celerity-SD issuances of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3533 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–388–000]

CenterPoint Energy—Mississippi River Transmission Corporation; Notice of Filing

June 27, 2005.

Take notice that on June 22, 2005, CenterPoint Energy—Mississippi River Transmission Corporation (MRT) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Second Revised Sheet No. 226C, with an effective date of July 22, 2005.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3534 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–397–000]

Eastern Shore Natural Gas Company; Notice of Proposed Change in Ferc Gas Tariff

June 28, 2005.

Take notice that on June 23, 2005, Eastern Shore Natural Gas Company (Eastern Shore) tendered for filing its annual fuel retention adjustment filing pursuant to section 31 of the general terms and conditions of its FERC Gas Tariff, Second Revised Volume No. 1.

Eastern Shore states that copies of its filing has been mailed to its customers and interested state commissions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3526 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG05–75–000]

Goshen Wind Farm LLC; Notice of Application for Commission Determination of Exempt Wholesale Generator Status

June 27, 2005.

Take notice that on June 23, 2005, Goshen Wind Farm LLC (Goshen) tendered for filing an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Goshen states that a copy of the application has been served on the U.S. Securities and Exchange Commission and the Idaho Public Utilities Commission.

Any person desiring to intervene or to protest in the above proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests

will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filing in the above proceeding is accessible in the Commission's eLibrary system. It is also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3530 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER03–438–000 and ER03–438–001]

ManChief Power Company, L.L.C.; Notice of Issuance of Order

June 27, 2005.

ManChief Power Company, L.L.C. (ManChief Power) filed an application for market-based rate authority, with an accompanying rate schedule. The proposed rate schedule provides for the sales of capacity and energy at market-based rates. ManChief Power also requested waiver of various Commission regulations. In particular, ManChief Power requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by ManChief Power.

On April 18, 2003, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—South, granted the request for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by ManChief Power should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is July 8, 2005.

Absent a request to be heard in opposition by the deadline above, ManChief Power is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of ManChief Power, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of ManChief Power issuances of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3531 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–387–000]

Natural Gas Pipeline Company of America; Notice of Application

June 27, 2005.

Take notice that on June 16, 2005, Natural Gas Pipeline Company of America (Natural), with an office at 747 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP05–387–000 an abbreviated application pursuant to section 7(c) of the Natural Gas Act, as amended, and part 157 of the Federal Energy Regulatory Commission's regulations requesting an amendment to the Certificate issued to Natural in 1965 when it acquired the Sayer gas storage field located in Beckham County, Oklahoma, to expressly include the bottom 200 feet of the Wellington formation as the necessary caprock of the Sayer field. Natural states that this amendment will enable it to acquire all necessary property interests in the lower 200 feet of the Wellington formation and thereby protect the integrity of the Sayer storage reservoir.

The application is on file with the Commission and open to public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or call (202) 502–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Counsel for Natural Gas Pipeline Company of America, Philip R. Tellen, 747 East 22nd Street Lombard, Illinois 60148, at (630) 691–3749.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will

not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protest must be filed on or before the date as indicated below. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Comment Date: July 18, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3535 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–743–000, ER05–743–001]

Pacific Summit Energy LLC; Notice of Issuance of Order

June 27, 2005.

Pacific Summit Energy LLC (Pacific) filed an application for market-based rate authority, with an accompanying rate schedule. The proposed rate schedule provides for the sales of capacity, energy, and ancillary services at market-based rates. Pacific also requested waiver of various Commission regulations. In particular, Pacific requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Pacific.

On June 24, 2005, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—South, granted the request for blanket approval under part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Pacific should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is July 27, 2005.

Absent a request to be heard in opposition by the deadline above, Pacific is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Pacific, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Pacific issuances of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3532 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–10–002]

Starks Gas Storage L.L.C.; Notice of Compliance Filing

June 28, 2005.

Take notice that on June 21, 2005, Starks Gas Storage L.L.C., (Starks) tendered for filing its *pro forma* FERC Gas Tariff in compliance with the ''Preliminary Determination on Non-Environment Issues'' issued on April 19, 2005, in the above-referenced docket.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern time on July 19, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3528 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–389–000]

West Texas Gas, Inc.; Notice of Gas Cost Reconciliation Report

June 27, 2005.

Take notice that on June 22, 2005, West Texas Gas Inc. (WTG) tendered for filing its annual purchased gas cost reconciliation for the period ending April 30, 2005.

WTG states that under section 19, any difference between WTC's actual purchased gas costs and its spot market based priced mechanism is refunded or surcharged to its two jurisdictional customers annually, with interest. WTS states that the report indicates that WTG under-collected its actual costs by $10,854 during the reporting period.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3529 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–180–003]

Discovery Gas Transmission LLC; Notice of Compliance Filing

June 28, 2005.

Take notice that on June 23, 2005, Discovery Gas Transmission LLC, (Discovery) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, to be effective April 1, 2005:

Second Substitute First Revised Sheet No. 143

Second Substitute Third Revised Sheet No. 144

Second Substitute First Revised Sheet No. 194

Discovery states that the filing is intended to comply with the Order on Rehearing and Compliance Filing issued by the Commission on June 8, 2005.

Discovery further states that copies of the filing have been mailed to each of its customers, interested State Commissions and other interested persons.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3527 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

June 29, 2005.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: *ER01–1265–007; ER01–1263–006; ER01–1266–006; ER01–1267–008; ER01–1268–007; ER01–1269–006; ER01–1270–008; ER01–1271–007; ER01–1272–006; ER01–1273–007; ER01–1274–007; ER01–1275–006; ER01–1276–006; ER01–1277–006; ER01–1278–008; ER02–537–006; ER02–900–005; ER02–1028–005; ER02–1052–005; ER02–1213–005; ER03–160–005.*

Applicants: Mirant Americas Energy Marketing, LP; Mirant Zeeland, LLC; Mirant Bowline, LLC; Mirant California, LLC; Mirant Canal, LLC; Mirant Chalk Point, LLC; Mirant Delta, LLC; Mirant Kendall, LLC; Mirant Lovett, LLC; Mirant Mid-Atlantic, LLC; Mirant New England, LLC; Mirant NY0Gen, LLC; Mirant Peaker, LLC; Mirant Potomac River, LLC; Mirant Potrero, LLC; Shady Hills Power Company, LLC; Mirant Sugar Creek, LLC; Wrightsville Power Facility, LLC; West Georgia Generating Company, LLC; Mirant Energy Trading, LLC; Mirant Las Vegas, LLC.

Description: *The above-referenced Mirant Entities submit an amendment to their Market-based rate tariff incorporating change in status language in compliance with FERC's 5/26/05 order, 111 FERC ¶ 61,252 (2005).*

Filed Date: 06/24/2005.

Accession Number: *20050628–0061.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: *ER01–1529–007; ER01–1529–007.*

Applicants: Sierra Pacific Power Company and Nevada Power Company.

Description: *Sierra Pacific Power Company and Nevada Power Company submit a compliance filing pursuant to the Commission's 5/26/05 order, 111 FERC ¶ 61,259 (2005).*

Filed Date: 06/24/2005.

Accession Number: *20050628–0225.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: *ER05–1139–000; ER05–1140–000; ER05–1141–000; ER05–1142–000.*

Applicants: Dominion Energy Marketing, Inc.; Dominion Nuclear Connecticut, Inc.; Dominion Nuclear Marketing III, L.L.C.; Kincaid Generation, L.L.C.

Description: *Dominion Energy Marketing, Inc., Dominion Nuclear*

Connecticut, Inc.; Dominion Nuclear Marketing III, L.L.C.; and Kincaid Generation, L.L.C. submits proposed changes to their respective market-based rate tariffs to incorporate a prohibition against making sales to Virginia Electric and Power Company absent advance authorization from the Commission.

Filed Date: 06/24/2005.

Accession Number: *20050628–0063.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: *ER05–6–029; EL04–135–031; EL02–111–049; EL03–212–045.*

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: *Midwest Independent Transmission System Operator, Inc. and the Midwest ISO Transmission Owners jointly submits a revision to a typographical error in their June 13, 2005 filing in the above-referenced docket numbers.*

Filed Date: 06/24/2005.

Accession Number: *20050628–0060.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: ER05–909–001.

Applicants Black Hills Power, Inc.

Description: *Black Hills Power, Inc. as Joint Tariff Administrator of the Joint Open Access Transmission Tariff of Black Hills Power, Basin Electric Power Cooperative, and Powder River Energy Corporation, submits a revised version of a service agreement filed on 4/29/2005 in Docket No. ER05–929–000.*

Filed Date: 06/24/2005.

Accession Number: *20050628–0223.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other and the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–3540 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

June 28, 2005.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: *ER02–2605–003.*

Applicants: Keystone Energy Group, Inc.

Description: *Keystone Energy Group, Inc. submits its triennial updated market analysis in compliance with the Commission's letter order issued 12/31/02 Order in Docket Nos. ER02–2605–000 and 001.*

Filed Date: 06/23/2005.

Accession Number: *20050627–0013.*

Comment Date: 5 p.m. eastern time on Thursday, July 14, 2005.

Docket Numbers: *ER04–691–053; EL04–104–050.*

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: *Midwest Independent Transmission System Operator, Inc., in compliance with the Commission's 6/1/05 letter order, 111 FERC ¶ 61,335, submits proposed revisions to its Open Access Transmission and Energy Markets Tariff, FERC Electric Tariff, Third Revised Volume 1.*

Filed Date: 06/24/2005.

Accession Number: *20050627–0012.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: *ER04–691–054;* EL04–104–051.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: *Midwest Independent Transmission System Operator, Inc., in compliance with the Commission's 5/26/05 order, 111 FERC ¶ 61,249, submits proposed revisions to its Open Access Transmission and Energy Markets Tariff, FERC Electric Tariff, Third Revised Volume 1.*

Filed Date: 06/24/2005.

Accession Number: *20050627–0011.*

Comment Date: 5 p.m. eastern time on Friday, July 15, 2005.

Docket Numbers: *ER05–1138–000.*

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: *Midwest Independent Transmission System Operator, Inc. submits proposed revisions to Attachment L of its Open Access Transmission and Energy Markets Tariff, FERC Electric Tariff, Third Revised Volume 1.*

Filed Date: 06/23/2005.

Accession Number: *20050627–0018.*

Comment Date: 5 p.m. eastern time on Thursday, July 14, 2005.

Docket Numbers: *ER05–727–001.*

Applicants: New York Independent System Operator, Inc.

Description: *New York Independent System Operator, Inc., pursuant to the Commission's 5/24/05 order (111 FERC ¶ 61,238 (2005)), submits revisions to its Open Access Transmission Tariff and its Market Administration Control Area Services Tariff.*

Filed Date: 06/23/2005.

Accession Number: *20050627–0015.*

Comment Date: 5 p.m. eastern time on Thursday, July 14, 2005.

Docket Numbers: *ER99–1757–010.*

Applicants: The Empire District Electric Company.

Description: *The Empire District Electric Company submits an amendment to its 3/31/05 & 5/2/05 compliance filings.*

Filed Date: 06/23/2005.

Accession Number: *20050627–0014.*

Comment Date: 5 p.m. eastern time on Thursday, July 7, 2005.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211

and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on other persons and the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–3541 Filed 7–5–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7933–4]

EPA Science Advisory Board Staff Office; Request for Nomination of Candidates for the EPA Science Advisory Board Committees

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency's Science Advisory Board (SAB) Staff Office is soliciting nominations for consideration of membership on three SAB standing committees. Nominees in response to this request for nominations will be considered for membership on the SAB Drinking Water, Ecological Processes and Effects, and Radiation Advisory Committees. This process supplements other efforts to identify qualified candidates.

DATES: Nominations should be submitted in time to arrive no later than August 5, 2005.

FOR FURTHER INFORMATION CONTACT: To submit a hard copy of the form noted below (for those unable to submit the information in electronic form), please contact Ms. Patricia L. Thomas, U.S. EPA SAB Staff Office (Mail Code 1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460 (FedEx/Courier address: U.S. EPA SAB, Suite 3600, 1025 F Street, NW., Washington DC 20004), (202) 343–9974 (telephone), (202) 233–0643 (fax), or via email at *thomas.patricial@epa.gov.* Inquiries regarding general scientific work of the SAB may be directed to Dr. Anthony F. Maciorowski, Associate Director for Science, U.S. EPA SAB Staff Office, (202) 343–9983 (telephone), or via email at *maciorowski.anthony@epa.gov.* Specific inquiries regarding the scientific work of the SAB Drinking Water Committee may be directed to Dr. Suhair Shallal, Designated Federal Officer, U.S. EPA SAB Staff Office, (202) 343–9977 (telephone), or via email at *shallal,suhair@epa.gov.* Specific inquiries regarding the scientific work of the SAB Ecological Processes and Effects Committee may be directed to Dr. Thomas Armitage, Designated Federal Officer, U.S. EPA SAB Staff Office, (202) 343–9995 (telephone), or via email at *armitage,thomas@epa.gov.* Specific inquiries regarding the scientific work of the SAB Radiation Advisory Committee may be directed to Dr. Jack Kooyoomjian, Designated Federal Officer, U.S. EPA SAB Staff Office, (202) 343–9984 (telephone), or via email at *kooyoomjiam.jack@epa.gov.*

Background: The U.S. EPA Science Advisory Board (SAB or the Board) is a chartered Federal Advisory Committee. The SAB was established by statute (42 U.S.C. 4365) to provide independent scientific peer review, advice, and recommendations on the scientific bases of EPA actions as may be requested by the Administrator. As a Federal Advisory Committee, SAB business is conducted in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. C) and related regulations. Accordingly, the Board announces its meetings in the **Federal Register**, conducts its business in public view, and provides opportunities for public input during its deliberations.

Members of the Board and its standing committees constitute a distinguished body of non-EPA scientists, engineers, economists, and social scientists who are recognized experts in their respective fields. The Board and its standing committees review a wide variety of EPA science activities. Generally, the Board and its standing committees function as technical peer review panels that critically examine Agency science activities and provide advice and recommendations regarding their technical merit. SAB standing committees have historically conducted most Science Advisory Board work. This notice requests nominations specifically for three SAB standing committees including: The Drinking Water Committee (DWC); the Ecological Processes and Effects Committee (EPEC); and the Radiation Advisory Committee (RAC). Typical subject matter for standing committee review may include research strategies, multi-year research plans, science initiatives, risk assessments, or agency guidance corresponding to specific subject matter designated by the standing committee title. Additional information about the SAB, and its standing committees can be accessed at the SAB Web site *http://www.epa.gov/sab.*

Expertise Sought: The SAB Staff Office is seeking nominations of nationally and internationally recognized non-EPA scientists for consideration of membership on the SAB Committees. The desired expertise for each committee is described below.

The Drinking Water Committee provides independent advice to the EPA Administrator, through the chartered SAB, on scientific aspects of EPA's national drinking water criteria and standards program. Ideal nominees for the SAB Drinking Water Committee will demonstrate nationally recognized

scientific expertise and research experience in one of the following areas: Clinical public health or clinical epidemiology of disease from pathogens, contaminants or mixtures of contaminants.

The Ecological Processes and Effects Committee provides independent advice to the EPA Administrator, through the chartered SAB, on scientific issues related to EPA environmental programs and supporting science and research to protect, sustain and restore the integrity of ecosystems. Ideal nominees for the Ecological Processes and Effects Committee will demonstrate nationally recognized scientific expertise and research experience in one of the following areas: Water quality criteria development for the protection of aquatic life; ecological risk assessment; biological or ecological indicators; or landscape ecology.

The Radiation Advisory Committee provides independent advice to the EPA Administrator, through the chartered SAB, on radiation protection, radiation science, and radiation risk assessment. Ideal nominees for the SAB Radiation Advisory Committee will demonstrate nationally recognized scientific expertise and research experience in one of the following areas: Health physics or biophysics with specialties in radiation dosimetry or radiation biology; or geochemistry, geology, hydrology or soil science with specialties in modeling, radioactive waste management, or radiation risk assessment.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to these SAB standing committees. Individuals may self-nominate. Qualified nominees will demonstrate appropriate scientific education, training, and experience to evaluate basic and applied science issues addressed by the standing committees. Successful nominees will have distinguished themselves professionally and be available to invest the time and effort in providing advice and recommendations on the development and application of science at EPA. Nominations should be submitted in electronic format (which is preferred over hard copy) through the *Form for Nominating Individuals to Panels of the EPA Science Advisory Board* provided on the SAB Web site. The form can be accessed through a link on the blue navigational bar on the SAB Web site at: *http://www.epa.gov/sab.* To be considered, all nominations should include the information requested on that form.

The nominating form requests contact information about: The person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's resume; and a general biosketch of the nominee indicating current position, educational background; areas of expertise and research activities; and recent service on other advisory committees or with professional associations. Persons who are unable to submit nominations through the SAB Web site should contact Ms. Patricia L. Thomas, as indicated above in this notice. Non-electronic submissions must follow the same format and contain the same information as the electronic form. The SAB Staff Office will acknowledge receipt of nominations.

The SAB Staff Office seeks nominees who possess the necessary domains of knowledge, and relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation) to adequately address scientific issues facing the Agency. General criteria for overall committee membership include the collective breadth and depth of scientific perspectives; a balance of scientific perspectives; continuity of knowledge and understanding of EPA missions and environmental programs, and diversity factors (e.g., geographical areas and professional affiliations). Specific criteria to be used in evaluating potential members include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) absence of financial conflicts of interest; (c) scientific credibility and impartiality; (d) availability and willingness to serve; and (e) ability to work constructively and effectively on committees.

During the selection process, nominees will be required to submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency'' (EPA Form 3110–48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address: *http://www.epa.gov/sab/pdf/epaform3110–48.pdf.* This form should not be submitted as part of a nomination.

Dated: June 28, 2005.

Anthony F. Maciorowski,

Acting Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–13277 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0189; FRL–7723–4]

Exposure Modeling Work Group; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Exposure Modeling Work Group (EMWG) will hold a 1–day meeting on July 21, 2005. This notice announces the location and time for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on July 21, 2005, from 9 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Office of Pesticide Programs (OPP), Crystal Mall #2, Room 1126 (Fishbowl), 1801 S. Bell St., Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Environmental Fate and Effects Division (7507C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–8578; fax number: (703) 308–6309; e-mail address: *echeverria.marietta@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA), the Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2005–0189. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background

On a quarterly interval, the Exposure Modeling Workgroup meets to discuss current issues in modeling pesticide fate, transport, and exposure to pesticides n support of risk assessment in a regulatory context.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to the person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number OPP–2005–0189 , must be received on or before *20 days after date of publication in the* **Federal Register**.

IV. Tentative Agenda

1. Welcome and introductions
2. Old action items
3. Brief updates:
- PRZM3.12.2 Evaluation (J. Hetrick)
- EXPRESS (R. Parker)
- EFED's Modeling Scenarios (M. Corbin)
- Spray Drift Update (N. Birchfield)
- Carbamate Cumulative (N. Thurman)

V. Major Topics:

1. Modeling sediment transport at field and watershed scales (C. Graf, USDA-ARS)
2. Recent investigations of PRZM erosion and runoff pesticide transport (TBD, EPA/OPP-EFED)
3. Coupled watershed - instream sediment and contaminant transport and fate modeling system (E. Hayter, EPA/ORD-NERL)
4. Pyrethroid workgroup sediment modeling approach (TBD, Pyrethroid Workgroup)
5. Multivariate statistical analysis of paired watershed event-based nutrient loading (W.D. Hively, USDA-ARS)

List of Subjects

Environmental protection, Modeling, Pesticides, Pests.

Dated: June 27, 2005.

Steve Bradbury,

Director, Environmental Fate and Effects Division, Office of Pesticide Programs.

[FR Doc. 05–13051 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7933–5]

Science Advisory Board Staff Office; Notification of an Upcoming Teleconference and Face-to-Face Meeting of the Polychlorinated Biphenyl—Artificial Reef Risk Assessment (PCB–ARRA) Consultative Panel of the EPA Science Advisory Board (SAB)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference and face-to-face meeting of the Polychlorinated Biphenyl—Artificial Reef Risk Assessment (PCB–ARRA) Consultative Panel .

DATES: A public teleconference of the Polychlorinated Biphenyl—Artificial Reef Risk Assessment (PCB–ARRA) Consultative Panel will be held on July 22, 2005 from 2 p.m. to 5 p.m. Eastern time. The face-to-face meeting will be held on August 1, 2005 from 9 a.m. to 5 p.m. eastern time and will continue on August 2, 2005 from 8:30 a.m. to 1 p.m. eastern time.

ADDRESSES: The public teleconference will take place via telephone only. The public face-to-face meeting of the PCB–ARRA Consultative Panel will be held at the SAB Conference Center located at the Woodies Building, 1025 F Street, NW., Room 3705, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the call-in number and access code to participate in the teleconference may contact Dr. Sue Shallal, EPA Science Advisory Board Staff (1400F), U.S. EPA, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone/voice mail: (202) 343–9977 or via e-mail at *shallal.suhair@epa.gov*. Technical Contact: For questions and information concerning the documents being reviewed, please contact Craig Brown at (404) 562–8990 or *brown.craig@epa.gov.*

SUPPLEMENTARY INFORMATION:

Summary: EPA's Region 4 and Office of Prevention, Pesticides and Toxic Substances (OPPTS) have requested that the EPA Science Advisory Board (SAB) conduct a Consultation followed by an Advisory on the human health and ecological risk assessments prepared and submitted by the U.S. Navy. The purpose of this upcoming teleconference is for the PCB–ARRA Consultative Panel to receive a briefing on the document to be reviewed and to clarify the charge to the panel. A meeting agenda and background information will be posted on the SAB Web site (*http://www.epa.gov/sab/*) prior to the meeting.

The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. A SAB panel composed of current members will conduct the consultation. The purpose of a consultation is to provide non-consensus, oral advice on the preliminary assessment. Following the consultation, the SAB will conduct an advisory to provide consensus written advice on the U.S. Navy's revised assessment. The advisory will be conducted by a panel consisting of current SAB members and additional outside experts. These panels will comply with the provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB

procedural policies. As such, all public meetings will be announced in the **Federal Register** at least 15 days prior to their scheduled times.

Background: The U.S. Navy and the State of Florida are planning to deploy the ex-Oriskany, a World War II era aircraft carrier, as an artificial reef in the Gulf of Mexico. In accordance with the Toxic Substances Control Act (TSCA) and its Federal PCB regulations (40 CFR part 761), the U.S. Navy has applied for and must obtain a risk-based PCB disposal approval prior to sinking the vessel with non-liquid PCBs onboard. The EPA may approve such an application if it finds the disposal action will not pose an unreasonable risk of injury to human health or the environment. To evaluate the potential transfer of non-liquid PCBs to the marine environment and the subsequent risk that they might pose to human and ecological receptors using the artificial reef, the Navy performed leaching studies of different on-board PCB containing materials followed by fate and transport modeling of the leaching results to evaluate how released chemicals might behave in the near-reef marine environment. The U.S. Navy has also developed a fate and transport model known as the Prospective Risk Assessment Model (PRAM). EPA Region 4 has requested that the SAB conduct a consultation followed by an advisory on the U.S. Navy's assessment of potential human health and environmental risks from PCBs released from the ex-Oriskany following deployment as an artificial reef. The focus of the SAB consultation and advisory includes the leaching studies, the PRAM, and characterization of potential risks.

Procedures for Providing Public Comment: The EPA SAB Staff Office will accept written public comments of any length for the SAB Panel's consideration, and accommodate oral public comments whenever possible. The EPA SAB Staff Office expects that public statements presented at this meeting will not repeat previously submitted oral or written statements to this Panel. Oral Comments: Requests to provide oral comments must be in writing (e-mail, fax or mail) and received by Dr. Shallal no later than five business days prior to the teleconference or meeting to reserve time on the meeting agenda. For teleconferences, opportunities for oral comment will usually be limited to no more than three minutes per speaker or organization and no more than fifteen minutes total. Written Comments: Written comments should be received in the SAB Staff Office at least five business days prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the DFO at the address/contact information noted above in the following formats: one hard copy with original signature and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 98/2000/XP format).

Dated: June 28, 2005.

Anthony F. Maciorowski,

Acting Director, EPA Science Advisory Board Staff Office.

[FR Doc. 05–13278 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0145; FRL–7721–5]

Boscalid; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0145, must be received on or before August 5, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address:*mcneilly.dennis@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0145. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets.

Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0145. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov,* Attention: Docket ID number OPP–2005–0145. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2005–0145.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0145. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 27, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the BASF Corporation, and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BASF CORPORATION

PP 4F6875, 3E6791, 5E6933

EPA has received pesticide petitions PP 4F6875, 3E6791, 5E6933 from BASF Corporation, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing tolerances for residues of boscalid (3-pyridinecarboxamide, 2-chloro-N-(4'-chloro(1,1'-biphenyl)-2-yl) in or on the raw agricultural commodity almond, hulls at 15 parts per million (ppm), vegetable, leafy, except brassica, group 4 at 50 ppm, and banana at 0.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Nature of the residue studies (OPPTS Harmonized Guideline 860.1300) were conducted in grapes, lettuce and beans as representative crops in order to characterize the fate of boscalid (BAS 510F) in all crop matrices. In all three crops the boscalid BAS 510F Residues of Concern (ROC) were characterized as parent boscalid (BAS 510F). A confined rotational crop study also determined that parent was the residue of concern in the representative crops of radish, lettuce and wheat.

2. *Analytical method*. In plants, the parent residue is extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and a column clean up. Quantitation is by gas chromatography using mass spectrometry (GC/MS). In livestock, the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by liquid/liquid partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column clean-up. The parent and acetylated metabolite are quantitated by gas chromatography with electron capture detection.

3. *Magnitude of residues*. Field trials were carried out in order to determine the magnitude of the residue in/on almond hulls, leafy vegetables (celery and spinach), and banana. Field trials were conducted in the United States in the required regions for almonds and leafy vegetables. A total of 12 trials were conducted on bananas during the growing season in the principal banana growing regions represented by the countries of Costa Rica, Colombia, Ecuador, Guatemala, Honduras, Martinique, and Mexico. The number and locations of field trials are in accordance with (OPPTS Harmonized Guideline 860.1500). Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum pre-harvest interval for each crop or crop group.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data, BAS 510F and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical Boscalid (BAS 510F) in toxicity category IV for acute oral; category III for acute dermal and category IV for acute inhalation. BAS 510F is category IV for both eye and skin irritation, and it is not a dermal sensitizer. For almonds, the formulated end use product proposed is as follows: A water dispersible granule (WG) termed Pristine (BAS 516 02/04F) containing a 2:1 mixture of boscalid (BAS 510F) and pyraclostrobin (BAS 500F). BAS 516 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

For leafy vegetables (except brassica vegetables), crop group 4, two formulated end use products are proposed as follows: a water dispersible granule (WG) termed Endura (BAS 510 02/04F) containing 70% boscalid (BAS 510F) and a water dispersible granule (WG) termed Pristine (BAS 516 02/04F) containing a 2:1 mixture of boscalid (BAS 510F) and pyraclostrobin (BAS 500F). BAS 510 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer. BAS 516 02F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

For banana, the formulated end use product used in the studies is a water dispersible granule (WG) with various proposed trade names such as Cantus, banastar, etc. containing 50% Boscalid

(BAS 510F). BAS 510F has an acute oral toxicity category of III, acute dermal of category III, acute inhalation of category IV, eye irritation of category III, skin irritation of category IV, and is not a dermal sensitizer.

2. *Genotoxicity*. Ames test 1 study; gene point mutation: Negative; *in vitro* CHO/HGPRT Locus Mammalian Cell Mutation Assay (1 study; point gene mutation): Negative; *in vitro* V79 Cell cytogenetic assay 1 study; chromosome damage: Negative; *in vivo* mouse micronucleus (1 study; chromosome damage): Negative; *in vitro* rat hepatocyte (1 study; DNA damage and repair): Negative. BAS 510F has been tested in a total of 5 genetic toxicology assays consisting of *in vitro* and *in vivo* studies. It can be stated that BAS 510F did not show any mutagenic, clastogenic or other genotoxic activity when tested under the conditions of the studies mentioned above. Therefore, BAS 510F does not pose a genotoxic hazard to humans.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of BAS 510F was investigated in a 2-generation rat reproduction study as well as in rat and rabbit teratology studies.

There were no adverse effects on reproduction in the 2-generation study at any dose tested. The reproductive no observed adverse effect level (NOAEL) is 10,000 ppm 1,165 and 1,181 milligrams/kilogram/body weight/day (mg/kg/bwt/day) for males and females, respectively), the highest dose tested (HDT). Pup effects were observed, at the HDT. In males of the F1 generation, reduced body weight and reduced body weight gain were observed at 10,000 ppm. Additionally, hepatocyte degeneration was observed in males in animals of both the F0 and F1 generations at 10,000 ppm. The parental systemic NOAEL is 1,000 and 10,000 113 and 1,181 mg/kg bwt/day) for males and females, respectively. Toxicity to the offspring was seen at 1,000 ppm in the form of decreased pup weights in the F2 males, and at 10,000 ppm in the form of decreased pup weights for both males and females of both the F1 and F2 generations. The offspring NOAEL is 100 and 1,000 ppm (12 and 116 mg/kg bwt/day) for males and females, respectively.

The Agency concluded that there are no residual uncertainties for prenatal and postnatal toxicity as the degree of concern is low for the susceptibility seen in the above studies, and the dose and endpoints selected for the overall risk assessments will address the concerns for the body weight effects seen in the offspring. Although, the dose selected for overall risk assessments (21.8 mg/kg bwt/day) is higher than the NOAELs in the 2-generation reproduction study (10.1 mg/kg bwt/day) and the developmental neurotoxicity study (14 mg/kg bwt/day), these differences are considered to be an artifact of the dose selection process in these studies. For example, there is a 10-fold difference between the lowest observed adverse effect level (LOAEL). (106.8 mg/kg bwt/day) and the NOAEL (10.1 mg/kg bwt/day) in the 2-generation reproduction study. A similar pattern was seen with regard to the developmental neurotoxicity study, where there is also a 10-fold difference between the LOAEL (147 mg/kg bwt/day) and the NOAEL (14 mg/kg bwt/day). There is only a 2–3-fold difference between the LOAEL (57 mg/kg bwt/day) and the NOAEL (21.8 mg/kg bwt/day) in the critical study used for risk assessment. Because the gap between the NOAEL and LOAEL in the 2-generation reproduction and developmental neurotoxicity studies was large and the effects at the LOAELs were minimal, the true no observed adverse effect level was probably considerably higher. Therefore, the selection of the NOAEL of 21.8 mg/kg bwt/day from the 1–year dog study is conservative and appropriate for the overall risk assessments. In addition, the endpoints for risk assessment are based on thyroid effects seen in multiple species (mice, rats and dogs) and after various exposure durations (subchronic and chronic exposures) which were not observed at the LOAELs in either the 2-generation reproduction or the developmental neurotoxicity studies. Based on these data, the Agency concluded that there are no residual uncertainties for prenatal and postnatal toxicity.

No teratogenic effects were noted in either the rat or rabbit developmental studies. In the rat study, evidence of maternal or developmental toxicity was not observed at any dose (highest dose tested of 1,000 mg/kg bwt/day). Neither a maternal nor developmental LOAEL were found since the highest dose tested was the NOAEL in both studies. In the rabbit teratology study, maternal toxicity observed at the mid dose of 300 mg/kg bwt/day consisted of discolored/reduced feces in one dam and an abortion in one dam. This finding is not necessarily indicative of a definitive test substance related adverse effect. The dam which displayed the fecal alterations and abortion also displayed decreased body weight and body weight gain, compared to the group mean during gestation. These decreases occurred even prior to compound administration. Food consumption was also dramatically decreased in this dam compared to the other animals in the group. Every day from gestation day (GD) 1–12, this dam had food consumption values which were less than half the mean for the group (compound administration began on GD 7). From GD 13 to 26 (when the animal aborted and was sacrificed) this dam ate essentially nothing (food consumption during this time period was less than or equal to 1.5 grams food/day). These decreases in body weight, body weight gain, and food consumption, prior to compound administration, all indicate an animal in poor health and this poor state of health, rather than compound exposure, was likely the reason for the fecal alterations and abortion.

At the high dose of 1,000 mg/kg bwt/day a maternal body weight gain decrease compared to controls of 81% was observed during the treatment period. Reduced food consumption, reduced body weight and abortions in three dams, were also seen at 1,000 mg/kg bwt/day. Evidence of developmental toxicity was not seen at any dose tested. Developmental neurotoxicity was not observed at any dose in the developmental neurotoxicity study. No maternal toxic effects were noted at any dose in this study. No developmental toxicity was seen at the low dose of 12 mg/kg bwt/day parts per million (100 ppm). Reduced body weights and body weight gains were seen at 118 mg/kg bwt/day 1,000 ppm during post natal day (PND) 1 4. Reduced body weights and body weight gains were seen at 1,183 mg/kg bwt/day (10,000 ppm) as well as decreased absolute pup brain weight at day PND 11 (both sexes) and decreased brain length (males only) at PND. The reduced pup brain weights and decreased brain length go hand-in-hand and both are due to the decreased pup weights seen at this dose. In this respect, it should be noted that pup brain weights relative to body weight at PND 11 were not significantly different from controls at this dose. Though no maternal toxicity was seen in this study, other studies using similar doses of BAS 510F resulted in maternal toxicity. A dose of 118 mg/kg bwt/day in female rats of the same strain in the multigeneration study, resulted in an increased incidence of hepatic centrilobular hypertrophy, a parameter which could not have been detected in the developmental neurotoxicity (DNT) study as liver histopathology on parental animals was not performed in the DNT study.

4. *Subchronic toxicity.* The subchronic toxicity of BAS 510F was

investigated in a 90 day feeding studies with rats, mice and dogs, and in a 28 day dermal administration study in rats. Additonally a 90 day neurotoxicity study in rats was performed. Generally, mild toxicity was observed. At high dose levels (doses above the LOAELs) in feeding studies, all three species displayed alterations in various clinical chemistry parameters. These clinical chemistry alterations were likely secondary to general toxicity. Statistically significant increased absolute and relative thyroid weights were observed in male rats only at doses at and above the LOAEL. Increased absolute and relative liver weights were observed in both sexes at doses above the LOAEL in rats and dogs. Increased absolute and relative liver weights were seen in both sexes of the mouse at lower doses. However, the increases in liver weights at these lower doses in the mouse were not deemed to be compound related due to the unusually low concurrent control liver weight values. At doses above the LOAELs, liver weight increases were supported by histopathology alterations in the rat and mouse, but not in the dog. Overall, only mild toxicity was observed in oral subchronic testing.

In the 28 day repeat dose dermal study, no systemic effects were noted up to the HDT of 1,000 mg/kg bwt/day. In a 90 day rat neurotoxicity study, there was no mortality, signs of clinical toxicity, or adverse effects on food consumption or body weight at any dose level in either sex. No signs of neurotoxicity were observed during clinical observations, functional observation batteries, motor activity measurements of neuropathology. Therefore, there were no selective neurotoxic effects. Adverse effects were not seen even at the highest dose level tested. A LOAEL was not found and the NOAEL is the highest tested of 15,000 ppm (1,050 mg/kg bwt/day in males; 1,272 mg/kg bwt/day in females).

5. *Chronic toxicity*. Based on review of the available data, the Reference Dose (RfD) for BAS 510F will be based on a 1–year feeding study in dogs with a NOAEL of 21.8 mg/kg bwt/day. Using an uncertainty factor of 100, the RfD is calculated to be 0.218 mg/kg bwt/day. The following are summaries of chronic toxicity studies submitted to EPA.

The chronic toxicity/oncogenicity studies with BAS 510F include a 12–month feeding study with Beagle dogs, an 18–month B63CF1 mouse feeding study, a 24 month Wistar rat chronic feeding study and a 24– month Wistar rat oncogenicity study.

At the HDT in dogs, effects observed consisted primarily of increased liver and thyroid weights and some serum clinical chemistry changes. The NOAEL was 800 ppm (21.8 mg/kg bwt/day males; 22.1 mg/kg bwt/day females.)

Decreased body weights were seen in males in the mouse chronic study at doses of 8,000 ppm (1,804 mg/kg bwt/day) and above. Decreased female body weight was seen at doses of 2,000 ppm (331 mg/kg bwt/day) and above. The target organ in this study was the liver. The NOAEL was 65 and 443 mg/kg bwt/day 8,000 and 2,000 ppm for male and female mice, respectively. In both the rat chronic and oncogenicity studies, the HDT of 15,000 ppm exceeded a maximum tolerated dose (MTD) and was discontinued after 17 months. Effects observed at the next highest dose of 2,500 ppm primarily centered around the thyroid and liver. The NOAEL was 23 and 30 mg/kg bwt/day 2,500 ppm for male and female rats, respectively.

Overall, mild toxicity was observed with chronic exposure to BAS 510F. No evidence of treatment-induced oncogenicity was observed in the mouse or dog studies. A slight increase in thyroid follicular cell adenomas was seen in both sexes at the high dose when the data from both rat bioassays are combined.

A mode of action (MOA) for the thyroid follicular cell adenomas has been proposed. This MOA is based on the EPA publication ''Assessment of Thyroid Follicular Cell Tumors,'' March 1998, EPA/630/R 97/002. This document describes the criteria which must be met in order for a compound to be considered under the MOA described in that publication. BASF Corporation believes that BAS 510F has met the cited criteria.

Threshold effects. Based on a review of the available chronic toxicity data, BASF believes EPA will establish the RfD for BAS 510F at 0.218 mg/kg bwt/day. This RfD for BAS 510F is based on the 2 year chronic and 2–year oncogenicity studies in rats and the 1–year dog study with the lowest threshold NOAEL of 21.8 mg/kg bwt/day for males. Using an uncertainty factor of 100, the RfD is calculated to be 0.218 mg/kg bwt/day. Based on the acute toxicity data, BASF believes that BAS 510F does not pose any acute dietary risks.

BAS 510F was shown to be noncarcinogenic in mice and dogs. There was a slight increase in thyroid follicular cell ademonas at the high dose in both sexes in the rat. A threshold based MOA for these tumors based on the EPA publication ''Assessment of thyroid follicular cell tumors'' (EPA/630/R 97/002, March, 1998), has been proposed. BASF believes the data to support this proposed mode of action are strong, and that the thyroid tumors seen in the rat following BAS 510F exposure have a threshold. In addition, a battery of genotoxicity studies demonstrated that BAS 510F has no genotoxic or clastogenic potential. Therefore, BASF believes that the threshold approach to regulating BAS 510F is appropriate. Also, it should be noted that, while the Agency has in the past considered tumors of this type to be potential human carcinogens, the European Union has published a policy which considers these tumor types, when they occur at low incidence rates in the rat, to not be relevant to man. The publication: European Commission, European Chemicals Bureau, ECBI/49/99 Add. 1 Rev. 2; ''Draft Summary Record, commission group of specialized experts in the fields of carcinogenicity, mutagenicity and reprotoxicity,'' meeting at Arona, September 1–2 1999), Therefore, BASF believes that these tumors are not likely relevant to humans and, if these tumors are to be considered relevant to humans, the threshold approach to cancer risk assessment is appropriate.

6. *Animal metabolism*. In the rat, the predominant route of excretion of BAS 510F is fecal with urinary excretion being minor. The half-life of BAS 510F is less than 24 hours. Saturation of absorption appears to be occurring at the high dose level. BAS 510F is rapidly and intensively metabolized to a large number of biotransformation products. The hydroxylation of the diphenyl moiety was the quantitatively most important pathway. Second most important was the substitution of the Cl of the 2-chloropyridine part against SH by conjugation with glutathione. No major differences were observed. In hens and goats the residues of concern were determined to be parent, the hydroxylated metabolite M510 F01 (2-chloro-N-(4'chloro-5-hydroxy-biphenyl-2-yl)nicotinamide), and the glucuronic acid of the metabolite M510 F02.

7. *Metabolite toxicology*. No additional studies were required for metabolite toxicology.

8. *Endocrine disruption*. No specific tests have been conducted with BAS 510F to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity studies (i.e., subchronic and chronic toxicity, teratology and multi-generation reproductive studies) which would suggest that BAS 510F produces endocrine related effects.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* An assessment was conducted to evaluate the potential risk due to chronic dietary exposure of the U.S. population and sub-populations to residues of BAS 510F (Boscalid). Tolerance values have previously been established and are listed in U.S. 40 CFR 180.589. This analysis included all crops with established tolerance values, crops pending tolerance assignment (vegetable, leafy crop group 4 at 50 ppm, almond hulls at 15 ppm and an import tolerance for banana pulp of 0.5 ppm).

a. *Acute dietary exposure assessment.* An acute assessment was not needed since EPA Toxicological Endpoint Selection (TES) Committees had previously evaluated the boscalid toxicity data and determined there was no toxic effect attributable to a single dose. Therefore, a quantitative acute dietary exposure and risk assessment were not required.

b. *Chronic dietary exposure assessment.* A Tier 1 chronic dietary exposure assessment was conducted assuming tolerance level residues in all crops and 100% crop treated for all registered, pending, and proposed crops. Default processing factors were also used in the assessment. EPA Food Commodity Ingredient Data Base (FCID) was also used in Exponent's Dietary Exposure Evaluation Module (DEEM-FCID) software. Residues in animal commodities (i.e. meat, meat byproducts, milk, eggs) were included at the tolerance levels currently established and listed in 40 CFR 180.589.

Dietary exposure estimates were compared against the established boscalid chronic population adjusted dose (cPAD) of 0.218 mg/kg bwt/day for all populations. Results of the chronic dietary assessments are listed in the Table 1. The estimated chronic dietary exposure from all crops and animal commodities was less than 33% of the cPAD for all sub-populations. Additional refinements such as the use of anticipated residues and adjusted crop treated factors would further reduce the estimated chronic dietary exposure. The results in the table below demonstrate that there are no safety concerns for any sub-population based on established and new uses, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

TABLE 1.–SUMMARY OF CHRONIC DIETARY EXPOSURE ASSESSMENT CONSIDERING CROPS WITH ESTABLISHED AND PROPOSED TOLERANCES FOR BAS 510F (BOSCALID).

Population Subgroup	Exposure Estimate (mg/kg bwt/day)	%cPAD
U.S. population	0.028430	13.0
All Infants	0.040972	18.8
Children 1–2 years old	0.069725	32.0
Children 3–5 years old	0.053362	24.5
Children 6–12 years old	0.032094	14.7
Youth 13–19 years old	0.02535	11.6
Females 13–49 years old	0.021689	9.9
Adults 20–49 years old	0.024906	11.4
Adults 50+ years old	0.025333	11.6

%cPAD = percent of chronic population adjusted dose Exposure estimates based on tolerance values, percent crop treated values for established crop tolerances, 100% CT for crops with proposed tolerances

ii. *Drinking water.* Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as %PAD. Instead, drinking water levels of concern (DWLOCs) are calculated and used as points of comparison against the model estimates of a pesticide's concentration in water. A DWLOC is the theoretical upper allowable limit of a pesticide's concentration in drinking water and is calculated with consideration of the aggregate exposure to a pesticide from food and residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses.

Different populations will have different DWLOCs. If the DWLOC is greater than the model water concentrations, the EPA concludes that exposure from drinking water is not a risk issue. The modeled water concentration is obtained from the FIRST model for surface water and the SCIGROW model for ground water. The values used for comparison to the DWLOC are the maximum concentrations for any use. When the EEC's are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water would not result in unacceptable levels of aggregate human health risk.

a. *Acute aggregate exposure and risk (food and water).* Since EPA Toxicological Endpoint Selection (TES) Committees has evaluated the boscalid toxicity data and determined there was no toxicologic endpoints for acute dietary exposure, the determination of an acute aggregate exposure and risk evaluation was not required.

b. *Chronic aggregate exposure and risk (food and water).* Table 2. summarizes the aggregate exposure and risk.

TABLE 2.–AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BAS 510F (BOSCALID)

Population Subgroup	Chronic Food Exposure (mg/kg bwt/day	cPAD[1]	Maximum Allowable Water Exposure (mg/kg/bwt/day)	DWLOC (µg/L)	Sci-Grow ground water (µg/L)	FIRST surface water (µg/L)
Infants (0–1 year)	0.040972	0.218	0.177028	1770		
Children (1–2 years)[1]	0.069725	0.218	0.148275	1,483	0.63	26.0
Adult females (13–49)	0.021689	0.218	0.196311	5,889		
U.S population	0.028430	0.218	0.189570	6,634		

[1]Inter/intra species safety factor = 100 FQPA safety factor = 1, NOAEL = 21.8 mg/kg bwt/day

The results in the summary table of chronic DWLOCs demonstrate that there are no safety concerns for any subpopulation based on established and new uses, and that the results clearly meet the FQPA standard of reasonable certainty of no harm.

In summary, we can conclude with reasonable certainty that no harm will occur from chronic aggregate exposure of boscalid.

Short-term and intermediate term aggregate exposure and Risk (food, water and residential exposure)

Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure from food and water. Residential exposure is used to refer to non-occupational and non-dietary exposure. No new residential uses are currently being registered for boscalid that would increase non-dietary exposure. The residential exposure value used in this risk assessment was previously determined by the EPA (July 30, 2003, 68 FR 44640) (FRL–7319–6) and considers dermal exposure to adults from the golf course use. The MOE and DWLOC presented in the table below are considered to be representative for youth playing golf because youth and adults possess similar body surface area to weight ratios and because the dietary exposure for youth (13–19 years old) is less than that of the general U.S. population. The aggregate risk for short-term exposure is summarized in Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BAS 510F (BOSCALID)

Pop	Short-Term Scenario									
	NOAEL(mg/kg/day)	Target MOE[1]	Max Exp[2] (mg/kg/day)	Avg. food exp (mg/kg/day)	Residential Exp[3] (mg/kg/day)	Aggregate MOE[4] (food and residential)	Max water Exp[5] (mg/kg/day)	Ground water EEC[6] (µg/L)	Surface water EEC[6] (µg/L)	Short-term DWLOC (µg/L)[7]
U.S.	21.8	100	0.218	0.028	0	746	0.189	0.63	26	5,663

[1]Target MOE is 100.
[2]Maximum Exposure (mg/kg/day) = NOAEL Target MOE.
[3]Residential Exposure = Exposure to adult while playing golf.
[4]Aggregate MOE = (NOAEL (Avg. Food + residential Exposure).
[5]Maximum Water Exposure (mg/kg/day) = Target Max Exposure (Food Exposure + Residential Exposure).
[6]Crop producing the highest EEC values were used for comparison.
[7]The DWLOC (µg/L) = maximum water exposure (mg.kg/day) x body weight (kg) water consumption (L) x 0.001 mg/ug. Adult female weight was used to calculate, which covers adult male risk. The dietary exposure for the U.S. population is higher than that of groups having residential golf exposure (i.e., adults, youth 13–19).

2. *Non-dietary exposure.* No new residential uses are currently being registered for boscalid that would increase non-dietary exposure. A non-occupational dermal post-application exposure/risk assessment for individuals golfing and harvesting fruit at ''U-Pick'' farms and orchards was previously conducted by EPA, (July 30, 2003, 68 FR 44640) (FRL–7319–6). Because U-Pick is a one-time event (duration <1 day) and the EPA found that the oral studies indicated there were no endpoints appropriate to quantify acute risk.

Therefore, only the golfing scenario was evaluated with respect to non-occupational, non-dietary exposure. The dermal MOE's for adults playing golf were 27,000 to 74,000. Although, specific MOE's were not calculated for youths playing golf, the adult MOEs are considered representative since the body surface area to weight ratios for adolescents do not vary significantly from those of adults.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative

effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' BAS 510F is a foliar fungicide chemically belonging to the carboxin class of fungicides. BAS 510F acts in the fungal cell by inhibiting mitochondrial respiration through inhibition of the succinate-ubiquinone oxidase reductase system in Complex II of the mitochondrial electron transport chain. BAS 510F shares this mode of action with only one other currently registered U.S. pesticide - carboxin.

EPA is currently developing methodology to perform cumulative risk assessments. At this time, there is no available data to determine whether BAS 510F has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, BAS 510F does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that dietary exposure to BAS 510F will utilize 13.0% of the cPAD for the U.S. population. The aggregate exposure including food, water, and residential golf exposure has shown that there is no concern from the exposure from drinking water. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of BAS 510F, including anticipated dietary and drinking water exposures and non-occupational exposures.

2. *Infants and children*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that dietary exposure to BAS 510F will utilize 32% of the cPAD for most highly exposure infant and children subgroup (children 1–2 years of age). The aggregate exposure including food, water, and residential golf exposure has shown that there is no concern to any subpopulation from the exposure from drinking water. BASF concludes that there is a reasonable certainty that no harm to infants or children will result from the aggregate exposure to residues of BAS 510F, including anticipated dietary and drinking water exposures and non-occupational exposures.

F. International Tolerances

A maximum residue level (MRL) has not been established for boscalid BAS 510F in any crop by the codex Alimentarius Commission.

[FR Doc. 05–13175 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0058; FRL–7719–3]

Ethaboxam; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0058, must be received on or before August 5, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Bryant Crowe, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: *crowe.bryant@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0058. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public

docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0058. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2005–0058. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2005–0058.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0058. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 23, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

LG Life Sciences, Ltd.

PP 4E6863

EPA has received a pesticide petition (4E6863) from LG Life Sciences, Ltd., c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for residues of ethaboxam (LGC-30473), (RS)-N-(alpha-cyano-2-thenyl)-4-ethyl-2-(ethylamino)-1,3-thiazole-5-carboxamide, in or on grapes, grape juice, raisins, and wine. The tolerances are set at the following values: Grapes at 3.5 parts per million (ppm), grape juice at 3.3 ppm, raisins at 5.8 ppm, and wine at 2.5 ppm.

A program of 19 residue trials was conducted in both Northern and Southern Europe over a 2–year period (2001–2002) on vines. In Northern Europe trials were conducted in France and Germany, while in Southern Europe the trials were in France, Italy, and Spain. Applications of ethaboxam 10% SC were made at the proposed GAP of 5 x 200 gram active substance/hectare (g a.s./ha) with a 21-day post harvest interval (PHI). Of the 19 trials, 8 were conducted as decline studies, with 5 in Southern Europe and 3 in Northern Europe. Residue levels in grapes ranged from less than the limit of detection (< 0.005 ppm) to 3.4 ppm with a mean value of 1.07 ppm. The proposed EU maximum residue level (MRL) for grapes is 3.5 parts per million (ppm) and the MRLs for grape processed commodities based on the concentration/dilution factors determined in the processing study are 2.5 ppm for young wine, 1.3 ppm for wine, 2.3 ppm for juice, and 5.8 ppm for raisins.

These proposed MRLs were combined with a program of seven trials conducted in 2004. This program was conducted in Chile (three trials), Australia (two trials), Argentina (one trial), and Mexico (one trial). Residues were analyzed resulting from five applications of ethaboxam 10% SC at 2 or 4 Liter/hectare (L/ha), sampled at 21 days following the final application. No residues of ethaboxam were detected above the limit of detection of 0.002 ppm in any non-treated samples from any of the trials. Residues of ethaboxam detected in grapes ranged from 0.183 to 1.827 ppm in samples sprayed at a rate of 2 L/ha and from 1.121 to 7.072 ppm for grapes sprayed at a rate of 4 L/ha. Residues detected in juice (must) samples were between 0.64 and 3.24 ppm (2 L/ha rate); in raisins residues were between 0.39 and 1.68 ppm (2 L/ha rate); in wine residues were between 0.11 and 0.49 ppm (2 L/ha rate). Combining the residues from the two programs the following tolerances are proposed: Grapes at 3.5 ppm, grape juice at 3.3 ppm, raisins at 5.8 ppm, and wine at 2.5 ppm.

Neither livestock feeding studies or livestock metabolism, distribution and expression of residue studies are required, as vines will not be utilized for feeding. The storage stability of ethaboxam was assessed in grape homogenates during freezer storage (-18° C). The results of the analysis show that ethaboxam was stable for a minimum of 17 months.

The primary metabolic pathways of ethaboxam in plants were established in grapes, tomatoes, and potatoes. Extensive metabolism occurred in the grape. The proposed bio-transformation pathway for ethaboxam in grapes is the formation of LGC-35523 from ethaboxam (by photolytic degradation) and incorporation of LGC-35523 into natural products (sugars). In the potato, most of the parent compound was metabolized and incorporated into starch. Following acid hydrolysis of the starch fraction to glucose, a substantial proportion of the radiolabel was converted to glucosazone. It was therefore concluded that the radiolabel was incorporated into the starch backbone and formed part of the carbohydrate pool. In the tomato, fruit taken at harvest showed that the major component at harvest was unchanged ethaboxam, accounting for 49–57% total radioactive residues. Studies of the absorption, distribution, metabolism and excretion of ethaboxam (LGC-30473) were carried out using [^{14}C]-LGC-30473, ^{14}C-thiophene LGC-30473 and [^{14}C-thiazole] LGC-30473 dosed separately. Studies were performed in rats of the same strain used for toxicity assessments at dose levels of 10 or 150 milligrams/kilogram (mg/kg) and oral gavage dosing in a 1%methylcellulose, 0.1% Tween 80 vehicle.

Excretion of radioactivity following either a single dose of [^{14}C-thiophene or ^{14}C-thiazole] LGC-30473 or 14 consecutive doses of [^{14}C-thiazole] LGC-30473 was rapid with <90% of radioactivity eliminated in urine or faeces within 48 hours. Faecal excretion (66–92% of dose in 120 hours (h)) substantially exceeded urinary excretion (13-30% of dose in 120 h) with the percentage excreted in the urine higher at the lower dose. These factors suggest capacity limited absorption. This was supported by the pharmacokinetic data which showed a slightly less than dose proportional increase in C^{max} and AUC (area under the plasma concentration-

time curve) between the 10 and 150 mg/kg doses (dose ratio 15, AUC ratio 11). Substantial radioactivity was detected in bile suggesting first-pass metabolism was significant. T^{max} was around three times longer at the high dose level (3–6 hours (h) at 150 mg/kg versus 1–2 h at 10 mg/kg). The plasma elimination half-life of 31–41 h was similar for both doses. The blood cell elimination half-life was considerably longer at 69–162 hours for both doses. AUC 120 was higher in blood plasma following 14 doses at 10 mg/kg/day than following one dose (~2 fold) but more notably higher in blood cells (~5 fold).

Distribution of radioactivity after a single dose at 10 or 150 mg/kg or 14 consecutive doses at 10 mg/kg was similar at both dose levels and was highest in thyroid (thiazole label only), liver and blood cells. Concentrations 120 hours after the 14th dose were 5–15 fold higher than after the single dose, but all tissue accumulation was low. There were no substantial differences in distribution or excretion pattern between sexes. Extent of absorption, assessed in biliary excretion experiments, was similar between the sexes at 10 mg/kg (71–72% dose) but higher in females at 150 mg/kg (males, 48% dose; females 61% dose). All elements of this study indicate similar results for both labels and there was little evidence of cleavage of the intact molecule. Five major metabolites were identified each accounting for >5% dose: LGC-32794, LGC-32800, LGC-32801, LGC-32802, and LGC-32803. In one pathway, ethaboxam was N-de-ethylated to LGC-32794 followed by oxidation of the thiazole sulphur to LGC-32800. Ethaboxam also underwent enolization. In a second pathway the enol form underwent hydrolysis to the amide LGC-32801. In a third pathway the enol underwent sulphate conjugation to LGC-32802 and hydroxylation/sulphate conjugation to LGC-32803. Ethaboxam was detected as a major component of faecal extracts at both dose levels. Destructive catabolism of the molecule appeared to be negligible.

[FR Doc. 05–13262 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Revised Exposure Draft
Accounting for Fiduciary Activities

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in April 2004, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued a revised exposure draft, *Accounting for Fiduciary Activities.* The proposed Exposure Draft would enhance reporting on fiduciary activities by clarifying the definition of fiduciary activities, reducing the number of acceptable approaches to accounting for these activities, and ensuring adequate disclosure in notes to the financial statements.

The Exposure Draft is available on the FASAB home page *http://www.fasab.gov/exposuredraft.htm.* Copies can be obtained by contacting FASAB at (202) 512–7350. Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by August 30, 2005, and should be sent to: Wendy M. Comes, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street, NW., Suite 6814, Mail Stop 6K17V, Washington, DC 20548.

A public hearing on the proposed standard has been scheduled for August 17, 2005.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G Street, NW., Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: June 29, 2005.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 05–13213 Filed 7–5–05; 8:45 am]

BILLING CODE 1610–01–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget

June 21, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before August 5, 2005. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov.* If you would like to obtain or view a copy of this new or revised information collection, you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0357.

Title: Request for Designation as a Recognized Private Operating Agency.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 10.

Estimated Time Per Response: 5 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 35 hours.

Total Annual Cost: $13,000.

Privacy Act Impact Assessment: No.

Needs and Uses: The Commission adopted and released a *Report and Order* in IB Docket No. 04–226, FCC 05–91, which adopted the proposals made in the preceding Notice of Proposed Rulemaking (NPRM) of the same title (FCC 04–133). This rulemaking is hereinafter referred to as the International E-Filing R&O. The International E-Filing R&O eliminates paper filings and requires applicants to

file electronically all applications and other filings related to international telecommunications services via the user-friendly, Internet-based International Bureau Filing System (IBFS).

At the request of the U.S. Department of State, the Commission adopted a voluntary program by which companies that provide enhanced services could seek designation as a recognized private operating agency (RPOA). The term RPOA was used in the International Telecommunications Convention, the international agreement that created the International Telecommunications Union (ITU), to refer to private-sector providers of international telecommunications services that had been ''recognized'' either by the government of the country in which they had been incorporated, or the country where they operated. Most providers of international telecommunications services to or from the U.S. hold either an authorization under Section 214 of the Communications Act or a radio license under Section 301 of the Act. The issuance of such authorizations or licenses is public evidence that the U.S. government ''recognizes'' the entities to which they are issued. However, providers of enhanced services are not licensed or authorized. They are permitted to begin operations without any formal applications or notifications. It is not immediately apparent to foreign governments that a U.S. enhanced service provider has been ''recognized'' within the meaning of the ITU Convention. As a consequence, such entities have sometimes found foreign governments unwilling to let them operate in those countries. As a result, the U.S. Department of State and the FCC developed a program whereby enhanced service providers could be formally designated as RPOAs. The program that was developed calls for those entities wishing to obtain such a designation to submit an application to the Commission setting forth pertinent information about the provider and the services it proposes to provide and a pledge by the provider that it would abide by all international obligations to which the U.S. is a signatory. The Commission places the application on public notice and allows interested parties to comment on the application. The Commission then makes a recommendation, based on the application and comments received and notifies the ITU of any applications that it grants. RPOA designation is voluntary. If an enhanced service provider does not find such a designation necessary, it is not required to file an application. In order to implement the program, the Commission adopted 47 CFR 63.701 to set forth the information that must be contained in an application for designation as a RPOA.

OMB Control No.: 3060–1028.

Title: International Signaling Point Code (ISPC).

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 40.

Estimated Time Per Response: 10 minutes (.166) hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Total Annual Burden: 7 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: No.

Needs and Uses: The Commission adopted and released a *Report and Order* in IB Docket No. 04–226, FCC 05–91, which adopted the proposals made in the preceding Notice of Proposed Rulemaking (NPRM) of the same title (FCC 04–133). This rulemaking is hereinafter referred to as the International E-Filing R&O. The International E-Filing R&O eliminates paper filings and requires applicants to file electronically all applications and other filings related to international telecommunications services via the user-friendly, Internet-based International Bureau Filing System (IBFS).

An International Signaling Point Code (ISPC) is a unique, seven-digit code synonymous with a telephone number, used to identify each international carrier. The IPSC has a unique format that is used at the international level for signaling message routing and identification of signaling points. The Commission has revised this collection to implement mandatory electronic filing and to seek OMB approval of three new ISPC applications that will be developed over time contingent upon the availability of budget funds, human resources and other factors. They are: (1) For other filings; (2) notification of signaling point code implementation; and (3) inactivation of international signaling point code. The information collection requirements contained in this collection will facilitate the Commission's assignment of unique ISPCs to international carriers for identification purposes. In addition, it will enhance the ability of the international carriers to communicate with each other internationally through the shared signaling network.

OMB Control No.: 3060–1029.

Title: Data Network Identification Code (DNIC).

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 5.

Estimated Time Per Response: .25 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 1 hour.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: No.

Needs and Uses: The Commission adopted and released a *Report and Order* in IB Docket No. 04–226, FCC 05–91, which adopted the proposals made in the preceding Notice of Proposed Rulemaking (NPRM) of the same title (FCC 04–133). This rulemaking is hereinafter referred to as the International E-Filing R&O. The International E-Filing R&O eliminates paper filings and requires applicants to file electronically all applications and other filings related to international telecommunications services via the user-friendly, Internet-based International Bureau Filing System (IBFS).

The Commission plans to develop three new DNIC applications that impact this information collection. The development is contingent upon the availability of budget funds, human resources and other factors. These applications will be for: (1) Other filings; (2) code reassignment; and (3) code surrender.

The Commission obtains relevant information from operators of public data networks through the filing of applications through IBFS. The electronic collection of information expedites the Commission's review and approval of DNIC applications for operators of public data networks.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13024 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

June 27, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden,

invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information, subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 6, 2005. 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: Direct all Paperwork Reduction Act (PRA) comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Leslie.Smith@fcc.gov.* If you would like to obtain or view a copy of this new or revised information collection, you may do so by visiting the FCC's PRA Web page at *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Les Smith at (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0874.

Title: Consumer Complaint Form/Obscene, Profane, and Indecent Material Complaint Form.

Form Number: FCC 475 and FCC 475–B.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit entities; Not-for-profit institutions; Federal government; State, local or Tribal Government.

Number of Respondents: FCC Form 475—83,287; FCC Form 475–B—1,271,332.

Estimated Time per Response: 30 minutes per form.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: FCC Form 475—41,644 hours; FCC Form 475–B—635,666 hours.

Total Annual Cost: None.

Privacy Impact Assessment: Yes.

Needs and Use: Consumers file FCC Form 475 to register their complaints about common carrier services and practices. By providing a concise, standardized format, the form helps consumers to provide the Commission with the necessary and relevant information it needs to assess the practices of common carriers and to resolve any informal complaints filed by consumers. FCC Form 475 is also important in the investigative work performed by Federal and State law enforcement agencies to monitor common carrier practices and to promote compliance with Federal and State regulations and other legal requirements, *i.e.*, in some instances, data on FCC Form 475 may become the basis for enforcement actions and/or rulemaking proceedings, as appropriate.

The Commission is developing a new form, FCC Form 475–B, Obscene, Profane, and Indecent Material Complaint Form, to provide consumers with a standardized form, designed specifically to collect detailed data about obscene, profane, and indecent programming. The Commission believes that providing a form specifically for these purposes will allow consumers to register their complaints about the nature of the aired material(s) more clearly and concisely, thereby reducing the uncertainty, confusion, frustration, and apprehension that consumers may otherwise experience when trying to express their objections to programming. The Commission also believes that such a standardized format as FCC Form 475–B can strengthen the effectiveness of its rules and improve its efforts to move forward quickly with enforcement actions to resolve these programming complaints, thus ridding the public airways of obscene, profane, and indecent content and programming.

Form 475–B will include these fields: (1) Complainant's contact information—name, address, e-mail address, and telephone number; (2) name of the station broadcasting the alleged obscene, profane, and/or indecent material, including the call sign, channel, and frequency; (3) name of the program or song, including host or personality/DJ; (4) broadcast time, the time zone, and the date of the broadcast; and (5) description of the incident—providing sufficient details about the specific words, languages, and images, to help the Commission determine whether the material was in fact obscene, profane, or indecent. The Commission may use the data as the basis for an enforcement action and/or rulemaking proceeding(s), as appropriate.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13030 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority

June 20, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction (PRA) comments should be submitted on or before September 6, 2005. 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: Direct all Paperwork Reduction Act (PRA) comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at 202–418–2918 or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0706.

Title: Cable Act Reform.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; State, local or tribal government.

Number of Respondents: 950.

Estimated Time per Response: 1–8 hours.

Frequency of Response: On occasion reporting requirement; third party disclosure requirement.

Total Annual Burden: 3,900 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On March 29, 1999, the FCC released a *Report and Order (R&O)*, In the Matter of the Implementation of the Cable Act Reform Provisions of the Telecommunications Act of 1996, FCC 99–57, CS Docket No. 96–85, which further amended the Commission's cable television rules pursuant to the Telecommunications Act of 1996. With this *R&O*, the FCC has accounted for various requirements in its rules not already accounted for in the initial and final rules. The regulations serve a variety of purposes for subscribers, cable operators, franchising authorities, and the FCC, *i.e.*, 47 CFR 76.952 requires a cable operator to include the franchising authority contact information in a subscriber's monthly billing statement; 47 CFR 76.990 requires a cable operator to certify in writing the franchising authority that it qualifies as ''small cable operator;'' and 47 CFR 76.1404 requires a local exchange carrier to file contract information with the FCC to determine whether its use of a cable operator's facilities is reasonably limited on scope and duration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13033 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

June 21, 2005.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before August 5, 2005. 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: Direct all comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov* or Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information concerning this information collection(s) contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov.* If you would like to obtain or view a copy of this revised information collection, you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0236.

Title: Section 74.703, Interference.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; State, local or tribal government.

Number of Respondents: 350.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirement; third party disclosure requirement.

Total Annual Burden: 1,420 hours.

Total Annual Cost: $852,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The Commission adopted an *Report and Order (R&O)* on September 9, 2004, In the Matter of the Amendment of parts 73 and 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, MB Docket No. 03–185, FCC 04–220. The *R&O* revised 47 CFR Section 74.703(f) to require the licensee of a digital low power TV (LPTV) or TV translator station operating on a channel from 52–69 to eliminate at its expense any condition of interference caused to the operation of or services provided by existing and future commercial or public safety wireless licensees in the 700 MHz bands. The offending digital LPTV or translator station must cease operations immediately upon notification by any primary wireless licensee, once it has been established that the digital low power TV or translator station is causing the interference.

The *R&O* also revised 47 CFR Section 74.703(g) to require that an existing or future wireless licensee in the 700 MHz bands may notify (certified mail, return receipt requested), a digital low power TV or TV translator operating on the same channel or first adjacent channel of its intention to initiate or change wireless operations and the likelihood of interference from the low power TV or translator station within its licensed geographic service area. The notice should describe the facilities, associated service area and operations of the wireless licensee with sufficient detail to permit an evaluation of the likelihood of interference.

47 CFR 74.703(h) requires in each instance where suspension of operation is required, the licensee shall submit a

full report to the FCC in Washington, DC, after operation is resumed, containing details of the nature of the interference, the source of the interfering signals, and the remedial steps taken to eliminate the interference.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13034 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review to the Office of Management and Budget

June 16, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before August 5, 2005. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Leslie F. Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., DC 20554 or via the Internet to *Leslie.Smith@fcc.gov.* If you would like to obtain or view a copy of this new or revised information collection, you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Leslie F. Smith at (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0854.

Title: Truth-in-Billing Format, CC Docket No. 98–170.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 5,309; 34,866 responses.

Estimated Time per Response: 5 to 465 hours.

Frequency of Response: On occasion reporting requirement; third party disclosure.

Total Annual Burden: 4,636,942 hours.

Total Annual Cost: $15,418,200.

Needs and Uses: On March 18, 2005, the Commission released the *Second Report and Order, Declaratory Ruling, and Second Further Notice of Proposed Rulemaking,* In the Matter of Truth-in-Billing and Billing Format; National Association of State Utility Consumer Advocates' Petition for Declaratory Ruling Regarding Truth-in-Billing, CC Docket No. 98–170, CG Docket No. 04–208, FCC 05–55, (*2005 Second Report and Order, Declaratory Ruling, and Further Notice of Proposed Rulemaking*). In the *2005 Second Report and Order, and Declaratory Ruling* the Commission determined that Commercial Mobile Radio Service (CMRS) providers no longer should be exempted from 47 CFR 64.2401(b), which requires billing descriptions to be brief, clear, non-misleading and in plain language. In addition, in its *2005 Second Further Notice of Proposed Rulemaking,* the Commission proposed and sought comment on measures to enhance the ability of consumers to make informed choices among competitive telecommunications providers.

The information collection requirements include the following: (1) Those requirements contained in the Truth-in-Billing Format rules, which were previously approved by OMB on November 30, 2004; (2) the adjustments pursuant to the new Census data; (3) changes to the existing rule § 64.2400 (b) pursuant to the *2005 Second Report and Order;* and (4) the proposed requirements contained in the *2005 Second Further Notice of Proposed Rulemaking.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13035 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

May 25, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 6, 2005. 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: Direct all Paperwork Reduction Act (PRA) comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0407.

Title: Section 73.3598, Period of Construction.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 120.

Estimated Time per Response: 15 minutes–3 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement.

Total Annual Burden: 240 hours.

Total Annual Cost: $18,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: When a permit is subject to tolling construction is encumbered due to an act of God, or when a construction permit is the subject of administrative or judicial review, 47 CFR Section 73.3 598(c) requires a permittee to notify the Commission as promptly as possible and, in any event, within 30 days, and to provide supporting documentation. All notifications must also be filed in the station's local public file. On March 17, 2005, the Commission released a *Second Order on Reconsideration and Further Notice of Proposed Rulemaking (FNPRM)*, the Matter of the Creation of a Low Power Radio Service, MM Docket No. 99–25, FCC 05–75. The *Second Order on Reconsideration* established an interim waiver policy to increase the likelihood that permittees will complete construction and commence operation. Therefore, the Commission delegated to the Media Bureau the authority to consider requests for waivers of the construction period as specified in 47 CFR Section 73.3598(a) even if the requirements under the tolling rules are not met. An Low Power FM (LPFM) permittee may request a waiver and the waiver may be granted if the permittee demonstrates that construction of its broadcast facilities cannot be completed within the allotted 18 months for reasons beyond its control, that the permittee expects to be able to complete construction within the additional 18 months that the construction extension would provide, and that the public interest would be served by the extension.

OMB Control Number: 3060–0920.

Title: Application for Construction Permit for a Low Power FM Broadcast Station; Report and Order in MM Docket No. 99–25 Creation of Low Power Radio Service.

Form Number: FCC Form 318.

Type of Review: Revision of a currently approved collection.

Respondents: Not-for-profit institutions; State, local or tribal government.

Number of Respondents: 16,422.

Estimated Time per Response: 15 minutes–12 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 33,866 hours.

Total Annual Cost: $23,850.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On March 17, 2005, the FCC released a *Second Order on Reconsideration and Further Notice of Proposed Rulemaking (FNPRM)*, In the Matter of Creation of a Low Power Radio Service, MM Docket No. 99–25, FCC 05–75. The *Second Order on Reconsideration* amended 47 CFR 73.870 and 73.871 to allow licensees and permittees to file minor change applications and minor amendments to pending FCC Form 318 applications by requesting authority for transmitter site location of up to 5.6 kilometers for LP 100 facilities and up to 3.2 kilometers for LP 10 facilities.

FCC Form 318 is required: (1) To apply for a construction permit for a new Low Power FM (LPFM) station; (2) to make changes in the existing facilities of such a station; or (3) to amend a pending FCC Form 318 application. The Commission authorizes the licensing of two classes of Low Power FM (LPFM) radio stations: a Low Power (LP) 100 Class which is used for stations operating at 50–100 watts effective radiated power at an antenna height above average terrain (HAAT) of 30 meters; and a Low Power (LP) 10 Class which is used for stations operating at 1–10 watts ERP and an antenna height of 30 meters HAAT.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13036 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–10–P

FEDERAL COMMUNICATIONS COMMISSION

[WT Docket No. 05–193; DA 05–1390]

Petition for Declaratory Ruling Filed by SunCom Wireless Operating Company, L.L.C. and Opposition and Cross-Petition for Declaratory Ruling Filed by Debra Edwards

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document seeks comment on two petitions. The first is a petition for declaratory ruling by SunCom Wireless Operating Company, L.L.C., f/k/a Triton PCS Operating Company, L.L.C., that requests that the Federal Communications Commission declare that early termination fees charged to commercial mobile radio service (CMRS) customers are ''rates charged'' under the Communications Act. The second is an opposition to petition for declaratory ruling and cross-petition for declaratory rulings filed by Debra Edwards that opposes the SunCom Petition and requests a declaratory ruling that the state-law claims concerning contractual early termination fees do not amount to regulation of cellular telephone service rates proscribed by the Communications Act.

DATES: Comments are due August 5, 2005, and Reply comments are due August 25, 2005.

ADDRESSES: You may submit comments, identified by WT Docket No. 05–193, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Federal Communications Commission's Web Site: *http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christina Clearwater, Spectrum & Competition Policy Division, Wireless Telecommunications Bureau, Federal Communications Commission, 202–418–1893.

SUPPLEMENTARY INFORMATION: On May 18, 2005 the Wireless Telecommunications Bureau released a public notice establishing the comment and reply comment dates associated with a petition for declaratory ruling filed by SunCom Wireless Operating Company, L.L.C. and an opposition and cross-petition for declaratory ruling filed by Debra Edwards, seeking determination of whether state law claims regarding early termination fees are subject to preemption under section 332(c)(3)(A) of the Communications Act.

Background

On February 22, 2005, SunCom Wireless Operating Company, L.L.C., f/k/a Triton PCS Operating Company, L.L.C. (SunCom) filed a petition for a declaratory ruling (SunCom Petition). *See* Petition for Declaratory Ruling filed by SunCom Operating Company L.L.C., WT Docket No. 05–193, on February 22, 2005. In its petition, SunCom requests that the Federal Communications Commission (Commission) declare that early termination fees charged to commercial mobile radio service (CMRS) customers are ''rates charged'' under section 332(c)(3)(A) of the Communications Act. This petition is filed pursuant to a court order in *Edwards* v. *SunCom,* a class action lawsuit brought in South Carolina state court that asserts certain state law claims regarding contractual early termination fees charged by SunCom. SunCom filed the petition at the direction of the court, which has stayed the litigation pending final resolution of the petition by the Commission. *See* Supplemental Order Requiring Defendant to File Petition for Declaratory Ruling at the Federal Communications Commission and Staying Case until Such Ruling is Issued dated January 18, 2005 (court order), *Edwards* v. *SunCom,* State of South Carolina, County of Horry, No. 02–CP–26–3359 (Ct. of Com. Pleas. May 25, 2004) (*Edwards* v. *SunCom*).

On March 4, 2005, Debra Edwards (Edwards), plaintiff in *Edwards* v. *SunCom,* filed an Opposition to Petition for Declaratory Ruling and Cross-Petition for Declaratory Rulings (Edwards Petition). *See* Opposition to Petition for Declaratory Ruling and Cross-Petition for Declaratory Rulings filed by Debra Edwards, WT Docket No. 05–193, on March 4, 2005. In the Edwards Petition, Edwards opposes the SunCom Petition and requests a declaratory ruling that the state-law claims concerning contractual early termination fees asserted in *Edwards* v. *SunCom* do not amount to regulation of cellular telephone service rates proscribed by section 332(c)(3)(A) of the Communications Act. The SunCom and Edwards Petitions raise important issues, and in the Public Notice, the Wireless Telecommunications Bureau seeks comment on these petitions. The Wireless Telecommunications Bureau notes that it is contemporaneously releasing a separate public notice seeking comment on another petition for declaratory ruling that raises preemption-related issues regarding early termination fees. *See Wireless Telecommunications Bureau Seeks Comment on Petition for Declaratory Ruling Filed by CTIA Regarding Whether Early Termination Fees Are ''Rates'' Within 47 U.S.C. 332(c)(3)(A),* Public Notice, WT Docket No. 05–194, DA 05–1389 (rel. May 18, 2005).

Electronic Access and Filing

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments in this proceeding on or before August 5, 2005, and reply comments may be filed on or before August 25, 2005. When filing comments, please reference WT Docket No. 05–193. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (May 1, 1998). Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must send an original and four (4) copies of each filing. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–B204, Washington, DC 20554.

Filings can be sent by hand or messenger delivery, by electronic media, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings or electronic media for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial and electronic media sent by 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 mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

This proceeding shall be treated as a ''permit but disclose'' proceeding in accordance with the Commission's *ex parte* rules, 47 CFR 1.1200. 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. *See* 47 CFR 1.1206(b). Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules, 47 CFR 1.1206(b).

The full text of the petitions and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554, (202) 418–0270. This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. at their Web site: *http://www.bcpiweb.com* or by calling 1–800–378–3160.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format) send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

Federal Communications Commission.

Catherine Seidel,

Acting Chief, Wireless Telecommunications Bureau.

[FR Doc. 05–13273 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons of the second meeting of the Technological Advisory Council (''Council'') under its charter renewed as of November 19, 2004.

DATES: July 28, 2005 at 10 a.m. to 3 p.m.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Commission Meeting Room (TW–C305), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jeffery Goldthorp, (202) 418–1096 (voice), (202) 418–2989 (TTY), or email: *Jeffery.Goldthorp@fcc.gov.*

SUPPLEMENTARY INFORMATION: Increasing innovation and rapid advances in technology have accelerated changes in the ways that telecommunications services are provided to, and accessed by, users of communications services. The Federal Communications Commission must remain abreast of new developments in technologies and related communications to fulfill its responsibilities under the Communications Act. At this second meeting under the Council's new charter, the Council will consider various topics related to advanced wireless technologies.

The Federal Communications Commission will attempt to accommodate as many persons as possible. Admittance, however, will be limited to the seating available. Unless so requested by the Council's Chair, there will be no public oral participation, but the public may submit written comments to Jeffery Goldthorp, the Federal Communications Commission's Designated Federal Officer for the Technological Advisory Council, before the meeting. Mr. Goldthorp's e-mail address is *Jeffery.Goldthorp@fcc.gov.* Mail delivery address is: Federal Communications Commission, 445 12th Street, SW., Room 7–A325, Washington, DC 20554.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–13031 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[WT Docket No. 05–194; DA 05–1389]

Petition for Declaratory Ruling Filed by CTIA

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document seeks comment on a petition for expedited declaratory rulemaking filed by the Cellular Telecommunications & Internet Association, seeking a declaratory ruling that early termination fees in wireless carriers' service contracts are ''rates charged'' for CMRS within the meaning of the Communications Act.

DATES: Submit comment on or before August 5, 2005, and reply comment on or before August 25, 2005.

ADDRESSES: You may submit comments, identified by WT Docket No. 05–194, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Federal Communications Commission's Web Site: *http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christina Clearwater, Spectrum & Competition Policy Division, Wireless Telecommunications Bureau, Federal Communications Commission, 202–418–1893.

SUPPLEMENTARY INFORMATION:

Background

On March 15, 2005, the Cellular Telecommunications & Internet Association (CTIA) filed a Petition for Expedited Declaratory Ruling (CTIA Petition), seeking a declaratory ruling by the Commission that early termination fees in wireless carriers' service contracts are ''rates charged'' for CMRS within the meaning of section 332(c)(3)(A) of the Communications Act and Commission precedent. *See* Petition of the Cellular Telecommunications & Internet Association for an Expedited Declaratory Ruling, WT Docket No. 194, filed March 15, 2005.

CTIA also seeks a declaration from the Commission that any application of state law by a court or other tribunal to invalidate, modify, or condition the use or enforcement of early termination fees based, in whole or in part, upon an assessment of reasonableness, fairness, or cost-basis of the early termination fee, or to prohibit the use of early termination fees as unlawful liquidated damages or penalties, constitutes prohibited rate regulation preempted by section 332(c)(3)(A) of the Communications Act. The CTIA Petition raises important issues, and in the Public Notice, the Wireless Telecommunications Bureau seeks comment on the Petition. The Wireless Telecommunications Bureau notes that it is contemporaneously releasing a separate public notice seeking comment on earlier-filed petitions for declaratory ruling that raise preemption-related issues regarding early termination fees. *See Wireless Telecommunications Bureau Seeks Comment on Petition for Declaratory Ruling Filed by Suncom, and Opposition and Cross-Petition for Declaratory Ruling Filed by Debra Edwards, Seeking Determination of Whether State Law Claims Regarding Early Termination Fees Are Subject to Preemption Under 47 U.S.C. Section 332(c)(3)(A),* Public Notice, WT Docket No. 05–193, DA 05–1390 (rel. May 18, 2005).

Electronic Access and Filing

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments in this proceeding on or before August 5, 2005, and reply comments may be filed on or before August 25, 2005. When filing comments, please reference WT Docket No. 05–194. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (May 1, 1998). Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*. Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or

rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must send an original and four (4) copies of each filing. All filings must be addressed to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–B204, Washington, DC 20554.

Filings can be sent by hand or messenger delivery, by electronic media, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings or electronic media for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial and electronic media sent by 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 mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules, 47 CFR 1.1200. 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. See 47 CFR 1.1206(b). Other rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules, 47 CFR 1.1206(b).

The full text of the petition and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554, (202) 418–0270. This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. at their Web site: *http://www.bcpiweb.com* or by calling 1–800–378–3160.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format) send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

Federal Communications Commission.

Catherine Seidel,

Acting Chief, Wireless Telecommunications Bureau.

[FR Doc. 05–13272 Filed 7–5–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 05–04]

Marco Mendoza and Cynthia Mendoza, DBA C&M Precision Instrument v. Georgio Gori USA, Inc., and Phillip Zelinka; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (''Commission'') by Marco Mendoza and Cynthia Mendoza, dba C&M Precision Instrument (''Complainants'') against Georgio Gori USA, Inc., and Phillip Zelinka (''Respondents''). Complainants contend that Respondents violated section 10 of the Shipping Act of 1984, 46 U.S.C. app. 1709. Complainants claim that Respondents' conduct amounts to the use of unjust means to obtain ocean transportation at less then the rates or charges that would otherwise be applicable. Complainants seeks an order commanding Respondents to pay reparations in the amount of $60,741.00 with interest and attorney's fees or such other sum as the Commission may deem proper and such other order or orders as the Commission determines to be proper.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by June 28, 2006 and the final decision of the Commission shall be issued by October 26, 2006.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 05–13254 Filed 7–5–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel—Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel—Operating Common Carrier Ocean Transportation Intermediary Applicants:

Anand J. Narain, 10122 Towhee Avenue, Adelphi, MD 20783, Sole Proprietor.

A.M.X. Logistics, Inc., 145–32 157th Street, Jamaica, NY 11434. Officer: Saleem Akhtar, President, (Qualifying Individual).

Bral Marine Service Inc., 7766 NW. 46 Street, Miami, FL 33166. Officers: Amalia Soraya Freire, General Manager, (Qualifying Individual), Alvaro Cruz, President.

Cargo Express Del Caribe, Inc., 1133 Morris Avenue, Bronx, NY 10456. Officer: Fernando Oviedo, President, (Qualifying Individual).

EZ Logistics, Inc., 2416 S. Sandpiper Pl., Ontario, CA 91761. Officers: Kitty X. Lantz, Secretary, (Qualifying Individual), Zhaogang Zhong, CFO.

Global Cargo Connection, 1815 W.

205th Street, #302, Torrance, CA 90501. Officer: Steve Lee, President, (Qualifying Individual).

Reyes Envios, 1170 SW. 6 Street, Miami, FL 33130, Sole Proprietor.

Transport Logistic International Corp., 7345 NW. 79 Terrace, Medley, FL 33166. Officers: Juan Carlos Avendano, President, (Qualifying Individual), Jennifer Granada, Director.

Worldwide Sea & Air Shipping Co. LLC, 815 South Country Glen Way, Anaheim, CA 92808. Officers: Mahbooba Sarah Omar, President, (Qualifying Individual), Haroon Surkhabi, Treasurer.

Non-Vessel—Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants:

Intersea Transport, Inc., 331 Winding Canyon Way, Algonquin, IL 60102. Officers: Byung H. Yoo, Director, (Qualifying Individual), Margarita Chung, President.

World International Cargo Transfer USA, Inc., 15832 S. Broadway Avenue, Ste. D, Gardena, CA 90248. Officer: Augusto G. Santos, President, (Qualifying Individual).

A&A Contract Customs Brokers USA, Inc., dba A&A International Freight Forwarding, #2—12th Street, Blaine, WA 98230. Officers: Edward M. Jones, Vice President, (Qualifying Individual), Graham S. Robins, President.

A.M.C. Shipping, 79 Edna Avenue, Bridgeport, CT 06610, Winston Dawson, Sole Proprietor.

NVO Container Line Inc., dba Global Logistics USA, 2350 Hylan Blvd., Staten Island, NY 10367. Officer: Kenney W. Whitman, President, (Qualifying Individual).

Unique Logistics International Inc., 801 Hanover Street, Suite 500, Grapevine, TX 76051. Officer: James Chou, President, (Qualifying Individual).

Hemisphere Cargo Corp. dba H. Cargo Lines, dba H. Cargo Logistics, 10850 NW. 21 Street, Suite 100, Miami, FL 33172. Officer: Carlos Felipe Proano, President, (Qualifying Individual).

A.P.R. Inc. dba Expresito Carga, 102–49 Corona Avenue, Corona, NY 11368. Officers: Alfredo Padilla, President, (Qualifying Individual), Marcela Cadena, Secretary.

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants:

Incline International Relocation, Inc., 8700 Barrister Way, Charlotte, NC 28216. Officers: Jennifer L. Hindmarch, President, (Qualifying Individual), Brian E. Hindmarch, Vice President.

Jamaica Shipping Co., 33 Edgemere Road, Livingston, NJ 07039, Donald Chin, Sole Proprietor.

Overseas Shipping, Inc., 7021 Grand National Drive, Suite 110, Orlando, FL 32819. Officers: Saleh M. Aboul, President, (Qualifying Individual), Firas Abdul, Secretary.

Dated: June 30, 2005.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 05–13257 Filed 7–5–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to sections 14 and 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License Number: 012361N.

Name: North American Van Lines, Inc.

Address: 5001 U.S. Highway 30 West, PO Box 988, Ft. Wayne, IN 46818.

Order Published: FR: 06/08/05 (Volume 70, No. 109, Pg. 33493).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 05–13256 Filed 7–5–05; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than July 21, 2005.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:

1. Putnam, LLC, Boston, Massachusetts; to acquire voting shares of Commerce Bancorp, Inc., Cherry Hill, New Jersey.

Board of Governors of the Federal Reserve System, June 29, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–13212 Filed 7–5–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 30, 2005.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice

President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Associated Banc–Corp, Green Bay, Wisconsin; to merge with State Financial Services Corporation, Milwaukee, Wisconsin, and thereby indirectly acquire State Financial Bank, National Association, Hales Corners, Wisconsin.

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. First Centralia Bancshares, Inc., Centralia, Kansas; to acquire voting shares of Century Capital Financial, Inc., Kilgore, Texas, and thereby indirectly acquire voting shares of Century Capital Financial–Delaware, Inc., Wilmington, Delaware, and City National Bank, Kilgore, Texas.

2. Morrill Bancshares, Inc., Merriam, Kansas; to acquire directly and indirectly a majority of the voting shares of Century Capital Financial, Inc., Kilgore, Texas, and thereby indirectly acquire voting shares of Century Capital Financial–Delaware, Inc., Wilmington, Delaware, and City National Bank, Kilgore, Texas.

3. Davis Bancorporation, Inc., Davis, Oklahoma; to acquire voting shares of Century Capital Financial, Inc., Kilgore, Texas, and thereby indirectly acquire voting shares of Century Capital Financial–Delaware, Inc., Wilmington, Delaware, and City National Bank, Kilgore, Texas.

C. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. First Banks, Inc., Hazelwood, Missouri; and its subsidiary bank holding company, The San Francisco Company, San Francisco, California; to acquire 100 percent of International Bank of California, Los Angeles, California.

D. Federal Reserve Bank of San Francisco (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. Beverly Hills Bancorp, Inc., WFC Inc., and Wilshire Acquisitions Corporation, all of Calabasas, California; to become bank holding companies by acquiring 100 percent of First Bank of Beverly Hills, Calabasas, California.

In connection with this application, Beverly Hills Bancorp, Inc., and WFC, Inc., have also applied to acquire Wilshire Acquisitions Trust 1, and thereby indirectly acquire WCICC, Inc., WFICC, Inc., Wilshire Mortgage Funding IV, Wilshire Mortgage Funding V, and Wilshire Mortgage Funding VI, all of Calabasas, California, and thereby engage in extending credit and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, June 29, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–13210 Filed 7–5–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 21, 2005.

A. Federal Reserve Bank of New York (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045-0001:

1. Fubon Financial Holding Co., Ltd., Taipei, Taiwan; to acquire Fubon Securities USA LLC, Pasadena, California, and thereby indirectly acquire Fubon Asset Management USA, LLC, Arcadia, California, and engage in limited securities activities, pursuant to sections 225.28(b)(6), (b)(7)(i), (b)(7)(ii), (b)(7)(iii), (b)(7)(v), and (b)(8)(i) of Regulation Y.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. German American Bancorp, Jasper, Indiana; to engage *de novo* through its subsidiary, German American Reinsurance Company, Ltd., Phoenix, Arizona, in reinsuring credit life and credit disability insurance, pursuant to section 225.28(b)(11)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, June 29, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.05–13211 Filed 7–5–05; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Office of Governmentwide Policy; Cancellation of an Optional Form by the Department of State

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The Department of State is cancelling the following Optional Form because of low usage: OF 261, Travel Advance Application Voucher and Account.

DATES: Effective July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Cunningham, Department of State, 202.647.0596.

Dated: June 27, 2005.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 05–13289 Filed 7–5–05; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Application To Develop Steps to Healthier Girls Program

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

Funding Opportunity Title: Steps to Healthier Girls Program.

Announcement Type: Sole source cooperative agreement notice.

Catalog of Federal Domestic Assistance: The Catalog of Federal Domestic Assistance number is 93.290.

Authority: 42 U.S.C. 300u–2(a)(1), 300u–6(e).

DATES: To receive consideration, the application must be received by the

Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS), no later than August 5, 2005. Mailed application will be considered as meeting the deadline if it is received by the Office of Grants Management, OPHS, DHHS no later than 5 p.m. e.d.t. on the application due date. The application due date requirement specified in this announcement supersedes the instructions in the OPHS–1.

SUMMARY: The Office on Women's Health (OWH) is the focal point for women's and girls' health within the OPHS, DHHS. Under the direction of the Deputy Assistant Secretary for Women's Health, OWH works to improve the health of women across the life cycles and increase awareness and understanding of women's health issues. In addition to its central office, OWH has regional offices located throughout the U.S. staffed by a Regional Women's Health Coordinator (RWHC).

Chartered by the U.S. Congress in 1950, Girl Scouts of the USA (GSUSA) is a national nonprofit organization dedicated to helping all girls build character and gain skills for success in the real world in an accepting and nurturing environment. GSUSA operates from its national headquarters in New York City along with its 300 local Girl Scout councils or offices, 236,000 troops/groups, and 986,000 adult volunteers.

OWH in collaboration with GSUSA is planning to provide grant support for a Steps to Healthier Girls Program. The purpose is to improve the health of diverse girls ages 11 years to 17 years through educational and experiential activities related to physical activity/fitness, good nutrition and healthy lifestyles consistent with the Steps to a HealthierUS initiative of the DHHS and the Memorandum of Understanding between DHHS and GSUSA. This project is based on the premise that motivating girls and adolescents to learn about and participate in activities that address these three subject areas can have a significant effect on increasing the quality and years of healthy life and on eliminating health disparities.

The Steps to Healthier Girls Program will be a collaborative effort among the Regional Women's Health Coordinators (RWHC), GSUSA, and the selected Girl Scout Councils in each of the eight (8) Regions of the DHHS, OPHS, OWH.

The Women's Health Coordinators from two Regions (II and III) will provide overall oversight for the grant, and Region III will be the primary contact, while the RWHC's will provide the technical assistance and local oversight of the project at the regional level.

The Federal Government will:

a. Conduct an orientation meeting for the grantee within the first month of funding.

b. Review and resolve requested project modifications.

c. Review the design of the Steps to Healthier Girls programs.

d. Make site visits to Steps to Healthier Girls program sites.

e. Review and resolve all initial, 3 month after award and final progress reports.

f. Participate in meetings with grantee and councils.

I. Funding Opportunity Description

This notice announces a sole source cooperative agreement award that is expected to be made, subject to conditions set forth below, to the GSUSA for a joint project to be known as ''Steps to Healthier Girls.''

The primary purpose of Steps to Healthier Girls is to educate, motivate, and empower 75–100 diverse girls, ages 11–17, in each of eight (8) targeted communities (one in each of 8 participating regions of the DHHS, OWH) to engage in activities that promote good health in the areas of physical activity/fitness, good nutrition, and healthy lifestyles.

Objectives

The DHHS is committed to achieving health promotion and disease prevention through its Healthy People 2010 Objectives and the Steps to a HealthierUS Initiative. Steps to Healthier Girls program activities and evaluations are to be aligned with both of these programs.

More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: *http://www.health.gov/healthypeople.* Another reference is Healthy People 2000: Final Review. One free copy may be obtained from the National Center for Health Statistics (NCHS), 6525 Belcrest Road, Room 1064, Hyattsville, MD 20782 or telephone (301) 458–4636 [DHHS Publication No. (PHS) 99–1256]. This document may also be downloaded from the NCHS Web site: *http://www.cdc.gov/nchs.*

Steps to a HealthierUS is a DHHS initiative that advances the President's goal of helping Americans live longer, better, and healthier lives. It lays out DHHS priorities and programs for Steps to a HealthierUS, focusing attention on promising approaches for promoting health and preventing disease. Additional information can be found on the Steps to a Healthier U.S. Web site: *http://www.healthierus.gov/steps.*

The President's Council on Physical Fitness and Sports Web site includes the President's Challenge to track physical activity/fitness. This free interactive Web site tool will be used to assess the girls' levels of physical activity/fitness and will assist with the evaluation of the Steps to Healthier Girls program. The Web site is: *http://www.presidentschallenge.org.*

The objectives of the Steps to Healthier Girls Program are to:

Increase the number of girls who engage regularly in moderate physical activity, preferably daily, for at least 60 minutes per day.

Increase girls' knowledge of healthy nutrition and healthy weight and promote strategies for accomplishing these.

Increase girls' knowledge about the ill health effects of tobacco and promote strategies for accomplishing these.

Increase girls' knowledge of the importance of a healthy environment and strategies to accomplish this.

The proposed program in each region must address girls' health from a gender-based, girl-centered, cultural and community-based perspective. Information provided must be culturally, linguistically, and age-appropriate for the program participants. The information for girls and their parents and guardians must be developed in accordance with health literacy principles. This includes assessing the capacity of the girls and adults to obtain, process, understand and apply the information and designing information that matches their capacities. It also includes evaluating the impact of enhancing their understanding and decision-making. In addition, in Region VI, the program must also address heart health and must engage the participating girls' mothers and encourage multigenerational physical activity.

The DHHS OWH is planning to award grant funds to GSUSA to carry out the following activities: (1) Identify and justify the selection of eight (8) programs to be implemented and evaluated through the GSUSA councils; one program shall be implemented in each of the following eight Regions of the OWH: Regions II, III, IV, V, VI, VII, VIII & X; (2) provide a stipend of up to $6,000.00 to each of the 8 selected GSUSA councils to implement and evaluate the program; and (3) facilitate collaboration between GSUSA councils and the corresponding DHHS Regional OWH in the implementation and evaluation of each program.

Program Parameters. Each GSUSA council will plan a special event to launch the Steps to Healthier Girls program in their community. The Steps to Healthier Girls community program may consist of a health expo, a health walk, a health symposium, or related activity addressing physical activity/fitness, nutrition, and healthy lifestyles by and for girls. All participants will be diverse Girl Scouts ages 11–17. This will be followed by a commitment by the Girl Scouts to engage in some physical activity/fitness daily over a period of 6 weeks, which they will track on an activity log. The activity log can be obtained from the President's Council on Physical Fitness and Sports under the existing President's Challenge program under ''Kids'' or ''Teens'' depending on the girls' ages. The log can be downloaded from the Web site: *http://www.presidentschallenge.org*. In addition, each GSUSA council will establish a baseline for the participating girls based on their pre-program activity/fitness level and understanding of and capacity to act on information about nutrition, tobacco, and environmental factors that promote healthy lifestyles. At the conclusion of the six weeks, the participating girls will be evaluated for understanding gained in the three areas of physical activity/fitness, nutrition, and healthy lifestyles as well as for an increase in physical activity/fitness by evaluating the logs and changes in healthy eating habits to include more fruit, vegetables, calcium and decrease in consumption of sugar. Each GSUSA council will prepare a final report on the activity carried out in each community. Upon satisfactory participation and completion of the Steps to Healthier Girls program, each of the girls will earn a Girl Scouts badge or award.

The GSUSA and selected Girl Scout Councils in collaboration with the eight DHHS Regional Women's Health Offices must: (1) Identify the date and place for a kick-off event that highlights the three targeted health subject areas for a minimum of 75 diverse girls ages 11 to 17 years; (2) put into place and track follow up activities that address the three targeted health areas for 6 weeks; (3) At the end of the 6 weeks collect the forms from the girls who have completed the program (4) the forms from each of the eight GSUSA councils will be provided to their National Office GSUSA in New York City, NY, which will then provide these forms to the primary project officer for evaluation of the program.

The GSUSA and selected Girl Scout Councils should use health literacy principles to design gender-based, culturally appropriate, and science-based literature on each health topic. The health literacy literature and principles can be found in the Institute of Medicine report, ''Health Literacy: a Prescription to End Confusion'' (2004). Other materials can be found in the National Women's Health Information Center (NWHIC) Toll-Free Information Line (1–800–994–WOMAN) and NWHIC's Web site at *http://www.4woman.gov* and the *http://www.4girls.gov* Web site, and The President's Council on Physical Fitness and Sports *http://www.fitness.gov* and *http://www.presidentschallenge.org*.

II. Award Information

Under this announcement, the Office on Women's Health Regions (OWHR) anticipates making, through the cooperative agreement grant mechanism, to the GSUSA, a one (1) year award in the amount of $60,000 for a 12-month budget period to support a jointly sponsored Steps to Healthier Girls project. The anticipated grant award project period under the proposed cooperative agreement is expected to be from September 1, 2005 through August 30, 2006.

Criteria for Selection

Basis for Sole Source Restriction on the Planned Cooperative Agreement: The Office of Grants Management, OPHS, has determined in accordance with AGAM 2.04 104A 1.e.(2) that this project is an outgrowth of a current ongoing collaboration between the OWH and GSUSA that is part of the Department's Steps to HealthierUS. In addition, responsible government officials have determined that the GSUSA:

(a) Is a well-established, trusted, national organization that serves diverse 11 to 17 year old girls.

(b) Has demonstrated evidence of commitment to girls' health.

(c) Has shown interest in the health promotion topics identified as priority subject areas under its MOU with DHHS which was the basis for an ongoing collaborative relationship and this particular project with OWH.

(d) Is able/willing to assist the local councils and the RWHCs in the design of the program.

(e) Is able/willing to implement the program designed by the RWHCs and the councils.

(f) Is able to support the evaluation process.

(g) Has the organizational potential in terms of an ongoing structure and resources to sustain and expand health promotion program activities for diverse girls 11 to 17 years of age.

Whether or not an award is actually made will depend on the application addressing the program components described in section I. Funding Opportunity Description and the amount of funds available for the Steps to Healthier Girls program (*see* Section IV.2 ''Application for Submission Information''). The government will not be obligated to make any awards as a result of this announcement.

III. Eligibility Information

Eligible Applicants. The GSUSA is the eligible applicant for the Steps to Healthier Girls program.

Cost Sharing or Matching Funds. Cost sharing, matching funds, and cost participation is not a requirement of this grant.

IV. Application and Submission Information

1. *Address to Request Application Package:* The application kit may be requested by calling (240) 453–8822 or writing to Ms. Karen Campbell, Director, Office of Grants Management, OPHS, DHHS, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852.

2. *Content of and Form of Application Submission:* The applicant must use Grant Application OPHS–1. Forms to be completed include the Face Page/Cover Page (SF424), Checklist, and Budget Information Forms for Non-Construction Programs (SF424A). The applicant is required to submit an original ink-signed and dated application and 2 photocopies. All pages must be numbered clearly and sequentially beginning with the Project Profile. The application must be typed double-spaced on one side of plain 8½″ x 11″ white paper, using at least a 12 point font, and contain 1″ margins all around. In addition to the application forms, applicants must provide the following:

The application shall consist of the Technical Proposal, which includes the Project Narrative and Budget Narrative, Appendices, and all required forms in the Application Package.

Project Narrative: The Project Narrative for this Steps to Healthier Girls announcement must: (a) Address the Application Review Factors (section V) listed in this announcement; (b) present a comprehensive Project Plan to develop Steps to Healthier Girls in all eight DHHS regions over a one-year period, including identification of project staff and a detailed time line for executing the Steps to Healthier Girls over the one year period; (c) reflect an understanding of the public health objectives and issues addressed in the Steps to Healthier Girls Project; and (d) include a Project Evaluation plan using

the activity tracking forms from the Girl Scout Councils in each of the eight participating DHHS Regional Offices on Women's Health.

The application narrative will include assurances signed by a GSUSA representative authorized to bind the organization that GSUSA will:

a. Work with the RWHC in each region to identify a group of girls for the implementation of the program in each of the eight (8) DHHS regions.

b. Ascertain that the councils provide a timeline and plan to conduct the kick-off event, which will focus on the three areas of physical activity/fitness, good nutrition, and healthy lifestyles.

c. Ascertain that the councils provide a plan and timeline showing the educational sessions and tracking of the girls' activities during the 6 week period following the kick-off event.

d. Submit the required initial, 3-month after the award, and final reports by the due dates stated in this announcement and the Notice of Grant Award.

The Project Narrative must not exceed a total of 25 double-spaced pages, excluding the appendices. The original and each copy must be stapled and/or otherwise securely bound. The applicant must pay particular attention to structuring the narrative to respond clearly and fully to each review factor and associated criteria. If the application does not adhere to these guidelines, it may not be reviewed.

Appendices

A. Memorandums of Agreement/Understanding/Partnership Letters.

B. Required Forms (Assurance of Compliance Form, etc.).

C. Key Staff Resumes.

D. Organizational Chart reflecting Girl Scouts of the U.S.A. Headquarters and Councils.

E. Other attachments (per #6 below ''Other Application Requirements'').

3. *Submission Date and Times: Application Submission:* The application should be submitted to: Ms. Karen Campbell, Director, Office of Grants Management, OPHS, DHHS, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852.

Application Submission Date and Time: To be considered for review, the application must be received by the Office of Grants Management, OPHS, DHHS, by 5 p.m. e.d.t. on August 5, 2005. The application will be considered as meeting the deadline if it is received on or before the deadline date. The application due date requirement in this announcement supersedes the instructions in the OPHS–1.

Electronic submission through the Grants.gov Web site Portal provides for the application to be submitted electronically. Information about the system is available on the Grants.gov Web site, *http://www.grants.gov*. The application submitted by facsimile transmission (FAX) or any other electronic format are ineligible for review and will not be accepted. The application that does not meet the deadline will be considered ineligible and will be returned to the applicant unread.

4. *Intergovernmental Review:* This cooperative agreement is not a grant for health services nor will it impact public health systems. Therefore, no Public Health System Impact Statement (PHSIS) is required, and Executive Order 12372 does not apply.

5. *Funding Restrictions:* The application shall include a Project Budget as part of the Technical Proposal. Out of a budget of up to $60,000.00, up to $48,000.00 may be designated for use by the Girl Scout Councils to implement the regional programs at the local level. The amount requested for the Councils is to be divided equally for a total of up to $6,000.00 for each of the eight selected. Not more than 10% (or up to $6,000.00) of the funds may be budgeted for administrative overhead, such as office supplies, mailing, and personnel to carry out these functions. The remaining part of the budget, up to $6,000.00, are to be used to create a report by an independent source that aggregates and summarizes the reports received from each of the Councils in the eight (8) DHHS Regions and identifies program outcomes. All budget requests must be justified fully in terms of the proposed Steps to Healthier Girls' program goals and objectives and include an itemized computational explanation/breakout of how costs were determined. Funds may not be used for construction, building alterations, equipment purchase, medical treatment, renovations, or to purchase food.

6. *Other Application Requirements:* Data Universal Numbering System (DUNS) number: Beginning October 1, 2003, all applicants are required to obtain a Data Universal Numbering System (DUNS) number as preparation for doing business electronically with the Federal Government. The DUNS number must be obtained prior to applying for Office on Women's Health funds. The DUNS number is a nine-character identification code provided by the commercial company Dun & Bradstreet, and serves as a unique identifier of business entities. There is no charge for requesting a DUNS number, and you may register and obtain a DUNS number by either of the following methods:

Telephone: 1–866–705–5711.

Web site: *https://www.dnb.com/product/eupdate/requestOptions.html.*

Be sure to click on the link that reads, ''DUNS Number Only'' at the right hand, bottom corner of the screen to access the free registration page. Please note that registration via the Web site may take up to 30 business days to complete.

V. Application Review Information

Review Criteria: The technical review of the application will consider the following factors:

A. Technical Proposal (45 Points)

The completeness, practicality, and feasibility of the applicant's approach/methodology in terms of its ability to address the specific requirements of the announcement, as well as evidence of creativity and innovation. Consideration shall be given for clarity, style, and format of the application. Soundness of evaluation objectives for measuring program effectiveness and changes in health outcomes.

B. Understanding Public Health Issues (30 Points)

Awareness and understanding of the complex issues in the area of girls' health relevant to disease prevention and health promotion; cultural, economic, and health literacy obstacles to achieving health goals; as well as demonstrated understanding of health literacy issues for target populations and the impact on program design and outcomes.

Familiarity with Healthy People 2010, the Nation's Health Promotion and Disease Prevention Objectives and the 10 Leading Health Indicators; and with Steps to a Healthier U.S. program.

Demonstrated understanding of the target populations.

C. Personnel Capability and Experience (10 Points)

Relatedness of the educational background and relevant work experience of proposed staff to their designated responsibility on the project and with the target population.

D. Offeror's Past Experience (10 Points)

Previous experience of this organization in managing similar or related contracts or grants comparable in technical complexity.

E. Facilities (05 Points)

Availability of, or access to, facilities and compatible equipment (including

appropriate computer hardware and software capabilities) to be used specifically for the proposed effort.

The application will be screened upon receipt. If judged to be incomplete or arrive after the deadline, it will be returned without review or comment. If the application exceeds the requested amount of $60,000.00 for a twelve-month budget period, it may also be returned without review or comment. If the applicant is judged to be in compliance, it will be notified by the Office of Grants Management. The accepted application will be reviewed for technical merit in accordance with DHHS policies. The application will be evaluated by a technical review panel composed of experts in the fields of program management, community service delivery, community outreach, health education, community-based research, and community leadership development and evaluation. Consideration for award will be given to the applicant demonstrating plans for the development of a sustainable, results-oriented, girl-centered program. The applicant is advised to pay close attention to the specific program guidelines and general instructions in the application kit that may be obtained from Ms. Karen Campbell, Office of Grants Management, OPHS, DHHS, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852 and to the definitions provided in this notice.

VI. Award Administration Information

1. *Award Notices:* Within two weeks of the review of the application, GSUSA will receive a letter stating whether they are likely to be or have not been approved for funding. The letter is not an authorization to begin performance of grant activities. The applicant selected for funding support will receive a Notice of Grant Award signed by the grants officer. This is the authorizing document and it will be sent electronically and followed up with a mailed copy. Pre-award costs are not supported.

2. *Administrative and National Policy Requirements:* (1) Requests that require prior approval from the awarding office (See Chapter 8, PHS Grants Policy Statement) must be submitted in writing to the GMO. Only responses signed by the GMO are to be considered valid. Grantees who take action on the basis of responses from other officials do so at their own risk. Such responses will not be considered binding by or upon the OWH. (2) Responses to reporting requirements, conditions, and requests for post-award amendments must be mailed to the attention and address of the Grants Management Specialist indicated below in ''Contacts.'' All correspondence requires the signature of an authorized business official and/or the project director. Failure to follow this guidance will result in a delay in responding to your correspondence. (3) The DHHS Appropriations Act requires that, to the greatest extent practicable, all products purchased with funds made available under this award should be American-made. (4) The DHHS Appropriations Act requires that, when issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, the issuance shall clearly state the percentage and dollar amount of the total costs of the program or project that will be financed with Federal money and the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources. (5) A notice in response to the President's Welfare-to-Work Initiative was published in the **Federal Register** on May 16, 1997. This initiative is designed to facilitate and encourage grantees to hire welfare recipients and to provide additional training and/or mentoring as needed. The text of the notice is available electronically on the OMB home page at *http://www.whitehouse.gov/wh/eop/omb.*

3. *Reporting:* In addition to those listed above, a successful applicant will submit 3 reports: an initial, a three-month after the award, and one final report that includes a discussion of steps taken to implement the Steps to Healthier Girls program in each Region, the impact of the program on the targeted girls, an initial Financial Status Report, a final Program Report, and a final Financial Status Report. The purpose of the initial and three month reports is to provide accurate and timely program information to program managers and to respond to Congressional, Departmental, and public requests for information about the Steps to Healthier Girls program. An original and two copies of the initial and three month progress report must be submitted by November 1, 2005, and December 1, 2005 (assuming a September 1, 2005 start date). The last final report will serve as the annual progress report and must describe all project activities for the entire year.

VII. Agency Contact(s)

For application kits and information on budget and business aspects of the application, please contact: the Office of Grants Management, OPHS, DHHS, 1101 Wootton Parkway, Suite 550, Rockville, MD 20857. Telephone: (240) 453–8822. Questions regarding programmatic information and/or requests for technical assistance in the preparation of the grant application should be directed in writing to CAPT Rosa Myers, Regional Women's Health Coordinator, DHHS Region III, at 150 S. Independence Mall West, Suite 436, Philadelphia, PA 19106, e-mail: *rmyers@osophs.dhhs.gov* or to Sandra Estepa, Regional Women's Health Coordinator, HHS Region II at 26 Federal Plaza, Room 3835, New York, NY 10278, e-mail: *sestepa@osophs.dhhs.gov.*

VII. Other Information

Information on girls' wellness can be found at the *http://www.4girls.gov* Web site. Information on health can also be found on the *http://www.healthfinder.gov* Web site.

**The Government is not obligated to make any awards as a result of this announcement.

Definitions

For the purposes of this cooperative agreement program, the following definitions are provided:

Culturally competent: Information and services provided at the educational level and in the language and cultural context that are most appropriate for the individuals for whom the information and services are intended. Additional information on cultural competency is available at the following Web site: *http://www.aoa.dhhs.gov/May2001/factsheets/Cultural-Competency.html.*

Cultural perspective: Recognizes that culture, language, and country of origin have an important and significant impact on the health perceptions and health behaviors that produce a variety of health outcomes.

Gender-based Care: Highlights inequalities between men and women in access to resources to promote and protect health, in responses from the health sector, and in the ability to exercise the right to quality health care.

Healthy People 2010: A set of national health objectives that outlines the prevention agenda for the Nation. Healthy People 2010 identifies the most significant preventable threats to health and establishes national goals for the first decade of the 21st century. Individuals, groups, and organizations are encouraged to integrate Healthy People 2010 into current programs, special events, publications, and meetings. Businesses can use the framework, for example, to guide worksite health promotion activities as well as community-based initiatives. Schools, colleges, and civic and faith-based organizations can undertake

activities to further the health of all members of their community. Health care providers can encourage their patients to pursue healthier lifestyles and to participate in community-based programs. By selecting from among the national objectives, individuals and organizations can build an agenda for community health improvement and can monitor results over time. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: *http://www.health.gov/healthypeople.*

Sustainability: An organization's or program's staying power: the capacity to maintain both the financial resources and the partnerships/linkages needed to provide the services.

Steps to HealthierUS: An initiative of the U. S. Department of Health and Human Services that advances the President's HealthierUS goal for helping Americans live longer, better, and healthier lives. The cornerstones of this program are physical fitness, prevention, nutrition, and making healthy choices. More can be found on the Web site: *http://www.healthierus.gov.*

Health Literacy: Degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions. In addition to the IOM report, information on health literacy can be found at: *http://odphp.osophs.dhhs.gov/projects/healthcomm/objective2.htm.*

Dated: June 23, 2005.

Dalton G. Paxman,

Regional Health Administrator, Region III, Philadelphia, PA.

[FR Doc. 05–13190 Filed 7–5–05; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Joint Meeting of the National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices

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 (DHHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) will hold a joint meeting. The meeting is open to the public.

DATES: The meeting will be held on July 19, 2005, from 9 a.m. to 4:30 p.m.

ADDRESSES: Department of Health and Human Services, 5635 Fishers Lane, Terrace Level Conference Room, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ms. Emma English, Program Analyst, National Vaccine Program Office, Department of Health and Human Services, Room 443–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; telephone (202) 690–5566, or email *nvac@osophs.dhhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. Section 300aa–1), the Secretary of Health and Human services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Assistant Secretary for Health, as the Director of the National Vaccine Program, on matters related to the program's responsibilities.

The ACIP is charged with advising the Director, Centers for Disease Control and Prevention (CDC), on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. Section 1396s, the ACIP is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

This is a special meeting of the NVAC and the ACIP. Discussions will surround the Department's draft Pandemic Influenza Preparedness and Response Plan. A tentative agenda will be made available on or about July 5, 2005 for review on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac.*

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the building. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to NVAC and ACIP members should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business July 15, 2005. Preregistration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should email *nvac@osophs.dhhs.gov* or call 202–690–5566.

For this special meeting, remote participation will be made available via a toll-free call-in phone number. This call-in number can be obtained from the contact person identified above and will be operator assisted to provide members of the public the opportunity to provide comments to the Committees. Additionally, this meeting will be Web cast at *http://www.videocast.nih.gov.* Online participants will be able to e-mail comments to the Committees. However, Committee members may not have the opportunity to read all written statements submitted on the day of the meeting and prior to any votes that may be taken by the Committees. It is recommended that written statements be provided to the Executive Secretary, NVAC, through the contact person listed above prior to close of business July 15, 2005.

Dated: June 29, 2005.

Bruce Gellin,

Director, National Vaccine Program Office.

[FR Doc. 05–13226 Filed 7–5–05; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–05CG]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Morbidity Monitoring Project (MMP)—New—National Center for HIV, STD and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: This proposed data collection supplements the HIV/AIDS surveillance programs in 26 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS and will incorporate data elements from two data collections: Supplement to HIV/AIDS Surveillance (SHAS) project (0920–0262) and the Adult/Adolescent Spectrum of HIV Disease (ASD). Both projects stopped data collection in 2004.

Although CDC receives surveillance data from all U.S. states, these supplemental surveillance data are needed to make estimates of key indicators, such as quality of HIV-related ambulatory care and the severity of need for HIV-related care and services. A large number of cities and states are heavily impacted by the HIV/AIDS epidemic, resulting in the need for population-based national estimates of HIV-related behaviors, clinical outcomes, and quality of HIV care.

This project will collect data on behaviors and clinical outcomes from a probability sample of HIV-infected adults receiving care in the U.S. Collection of data from interviews with HIV-infected patients will provide information on patient demographics, and the current levels of behaviors that may facilitate HIV transmission: sexual and drug use behaviors; patients' access to, use of and barriers to HIV-related secondary prevention services; utilization of HIV-related medical services; and adherence to drug regimens. Collection of data from patient medical records will provide information on: demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to Public Health Service guidelines. No other Federal agency collects national population-based behavioral and clinical information from HIV-infected adults in care. The data will have significant implications for policy, program development, and resource allocation at the state/local and national levels.

CDC is requesting approval for a 3-year clearance for data collection. Data will be collected by 26 Reporting Areas (19 states, Puerto Rico and 6 separately funded cities). CDC estimates an average of 400 respondents per site, resulting in 10,400 respondents for the interview portion. There will be 2 medical record abstractors per site, resulting in 52 respondents for the medical record abstraction. Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of data collection	Number of sites	Average number of respondents/site	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Persons interviewed	26	400	10,400	1	45/60	7,800
Medical record abstractors	26	2	52	200	1	10,400
Total						18,200

Dated: June 21, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–13244 Filed 7–5–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0425X]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Study—New—National Center for Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, correlates, and causes of autism and related disabilities. Under the

provisions of this act, CDC funded 5 CADDRE centers including the California Department of Health and Human Services, Colorado Department of Public Health and Environment, Johns Hopkins University, the University of Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center for Birth Defect and Developmental Disabilities will participate as the 6th site. The multi-site, collaborative study will be an epidemiological investigation of possible causes for the autism spectrum disorders.

Data collection methods will consist of the following: (1) Medical and educational record review of the child participant; (2) medical record review of the biological mother of the child participant; (3) a packet sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development interview (for case participants only) administered over the telephone or in-person; (6) a developmental and physical exam of the child participant; (7) biological sampling of the child participant (blood and hair); and, (8) biological sampling of the biological parents of the child participant (blood only). OMB clearance is requested for the self administered questionnaires and buccal swab kit, the primary caregiver interview, and the child development interview. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Survey	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Cases:				
—Self administered questionnaires and buccal swab kit	644	1	3.0	1932
—Primary caregiver interview	644	1	40/60	429
—Child development interview	644	1	3.0	1932
Controls:				
—Self administered questionnaires and buccal swab kit	1288	1	3.0	3864
—Primary caregiver interview	1288	1	40/60	859
—Child development interview	1288	1	1.0	1288
Total				10,304

Dated: June 21, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–13245 Filed 7–5–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–05–0010]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (OMB 0920–0010)—Extension—The Division of Birth Defects and Developmental Disabilities (DBDDD), National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serve as an early warning system for new teratogens. From 1993 to 1996, the Division of Birth Defects and Developmental Disabilities (DBDDD) conducted the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects. Infants with birth defects were identified through MACDP and maternal interviews and clinical/laboratory tests were conducted on approximately 300 cases and 100 controls per year. Controls were selected from among normal births in the same population. In 1997 the BDRFS became the National Birth Defects Prevention Study (NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect

surveillance registries in ten states (including metropolitan Atlanta). Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. Parents are asked to collect cheek cells from themselves and their infants for DNA testing. Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of burden	Number of respondents	Frequency of response	Average burden/response (in hours)	Annual burden (in hours)
NBDPS case/control interview	400	1	1	400
Biologic specimen collection	1,200	1	10/60	200
Total				600

Dated: June 21, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–13246 Filed 7–5–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Augmenting Laboratory Outcomes in HIV Assessment (ALOHA)

Announcement Type: Supplemental (04017).

Funding Opportunity Number: AA120.

Catalog of Federal Domestic Assistance Number: 93.944.

Key Dates:

Application Deadline: August 5, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under sections 317(k)(2) and 318b of the Public Health Service Act (42 U.S.C. Sections 247b(k)(2) and 247c), as amended.

Purpose: CD4+ T-lymphocyte (CD4) and viral load (VL) tests are used to stage disease and, when opportunistic infections (OI) are present, to guide therapeutic decisions. Because CD4 and VL testing should be performed throughout the course of HIV disease, reporting of these lab tests has been used as a marker for whether HIV-infected persons are receiving healthcare. Augmenting Laboratory Outcomes in HIV Assessment (ALOHA) will augment routine HIV/AIDS surveillance data collection for the purpose of assessing the completeness and validity of laboratory (*i.e.*, CD4 count and VL) and OI information. This will be accomplished by the following:

1. Assessing the stage of HIV disease at initial diagnosis among a cohort of newly diagnosed HIV-infected persons, over the age of 13, using routine and augmented laboratory and clinical information.
2. Better characterizing CD4 count and VL, and correlating this laboratory information with available data on OIs. If, after complete enumeration of lab and OI information, OIs add little to nothing to help stage HIV disease, then future surveillance practices may be streamlined.
3. Identifying surveillance practices (*e.g.*, laboratory reporting requirements, electronic lab reporting, and program policies or organization) that affect the completeness and accuracy of surveillance laboratory data.
4. Assessing lab reporting as a marker for access and adherence to care following HIV diagnosis.
5. Identifying correlates for not being in care, as indicated by the presence or absence of laboratory reports.
6. Systematically evaluating the availability of clinical and laboratory data on the prevalence of common co-morbid conditions (*e.g.*, hepatitis B, hepatitis C, tuberculosis, and cancer) that are associated with risk factors for HIV infection and influence the clinical course of HIV disease. Data on these conditions will be compared to levels of CD4 and VL to assess the effects of co-morbid conditions on levels of immunosuppression at the time of HIV diagnosis.

A variety of HIV/AIDS reporting areas with different surveillance practices and procedures will be sought for ALOHA. This project will attempt to include an area that currently warehouses lab results, specifically CD4, in a separate lab results database, and does not report this information to the national HIV/AIDS surveillance system. The completeness of reporting for CD4 results will be assessed to determine if these reports truly indicate access to care. This proportion has not been reliably estimated by national surveillance data. Some reporting areas report a high proportion (greater than 75 percent) of newly diagnosed cases with CD4 and/or VL results within 12 months of diagnosis.

The factors that contribute to the ability of lower morbidity areas to report completely has not been fully examined, but may be due to their ability to conduct active case finding and medical record abstraction. These practices may have national surveillance policy implications. Since lab reporting data is critical to the expectations of the Morbidity Monitoring Project (MMP), an area will be sought to provide validation of lab reporting as a marker for receiving health care, and to collect information about reasons for no lab testing and the inability to link a person to care.

Lastly, ALOHA will include at least one area that will match its HIV/AIDS case registry to infectious disease databases to identify, apart from medical record review, OIs that occurred six months before and after HIV diagnosis. Examples of these databases include the National Electronic Disease Surveillance System (NEDSS); cancer, hepatitis or tuberculosis registries; or prescription medication databases (*e.g.*, Medicaid or AIDS Drug Assistance Program).

As part of this project, participating areas will conduct their usual surveillance activities for information on CD4 and VL lab results and OIs. These activities include active case surveillance, medical record review and data extraction for newly diagnosed cases (over the age of 13). When no lab result is received by the HIV/AIDS surveillance program, ongoing active case follow-up will be needed to determine case disposition and record specific categorical information, such as

the source of CD4 and OI results and, alternatively, reasons for no CD4 testing (*e.g.*, lost to follow-up, did not return for HIV test results, etc). Surveillance information will be entered into the national HIV/AIDS surveillance system and uploaded monthly to CDC; ancillary data will be sent to CDC without personal identifiers.

Annual reported cases to CDC will be used as an eligibility criterion. Eligible areas are restricted to those submitting HIV data to CDC because this project is an evaluation of data included in the national HIV/AIDS reporting system, which includes only those surveillance data collected in confidential name-based systems, and because HIV (not AIDS) cases are currently more likely to be missing CD4 information. Because a limited number of sites (approximately five to seven sites) will be funded, racial and ethnic diversity of cases among each of the participating sites will be required to ensure a measure of representation of national data.

This program addresses the ''Health People 2010'' focus area of HIV. Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for HIV, STD, and TB Prevention (NCHSTP): Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions, and evaluate prevention programs.

Activities: Awardee activities for this program are as follows:

1. Accurately linking incoming lab results to all HIV and AIDS cases or an agreed upon sample, over the age of 13, in the local HIV/AIDS registry, and transmitting that information to the national HIV/AIDS surveillance system for the duration of ALOHA.

2. Conducting active surveillance and medical record abstraction, following a protocol developed in collaboration with CDC, of all cases or the agreed upon sampled cases. A minimum of 500 diagnosed HIV/AIDS cases annually, of which 300 cases were initially diagnosed with HIV (not AIDS), will be prospectively followed for a period of time (to be determined through collaborative development of a protocol). This protocol will include the collection of CD4 and VL results, OIs, and ancillary information on data collection forms.

3. Conducting active, ongoing follow-up of cases without any CD4 or VL results following diagnosis. Identifiable reasons for lack of linkage or failure to access health care will be sought from medical records and recorded on project data collection forms. No interview of cases will occur as part of this follow-up.

4. Documenting methods of linking lab results to registry cases, including methods of reconciling possible matches.

5. Participating in a conference call (within one month of the award) with CDC and other awardees to begin to develop a project plan and 16-month timeline.

6. Collaborating with CDC staff members to develop data collection forms for ancillary information about co-morbidities and barriers to reporting lab results, as well as whether samples for CD4/VL testing are drawn at post test counseling, possible reasons for no CD4/VL testing, and the inability to link newly diagnosed persons to care.

7. Meeting with CDC. The area project collaborator will travel to Atlanta for one meeting and participate in monthly conference calls related to planning, coordinating, and conducting this project.

8. Transferring collected data to CDC monthly.

CDC Activities for this program are as follows:

1. Conduct a conference call, within one month of award, to develop a project plan and time line for the collection and reporting of data to CDC.

2. Support and assist training needed to conduct project including monthly conference calls with awardees.

3. Collaborate with awardees to develop strategies for enhancing surveillance activities that address barriers to reporting of opportunistic infections, CD4, and viral load test results.

4. Receive data monthly, assess data quality, and store data in secure environment.

5. Provide quarterly analytic progress reports to participating areas.

6. Analyze data and write reports in collaboration with awardees.

II. Award Information

Type of Award: Cooperative agreement.

Fiscal Year Funds: 2005.

Approximate Total Funding: $500,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: Five to Seven.

Approximate Average Award: $100,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: $75,000.

Ceiling of Award Range: $125,000.

Anticipated Award Date: August 31, 2005.

Budget Period Length: Four months.

Project Period Length: 16 months. Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government.

III. Eligibility Information

III.1. Eligible Applicants

1. Eligible applicants are state or territorial health departments or directly funded city health departments currently engaged in HIV/AIDS surveillance funded through Program Announcement 04017. Eligible applicants must have reported a minimum of 500 HIV and AIDS cases in 2003, of which at least 300 are HIV cases, as reflected in Volume 15 (Tables 14 and 16) of the CDC HIV/AIDS Surveillance Report. Single reporting areas that do not have sufficient cases may form a consortium with an adjoining area or areas so that the combined total number of HIV and AIDS cases is at least 500, of which at least 300 are HIV cases reported in 2003. Areas wishing to collaborate must designate a lead grantee for protocol implementation, data collection, communication, and coordination of financial remuneration.

2. Eligible applicants must be located in areas where persons of color (Asian, Pacific Islanders, Black, American Indian/Alaskan Native, Hispanic and Multiracial) comprise more than 30 percent of new HIV/AIDS cases with known race/ethnicity.

Known eligible areas include: Alabama, Arizona, Colorado, Florida, Houston, Indiana, Louisiana, Michigan, Mississippi, Missouri, New Jersey, New York, New York City, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, and Virginia.

Eligible areas are restricted to those with confidential, name-based HIV (with or without AIDS at the time of diagnosis) reporting (those submitting HIV data to CDC) because this project will augment surveillance data with complete laboratory data and other sources of surveillance data where the use of name is the most accurate method to link HIV surveillance data to supplemental data. Furthermore, to most efficiently use available resources, the standard surveillance software will be used and only those areas with confidential, name-based reporting currently submit both HIV and AIDS data to CDC.

In each area, HIV morbidity must be sufficient to allow for adequate sample sizes therefore, annual reported cases to CDC will be used as a criterion for eligibility. The sizes of the samples must be large enough to be able to detect HIV opportunistic infections which are uncommon.

Eligible applicants must have reported to the CDC HIV/AIDS reporting system a minimum of 500 HIV and AIDS cases in 2003, of which at least 300 are HIV cases, as reflected in Volume 15 (Tables 14 and 16) of the CDC HIV/AIDS Surveillance Report. Single reporting areas that do not have sufficient cases may form a consortium with an adjoining area or areas so that the combined total number of HIV and AIDS cases is at least 500, of which at least 300 are HIV cases reported in 2003.

Eligible applicants are areas where persons of color (Asian, Pacific Islanders, Black, American Indian/Alaskan Native, Hispanic and Multiracial) comprise ≥30% of new HIV/AIDS cases with known race/ethnicity. Because a limited number of sites will be funded, racial and ethnic diversity of cases among each of the participating sites will be required to ensure a measure of representation of national data.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

CDC will accept and review applications with budgets greater than the ceiling of the award range.

Special Requirements: If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified the application did not meet submission requirements.

- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- **NOTE:** Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

The following are general considerations that will affect decisions on funding levels. At least one unique reporting area for each of the following categories should be funded:

- *Separate laboratory results database that complements the national HIV/AIDS surveillance system data.* Areas have received, entered, and maintained CD4 counts, with or without VL values, for HIV/AIDS registry cases, in a separate laboratory database for a period of not less than one year from application date. This activity should be ongoing, with plans to further expand capacity, including VL reporting if this is not already being conducted. Areas that have not routinely uploaded CD4 counts to the national HIV/AIDS surveillance system will be required to do so. Source of lab results (*e.g.*, electronic lab reporting, results received on paper, medical record extraction, etc.) will be recorded.
- *More than 55 percent of the area's combined HIV and AIDS cases have at least one CD4 count within 12 months of initial HIV diagnosis.* At least one CD4 count, obtained within 12 months following the initial diagnosis, was reported for most (greater than 55 percent) of the combined HIV and AIDS cases diagnosed in 2002 and 2003. This information should have been transmitted to CDC as part of the national HIV/AIDS surveillance system. Areas may average two years of diagnostic data to reach the 55 percent prevalence estimate, if each year's cases do not exceed 55 percent.
- *Current participant in the Morbidity Monitoring Project.* Not all cases enrolled in the Morbidity Monitoring Project (MMP), formerly announced as the Morbidity and Risk Behavior Surveillance Project, will be eligible for this project. Systematic sampling of newly diagnosed cases will be used to identify the population for ALOHA. At a minimum, include 500 HIV/AIDS cases annually, of which no less than 300 cases were initially diagnosed with HIV only. All cases included in ALOHA will require medical record abstraction and possible case follow-up. Cases enrolled in both the MMP and ALOHA will be identified as such.
- *Experience conducting large electronic database matching to HIV/AIDS case registry.* Areas will be required to match to another database to add comprehensive OI and co-morbidity information to their HIV/AIDS case registry. OIs will be limited to those diagnosed six months before and after initial HIV diagnosis. Database areas may match to include infectious disease (*e.g.*, NEDSS; hepatitis, cancer or tuberculosis registries), prescription medication databases (*e.g.*, Medicaid; AIDS Drug Assistance Program; etc.), or other databases with similar information. It may be necessary to match to multiple databases to provide a comprehensive review of OIs for a newly diagnosed case. The participating HIV/AIDS surveillance program will need a memorandum of understanding or similar written agreement with the program that manages the matched-to database. Case follow-up that examines periods of antibiotic/antiviral use should provide information about opportunistic infections being treated, if this is not obvious from the class of medication.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form CDC 5161–1.

Electronic Submission: CDC strongly encourages the applicant to submit the application electronically by utilizing the forms and instructions posted for this announcement on *http://www.Grants.gov,* the official Federal agency wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms.

Paper Submission: Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If access to the Internet is not available, or if there is difficulty accessing the forms on-line, contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at 770–488–2700 and the application forms can be mailed.

IV.2. Content and Form of Submission

Application: A project narrative must be submitted with the application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 15 pages. If the narrative exceeds the page limit, only the first pages that are within the page limit will be reviewed.
- Font size: 12 point unreduced
- Line spacing: Double-spaced
- Paper size: 8.5 by 11 inches
- Page margin: One inch
- Printing: Only on one side of page
- Binding: Hold document together only by rubber bands or metal clips; do not bind document in any other way.

The narrative should address activities that will be conducted over the entire project period, and must include the following items in the order listed:

- Program Plan
- Objectives
- Understanding
- Methods
- Performance Measures
- Budget Justification (not included in the narrative page limitation)

Additional information may be included in the application appendices. The appendices will not count toward the narrative page limit. This additional information includes:

- State laboratory reporting laws
- Evidence of legal authority to follow-up, and abstract medical records
- State specific statistics to support application
- Curriculum Vitas or Resumes

The agency or organization is required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, go to *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If the application form does not have a DUNS number field, please write the DUNS number at the top of the first page of the application, and/or include the DUNS number in the application cover letter.

Additional requirements that may require submittal of additional documentation with the application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Application Deadline Date: August 5, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date.

Applications may be submitted electronically at *http://www.grants.gov.* Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to *http://www.grants.gov.*

Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If submittal of the application is done electronically through Grants.gov (*http://www.grants.gov*), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an e-mail notice of receipt when CDC receives the application.

If submittal of the application is by the United States Postal Service or commercial delivery service, the applicant must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives the submission after the closing date due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, the applicant will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

If a hard copy application is submitted, CDC will not notify the applicant upon receipt of the submission. If questions arise on the receipt of the application, the applicant should first contact the carrier. If the applicant still has questions, contact the PGO–TIM staff at (770) 488–2700. The applicant should wait two to three days after the submission deadline before calling. This will allow time for submissions to be processed and logged.

This announcement is the definitive guide on application content, submission address, and deadline. It supersedes information provided in the application instructions. If the submission does not meet the deadline above, it will not be eligible for review, and will be discarded. The applicant will be notified the application did not meet the submission requirements.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. To get the current SPOC list, go to *http://www.whitehouse.gov/omb/grants/spoc.html.*

IV.5. Funding Restrictions

The following restrictions must be taken into account while writing your budget:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.

If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing the budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

Application Submission Address: Electronic Submission: CDC strongly encourages applicants to submit applications electronically at *http://www.Grants.gov.* The application package can be downloaded from *http://www.Grants.gov.* Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. E-mail submissions will not be accepted. If the applicant has technical difficulties in Grants.gov, customer service can be reached by e-mail at *http://www.grants.gov/CustomerSupport* or by phone at 1–800–518–4726 (1–800–518–GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. Eastern Time, Monday through Friday.

CDC recommends that submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: ''BACK–UP FOR ELECTRONIC SUBMISSION.'' The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

It is strongly recommended that the applicant submit the grant application using Microsoft Office products (*e.g.*, Microsoft Word, Microsoft Excel, etc.). If the applicant does not have access to Microsoft Office products, a PDF file may be submitted. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in the file being unreadable by staff.

or

Paper Submission: Applicants should submit the original and two hard copies of the application by mail or express delivery service to: Technical Information Management—RFA# AA120, CDC Procurement and Grants

Office, 2920 Brandywine Road, Atlanta, GA 30341.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The application will be evaluated against the following criteria:

1. Methods (30 points)

The extent to which the applicant demonstrates the technical capability to conduct the project using appropriate data collection and analytic methods for the following:

a. Accurately linking incoming lab results to all HIV and AIDS cases.

b. Transmitting that information to the national HIV/AIDS surveillance system for the duration of ALOHA.

c. Conducting active surveillance and medical record abstraction, including CD4 and VL results, OIs, and ancillary information, following a protocol developed in collaboration with CDC.

d. Conducting active, ongoing follow-up of cases.

e. Documenting methods for linking lab results to registry cases, including methods of reconciling possible matches.

f. Describing specific activities in support of the general funding considerations (Section III.3., bullets 1–4).

2. Understanding of Project Objectives (25 points)

The applicant's understanding of ALOHA objectives and the applicant's specific role in achieving those objectives.

3. Performance Measures (20 points)

The applicant's ability to evaluate progress, including:

a. Measures of success in improving CD4, VL, and OI ascertainment and their impact on overall reporting, compared with cases diagnosed in calendar year 2004.

b. Documenting collaboration with CDC staff to develop data collection forms for ancillary information about co-morbidities, barriers to reporting lab results, whether samples for CD4/VL testing are drawn at post test counseling, possible reasons for no CD4/VL testing, and the inability to link newly diagnosed persons to care.

c. Transfer data collected to CDC on a monthly basis.

4. Program Plan (15 points)

Applicants must demonstrate that they meet the eligibility criteria. Applicants must indicate the general consideration (Section III.3., bullets 1–4) under which they want to be evaluated (choose only one) and provide supporting documentation, as needed. Is the plan adequate to carry out the proposed objectives? How complete and comprehensive is the plan for the entire project period? Does the plan include quantitative process and outcome measures?

5. Objectives (10 points)

The extent to which the objectives are specific (with time frames), realistic, and address the required recipient activities.

6. Budget Justification (Reviewed, but not scored).

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds. All budget categories should be itemized.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by NCHSTP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. The objective review process will follow the policy requirements as stated in the GPD 2.04 [*http://198.102.218.46/doc/gpd204.doc*].

Applications will be funded according to their score and rank, which will be determined by the review panel. All persons serving on the panel will be external to the funding division of NCHSTP. In addition, the following factor may affect the funding decision: At least one applicant should be funded in each of the four general consideration areas (See Section III.3., bullets 1–4).

CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Award Date

August 31, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 and Part 92 as Appropriate. The following additional requirements apply to this project:

- AR–4 HIV/AIDS Confidentiality Provisions
- AR–5 HIV Program Review Panel Requirements
- AR–7 Executive Order 12372
- AR–8 Public Health System Reporting Requirements
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–14 Accounting System Requirements
- AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

An additional Certifications form from the PHS5161–1 application needs to be included in the Grants.gov electronic submission only. Applicants should refer to *http://www.cdc.gov/od/pgo/funding/PHS5161–1–Certificates.pdf.* Once the applicant has filled out the form, it should be attached to the Grants.gov submission as Other Attachments Form.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the

budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Annual progress report, due 90 days after the end of the budget period.

3. Financial status report, no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Debra Hayes-Hughes, Project Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E–47, Atlanta, GA 30333, Telephone: 404–639–4493, E-mail: *DHayes-Hughes@cdc.gov.*

For financial, grants management, or budget assistance, contact: Kang Lee, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 404–498–1917, E-mail: *kil8@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found at *http://www.cdc.gov.* Click on ''Funding,'' then ''Grants and Cooperative Agreements.''

Dated: June 28, 2005.

Alan A. Kotch,

Acting Deputy Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–13223 Filed 7–5–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a new System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records titled, ''Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), System No. 09–70–0544.'' The Office of E-Health Standards and Services (OESS) has been delegated the responsibility to regulate and enforce compliance for violations of Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA. Enforcement of these provisions is a complaint driven process; seeking voluntary compliance from all HIPAA covered entities. OESS has procured the services of a contractor to provide a database for complaint intake and management, to manage and maintain the overall electronic complaint process. Due to investigatory activities, CMS is exempting this system from the notification, access, correction and amendment provisions of the Privacy Act of 1974.

The purpose of this system is to store the results of all OESS regional investigations, to determine if there were violations as charged in the original complaint, to investigate complaints that appear to be in violation of the Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations. Information retrieved from this SOR will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, HIPAA entities, or by a contractor or consultant; (2) assist another Federal or state agency in the enforcement of HIPAA regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a congressional representative; (4) support litigation involving the agency; and (5) combat fraud and abuse in certain health benefits programs. We have provided background information about the modified system in the ''Supplementary Information'' section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See ''Effective Dates'' section for comment period.

DATES: *Effective Date:* CMS filed a new SOR report with the Chair of the house Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on June 28, 2005. We will not disclose any information under a routine use until 30 days after publication. We may defer implementation of this SOR or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comment to the CMS Privacy Officer, Mail-stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Michael Phillips, Health Insurance Specialist, OESS, CMS, 7500 Security Boulevard, Mail Stop S2–24–15, Baltimore, Maryland 21244–1849, Telephone Number (410) 786–6713, *mphillips@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: HITS is used by OESS staff and consists of an electronic repository of information and documents and supplementary paper document files. The HITS system allows OESS to integrate all of OESS' various business process including all of its investigation activities to allow real time access and results reporting and other varied information management needs. HITS provides (1) a single, central, electronic repository of all OHS complaint documents and information including investigative files, correspondence, and administrative records; (2) easy, robust capability to search all of the information in OESS' repository; (3) better quality control at the front end with simplified data entry and stronger data validation; (4) tools to help staff work on and manage their casework; and (5) includes supplementary paper files. The system

has the capacity to generate reports concerning the status of current and closed complaints, reviews and correspondence.

OESS investigative files maintained in HITS are either received as electronic documents or paper records that are compiled for law enforcement purposes. In the course of investigations, OESS often has a need to obtain confidential information involving individuals other than the complainant. In these cases, it is necessary for OHS to: (1) Preserve the confidentiality of this information, (2) avoid unwarranted invasions of personal privacy, and (3) assure recipients of Federal financial assistance that such information provided to OESS will be kept confidential. This assurance facilitates prompt and effective completion of the investigations.

Unrestricted disclosure of confidential information in OESS files can impede ongoing investigations, invade personal privacy of individuals and organizations, reveal the identities of confidential sources, or otherwise impair the ability of OESS to conduct investigations. For these reasons, the CMS is exempting all investigative files from the notification, access, correction and amendment provisions under subsection (k)(2) of the Privacy Act.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

Authority for maintenance of this system is given under provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law (Pub. L. 104–191), published at 68 FR 60694 (October 23, 2003). These regulations are codified at 45 Code of Federal Regulation, parts 160, 162, and 164.

B. Collection and Maintenance of Data in the System

HITS will maintain a file of complaint allegations, information gathered during the complaint investigation, findings, and results of the investigation, and correspondence relating to the investigation. The collected information will contain name, address, telephone number, health insurance claim (HIC) number, geographic location, as well as, background information relating to Medicare or Medicaid issues of the complainant.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release HITS information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of HITS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the SOR will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.*, to store the results of all OESS regional investigations, to determine if there were violations as charged in the original complaint, to investigate complaints that appear to be in violation of the HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors or consultant who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS function relating to purposes for this system or records.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Assist in the enforcement of HIPAA regulations for violations of Transactions and Code Sets, Security, and Unique Identifiers where sharing the information is necessary to complete the processing of a complaint,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

Other Federal or state agencies in their administration of a Federal health program may require HITS information in order to investigate complaint

allegations, evaluate information gathered during the complaint investigation, review findings and results of the investigation relating to the enforcement of HIPAA regulations for violations of Transactions and Code Sets, Security, and Unique Identifiers.

3. To a member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an issue relating to a matter before CMS. The member of Congress then writes CMS, and CMS must be able to give sufficient information to be responsive to the inquiry.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS' policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

5. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

CMS occasionally contracts out certain of its functions and makes grants when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

Other agencies may require HITS information for the purpose of combating fraud and abuse in such Federally funded programs.

B. Additional Provisions Affecting Routine Use Disclosures. This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E. Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent NIST publications; the DHHS Information Security Program Handbook and the CMS Information Security Handbook.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures (see item IV above) to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on

individual privacy as a result of information relating to individuals.

John R. Dyer,

Chief Operating Officer.

SYSTEM NO. 09–70–0544

SYSTEM NAME:

''Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), HHS/CMS/OESS''.

SECURITY CLASSIFFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Atlantic Telephone & Telegraph Company, Ashburn, Virginia facility under the control of the Center for Medicare & Medicaid Services.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed complaints alleging violations of the Transactions and Code Sets, Security, and Unique Identifier provisions under the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 68 FR 60694 (October 23, 2003). These regulations are codified at 45 CFR, parts 160, 162 and 164.

CATEGORIES OF RECORDS IN THE SYSTEM:

HITS will maintain a file of complaint allegations, information gathered during the complaint investigation, findings, and results of the investigation, and correspondence relating to the investigation. The collected information will contain name, address, telephone number, health insurance claim (HIC) number, geographic location, as well as, background information relating to Medicare or Medicaid issues.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for maintenance of this system is given under provisions of the Health Insurance Portability and Accountability Act of 1996, (Pub. L. 104–191), published at 68 FR 60694 (October 23, 2003). These regulations are codified at 45 Code of Federal Regulation, parts 160, 162, and 164.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to store the results of all OESS regional investigations, to determine if there were violations as charged in the original complaint, to investigate complaints that appear to be in violation of the Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations. Information retrieved from this SOR will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency, HIPAA entities, or by a contractor or consultant; (2) assist another Federal or state agency in the enforcement of HIPAA regulations where sharing the information is necessary to complete the processing of a complaint, contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or enable such agency to administer a Federal health benefits program; (3) support constituent requests made to a congressional representative; (4) support litigation involving the agency; and (5) combat fraud and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' We are proposing to establish the following routine use disclosures of information maintained in the system. Information will be disclosed:

1. To agency contractors or consultants who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity.

2. To another Federal or state agency to:

a. Assist in the enforcement of HIPAA regulations for violations of Transactions and Code Sets, Security, and Unique Identifiers where sharing the information is necessary to complete the processing of a complaint,

b. Contribute to the accuracy of CMS's proper payment of Medicare benefits, and/or

c. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds.

3. To a member of congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b.Any employee of the agency in hisor h4r official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures This system contains Protected Health Information as defines by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E). Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the complaint population is so small that individuals who are familiar with the complainants could, because of

the small size, use this information to deduce the identity of the complainant).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored electronically.

RETRIEVABILITY:

The complaint data are retrieved by an individual identifier i.e., name of complainant.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implements appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent NIST publications; the DHHS Information Security Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will retain complaint information for a total period not to exceed 25 years.

SYSTEM MANAGER AND ADDRESS:

Director, Office of E-Health Standards and Services, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

Exempt. However, portions of this system notice are non-exempt and consideration will be given to requests addressed to the system manager for those portions. For general inquiries, it would be helpful if the request included the system name, address, age, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable) and complaint tracking ID number.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also specify the record contents being sought.

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

OESS investigative files maintained in HITS are either received as electronic documents or paper records that are compiled for law enforcement purposes. In the course of investigations, OESS often has a need to obtain confidential information involving individuals other than the complainant.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

HHS claims exemption of certain records (case files on active fraud investigations) in the system from notification and access procedures under 5 U.S.C. 552a(k)(2) inasmuch as these records are investigatory materials compiled for program (law) enforcement in anticipation of a criminal or administrative proceedings. (See Department Regulation (45 CFR 5b.11)).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families, Children's Bureau

Funding Opportunity Title: Developing Adoption Services and Supports for Youth Who Wish to Retain Contact with Family Members in Order to Improve Permanency Outcomes.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2005–ACF–ACYF–CO–0051.

CFDA Number: 93.652.

Due Date for Applications: Application is due August 10, 2005.

Category of Funding Activity: Social Services and Income Security.

Executive Summary

The purposes of funding these demonstration projects are to: (1) Demonstrate the effective implementation of strategies for introducing the concept of open adoption to youth and/or sibling groups who prefer to maintain contact with birth families and/or siblings; (2) demonstrate effective implementation strategies for connecting youth to adults to promote a range of permanency options, particularly adoption and open adoption, and including guardianship and kinship care; (3) demonstrate the effective models of youth leadership and collaboration between youth, siblings and other family members, caseworkers and possible adoptive families in planning for youth permanency; (4) evaluate the processes and outcomes of these strategies and models; and (5) disseminate information about these strategies and models so that other States/locales seeking to implement effective open adoption programs for youth and sibling groups have a demonstrated resource for guidance, insight, and possible replication.

Priority Area 1

I. Funding Opportunity Description

The purposes of funding these demonstration projects are to: (1) Demonstrate the effective implementation of strategies for introducing the concept of open adoption to youth and/or sibling groups who prefer to maintain contact with birth families and/or siblings; (2) demonstrate effective implementation strategies for connecting youth to adults to promote a range of permanency options, particularly adoption and open adoption, and including guardianship and kinship care; (3) demonstrate the effective models of youth leadership and collaboration between youth, siblings and other family members, caseworkers and possible adoptive families in planning for youth permanency; (4) evaluate the processes and outcomes of these strategies and models; and (5) disseminate information about these strategies and models so that other States/locales seeking to implement effective open adoption programs for youth and sibling groups have a demonstrated resource for

guidance, insight, and possible replication.

Background

ACF completed the initial round of 52 CFSRs in March 2004. Among the most notable findings is that no State achieved substantial conformity on the outcome that evaluates the timely achievement of permanency goals for children in foster care. On the performance indicator that addresses the establishment of appropriate permanency goals (Item 7) only 5 States performed satisfactorily. The CFSRs found that long-term foster care or Alternative Planned Permanent Living Arrangement (APPLA) are being over-used as plans for youth and large sibling groups which contain youth due to the youth's interest in maintaining some level of contact with the birth family. Assumptions are frequently made that adoption precludes continuing contact with the birth family whether it be parents or siblings. In the 35 States reviewed in the CFSR between 2002–2004, while the goal of reunification was the single goal most commonly recorded for youth in FC age 13 and older (39 percent), the combined goals of emancipation and long-term foster care represented 46 percent of the permanency goals for this age group. This suggests that the plan for nearly half the children reviewed, who were aged 13 and older, was for them to remain in foster care. The long-term implications of adoption versus APPLA is not being sufficiently explored with youth so they can be involved in an informed, decision-making process about future plans for their life. Additionally, some child welfare professionals and court personnel think that finding an adoptive home for youth is simply too difficult. Therefore, these youth, and sometimes their siblings, age out of foster care without a family they can turn to once discharged from the foster care system.

Assumptions are frequently made that impact positive permanency outcomes for youth. Barriers exist because caseworkers, attorneys and judges believe that youth don't want to be adopted, that no one is interested in adopting them, and that adoptive placements of teens are unsuccessful.

These barriers are reflected in the data reported in AFCARS. The percent of children who are placed for adoption dramatically decreases as the child ages. At the end of FY 2000, children nine and older with termination of parental rights had been waiting to be adopted three times longer than children under the age of nine. Preliminary analyses show that although children nine and older constitute 50 percent of the children in foster care, they are only 37 percent of the waiting population, (includes most children with a goal of adoption with or without a termination of parental rights), 39 percent of the children with termination of parental rights, but only 24 percent of the adoptions. Additional barriers to permanency include inappropriate placements, poorly selected and improperly trained foster parents, and caseworkers failing to address permanency issues early and often in their work with youth. Placements in group home settings often limit contact with a broad range of caring adults with whom the youth could establish and maintain a permanent lifelong connection.

There is a need to design models of open adoption to facilitate permanency for youth over age 12 (or State's age of consent) in foster care. It is not unusual for youth to have reasons to prefer a continuing attachment to parents even though it is not safe for them to live with their own family. These reasons can include other siblings still in the home or parents with lower level cognitive skills that the youth is concerned about. Open adoption can also be a model to allow siblings to have contact with each other after they're adopted by separate families. Models which support youth in processing the implications of adoption and open adoption versus APPLA, while helping youth to address their emotional/mental health issues, either through individual counseling, or youth group adoption counseling need to be demonstrated and evaluated.

Preparation of pre-adoptive families is required to help them be aware of the issues implicit in open adoptions such as supporting the youth in relating to and understanding their birth family and managing contact, safety, supervision and guidelines for contact with family members. Projects under this funding announcement will be expected to identify, provide and evaluate the services that are required to help these families (e.g., foster families, relatives or other individuals who have already or have not yet developed other connections with the youth) successfully address these issues.

Effective models that empower and support youth in achieving permanency must be multidimensional. These include recruiting and training appropriate foster and adoptive family resources. They also include connecting youth to caring adults. This can be done through a broad outreach. Outreach can include mentoring and building connections with extended family, strategies to effectively address the emotional/mental health issues of youth including grief and loss. Strategies can also include community connections, family connections, and caseworker and supervisor support in assessing and supporting a range of permanency options early and often in their work with youth.

The Children's Bureau will expect grantees to engage in a strong evaluation in order to demonstrate linkages between these strategies and improved outcomes. Grantees will also be expected to package information which can readily be used by T/TA grantees for work with states.

Legislative Authority

The Adoption Opportunities program, section 205 of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978, (Pub. L. 95–266), as amended by the Keeping Children and Families Safe Act of 2003 (Pub. L. 108–36).

Projects funded under this announcement will be expected to:

1. Have the project fully functioning within 90 days following the notification of the grant award.

2. Participate if the Children's Bureau chooses to do a national evaluation or a technical assistance contract that relates to this funding announcement.

3. Submit all performance indicator data, program and financial reports in a timely manner, in recommended format (to be provided), and submit the final report on disk or electronically using a standard word-processing program.

4. Submit a copy of the final report, the evaluation report, and any program products to the National Clearinghouse on Child Abuse and Neglect Information, 330 C Street, SW., Washington, DC 20447, within 90 days of project end date. This is in addition to the standard requirement that the final program and evaluation report must also be submitted to the Grants Management Specialist and the Federal Project Officer.

5. Allocate sufficient funds in the budget to:

(a) Provide for the project director, the evaluator and a child welfare representative to attend an annual 3-day grantees' meeting in Washington, DC.

(b) Provide for the project director, the evaluator and a child welfare representative to attend an early kickoff meeting for grantees funded under this priority area to be held within the first three months of the project (first year only) in Washington, DC; and

(c) Provide for 10–15 percent of the proposed budget to project evaluation.

II. Award Information

Funding Instrument Type: Cooperative Agreement.

Federal Substantial Involvement with Cooperative Agreement

A cooperative agreement is a specific method of awarding Federal assistance in which substantial Federal involvement is anticipated. A cooperative agreement clearly defines the respective responsibilities of the Children's Bureau and the grantee prior to the award. The Children's Bureau anticipates that agency involvement will produce programmatic benefits to the recipient otherwise unavailable to them for carrying out the project. The involvement and collaboration includes Children's Bureau review and approval of planning stages of the activities before implementation phases may begin; Children's Bureau involvement in the establishment of policies and procedures that maximize open competition, and rigorous and impartial development, review and funding of grant or sub-grant activities, if applicable; and Children's Bureau and recipient joint collaboration in the performance of key programmatic activities (*i.e.*, strategic planning, implementation, information technology enhancements, training and technical assistance, publications or products, and evaluation). It also includes close monitoring by the Children's Bureau of the requirements stated in this announcement that limit the grantee's discretion with respect to scope of services offered, organizational structure and management processes, coupled with close Children's Bureau monitoring during performance, which may, in order to ensure compliance with the intent of this funding, exceed those Federal stewardship responsibilities customary for grant activities.

Anticipated Total Priority Area Funding: $1,800,000.

Anticipated Number of Awards: 0 to 6.

Ceiling on Amount of Individual Awards Per Budget Period: $300,000.

Average Projected Award Amount: $300,000.

Length of Project Periods: 60-month project with five 12-month budget periods.

Other.

Explanation of Other: In the first budget period, the maximum Federal share of each project is not to exceed $300,000. The projects awarded will be for a project period of 60 months. The initial grant award will be for a 12-month budget period. The award of continuation beyond each 12-month budget period will be subject to the availability of funds, satisfactory progress on the part of the grantee, and a determination that continued funding would be in the best interest of the government.

Floor on amount of individual awards: None.

III. Eligibility Information

1. Eligible Applicants

State governments.

County governments.

City or township governments.

Native American tribal governments (Federally recognized).

Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education.

Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education.

Additional Information on Eligibility

Faith-based and community organizations that meet all other eligibility requirements are eligible to apply.

Applicants should demonstrate a strong partnership between the child welfare agency, the courts, and youth development organizations.

Collaborative efforts are encouraged, but applications should identify a primary applicant responsible for administering the grant.

2. Cost Sharing/Matching

Cost Sharing/Matching: Yes.

Matching/Cost-Sharing

Grantees must provide at least 10 percent of the total approved cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $ 300,000 in Federal funds (based on an award of $300,000 per budget period) must provide a match of at least $33,333 (10 percent of the total approved project costs). Grantees will be held accountable for commitments of non-Federal resources even if over the amount of the required match. Failure to provide the amount will result in disallowance of Federal funds. Lack of supporting documentation at the time of application will not impact the responsiveness of the application for competitive review.

3. Other Eligibility Information

All applicants must have a Dun & Bradstreet number. On June 27, 2003 the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (*http://www.Grants.gov*). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1–866–705–5711 or you may request a number on-line at *http://www.dnb.com.*

Non-profit organizations applying for funding are required to submit proof of their non-profit status.

Proof of non-profit status is any one of the following:

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code.
- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earning accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.
- Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Disqualification Factors

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application post-marked after 4:30 p.m. eastern time zone on the deadline date will not be considered for competition.

IV. Application and Submission Information

1. Address To Request Application Package

ACYF Operations, The Dixon Group ATTN: Children's Bureau, 118 Q St., NE., Washington, DC 20002–2132, Phone: 866–796–1591, URL: *http://www.acf.hhs.gov/grants/open/HHS–2005-ACF-ACYF-CA–0001.html.*

2. Content and Form of Application Submission

Each application must contain the following items in the order listed:

Application for Federal Assistance (Standard Form 424). Follow the instructions below and those that accompany the form.

In Item 5 of Form 424, put DUNS number in ''Organizational DUNS:'' box.

In Item 5 of Form 424, include name, phone number, and, if available, email and fax numbers of the contact person.

In Item 8 of Form 424, check 'New.'

In Item 10 of Form 424, clearly identify the Catalog of Federal Domestic Assistance (CFDA) program title and number for the program for which funds are being requested as stated in this funding opportunity announcement.

In Item 11 of Form 424, identify the single funding opportunity the application addresses.

In Item 12 of Form 424, identify the specific geographic area to be served.

In Item 14 of Form 424, identify Congressional districts of both the applicant and project.

Budget Information Non-Construction Programs (Form 424A) and Budget Justification. Follow the instructions provided here and those in Section V. Application Review Information.

Description—Please see Section V.1. Criteria, for instructions on preparing the project summary/abstract and the full project description.

Proof of non-profit status (if applicable). Please see Section III.3 Other Eligibility for ways to demonstrate non-profit status.

Indirect cost rate agreement. If claiming indirect costs, provide documentation that applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

Letters of agreement and memoranda of understanding. If applicable, include a letter of commitment or Memorandum of Understanding from each partner and/or sub-contractor describing their role, detailing specific tasks to be performed, and expressing commitment to participate if the proposed project is funded.

Match. Provide a letter of commitment verifying the actual amount of the non-Federal share of project costs (see Section III.2).

General Content and Form information: The application limit is 75 pages total including all forms and attachments. Pages over this page limit will be removed from the application and will not be reviewed.

The application must be typed, double spaced, printed on only one side, with at least ½ inch margins on each side and 1 inch at the top and bottom, using standard 12 Point fonts (such as Times New Roman or Courier). Pages must be numbered.

All copies of an application must be submitted in a single package, and a separate package must be submitted for each funding opportunity. The package must be clearly labeled for the specific funding opportunity it is addressing.

Because each application will be duplicated, do not use or include separate covers, binders, clips, tabs, plastic inserts, maps, brochures, or any other items that cannot be processed easily on a photocopy machine with an automatic feed. Do not bind, clip, staple, or fasten in any way separate subsections of the application, including supporting documentation; however, each complete copy must be stapled securely in the upper left corner. Applicants are advised that the copies of the application submitted, not the original, will be reproduced by the Federal government for review.

Tips for Preparing a Competitive Application. It is essential that applicants read the entire announcement package carefully before preparing an application and include all of the required application forms and attachments. The application must reflect a thorough understanding of the purpose and objectives of the applicable legislation. Reviewers expect applicants to understand the goals of the legislation and the Children's Bureau's interest in each topic. A ''responsive application'' is one that addresses all of the evaluation criteria in ways that demonstrate this understanding. Applications that are considered to be ''unresponsive'' generally receive very low scores and are rarely funded.

The Children's Bureau's Web site (*http://www.acf.dhhs.gov/programs/cb*) provides a wide range of information and links to other relevant web sites. Before you begin preparing an application, we suggest that you learn more about the mission and programs of the Children's Bureau by exploring the Web site.

Organizing Your Application. The specific evaluation criteria in Section V of this funding announcement will be used to review and evaluate each application. The applicant should address each of these specific evaluation criteria in the project description. Applicants should organize their project description in this sequence: (1) Objectives and Need for Assistance; (2) Approach; (3) Organizational Profiles; (4) Budget and Budget Justification; and should use the same headings as these criteria, so that reviewers can readily find information that directly addresses each of the specific review criteria.

Project Evaluation Plan. Project evaluations are very important. If you do not have the in-house capacity to conduct an objective, comprehensive evaluation of the project, then the Children's Bureau advises that you propose contracting with a third-party evaluator specializing in social science or evaluation, or a university or college, to conduct the evaluation. A skilled evaluator can assist you in designing a data collection strategy that is appropriate for the evaluation of your proposed project. Additional assistance may be found in a document titled ''Program Manager's Guide to Evaluation.'' A copy of this document can be accessed at *http://www.acf.hhs.gov/programs/opre/other_resrch/pm_guide_eval/reports/pmguide/pmguide_toc.html.*

Logic Model. A logic model is a tool that presents the conceptual framework for a proposed project and explains the linkages among program elements. While there are many versions of the logic model, they generally summarize the logical connections among the needs that are the focus of the project, project goals and objectives, the target population, project inputs (resources), the proposed activities/processes/outputs directed toward the target population, the expected short- and long-term outcomes the initiative is designed to achieve, and the evaluation plan for measuring the extent to which proposed processes and outcomes actually occur. Information on the development of logic models is available on the Internet at *http://www.uwex.edu/ces/pdande/,* or *http://www.extension.iastate.edu/cyfar/capbuilding/outcome/outcome_logicmdir.html.*

Project Use of Human Subjects. If your evaluation plan includes gathering data from or about clients, there are specific procedures which must be followed in order to protect their privacy and ensure the confidentiality of the information about them. Applicants planning to gather such data are asked to describe their plans regarding an Institutional Review Board

(IRB) review. If applicable, applicants must include a completed Form 310, Protection of Human Subjects. For more information about use of human subjects and IRB's you can visit these web sites: *http://www.hhs.gov/ohrp/irb/irb_chapter2.htm#d2,* and *http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm.*

You may submit your application to us in either electronic or paper format. To submit an application electronically, please use the *www.Grants.gov* apply site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please note the following if you plan to submit your application electronically via Grants.Gov

- Electronic submission is voluntary, but strongly encouraged.
- When you enter the Grants.Gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.Gov.
- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grants.gov.
- We may request that you provide original signatures on forms at a later date.
- You may access the electronic application for this program on *www.Grants.gov.*
- You must search for the downloadable application package by the CFDA number.

Applicants that are submitting their application in paper format should submit an original and two copies of the complete application. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, have original signatures, and be submitted unbound.

Private, non-profit organizations are encouraged to submit with their applications the survey located under ''Grant Related Documents and Forms,'' ''Survey for Private, Non-Profit Grant Applicants,'' titled, ''Survey on Ensuring Equal Opportunity for Applicants,'' at: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Standard Forms and Certifications

Applicants seeking financial assistance under this announcement must file the Standard Form (SF) 424, Application for Federal Assistance; SF–424A, Budget Information—Non-Construction Programs; SF–424B, Assurances—Non-Construction Programs. The forms may be reproduced for use in submitting applications. Applicants must sign and return the standard forms with their application.

Applicants must furnish prior to award an executed copy of the Standard Form LLL, Certification Regarding Lobbying, when applying for an award in excess of $100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form, if applicable, with their applications (approved by the Office of Management and Budget under control number 0348–0046). Applicants must sign and return the certification with their application.

Applicants must also understand they will be held accountable for the smoking prohibition included within Pub. L. 103–227, Title XII Environmental Tobacco Smoke (also known as the PRO–KIDS Act of 1994). A copy of the **Federal Register** notice which implements the smoking prohibition is included with forms. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must make the appropriate certification of their compliance with all Federal statutes relating to nondiscrimination. By signing and submitting the applications, applicants are providing the certification and need not mail back the certification form. Complete the standard forms and the associated certifications and assurances based on the instructions on the forms. The forms and certifications may be found at: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Those organizations required to provide proof of non-profit status, please refer to Section III.3.

Please see Section V.1, for instructions on preparing the full project description.

3. Submission Dates and Times

Explanation of Due Dates

The closing time and date for receipt of applications is 4:30 p.m. (Eastern Time Zone) on the date noted above. Mailed or hand carried applications received after 4:30 p.m. on the closing date will be classified as late.

Deadline: Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the ACYF Operations Center, c/o The Dixon Group, Inc., ATTN: Children's Bureau, 118 Q Street NE., Washington, DC 20002–2132. Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

Applications handcarried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., EST, at the ACYF Operations Center, c/o The Dixon Group, Inc., ATTN: Children's Bureau, 118 Q Street NE., Washington, DC 20002–2132, between Monday and Friday (excluding Federal holidays). This address must appear on the envelope/package containing the application with the note. Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

Late applications: Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition. Any application received after 4:30 p.m. on the deadline date will not be considered for competition. Applicants using express/overnight mail services should allow two working days prior to the deadline date for receipt of applications. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed).

Extension of deadlines: ACF may extend application deadlines when

circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Checklist:

What to submit	Required content	Required form or format	When to submit
Project Abstract	See Section IV and V	Format described in Section IV and V	By application due date.
Project Narrative	See Section IV and V	Format described in Section IV and V	By application due date.
SF424	See Section IV	Format described in Section IV	By application due date.
SF424A	See Section IV	Format described in Section IV	By application due date.
SF424B	See Section IV	Format described in Section IV	By application due date.
Assurances and Certifications	See Section IV	Format described in Section IV	By Time of Award.
Proof of Non-profit status, if applicable	See Section III and IV	Format described in Section III	By Time of Award.
Indirect Cost rate Agreement, if applicable.	See Section IV	Format described in IV	By Time of Award.
Letters of commitment from partner organizations, if applicable.	See Section IV	Format described in IV	By Time of Award.
Non-Federal match commitment documentation.	See Section III.2	Format described in III.2	By Time of Award.

Additional Forms: Private, nonprofit organizations are encouraged to submit with their applications the survey located under ''Grant Related Documents and Forms'' titled ''Survey for Private, Non-Profit Grant Applicants'' at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

What to submit	Required content	Required form or format	When to submit
Survey for Private, Non-Profit Grant Applicants.	Per required form	May be found on *www.acf.hhs.gov/programs/ofs/forms.htm.*	With application.

4. Intergovernmental Review

State Single Point of Contact (SPOC)

The Adoption Opportunities program is NOT covered under Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' and 45 CFR Part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.''

5. Funding Restrictions

Grant awards will not allow reimbursement of pre-award costs.

Construction is not an allowable activity or expenditure under this solicitation.

Applicants should note that grants to be awarded under this program announcement are subject to the availability of funds. The size of the actual awards will vary.

6. Other Submission Requirements

Submission by Mail: An applicant must provide an original application with all attachments, signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications should be mailed to: ACYF Operations Center, The Dixon Group, 118 Q St. NE., Washington DC 20002–2132, Attention: Children's Bureau.

Hand Delivery: An applicant must provide an original application with all attachments signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications should be delivered to: ACYF Operations Center, The Dixon Group, 118 Q St. NE., Washington DC 20002–2132, Attention: Children's Bureau.

Electronic Submission: http://www.grants.gov Please see section IV. 2 Content and Form of Application Submission, for guidelines and requirements when submitting applications electronically.

V. Application Review Information

The Paperwork Reduction Act of 1995 (Pub. L. 104–13)

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

The project description is approved under OMB control number 0970–0139 which expires 4/30/2007.

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 following are instructions and guidelines on how to prepare the ''Project Summary/Abstract'' and ''Full Project Description'' sections of the application. Under the evaluation criteria section, note that each criterion is preceded by the generic evaluation requirement under the ACF Uniform Project Description (UPD).

1. Criteria

General Instructions

ACF is particularly interested in specific project descriptions that focus on outcomes and convey strategies for achieving intended performance. Project descriptions are evaluated on the basis of substance and measurable outcomes, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant funded activity should be placed in an appendix. Pages should be numbered and a table of contents should be included for easy reference.

Introduction

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions while being aware of the specified evaluation criteria. The text options give a broad overview of what your project description should include while the evaluation criteria identifies the measures that will be used to evaluate applications.

Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

Objectives and Need for Assistance

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

Approach

Outline a plan of action that describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors that might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement. Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished.

When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates. If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any ''collection of information that is conducted or sponsored by ACF.'' List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners, such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. If the applicant is a non-profit organization, submit proof of non-profit status in its application. The non-profit agency can accomplish this by providing: (a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate, (c) a statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status, (e) any of the items immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Budget and Budget Justification

Provide a budget with line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF–424. Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

General

Use the following guidelines for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. ''Federal resources'' refers only to the ACF grant for which you are applying. ''Non Federal resources'' are all other Federal and non-Federal resources. It is suggested that budget amounts and computations be presented in a columnar format: First column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

Personnel

Description: Costs of employee salaries and wages. Justification: Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe Benefits

Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate. Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

Travel

Description: Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel). Justification: For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops should be detailed in the budget.

Equipment

Description: ''Equipment'' means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5,000. (**Note:** Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.) Justification: For each type of

equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

Supplies

Description: Costs of all tangible personal property other than that included under the Equipment category. Justification: Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

Contractual

Description: Costs of all contracts for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant.

Justification: Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at $100,000).

Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc. **Note:** Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

Other

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs. Justification: Provide computations, a narrative description and a justification for each cost under this category.

Indirect Charges

Description: Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency. Justification: An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, upon notification that an award will be made, it should immediately develop a tentative indirect cost rate proposal based on its most recently completed fiscal year, in accordance with the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. When an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Evaluation Criteria

The following evaluation criteria appear in weighted descending order. The corresponding score values indicate the relative importance that ACF places on each evaluation criterion; however, applicants need not develop their applications precisely according to the order presented. Application components may be organized such that a reviewer will be able to follow a seamless and logical flow of information (*e.g.,* from a broad overview of the project to more detailed information about how it will be conducted.

In considering how applicants will carry out the responsibilities addressed under this announcement, competing applications for financial assistance will be reviewed and evaluated against the following criteria:

Approach—50 Points

In reviewing the approach, the following factors will be considered: (50 points)

(1) The extent to which there is a sound timeline for effectively implementing the proposed project, including major milestones and target dates. The extent to which the proposed project would complete its activities in a timely manner and conduct a thorough evaluation of its effectiveness within the project time frame.

(2) The extent to which the proposed project would enhance capacity to meet the needs of the target population. The extent to which specific measurable outcomes will occur as a result of the proposed project activities. The extent to which there will be a strong relationship between the proposed project activities and improved outcomes for youth in foster care.

(3) The extent to which there will be an effective administrative and organizational interface between the applicant and the appropriate partner organizations. The extent to which there are appropriate letters of commitment from these partner organizations.

(4) The extent to which the application demonstrates a thorough understanding of the challenges of implementing the proposed project. The extent to which the applicant provides a sound plan explaining how the project would successfully overcome these challenges.

(5) The extent to which the proposed project will provide culturally competent services to the target population.

(6) The extent to which the design of the proposed project reflects up-to-date knowledge from research and literature. The extent to which the proposed project is innovative and involves strategies that build on, or are an alternative to, existing strategies.

(7) The extent to which the project's evaluation plan would measure achievement of project objectives, customer satisfaction, acquisition of competencies, effectiveness of program services and project strategies, the efficiency of the implementation process, and the impact of the project. The extent to which the methods of evaluation would provide performance feedback, support periodic assessment of program progress and provide a sound basis for program adjustments. The extent to which the proposed evaluation plan would be likely to yield useful findings or results about effective strategies, and contribute to and promote evaluation research and evidence-based practices that could be used to guide replication or testing in other settings. The extent to which applicants that do not have the in-house capacity to conduct an objective, comprehensive evaluation of the project present a sound plan for contracting with a third-party evaluator specializing

in social science or evaluation, or a university or college to conduct the evaluation.

(8) The extent to which there is a sound plan for documenting project activities and results, including the development of a data collection infrastructure that is sufficient to support a methodologically sound and rigorous evaluation. The extent to which relevant data would be collected. The extent to which there is a sound plan for collecting these data, securing informed consent and implementing an Institutional Review Board (IRB) review, if applicable.

(9) The extent to which there is a sound plan for developing useful products during the proposed project and a reasonable schedule for developing these products. The extent to which the intended audience (*e.g.*, researchers, policymakers, and practitioners) for product dissemination is comprehensive and appropriate. The extent to which the dissemination plan includes appropriate mechanisms and forums that would effectively convey the information and support successful replication by other interested agencies.

(10) The extent to which there is a sound plan for continuing this project beyond the period of Federal funding.

Organizational Profiles—20 Points

In reviewing the organizational profiles, the following factors will be considered: (20 points)

(1) The extent to which the application evidences sufficient experience and expertise in youth adoption, in collaboration with partner organizations; in culturally competent service delivery; and in administration, development, implementation, management, and evaluation of similar projects. The extent to which each participating organization (including partners and/or subcontractors) possesses the organizational capability to fulfill their assigned roles and functions effectively (if the application involves partnering and/or subcontracting with other agencies/organizations) in serving the target populations.

(2) The extent to which the proposed project director and key project staff possess sufficient relevant knowledge, experience and capabilities to implement and manage a project of this size, scope and complexity effectively (*e.g.,* resume). The extent to which the role, responsibilities and time commitments of each proposed project staff position, including consultants, subcontractors and/or partners, are clearly defined and appropriate to the successful implementation of the proposed project with respect to the target population.

(3) The extent to which there is a sound management plan for achieving the objectives of the proposed project on time and within budget, including clearly defined responsibilities, for accomplishing project tasks and ensuring quality. The extent to which the plan clearly describes the effective management and coordination of activities carried out by any partners, subcontractors and consultants (if appropriate). The extent to which there would be a mutually beneficial relationship between the proposed project and other work planned, anticipated or underway with Federal assistance by the applicant.

Objectives and Need for Assistance—20 Points

In reviewing the objectives and need for assistance, the following factors will be considered: (20 points)

(1) The extent to which the application demonstrates an understanding of the requirements of the Adoption Opportunities legislation and the Child and Family Services Reviews, and the extent to which the proposed project will contribute to meeting those requirements. The extent to which the application demonstrates a clear understanding of youth adoption issues.

(2) The extent to which the application demonstrates a thorough understanding of the need for knowledge about what works in youth adoption.

(3) The extent to which the application presents a thorough review of the relevant literature that reflects a clear understanding of the research on best practices and promising approaches as it relates to the proposed project. The extent to which the review of the literature sets a sound context and rationale for the project. The extent to which it provides evidence that the proposed project is innovative and, if successfully implemented and evaluated, likely to contribute to the knowledge base on youth adoption.

(4) The extent to which the application presents a clear vision for the proposed project to be developed and implemented. The extent to which the applicant makes a clear statement of the goals (end products of an effective project) and objectives (measurable steps for reaching these goals) of the proposed project. The extent to which these goals and objectives closely relate to the purposes of this funding announcement.

(5) The extent to which the lessons learned through the proposed project would benefit policy, practice and theory development in addressing the needs of the target populations as described in this funding announcement.

(6) The extent to which the proposed project would develop strong partnerships to meet the goals described in this funding announcement.

Budget and Budget Justification—10 Points

In reviewing the budget and budget justification, the following factors will be considered: (10 points)

(1) The extent to which the costs of the proposed project are reasonable and appropriate, in view of the activities to be conducted and expected results and benefits.

(2) The extent to which the applicant's fiscal controls and accounting procedures would ensure prudent use, proper and timely disbursement and accurate accounting of funds received under this program announcement.

2. Review and Selection Process

Since ACF will be using non-Federal reviewers in the review process, applicants have the option of omitting from the application copies (not the original) of specific salary rates or amounts for individuals specified in the application budget.

No grant award will be made under this announcement on the basis of an incomplete application.

A panel of at least three reviewers (primarily experts from outside the Federal government) will use the evaluation criteria described in this announcement to evaluate each application. The reviewers will determine the strengths and weaknesses of each application, provide comments about the strengths and weaknesses and give each application a numerical score.

The results of the competitive review are a primary factor in making funding decisions. In addition, Federal staff conducts administrative reviews of the applications and, in light of the results of the competitive review, will recommend applications for funding to the ACYF Commissioner. ACYF reserves the option of discussing applications with other funding sources when this is in the best interest of the Federal government. ACYF may also solicit and consider comments from ACF Regional Office staff in making funding decisions. ACYF may take into consideration the involvement (financial and/or programmatic) of the private sector, national, or State or community foundations; a favorable balance between Federal and non-

Federal funds for the proposed project; or the potential for high benefit from low Federal investment. ACYF may elect not to fund any applicants having known management, fiscal, reporting, programmatic, or other problems which make it unlikely that they would be able to provide effective services or effectively complete the proposed activity.

With the results of the peer review and the information from Federal staff, the Commissioner of ACYF makes the final funding decisions. The Commissioner may give special consideration to applications proposing services of special interest to the Government and to achieve geographic distributions of grant awards. Applications of special interest may include, but are not limited to, applications focusing on unserved or inadequately served clients or service areas and programs addressing diverse ethnic populations.

Approved but Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Applications will be reviewed in the summer of 2005. Grant awards will have a start date no later than September 30, 2005.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Direct Federal grants, sub-award funds, or contracts under this program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment for Faith-based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

45 CFR Part 74; 92. Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental) organizations.

3. Reporting Requirements

Program Progress Reports: Semi-Annually.

Financial Reports: Semi-Annually.

Grantees will be required to submit program progress reports and financial reports (SF269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

VII. Agency Contacts

Program Office Contact: Patsy Buida, Children's Bureau, 330 C Street, SW., Washington, DC 20447, Phone: 202–205–8769, E-mail: *pbuida@acf.hhs.gov.*

Grants Management Office Contact: Peter Thompson, Grants Officer, Administration for Children and Families, Children's Bureau, 330 C Street, SW., Room 2070, Washington, DC 20447, Phone: 202–401–4608, E-mail: *pathompson@acf.hhs.gov.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov*. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/cb/.*

For general questions regarding this announcement please contact: ACYF Operations Center, The Dixon Group ATTN: Children's Bureau, 118 Q Street, NE., Washington DC 20002–2132, Telephone: 866–796–1591.

Applicants will not be sent acknowledgements of received applications.

Dated: June 28, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–13302 Filed 7–5–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth, and Families, Children's Bureau

Funding Opportunity Title: National Data Archive on Child Abuse and Neglect.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2005–ACF–ACYF–CA–0086.

CFDA Number: 93.670.

Due Date for Applications: Applications are due August 10, 2005.

Category of Funding Activity: Social Security and Income Services.

Executive Summary

The purpose of this funding announcement is to award a cooperative agreement to continue the operation of the national data archive on child abuse and neglect, and to continue the processing and housing of high quality data sets and related activities that facilitate the use of archived data.

In year 1, the grantee will provide supplementary support to data users who access National Survey of Child and Adolescent Well-Being (NSCAW) data through the National Data Archive on Child Abuse and Neglect.

Priority Area 1

I. Funding Opportunity Description

The purpose of this funding announcement is to award a cooperative agreement to continue the operation of the national data archive on child abuse and neglect, and to continue the processing and housing of high quality data sets and related activities that facilitate the use of archived data.

In year 1, the grantee will provide supplementary support to data users who access National Survey of Child and Adolescent Well-Being (NSCAW) data through the National Data Archive on Child Abuse and Neglect.

Background

The purpose of this funding announcement is to award a cooperative agreement to continue the operation of the national data archive on child abuse and neglect and to continue the processing and housing of high quality

data sets and related activities that facilitate the use of archived data.

In year 1, the grantee will provide supplementary support to data users who access National Survey of Child and Adolescent Well-Being (NSCAW) data through the National Data Archive on Child Abuse and Neglect.

In this funding announcement, ACYF seeks to ensure funding for one of the components of a research structure identified as critical in the report of the Panel on Research on Child Abuse and Neglect of the National Research Council. The Archive is needed to make available and support research on the prevention, identification and treatment of child abuse and neglect, adoption, foster care, and related child welfare issues. Since September 30, 1988, the National Center on Child Abuse and Neglect (NCCAN), and now the Children's Bureau (CB), has provided funding for the National Data Archive on Child Abuse and Neglect. The Archive is currently located at Cornell University, Family Life Development Center, MVR Hall, Ithaca, New York, 14853–4401 (telephone 607–255–7799). The Archive is a centralized facility for the acquisition, preservation, and dissemination of machine-readable data sets relevant to the study of child maltreatment and child welfare. The Archive currently holds 24 data sets and has produced an updated document that has been widely disseminated to the field: 'Depositing Data with the National Archive on Child Abuse and Neglect: A Handbook for Investigators.' Information on the data sets can be obtained from the Archive. The Handbook can be obtained from the Archive directly or downloaded through its Web page, *http://www.ndacan.cornell.edu/,* or through the National Clearinghouse on Child Abuse and Neglect Information.

This is a full and open competition. It is expected that the successful applicant, whether the current grantee or a new grantee, will continue to build on the present activities and negotiate transition of the project in a professional manner, respectful of the proprietary nature of some of the material housed at and created by the current grantee, as necessary.

The Archive is responsible for a variety of activities: To prepare, process, house and preserve quality data sets; to establish standards and procedures for documentation and produce related materials; to facilitate collaboration through training, technical assistance, workshops featuring specific data sets (including the National Survey of Child and Adolescent Well-Being), and summer institutes; to create and utilize an advisory board of some kind; and dissemination through a variety of outreach methods. Applicants are encouraged to consider this list of activities as minimal requirements.

While a major function of the Archive is to process, house, and preserve quality data sets from studies on child abuse and neglect, an archive also plays a critical role in setting standards and establishing good practices for documentation of data sets. Establishing such procedures enables data to be more readily available and easily shared with other researchers and provides the additional capacity for further and secondary analysis.

Any child welfare investigator, regardless of the funding source, is welcome to house data with the Archive. Since FY 1994, all research grantees funded by the National Center on Child Abuse and Neglect (NCCAN), and now all those funded by the Children's Bureau, have been required, as a condition of their award, to archive their data. They must prepare data sets according to sound data processing and documentation practices and to house those data sets at the Archive within two years of the end of their funding period. Archive staff provide technical support on data entry, processing, analysis, and documentation. Thus, the application submitted in response to this priority area should be responsive to housing data sets from a variety of sources, including but not limited to national surveys such as those conducted by the National Center for Health Statistics, the National Incidence Studies, the National Child Abuse and Neglect Data System (NCANDS), and the Adoption and Foster Care Analysis and Reporting System (AFCARS), and the National Survey of Child and Adolescent Well-Being (NSCAW).

A centralized archive can facilitate collaboration among researchers for knowledge building and encourage new researchers to enter the field. An archive should also provide training and technical assistance opportunities for new researchers or postdoctoral candidates by conducting training institutes that convene a small number of researchers to work in a guided setting with these data sets. Support for secondary analysis of various data sets in the Archive can be provided through these training institutes as well as through small grants to researchers to work with these data sets. Support may be provided for graduate research or postdoctoral research fellows to work in residence with Archive staff on research related to the holdings. Workshops and training sessions can also be convened at major national conferences.

There is an increasing recognition that some data sets cannot be archived in their entirety for public use without undue risk to the study respondents. Researchers are understandably concerned about the possibility of breaches of confidentiality, and the intentional and unintentional unmasking of identifying information in these sensitive data sets. In order to protect participants' identities in a public use data set, researchers often must delete or mask important variables in the data set, which limits the utility of the data for secondary analyses. One solution has been to provide access to the more detailed data on a restricted basis, by obtaining assurances from the user that the data sets will be carefully handled and will be used only for legitimate research purposes. For example, the National Center for Educational Statistics has developed licensing and monitoring procedures that allow for the release of micro-data that otherwise would not be available to the broader research community. The Archive should anticipate the need for maintaining similar licensing and monitoring procedures for similarly sensitive data sets, including the data from the National Survey of Child and Adolescent Well-Being.

Dissemination is a major function of an archive. This includes providing innovative tools such as CD–ROMs and a range of ready-to-use formats that make archived data sets more easily accessible to the research community; answering AFCARS data requests from the public and referring these requests to the Children's Bureau as needed, publishing information on projects of the Archive and new acquisitions; preparation of technical guidelines outlining data processing standards and user guides to archive holdings; and the development and maintenance of electronic mail services to facilitate networking and information exchange among researchers in the field of child abuse and neglect, including their access to a database on measures appropriate for researchers in this field. Cooperation and appropriate collaboration with other archives also is expected.

Legislative Authority

The Child Abuse Prevention and Treatment Act Section 105(b)(5) (42 U.S.C. 5106) Section 429 of the Personal Responsibility and Work Opportunities Reconciliation Act (Pub. L. 104–193).

Projects funded under this announcement will be expected to:

1. Have the project fully functioning within 90 days following the notification of the grant award.

2. Participate if the Children's Bureau chooses to do a national evaluation or a technical assistance contract that relates to this funding announcement.

3. Submit all performance indicator data, program and financial reports in a timely manner, in recommended format (to be provided), and submit the final report on disk or electronically using a standard word-processing program.

4. Submit a copy of the final report, the evaluation report, and any program products to the National Clearinghouse on Child Abuse and Neglect Information, 330 C Street, SW., Washington, DC 20447, within 90 days of project end date. This is in addition to the standard requirement that the final program and evaluation report must also be submitted to the Grants Management Specialist and the Federal Project Officer.

5. Allocate sufficient funds in the budget to:

(a) Provide for the project director, the evaluator and a child welfare representative to attend an annual 3-day grantees' meeting in Washington, DC.

(b) Provide for the project director, the evaluator and a child welfare representative to attend an early kickoff meeting for grantees funded under this priority area to be held within the first three months of the project (first year only) in Washington, DC; and

(c) Provide for 10–15 percent of the proposed budget to project evaluation.

II. Award Information

Funding Instrument Type: Cooperative Agreement.

Federal Substantial Involvement With Cooperative Agreement

A cooperative agreement is a specific method of awarding Federal assistance in which substantial Federal involvement is anticipated. A cooperative agreement clearly defines the respective responsibilities of the Children's Bureau and the grantee prior to the award. The Children's Bureau anticipates that agency involvement will produce programmatic benefits to the recipient otherwise unavailable to them for carrying out the project. The involvement and collaboration includes Children's Bureau review and approval of planning stages of the activities before implementation phases may begin; Children's Bureau involvement in the establishment of policies and procedures that maximize open competition, and rigorous and impartial development, review and funding of grant or sub-grant activities, if applicable; and Children's Bureau and recipient joint collaboration in the performance of key programmatic activities (*i.e.*, strategic planning, implementation, information technology enhancements, training and technical assistance, publications or products, and evaluation). It also includes close monitoring by the Children's Bureau of the requirements stated in this announcement that limit the grantee's discretion with respect to scope of services offered, organizational structure and management processes, coupled with close Children's Bureau monitoring during performance, which may, in order to ensure compliance with the intent of this funding, exceed those federal stewardship responsibilities customary for grant activities.

Anticipated Total Priority Area Funding: $600,000.

Anticipated Number of Awards: 0 to 1.

Ceiling on Amount of Individual Awards Per Budget Period: $600,000.

Average Projected Award Amount: $600,000.

Length of Project Periods: 60-month project with five 12-month budget periods.

Other.

Explanation of Other: In the first budget period, the maximum Federal share of the project is not to exceed $600,000. In subsequent budget periods, the maximum Federal share of the project is not to exceed $500,000. The projects awarded will be for a project period of 60 months. The initial grant award will be for a 12-month budget period. The award of continuation beyond each 12-month budget period will be subject to the availability of funds, satisfactory progress on the part of the grantee, and a determination that continued funding would be in the best interest of the government.

Floor on amount of individual awards: None.

III. Eligibility Information

1. Eligible Applicants

State governments
County governments
City or township governments
Special district governments
Independent school districts
State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public Housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
Individuals
For-profit organization other than small businesses
Small businesses

Additional Information on Eligibility

Faith-based and community organizations that meet all other eligibility requirements are eligible to apply.

Applicant should have experience with archiving and analyzing AFCARS and NCANDS data, the two primary databases utilized by the Children's Bureau.

Applicant should possess a sound working knowledge of ACF data collection activities related to the data archive.

Collaborative and interdisciplinary efforts are acceptable, but applications should identify a primary applicant responsible for administering the grant.

2. Cost Sharing/Matching

Cost Sharing/Matching: None.

3. Other Eligibility Information

All applicants must have a Dun & Bradstreet number. On June 27, 2003 the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (*http://www.Grants.gov*). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1–866–705–5711 or you may request a number on-line at *http://www.dnb.com.*

Non-profit organizations applying for funding are required to submit proof of their non-profit status.

Proof of non-profit status is any one of the following:

- A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list

of tax-exempt organizations described in the IRS Code.

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earning accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.
- Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Disqualification Factors

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application post-marked after 4:30 p.m. eastern time zone on the deadline date will not be considered for competition.

IV. Application and Submission Information

1. Address To Request Application Package

ACYF Operations, The Dixon Group ATTN: Children's Bureau, 118 Q St., NE., Washington, DC 20002–2132, Phone: 866–796–1591, URL: *http://www.acf.hhs.gov/grants/open/HHS–2005–ACF–ACYF–CA–0001.html.*

2. Content and Form of Application Submission

Originals, Copies and Signatures

If submitting your application in paper format, an original and two copies of the complete application are required. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, have original signatures, and be submitted unbound.

Each application must contain the following items in the order listed:

Application for Federal Assistance (Standard Form 424). Follow the instructions below and those that accompany the form.

In Item 5 of Form 424, put DUNS number in ''Organizational DUNS:'' box.

In Item 5 of Form 424, include name, phone number, and, if available, email and fax numbers of the contact person.

In Item 8 of Form 424, check 'New.'

In Item 10 of Form 424, clearly identify the Catalog of Federal Domestic Assistance (CFDA) program title and number for the program for which funds are being requested as stated in this funding opportunity announcement.

In Item 11 of Form 424, identify the single funding opportunity the application addresses.

In Item 12 of Form 424, identify the specific geographic area to be served.

In Item 14 of Form 424, identify Congressional districts of both the applicant and project.

Budget Information Non-Construction Programs (Form 424A) and Budget Justification

Follow the instructions provided here and those in Section V. Application Review Information.

If applicable, applicants must include a completed SPOC certification (Single Point of Contact) with the date of the SPOC contact entered in line 16, page 1 of the Form 424.

Proof of non-profit status (if applicable). Please see Section III.3 Other Eligibility for ways to demonstrate non-profit status.

Indirect cost rate agreement. If claiming indirect costs, provide documentation that applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

Letters of agreement and memoranda of understanding. If applicable, include a letter of commitment or Memorandum of Understanding from each partner and/or sub-contractor describing their role, detailing specific tasks to be performed, and expressing commitment to participate if the proposed project is funded.

General Content and Form Information

The application limit is 75 pages total including all forms and attachments. Pages over this page limit will be removed from the application and will not be reviewed.

To be considered for funding, each application must be submitted with the Standard Federal Forms (provided at the end of this announcement or through the electronic links provided) and following the guidance provided. The application must be signed by an individual authorized to act for the applicant agency and to assume responsibility for the obligations imposed by the terms and conditions of the grant award.

The application must be typed, double spaced, printed on only one side, with at least ½ inch margins on each side and 1 inch at the top and bottom, using standard 12 Point fonts (such as Times New Roman or Courier). Pages must be numbered.

All copies of an application must be submitted in a single package, and a separate package must be submitted for each funding opportunity. The package must be clearly labeled for the specific funding opportunity it is addressing.

Because each application will be duplicated, do not use or include separate covers, binders, clips, tabs, plastic inserts, maps, brochures, or any other items that cannot be processed easily on a photocopy machine with an automatic feed. Do not bind, clip, staple, or fasten in any way separate subsections of the application, including supporting documentation; however, each complete copy must be stapled securely in the upper left corner. Applicants are advised that the copies of the application submitted, not the original, will be reproduced by the Federal government for review.

Tips for Preparing a Competitive Application. It is essential that applicants read the entire announcement package carefully before preparing an application and include all of the required application forms and attachments. The application must reflect a thorough understanding of the purpose and objectives of the applicable legislation. Reviewers expect applicants to understand the goals of the legislation and the Children's Bureau's interest in each topic. A ''responsive application'' is one that addresses all of the evaluation criteria in ways that demonstrate this understanding. Applications that are considered to be ''unresponsive'' generally receive very low scores and are rarely funded.

The Children's Bureau's Web site (*http://www.acf.dhhs.gov/programs/cb*) provides a wide range of information and links to other relevant Web sites. Before you begin preparing an application, we suggest that you learn more about the mission and programs of the Children's Bureau by exploring the Web site.

Organizing Your Application. The specific evaluation criteria in Section V of this funding announcement will be used to review and evaluate each application. The applicant should address each of these specific evaluation criteria in the project description. Applicants should organize their project description in this sequence: (1) Objectives and Need for Assistance; (2) Approach; (3) Organizational Profiles; (4) Budget and Budget Justification; and should use the same headings as these criteria, so that reviewers can readily find information that directly addresses each of the specific review criteria.

Project Evaluation Plan. Project evaluations are very important. If you do not have the in-house capacity to conduct an objective, comprehensive evaluation of the project, then the Children's Bureau advises that you propose contracting with a third-party evaluator specializing in social science or evaluation, or a university or college, to conduct the evaluation. A skilled evaluator can assist you in designing a data collection strategy that is appropriate for the evaluation of your proposed project. Additional assistance may be found in a document titled ''Program Manager's Guide to Evaluation.'' A copy of this document can be accessed at *http://www.acf.hhs.gov/programs/opre/other_resrch/pm_guide_eval/reports/pmguide/pmguide_toc.html.*

Logic Model. A logic model is a tool that presents the conceptual framework for a proposed project and explains the linkages among program elements. While there are many versions of the logic model, they generally summarize the logical connections among the needs that are the focus of the project, project goals and objectives, the target population, project inputs (resources), the proposed activities/processes/outputs directed toward the target population, the expected short- and long-term outcomes the initiative is designed to achieve, and the evaluation plan for measuring the extent to which proposed processes and outcomes actually occur. Information on the development of logic models is available on the Internet at *http://www.uwex.edu/ces/pdande/,* or *http://www.extension.iastate.edu/cyfar/capbuilding/outcome/outcome_logicmdir.html.*

Use of Human Subjects. If your evaluation plan includes gathering data from or about clients, there are specific procedures which must be followed in order to protect their privacy and ensure the confidentiality of the information about them. Applicants planning to gather such data are asked to describe their plans regarding an Institutional Review Board (IRB) review. If applicable, applicants must include a completed Form 310, Protection of Human Subjects. For more information about use of human subjects and IRB's you can visit these Web sites: *http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm, http://www.hhs.gov/ohrp/humansubjects/assurance/OF310.rtf, http://www.hhs.gov/ohrp/irb/irb_chapter2.htm#d2,* and *http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm.*

You may submit your application to us in either electronic or paper format. To submit an application electronically, please use the *http://www.Grants.gov/Apply* site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. ACF will not accept grant applications via e-mail or facsimile transmission.

Please note the following if you plan to submit your application electronically via Grants.gov:

- Electronic submission is voluntary, but strongly encouraged.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.
- We recommend you visit Grants.gov at least 30 days prior to filing your application to fully understand the process and requirements. We encourage applicants who submit electronically to submit well before the closing date and time so that if difficulties are encountered an applicant can still send in a hard copy overnight. If you encounter difficulties, please contact the Grants.gov Help Desk at 1–800–518–4276 to report the problem and obtain assistance with the system.
- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grants.gov.
- We may request that you provide original signatures on forms at a later date.
- You may access the electronic application for this program on *www.Grants.gov.*
- You must search for the downloadable application package by the CFDA number.

Private, non-profit organizations are encouraged to submit with their applications the survey located under ''Grant Related Documents and Forms,'' ''Survey for Private, Non-Profit Grant Applicants,'' titled, ''Survey on Ensuring Equal Opportunity for Applicants,'' at: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Standard Forms and Certifications

The project description should include all the information requirements described in the specific evaluation criteria outlined in the program announcement under Section V Application Review Information. In addition to the project description, the applicant needs to complete all the standard forms required for making applications for awards under this announcement.

Applicants seeking financial assistance under this announcement must file the Standard Form (SF) 424, Application for Federal Assistance; SF–424A, Budget Information—Non-Construction Programs; SF–424B, Assurances—Non-Construction Programs. The forms may be reproduced for use in submitting applications. Applicants must sign and return the standard forms with their application.

Applicants must furnish prior to award an executed copy of the Standard Form LLL, Certification Regarding Lobbying, when applying for an award in excess of $100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form, if applicable, with their applications (approved by the Office of Management and Budget under control number 0348–0046). Applicants must sign and return the certification with their application.

Applicants must also understand they will be held accountable for the smoking prohibition included within Public Law 103–227, Title XII Environmental Tobacco Smoke (also known as the PRO–KIDS Act of 1994). A copy of the **Federal Register** notice which implements the smoking prohibition is included with forms. By signing and submitting the application, applicants are providing the certification and need not mail back the certification with the application.

Applicants must make the appropriate certification of their compliance with all Federal statutes relating to nondiscrimination. By signing and submitting the applications, applicants

are providing the certification and need not mail back the certification form. Complete the standard forms and the associated certifications and assurances based on the instructions on the forms. The forms and certifications may be found at: *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Those organizations required to provide proof of non-profit status, please refer to Section III.3.

Please see Section V.1, for instructions on preparing the full project description.

3. Submission Dates and Times

Explanation of Due Dates

The closing time and date for receipt of applications is 4:30 p.m. (Eastern Time Zone) on the date noted above. Mailed or hand carried applications received after 4:30 p.m. on the closing date will be classified as late.

Deadline: Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the ACYF Operations Center, c/o The Dixon Group, Inc., ATTN: Children's Bureau, 118 Q Street NE., Washington, DC 20002–2132. Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

Applications handcarried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., EST, at the ACYF Operations Center, c/o The Dixon Group, Inc., ATTN: Children's Bureau, 118 Q Street NE., Washington, DC 20002–2132, between Monday and Friday (excluding Federal holidays). This address must appear on the envelope/package containing the application with the note. Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

Late applications: Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition. Any application received after 4:30 pm on the deadline date will not be considered for competition. Applicants using express/overnight mail services should allow two working days prior to the deadline date for receipt of applications. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed).

Extension of deadlines: ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Applicants will not be sent acknowledgements of received applications.

Checklist:

What to submit	Required content	Required form or format	When to submit
Project Abstract	See Section IV and V	Format described in Section IV and V	By application due date.
Project Narrative	See Section IV and V	Format described in Section IV and V	By application due date.
SF424	See Section IV	Format described in Section IV	By application due date.
SF424A	See Section IV	Format described in Section IV	By application due date.
SF424B	See Section IV	Format described in Section IV	By application due date.
Assurances and Certifications	See Section IV	Format described in Section IV	By Time of Award.
Proof of Non-profit status, if applicable	See Section III and IV	Format described in Section III	By Time of Award.
Indirect Cost rate Agreement, if applicable.	See Section IV	Format described in IV	By Time of Award.
Letters of commitment from partner organizations, if applicable.	See Section IV	Format described in IV	By Time of Award.

Additional Forms: Private, nonprofit organizations are encouraged to submit with their applications the survey located under ''Grant Related Documents and Forms'' titled ''Survey for Private, Non-Profit Grant Applicants'' at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

What to submit	Required content	Required form or format	When to submit
Survey for Private, Non-Profit Grant Applicants.	Per required form	May be found on *http://www.acf.hhs.gov/programs/ofs/forms.htm.*	With application.

4. Intergovernmental Review

State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' and 45 CFR Part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.'' Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

As of October 1, 2004, the following jurisdictions have elected to participate in the Executive Order process: Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Kentucky, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, New York, North Dakota, Rhode Island, South Carolina, Texas, Utah, West Virginia, Wisconsin, American Samoa, Guam, North Mariana Islands, Puerto Rico, and Virgin Islands. As these jurisdictions have elected to participate in the Executive Order process, they have established SPOCs. Applicants from participating jurisdictions should contact their SPOC, as soon as possible, to alert them of prospective applications and receive instructions. Applicants must submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2).

A SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. SPOCs are

encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the ''accommodate or explain'' rule.

When comments are submitted directly to ACF, they should be addressed to the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade SW., 4th floor, Washington, DC 20447.

Although the remaining jurisdictions have chosen not to participate in the process, entities that meet the eligibility requirements of the program are still eligible to apply for a grant even if a State, Territory, Commonwealth, etc. does not have a SPOC. Therefore, applicants from these jurisdictions, or for projects administered by Federally-recognized Indian Tribes, need take no action in regard to E.O. 12372.

The official list, including addresses, of the jurisdictions elected to participate in E.O. 12372 can be found on the following URL: *http://www.whitehouse.gov/omb/grants/spoc.html.*

5. Funding Restrictions

Grant awards will not allow reimbursement of pre-award costs.

Construction is not an allowable activity or expenditure under this solicitation.

Applicants should note that grants to be awarded under this program announcement are subject to the availability of funds. The size of the actual awards will vary.

6. Other Submission Requirements

Submission by Mail: An Application must provide an original application with all attachments, signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications should be mailed to: ACYF Operations Center, The Dixon Group, 118 Q St. NE., Washington DC, DC 20002–2132, Attention: Children's Bureau.

Hand Delivery: An Applicant must provide an original application with all attachments signed by an authorized representative and two copies. Please see Section IV.3 for an explanation of due dates. Applications should be delivered to: ACYF Operations Center, The Dixon Group, 118 Q St. NE., Washington DC 20002–2132, Attention: Children's Bureau.

Electronic Submission: http://www.grants.gov Please see section IV. 2 Content and Form of Application Submission, for guidelines and requirements when submitting applications electronically.

V. Application Review Information

The Paperwork Reduction Act of 1995 (Pub. L. 104–13)

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

The project description is approved under OMB control number 0970–0139 which expires 4/30/2007.

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 following are instructions and guidelines on how to prepare the ''Project Summary/Abstract'' and ''Full Project Description'' sections of the application. Under the evaluation criteria section, note that each criterion is preceded by the generic evaluation requirement under the ACF Uniform Project Description (UPD).

1. Criteria

General Instructions

ACF is particularly interested in specific project descriptions that focus on outcomes and convey strategies for achieving intended performance. Project descriptions are evaluated on the basis of substance and measurable outcomes, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant funded activity should be placed in an appendix. Pages should be numbered and a table of contents should be included for easy reference.

Introduction

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions while being aware of the specified evaluation criteria. The text options give a broad overview of what your project description should include while the evaluation criteria identifies the measures that will be used to evaluate applications.

Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

Objectives and Need for Assistance

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

Approach

Outline a plan of action that describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors that might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement. Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished.

When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates. If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any ''collection of information that is conducted or sponsored by ACF.'' List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners, such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. If the applicant is a non-profit organization, submit proof of non-profit status in its application. The non-profit agency can accomplish this by providing: (a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate, (c) a statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status, (e) any of the items immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Budget and Budget Justification

Provide a budget with line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF–424. Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

General

Use the following guidelines for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. ''Federal resources'' refers only to the ACF grant for which you are applying. ''Non Federal resources'' are all other Federal and non-Federal resources. It is suggested that budget amounts and computations be presented in a columnar format: First column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

Personnel

Description: Costs of employee salaries and wages. Justification: Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe Benefits

Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate. Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

Travel

Description: Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel). Justification: For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops should be detailed in the budget.

Equipment

Description: ''Equipment'' means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.) Justification: For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

Supplies

Description: Costs of all tangible personal property other than that included under the Equipment category. Justification: Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

Contractual

Description: Costs of all contracts for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant. Justification: Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at $100,000).

Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc. Note: Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

Other

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to

insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs. Justification: Provide computations, a narrative description and a justification for each cost under this category.

Indirect Charges

Description: Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency. Justification: An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, upon notification that an award will be made, it should immediately develop a tentative indirect cost rate proposal based on its most recently completed fiscal year, in accordance with the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. When an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Evaluation Criteria

The following evaluation criteria appear in weighted descending order. The corresponding score values indicate the relative importance that ACF places on each evaluation criterion; however, applicants need not develop their applications precisely according to the order presented. Application components may be organized such that a reviewer will be able to follow a seamless and logical flow of information (*e.g.* from a broad overview of the project to more detailed information about how it will be conducted.

In considering how applicants will carry out the responsibilities addressed under this announcement, competing applications for financial assistance will be reviewed and evaluated against the following criteria:

Approach—50 Points

In reviewing the approach, the following factors will be considered: (50 points)

1. The extent to which there is a sound timeline for effectively implementing the proposed project, including major milestones and target dates.

2. The extent to which the proposed project would enhance policy, improve practice, and advance science in child maltreatment research. The extent to which the proposed project would be significant to the field of child welfare researchers.

3. The extent to which the proposed project would contribute to the overall effort to improve the safety, permanence and well-being of children and address particular outcome measures, as applicable.

4. The extent to which the applicant identifies relevant barriers and problems associated with a national archive and proposes effective solutions to these problems.

5. The extent to which the applicant demonstrates an awareness of current activities being undertaken in the field of archiving and describes how the approach being proposed would effectively build on this work. The extent to which the proposed project would be different from previous efforts in ways that improve processes and results.

6. The extent to which the proposed project would reflect cultural sensitivity to the issues being addressed.

7. The extent to which the proposed project would address the issues related to the particular challenges of archiving and confidentiality, including the strengths and weaknesses of possible strategies that address masking individual identifiers, and user agreements that particularly address protections for confidentiality and limit liability. The extent to which the proposed project would explain the relationship between archiving and the protection of human subjects, informed consent, protection from research risks, and Institutional Review Boards (IRB) in general. The extent to which the proposed project would address the relationship of the funded archive to Institutional Review Boards and the Department of Health and Human Services Office for Protection from Research Risks and Certificates of Confidentiality, specifically.

8. The extent to which the proposed project would address the strengths and weaknesses of possible strategies that deal with limited, hierarchical, or controlled access and user agreements that particularly address confidentiality and liability. The extent to which the applicant discusses a variety of models for delimiting access and the impact of fee structures related to access and proposes recommendations regarding access controls for the proposed activity.

9. The extent to which the applicant demonstrates an ability to gain access to necessary information, data sets, and data bases, as applicable, and delineates a sound plan for addressing any ethical issues that may arise in the use of these data sets.

10. The extent to which the application effectively addresses the uses and merits of an advisory committee.

11. The extent to which there are sound strategies for dissemination of products and reports that would be of use to other researchers and practitioners in the field.

12. The extent to which the applicant proposes a sound strategy for providing supplementary support to data users who access National Survey of Child and Adolescent Well-Being (NSCAW) data through the National Data Archive on Child Abuse and Neglect during Year 1.

Organizational Profiles—20 Points

In reviewing the organizational profiles, the following factors will be considered: (20 points)

1. The extent to which the applicant demonstrates strong organizational experience specifically related to archiving, and its sub-tasks, and conducting child maltreatment and child welfare research. The extent to which the applicant demonstrates a sound working knowledge of ACF data collection activities related to the data archive. The extent to which each participating university or agency partner possesses the organizational capabilities required for implementation of this activity.

2. The extent to which the applicant demonstrates sufficient resources and the appropriate facilities to undertake the project.

3. The extent to which the proposed project director and key project staff possess sufficient relevant knowledge, experience and the capabilities to implement and manage a project of this size, scope and complexity effectively (*e.g.*, resumes). The extent to which the roles, responsibilities and time commitments of each proposed project staff position, including consultants, subcontractors and/or partners, are clearly defined and appropriate to the successful implementation of the proposed project with respect to

developing and maintaining a national archive on child welfare and child abuse and neglect data.

The extent to which there is a sound management plan for achieving the objectives of the proposed project on time and within budget, including clearly defined responsibilities, for accomplishing project tasks and ensuring quality. The extent to which the plan clearly describes the effective management and coordination of activities carried out by any partners, subcontractors and consultants (if appropriate). The extent to which there would be a mutually beneficial relationship between the proposed project and other work planned, anticipated or underway with Federal assistance by the applicant.

Objectives and Need for Assistance—20 Points

In reviewing the objectives and need for assistance, the following factors will be considered: (20 points)

1. The extent to which the applicant demonstrates an understanding of the general need for archiving, and specifically, the need for archiving the Children's Bureau (CB) child welfare and child abuse and neglect data. The extent to which the application clearly describes specific measurable objectives.

2. The extent to which the applicant demonstrates an awareness of current initiatives in the field of child maltreatment and archiving and clearly describes how the approach being proposed would address both.

3. The extent to which the applicant discusses current issues in archiving including but not limited to topics such as the world wide web, dissemination strategies, liability, and terms of use agreements.

4. The extent to which the applicant clearly describes the audience of users of the data archive, provides a reasonable estimate of their number and describes their needs.

Budget and Budget Justification—10 Points

In reviewing the budget and budget justification, the following factors will be considered: (10 points)

1. The extent to which the costs of the proposed project are reasonable and appropriate in view of the activities to be conducted and expected results and benefits.

2. The extent to which the applicant's fiscal controls and accounting procedures would ensure prudent use, proper and timely disbursement and accurate accounting of funds received under the program announcement.

2. Review and Selection Process

Since ACF will be using non-Federal reviewers in the review process, applicants have the option of omitting from the application copies (not the original) of specific salary rates or amounts for individuals specified in the application budget.

No grant award will be made under this announcement on the basis of an incomplete application.

When the Operations Center receives your application it will be screened to confirm that your application was received by the deadline. Federal staff will verify that you are an eligible applicant and that the application contains all the essential elements. Applications received from ineligible organizations and applications received after the deadline will be withdrawn from further consideration.

A panel of at least three reviewers (primarily experts from outside the Federal government) will use the evaluation criteria described in this announcement to evaluate each application. The reviewers will determine the strengths and weaknesses of each application, provide comments about the strengths and weaknesses and give each application a numerical score.

The results of the competitive review are a primary factor in making funding decisions. In addition, Federal staff conducts administrative reviews of the applications and, in light of the results of the competitive review, will recommend applications for funding to the ACYF Commissioner. ACYF reserves the option of discussing applications with other funding sources when this is in the best interest of the Federal government. ACYF may also solicit and consider comments from ACF Regional Office staff in making funding decisions. ACYF may take into consideration the involvement (financial and/or programmatic) of the private sector, national, or State or community foundations; a favorable balance between Federal and non-Federal funds for the proposed project; or the potential for high benefit from low Federal investment. ACYF may elect not to fund any applicants having known management, fiscal, reporting, programmatic, or other problems which make it unlikely that they would be able to provide effective services or effectively complete the proposed activity.

With the results of the peer review and the information from Federal staff, the Commissioner of ACYF makes the final funding decisions. The Commissioner may give special consideration to applications proposing services of special interest to the Government and to achieve geographic distributions of grant awards. Applications of special interest may include, but are not limited to, applications focusing on unserved or inadequately served clients or service areas and programs addressing diverse ethnic populations.

Approved But Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

3. Anticipated Announcement and Award Dates

Anticipated Announcement and Award Dates. Applications will be reviewed in the summer of 2005. Grant awards will have a start date no later than September 30, 2005.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Direct Federal grants, sub-award funds, or contracts under this CB National Data Archive on Child Abuse and Neglect program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment For Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

45 CFR Part 74, 92. Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR

part 92 (governmental) as well as 45 CFR part 87.

3. Reporting Requirements

Program Progress Reports: Semi-Annually.

Financial Reports: Semi-Annually.

Grantees will be required to submit program progress reports and financial reports (SF269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

VII. Agency Contacts

Program Office Contact

John Gaudiosi, Children's Bureau, 330 C Street, SW., Washington, DC 20447, Phone: 202–205–8625, E-mail: *jgaudiosi@acf.hhs.gov.*

Grants Management Office Contact

Peter Thompson, Grants Officer, Administration for Children and Families, Children's Bureau, 330 C Street, SW., Room 2070, Washington, DC 20447, Phone: 202–401–4608, E-mail: *pathompson@acf.hhs.gov.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/cb/.*

For general questions regarding this announcement please contact: ACYF Operations Center, The Dixon Group ATTN: Children's Bureau, 118 Q Street, NE., Washington DC 20002–2132, Telephone: 866–796–1591.

Applicants will not be sent acknowledgements of received applications.

Dated: June 28, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05–13303 Filed 7–5–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Correction for Services to Unaccompanied Alien Children Services (UAC) Program To Provide Temporary Shelter Care and Other Related Services to Children in Office of Refugee Resettlement (ORR) Custody

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families, ACF, DHHS.

ACTION: Notice of Correction.

Funding Opportunity Title: Services to Unaccompanied Alien Children.

Funding Opportunity Number: HHS–2005–ACF–ORR–ZU–0007.

SUMMARY: This notice is to inform interested parties of a clarification made to Services to Unaccompanied Alien Children funding announcement published on Monday, June 17, 2005. The following clarifications should be noted:

Section I, Group I, Chart I on Page # 32345:

Group I.—Geographic Location

No. 14, Up to 120 suitability assessment cases per applicant (two awards available) $1.9 million (for a total of $3.8 million for this category).

Group II.—Geographic Location

No. 1, Los Angeles, Basic Shelter and/or Group Homes, 24 beds $1.76 million.

Section II. Award Information on Page #32350 stated the following:

''Floor on Amount of Individual Awards: $3,300,000 per budget period.''

Section I, Group I, Chart I on Page #32345 is replaced with:

Group I.—Geographic Location

''No. 14, Up to 120 suitability assessment cases per application (two awards available) $800,000 (for a total of $1.6 million for this category).''

Group II.—Geographic Location

''No. 1, Los Angeles, Basic Shelter and/or Group Homes, 24 beds $1.75 million.''

Section II. Award Information on Page #32350 is replaced with:

''Floor on Amount of Individual Awards: $218,000 per budget period.''

Dated: June 28, 2005.

Nguyen Van Hanh,

Director, Office of Refugee Resettlement.

[FR Doc. 05–13299 Filed 7–5–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System 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: Peripheral and Central Nervous System 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 August 4, 2005, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research (CDER) Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Anuja Patel, 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: *patelA@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Peripheral and Central Nervous System Drugs Advisory Committee).

Agenda: The committee will discuss new drug application (NDA) 21–645, proposed trade name MT100 (naproxen sodium and metoclopramide hydrochloride) Tablets, Pozen, Inc., for the proposed indication of acute treatment of migraine headache with or without aura.

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 by July 22, 2005. Oral presentations from the public will be scheduled between approximately 1

p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 22, 2005, 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.

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 John Lauttman at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 23, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–13206 Filed 7–5–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: Toolkit Protocol for the Crisis Counseling Assistance and Training Program (CCP)—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) will create a toolkit to be used for the purposes of collecting data on the Crisis Counseling Assistance and Training Program (CCP). The CCP provides supplemental funding to states and territories for individual and community crisis intervention services during a federal disaster.

The CCP has provided disaster mental health services to millions of disaster survivors since its inception and, as a result of 30 years of accumulated expertise, it has become an important model for Federal response to a variety of catastrophic events. State CCPs, such as Project HOPE (after Hurricane Floyd in North Carolina), Project Heartland (in Oklahoma City after the Murrah Federal Building bombing), Project Liberty (in New York after 9/11), and Project Outreach for Recovery (after the Rhode Island nightclub fire) have primarily addressed the short-term mental health needs of communities through (a) outreach and public education, (b) individual and group counseling, and (c) referral. Outreach and public education serve primarily to normalize reactions and to engage people who might need further care. Crisis counseling assists survivors to cope with current stress and symptoms in order to return to predisaster functioning. Crisis counseling relies largely on ''active listening,'' and crisis counselors also provide psycho-education (especially about the nature of responses to trauma) and help clients build coping skills. Crisis counseling typically continues no more than a few times. Because crisis counseling is time-limited, referral is the third important functions of CCPs. Counselors are expected to refer clients to formal treatment if the person has developed more serious psychiatric problems.

Data about services delivered and users of services will be collected throughout the program period. The data will be collected via the use of a toolkit that relies on standardized forms. At the program level, the data will be entered quickly and easily into a cumulative database to yield summary tables for quarterly and final reports for the program. SAMHSA has confirmed the feasibility of using scanable forms for most purposes. Because the data will be collected in a consistent way from all programs, they can be uploaded into an ongoing national database that likewise provides CMHS with a way of producing summary reports of services provided across all programs funded.

The components of the tool kit are listed and described below:

- Encounter logs. These forms will document all services provided. Completion of these logs will be required by the crisis counselors. There will be three types of encounter logs: (1) Individual Crisis Counseling Services Encounter Log; (2) Group Encounter Log; and (3) Weekly Tally Sheet.
  - Individual Crisis Counseling Services Encounter Log. Crisis counseling is defined as an interaction that lasts at least 15 minutes and involves participant disclosure. This form will be completed by the Crisis Counselor for each service recipient, defined as the person or persons who actively participated in the session (*e.g.*, by verbally participating), not someone who is merely present. For families, crisis counselors will complete separate forms for all family members who are actively engaged in the visit. Information to be collected includes demographics, service characteristics, risk factors, and referral data.
  - Group Encounter Log. This form will be used to identify either a group crisis counseling encounter or a group public education encounter. A check at the top will identify the class of activities (*i.e.*, counseling or education). This form will be completed by the Crisis Counselor for each group encounter. Information to be collected includes services characteristics, group identity and characteristics, and group activities.
  - Weekly Tally Sheet. This form will document brief educational and supportive encounters not captured on any other form. Information to be collected will include service characteristics, daily tallies and weekly totals for brief educational or supportive contacts and material distribution with no or minimal interaction.
- Assessment and Referral Tool. This tool will provide descriptive information about intense users of services, defined as all individuals receiving a third or fifth individual crisis counseling visit. This tool will be used beginning three months postdisaster and will be completed by the crisis counselor for each individual who accesses individual crisis counseling a third or fifth time.
- Participant Feedback. These surveys will be completed by and collected from a sample of service recipients, not every recipient. A time sampling approach (*e.g.*, soliciting participation from all counseling encounters one week per quarter) will be used. Information to be collected includes satisfaction with services, perceived improvements in self-functioning, types of exposure, and event reactions.
- CCP Service Provider Feedback. These surveys will be completed by and collected from the CCP service providers anonymously at six months and one year postevent. The survey will be coded on several program-level as well as worker-level variables. However, the program itself will be identified and shared with program management only if the number of individual workers is greater than 20.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form	Number of respondents	Responses per respondents	Hours per responses	Total hour burden
Individual Crisis Counseling Services Encounter Log	7,500	1	.03	225
Group Encounter Log Form	4,000	1	.03	120
Weekly Tally Sheet	4,000	1	.08	320
Assessment & Referral Tool	100	1	.08	8
Participant Feedback	1,000	1	.06	60
CCP Service Provider Feedback	100	1	.08	8
Total	16,700			741

Written comments and recommendations concerning the proposed information collection should be sent by August 5, 2005, to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: June 29, 2005.

Patricia S. Bransford,

Acting Executive Officer, SAMHSA.

[FR Doc. 05–13238 Filed 7–5–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200/800–735–5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2661/800–898–0180, (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.

Dynacare Kasper Medical Laboratories*, 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702/800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Express Analytical Labs, 3405 7th Ave., Suite 106, Marion, IA 52302, 319–377–0500.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Laboratory Specialists, Inc.).

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 10788 Roselle St., San Diego, CA 92121, 800–882–7272, (Formerly: Poisonlab, Inc.).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734.

MAXXAM Analytics Inc.*, 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700, (Formerly: NOVAMANN (Ontario), Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.

Northwest Toxicology, a LabOne Company, 2282 South Presidents Drive, Suite C, West Valley City, UT 84120, 801–606–6301/800–322–3361, (Formerly: LabOne, Inc., dba Northwest Toxicology; NWT Drug Testing, NorthWest Toxicology, Inc.; Northwest Drug Testing, a division of NWT Inc.).

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134.

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7897x7.

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372/800–821–3627.

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590/800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800–824–6152, (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750, (Formerly: Associated Pathologists Laboratories, Inc.).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995/847–885–2010, (Formerly: SmithKline Beecham Clinical Laboratories; International Toxicology Laboratories).

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520/800–877–2520, (Formerly: SmithKline Beecham Clinical Laboratories).

Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130.

Sciteck Clinical Laboratories, Inc., 317 Rutledge Road, Fletcher, NC 28732, 828–650–0409.

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176x276.

Southwest Laboratories, 4645 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.

Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–364–7400, (Formerly: St. Lawrence Hospital & Healthcare System).

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.

Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166, 305–593–2260.

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in

the NLCP certification maintenance program.

Pat Bransford,

Acting Executive Officer, SAMHSA.

[FR Doc. 05–13326 Filed 7–5–05; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4837–D–58]

Revocation and Redelegation of Fair Housing Act Complaint Processing Authority

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice of revocation and redelegation of authority.

SUMMARY: The General Deputy Assistant Secretary for Fair Housing and Equal Opportunity (FHEO) revokes the prior redelegation of his authority for Fair Housing Act complaint processing, made on August 4, 2003 (68 FR 45846), and redelegates complaint processing authority to FHEO field and headquarters staff.

EFFECTIVE DATE: June 23, 2005.

FOR FURTHER INFORMATION CONTACT: Karen A. Newton, Deputy Assistant Secretary for Operations and Management, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 Seventh Street SW., Room 5128, Washington, DC 20410–0001, telephone (202) 708–0768. (This is not a toll-free number.) Hearing- and speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: In a March 30, 1989, notice (54 FR 13121), the Secretary of HUD delegated the authority to enforce the Fair Housing Act to the Assistant Secretary for FHEO and the General Counsel. On August 4, 2003 (68 FR 45846), the Assistant Secretary for FHEO revoked all prior redelegations of authority for complaint processing under the Fair Housing Act (42 U.S.C. 3601 *et seq.*) and redelegated that authority to the General Deputy Assistant Secretary for Fair Housing and Equal Opportunity. The General Deputy Assistant Secretary then further redelegated that complaint processing authority to field and headquarters staff. After the August 4, 2003 redelegations, the FHEO Hub Directors' titles were changed to FHEO Region Directors. Additionally the Young Implementation Office closed and, consequently, there is no longer a need for delegations of authority to the Young Implementation Office. Additionally, effective January 23, 2005, FHEO created an Office of Systemic Investigations.

The Assistant Secretary's August 4, 2003 redelegation of authority for complaint processing under the Fair Housing Act to the General Deputy Assistant Secretary for FHEO remains intact. However, the General Deputy Assistant Secretary revokes the redelegations of Fair Housing Act complaint processing authority issued by him on August 4, 2003, and redelegates that authority as provided in this notice.

Section A. Authority Redelegated

The General Deputy Assistant Secretary for FHEO retains and redelegates the Fair Housing Act complaint processing authority under 24 CFR part 103 to the Deputy Assistant Secretary for Enforcement and Programs.

The Deputy Assistant Secretary for Enforcement and Programs retains and further redelegates the Fair Housing Act complaint processing under 24 CFR part 103, subparts A, B, C, D (with the exception of the filing of a Secretary-initiated complaint under *24 CFR 103.204(a)*), E, and F, to the FHEO Region Directors, the FHEO Director of the Office of Enforcement, and the FHEO Director of the Office of Systemic Investigations.

The Deputy Assistant Secretary for Enforcement and Programs for FHEO retains and further redelegates the authority under *24 CFR 103.510(a) and (d) of 24 CFR subpart H* to the FHEO Region Directors, the Director of the Office of Enforcement, and the Director of the Office of Systemic Investigations, with the exception of pattern and practice referrals to the Attorney General, which are redelegated only to the Director of the Office of Enforcement, and the Director of the Office of Systemic Investigations.

The Deputy Assistant Secretary for Enforcement and Programs for FHEO retains and further redelegates the authority to reconsider no cause determinations (issued pursuant to 24 CFR 103.400(a)(2)(ii)) to the Director of the Office of Enforcement.

Section B. Authority To Further Redelegate

The Deputy Assistant Secretary for Enforcement and Programs may redelegate the authorities provided in Section A of this notice. The Director of the Office of Enforcement, the FHEO Region Directors, and the Director of the Office of Systemic Investigations may not redelegate the authorities provided in Section A of this notice.

Section C. Authority Revoked

The August 4, 2003, redelegation of the General Deputy Assistant Secretary's authority (68 FR 45846) is revoked.

Authority: Section 7(d) of the Department of Housing and Urban Development Act *(42 U.S.C. 3535(d))*.

Dated: June 23, 2005.

Floyd O. May,

General Deputy, Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. E5–3499 Filed 7–5–05; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Reviews of the Mariana Fruit Bat (*Pteropus mariannus mariannus*), Mariana Crow (*Corvus hawaiiensis*), Laysan Duck (*Anas laysanensis*), Kauai Akialoa (Honeycreeper) (*Hemignathus procerus*), Large Kauai Thrush (*Myadestes myadestinus*), Kauai Oo (Honeyeater) (*Moho braccatus*), Ou (Honeycreeper) (*Psittirostra psittace*), Molokai Creeper (*Paroreomyza flammea*), Molokai Thrush (*Myadestes lanaiensis rutha*), Kauai Cave Wolf Spider (*Adelocosa anops*) Kauai Cave Amphipod (*Spelaeorchestia koloana*), *Alsinidendron obovatum* (No Common Name), *Amaranthus brownii* (No Common Name), *Chamaesyce celastroides* var. *kaenana* (Akoko), *Chamaesyce deppeana* (Akoko), *Chamaesyce herbstii* (Akoko), *Chamaesyce skottsbergii* var. *kalaeloana* (Ewa Plains Akoko), *Clermontia pyrularia* (Oha Wai), *Cyanea grimesiana* ssp. *obatae* (No Common Name), *Cyanea pinnatifida* (Haha), *Cyanea st.-johnii* (Haha), *Cyanea superba* (Haha), *Cyanea truncata* (Haha), *Cyrtandra dentate* (Haiwale), *Gouania vitifolia* (No Common Name), *Hedyotis degeneri* (No Common Name), *Hibiscadelphus woodii* (Hau Kuahiwi), *Castilleja levisecta* (Golden paintbrush), Fender's Blue Butterfly (*Icaricia icarioides fenderi*), *Erigeron decumbens* var. *decumbens* (Willamette Daisy), *Lupinus sulphureus* ssp. *kincaidii* (Kincaid's Lupine), *Lomatium bradshawii* (Bradshaw's Desert Parsley), and *Sidalcea nelsoniana* (Nelson's Checker-mallow)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the initiation of a 5-year review of 33 species listed in Table 1 below, under section 4(c)(2)(B) of the Endangered Species Act (Act). The purpose of a 5-year review is to ensure that the classification of a species as threatened or endangered on the List of Endangered and Threatened Wildlife and Plants is accurate and consistent with the best scientific and commercial data available at the time of the review. We are requesting submission of any such information that has become available since the original listing of each of these 33 species. Based on the results of these 5-year reviews, we will consider whether the status of the species should be changed, pursuant to section 4(c)(2)(B) of the Act.

BILLING CODE 4310–55–P

Table 1. Summary of the Listing Information for the Following 33 Species				
Common name	Scientific name	Status	Where listed	Final Listing Rule
Mariana fruit bat (=Mariana flying fox)	Pteropus mariannus mariannus	Endangered	Western Pacific Ocean – U.S.A. (GU, MP)	49 FR 33885 (27-AUG-84)
Hawaiian crow	Corvus hawaiiensis	Endangered	U.S.A. (HI)	32 FR 4001 (11-MAR-67)
Laysan duck	Anas laysanensis	Endangered	U.S.A. (HI)	32 FR 4001 (11-MAR-67)
Kauai akialoa (honeycreeper)	Hemignathus procerus	Endangered	U.S.A. (HI)	32 FR 4001 (11-MAR-67)
Large Kauai thrush	Myadestes myadestinus	Endangered	U.S.A (HI)	35 FR 16047 (13-OCT-70)
Kauai oo (honeyeater)	Moho braccatus	Endangered	U.S.A. (HI)	32 FR 4001 (11-MAR-67)
Ou (honeycreeper)	Psittirostra psittacea	Endangered	U.S.A. (HI)	32 FR 4001 (11-MAR-67)
Molokai creeper	Paroreomyza flammea	Endangered	U.S.A. (HI)	35 FR 16047 (13-OCT-70)
Molokai thrush	Myadestes lanaiensis rutha	Endangered	U.S.A. (HI)	35 FR 16047 (13-OCT-70)
Kauai cave wolf spider	Adelocosa anops	Endangered	U.S.A. (HI)	65 FR 2357 (14-JAN-00)
Kauai cave amphipod	Spelaeorchestia koloana	Endangered	U.S.A. (HI)	65 FR 2357 (14-JAN-00)
None	Alsinidendron obovatum	Endangered	U.S.A. (HI)	56 FR 55785 (29-OCT-91)
None	Amaranthus brownii	Endangered	U.S.A. (HI)	61 FR 43184 (21-AUG-96)
Akoko	Chamaesyce celastroides var. kaenana	Endangered	U.S.A. (HI)	56 FR 55785 (29-OCT-91)
Akoko	Chamaesyce deppeana	Endangered	U.S.A. (HI)	59 FR 14493 (28-MAR-94)
Akoko	Chamaesyce herbstii	Endangered	U.S.A. (HI)	61 FR 53107 (10-OCT-96)
Ewa Plains akoko	Chamaesyce skottsbergii var. kalaeloana	Endangered	U.S.A. (HI)	47 FR 36849 (24-AUG-82)
Oha wai	Clermontia pyrularia	Endangered	U.S.A. (HI)	59 FR 10324 (04-MAR-94)

None	Cyanea grimesiana ssp. obatae	Endangered	U.S.A. (HI)	59 FR 32937 (27-JUN-94)
Haha	Cyanea pinnatifida	Endangered	U.S.A. (HI)	56 FR 55785 (29-OCT-91)
Haha	Cyanea st.-johnii	Endangered	U.S.A. (HI)	61 FR 53107 (10-OCT-96)
Haha	Cyanea superba	Endangered	U.S.A. (HI)	56 FR 46239 (11-SEP-91)
Haha	Cyanea truncate	Endangered	U.S.A. (HI)	59 FR 14493 (28-MAR-94)
Haiwale	Cyrtandra dentata	Endangered	U.S.A. (HI)	61 FR 53107 (10-OCT-96)
None	Gouania vitifolia	Endangered	U.S.A. (HI)	59 FR 32937 (27-JUN-94)
None	Hedyotis degeneri	Endangered	U.S.A. (HI)	56 FR 55785 (29-OCT-91)
Hau kuahiwi	Hibiscadelphus woodii	Endangered	U.S.A. (HI)	61 FR 53088 (10-OCT-96)
Golden paintbrush	Castilleja levisecta	Threatened	U.S.A. (OR, WA) Canada (B.C.)	62 FR 31748 (11-JUN-97)
Fender's blue butterfly	Icaricia icarioides fenderi	Endangered	U.S.A. (OR)	65 FR 3890 (25-JAN-00)
Willamette daisy	Erigeron decumbens var. decumbens	Endangered	U.S.A. (OR)	65 FR 3890 (25-JAN-00)
Kincaid's lupine	Lupinus sulphureus ssp. kincaidii	Threatened	U.S.A. (OR, WA)	65 FR 3890 (25-JAN-00)
Bradshaw's desert parsley	Lomatium bradshawii	Endangered	U.S.A. (OR, WA)	53 FR 38451 (28-SEP-88)
Nelson's checker-mallow	Sidalcea nelsoniana	Threatened	U.S.A. (OR, WA)	58 FR 8242 (12-FEB-93)

BILLING CODE 4310–55–C

DATES: To allow us adequate time to conduct these reviews, we must receive your information no later than September 6, 2005. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: Information may be submitted to the following Service Fish and Wildlife Offices:

For the Mariana fruit bat, Mariana crow, Laysan duck, Kauai akialoa (honeycreeper), large Kauai thrush, Kauai oo (honeyeater), ou (honeycreeper), Molokai creeper, Molokai thrush, Kauai cave wolf spider, Kauai cave amphipod, *Alsinidendron obovatum, Amaranthus brownii, Chamaesyce celastroides var. kaenana, Chamaesyce deppeana, Chamaesyce herbstii, Chamaesyce skottsbergii var. kalaeloana, Clermontia pyrularia, Cyanea grimesiana ssp. obatae, Cyanea pinnatifida, Cyanea st.-johnii, Cyanea superba, Cyanea truncata, Cyrtandra dentata, Gouania vitifolia, Hedyotis degeneri,* and *Hibiscadelphus woodii,* submit comments to the Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Box 50088, Honolulu, Hawaii 96850. Information may also be submitted electronically at *pifwo-5yr-review@fws.gov.*

For *Castilleja levisecta,* submit comments to the Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Western Washington Fish and Wildlife Office, 510 Desmond Drive SE., Suite 102, Lacey, Washington 98503–1273. Information may also be submitted electronically at *goldenpaintbrush@fws.gov.*

For the Fender's blue butterfly, *Erigeron decumbens* var. *decumbens, Lupinus sulphureus* ssp. *kincaidii,*

Lomatium bradshawii, and *Sidalcea nelsoniana,* submit comments to the Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE. 98th Avenue, Suite 100, Portland, Oregon 97266. Information may also be submitted electronically at *FW1OR5yearReview@fws.gov.*

Information received in response to this notice will be available for public inspection, by appointment, during normal business hours, at the appropriate above-named Service Fish and Wildlife Offices.

FOR FURTHER INFORMATION CONTACT: For the Mariana fruit bat, Mariana crow, Laysan duck, Kauai akialoa (honeycreeper), large Kauai thrush, Kauai oo (honeyeater), ou (honeycreeper), Molokai creeper, Molokai thrush, Kauai cave wolf spider, Kauai cave amphipod, *Alsinidendron obovatum, Amaranthus brownii, Chamaesyce celastroides* var. *kaenana, Chamaesyce deppeana, Chamaesyce herbstii, Chamaesyce skottsbergii* var. *kalaeloana, Clermontia pyrularia, Cyanea grimesiana* ssp. *obatae, Cyanea pinnatifida, Cyanea st.-johnii, Cyanea superba, Cyanea truncata, Cyrtandra dentata, Gouania vitifolia, Hedyotis degeneri,* and *Hibiscadelphus woodii,* contact Gina Shultz at the Pacific Islands Fish and Wildlife Office at (808) 792–9400. For *Castilleja levisecta,* contact Ted Thomas at the Western Washington Fish and Wildlife Office at (360) 753–9440. For the Fender's blue butterfly, *Erigeron decumbens* var. *decumbens, Lupinus sulphureus* ssp. *kincaidii, Lomatium bradshawii,* and *Sidalcea nelsoniana,* contact Rollie White at the Oregon Fish and Wildlife Office at (503) 231–6179.

SUPPLEMENTARY INFORMATION:

Why Is a 5-Year Review Conducted?

Under the Act (16 U.S.C. 1531 *et seq.*) we maintain a List of Endangered and Threatened Wildlife and Plants (List) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the Act requires that we conduct a review of listed species at least once every 5 years. Then, on the basis of such reviews under section 4(c)(2)(B), we determine whether or not any species should be removed from the List (delisted), or reclassified from endangered to threatened or from threatened to endangered. Delisting a species must be supported by the best scientific and commercial data available and only considered if such data substantiates that the species is neither endangered nor threatened for one or more of the following reasons: (1) The species is considered extinct; (2) the species is considered to be recovered; and/or (3) the original data available when the species was listed, or the interpretation of such data, were in error. Any change in Federal classification would require a separate rulemaking process. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently under active review. This notice announces our active review of 33 species listed in Table 1 above.

What Information Is Considered in the Review?

A 5-year review considers all new information available at the time of the review. These reviews will consider the best scientific and commercial data that has become available since the current listing determination or most recent status review, such as:

A. Species biology including, but not limited to, population trends, distribution, abundance, demographics, and genetics;

B. Habitat conditions including, but not limited to, amount, distribution, and suitability;

C. Conservation measures that have been implemented that benefit the species;

D. Threat status and trends (see five factors under heading ''How Do We Determine Whether a Species is Endangered or Threatened?''); and

E. Other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

How Do We Determine Whether a Species Is Endangered or Threatened?

Section 4(a)(1) of the Act requires that we determine whether a species is endangered or threatened based on one or more of the five following factors:

A. The present or threatened destruction, modification, or curtailment of its habitat or range;

B. Overutilization for commercial, recreational, scientific, or educational purposes;

C. Disease or predation;

D. The inadequacy of existing regulatory mechanisms; or

E. Other natural or manmade factors affecting its continued existence.

Our assessment of these factors is required, under section 4(b)(1) of the Act, to be based solely on the best scientific and commercial data available.

What Could Happen as a Result of This Review?

If we find that there is information concerning the 33 species listed in Table 1 above indicating a change in classification may be warranted, we may propose a new rule that could do one of the following: (a) Reclassify the species from threatened to endangered; (b) reclassify the species from endangered to threatened; or (c) remove the species from the List. If we find that a change in classification is not warranted, the species will remain on the List under its current status.

Public Solicitation of New Information

To ensure that these 5-year reviews are complete and based on the best available scientific and commercial information, we are soliciting new information from the public, concerned governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of the 33 species listed in Table 1 above.

If you wish to provide information for any species included in these 5-year reviews, you may submit your comments and materials to the Field Supervisors at the appropriate Service Fish and Wildlife Office in the **ADDRESSES** section above. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Respondents may request that we withhold a respondent's identity, as allowable by law. If you wish us to withhold your name or address, you must state this request prominently at the beginning of your comment. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours (*see* **ADDRESSES** section).

Authority: This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 15, 2005.

David J. Wesley,

Regional Director, Region 1, U.S. Fish and Wildlife Service.

[FR Doc. 05–13219 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Wildlife and Plants; Initiation of a 5-Year Review of 5 Listed Species: The Virginia Northern Flying Squirrel (*Glaucomys sabrinus fuscus*), Delmarva Peninsula Fox Squirrel (*Sciurus niger cinereus*), Northeastern Bulrush (*Scirpus ancistrochaetus*), Chittenango Ovate Amber Snail (*Succinea chittenangoensis*), and Virginia Round-Leaf Birch (*Betula uber*)

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces a 5-year review of the endangered Virginia northern flying squirrel (*Glaucomys sabrinus fuscus*), Delmarva Peninsula fox squirrel (*Sciurus niger cinereus*), northeaster bulrush (*Scirpus ancistrochaetus*), and the threatened Chittenango ovate amber snail (*Novisuccinea chittenangoensis*), and Virginia round-leaf birch (*Betula uber*) under section 4(c)(2)(A) of the Endangered Species Act (ESA) of 1973 (16 U.S.C. 1531 *et seq.*). A 5-year review is a periodic process conducted to ensure that the listing classification of a species is accurate. A 5-year review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information on the Virginia northern flying squirrel, Delmarva Peninsula fox squirrel, and northeastern bulrush that has become available since their original listings as endangered species in 1985 (50 FR 26999–27002), 1967 (32 FR 4001), and 1991 (56 FR 21091–21096), respectively. In addition, we are requesting submission of any such information on the Chittenango ovate amber snail that has become available since its listing as a threatened species in 1978 (43 FR 28932–28935), and on the Virginia round-leaf birch, which was originally listed as endangered in 1978 (43 FR 17910–17916) and reclassified as threatened in 1994 (59 FR 59173–59177). Based on the results of these 5-year reviews, we will make the requisite findings under section 4(c)(2)(B) of the ESA.

DATES: To allow adequate time to conduct this review, we must receive your information no later than September 6, 2005. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: Submit information to the U.S. Fish and Wildlife Service, Northeast Regional Office, 300 Westgate Center Drive, Hadley, Massachusetts 01035, to the attention of Ms. Mary Parkin. Information received in response to this notice and review will be available for public inspection, by appointment, during normal business hours, at the above address. Information may also be sent to *Mary_Parkin@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Mary Parkin at the above address or at 617–876–6173.

SUPPLEMENTARY INFORMATION: Under the ESA, the Service maintains a list of endangered and threatened wildlife and plant species at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every 5 years. Then, on the basis of such reviews under section 4(c)(2)(B), we determine whether or not any species should be removed from the list (delisted), or reclassified from endangered to threatened or from threatened to endangered. Delisting a species must be supported by the best scientific and commercial data available and only considered if such data substantiates that the species is neither endangered nor threatened for one or more of the following reasons: (1) The species is considered extinct; (2) the species is considered to be recovered; and/or (3) the original data available when the species was listed, or the interpretation of such data, were in error. Any change in Federal classification would require a separate rulemaking process. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently under active review. This notice announces our active review of the Virginia northern flying squirrel, Delmarva Peninsula fox squirrel, and northeastern bulrush, currently listed as endangered, and the Chittenango ovate amber snail and Virginia round-leaf birch, currently listed as threatened.

Public Solicitation of New Information: To ensure that the 5-year review is complete and based on the best available scientific and commercial information, we are soliciting new information from the public, concerned governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of the Virginia northern flying squirrel, Delmarva Peninsula fox squirrel, northeastern bulrush, Chittenango ovate amber snail, and Virginia round-leaf birch.

The 5-year review considers that the best scientific and commercial data and all new information that has become available since the listing determination or most recent status review. Categories of requested information include:
(A) Species biology, including, but not limited to, population trends, distribution, abundance, demographics, and genetics; (B) habitat conditions, including, but not limited to, amount, distribution, and suitability;
(C) conservation measure that have been implemented that benefit the species;
(D) threat status and trends; and
(E) other new information, data, or corrections, including, but not limited, taxonomic or nonmenclatural changes, identification of erroneous information contained in the list, and improved analytical methods.

If you wish to provide information for this 5-year review, you may submit your comments and materials to Ms. Mary Parkin (*see* **ADDRESSES** section). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Respondents may request that we withhold a respondent's identity, as allowable by law. If you wish us to withhold your name or address, you must state this request prominently at the beginning of your comment. We will not, however, consider anonymous comments. To the extent consistent with applicable laws, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours (*see* **ADDRESSES** section).

Authority: This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 21, 2005.

Richard O. Bennett,

Acting Regional Director, Region 5, U.S. Fish and Wildlife Service.

[FR Doc. 05–13239 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Environmental Assessment and Receipt of an Application for a Permit To Enhance the Survival of the Gunnison Sage-Grouse in Southwestern Colorado Through a Candidate Conservation Agreement With Assurances

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and receipt of application.

SUMMARY: Colorado Division of Wildlife (CDOW) has applied to the Fish and Wildlife Service (Service) for an Enhancement of Survival Permit for the Gunnison Sage-Grouse (*Centrocercus minimus*) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA). The permit application includes a proposed Candidate Conservation Agreement with Assurances (Agreement) between the CDOW and the Service. The Agreement, the permit application, and the Environmental Assessment are available for public comment.

The purpose of the Agreement is for the CDOW and the Service to implement conservation measures for the Gunnison sage-grouse in 15 counties in southwestern Colorado. The effort is in support of the CDOW's ongoing efforts to enhance the abundance and distribution of the Gunnison sage-grouse throughout its historic range in Colorado. The conservation measures would be implemented by the CDOW and by participating landowners. The selected conservation measures would primarily come from the Gunnison Sage-Grouse Rangewide Conservation Plan, which was completed in April 2005 by numerous cooperating agencies and nongovernmental organizations. Consistent with the Service's Candidate Conservation Agreement with Assurances Final Policy (64 FR 32726, June 17,1999), the Agreement is intended to facilitate the conservation of Gunnison sage-grouse by giving the State of Colorado and cooperating private landowners incentives to implement conservation measures. Participating Landowners would receive regulatory certainty concerning land use restrictions that might otherwise apply should the Gunnison sage-grouse become listed under the ESA. Participating Landowners with eligible property in southwestern Colorado could sign up under the Agreement and the associated permit through a Certificate of Inclusion. The proposed term of the Agreement and the permit is 20 years. The Service has prepared an Environmental Assessment for approval of the Agreement and issuance of the permit.

The environmental assessment considers the biological, environmental, and socioeconomic effects of the proposed Agreement and permit. The assessment also evaluates two alternatives to the Agreement and permit, and their potential impacts on the environment.

We request comments from the public on the permit application, Agreement, and Environmental Assessment. All comments we receive, including names and addresses, will become part of the administrative record and may be released to the public.

DATES: Written comments on the permit application must be received on or before September 6, 2005.

ADDRESSES: Written data or comments concerning the permit application, the Agreement, or the Environmental Assessment should be submitted to Allan R. Pfister, Western Colorado Field Supervisor, U.S. Fish and Wildlife Service, 764 Horizon Drive, Building B, Grand Junction, Colorado 81506–3946. Written comments also may be provided electronically to *al_pfister@fws.gov,* or by facsimile to 970–245–6933. Comments must be submitted in writing to be adequately considered in the Service's decision-making process.

FOR FURTHER INFORMATION CONTACT: Allan R. Pfister or Terry Ireland at the above address, or telephone 970–243–2778

SUPPLEMENTARY INFORMATION:

Document Availability

Persons wishing to review the permit application, Agreement, and the Environmental Assessment may obtain a copy by writing the Service's Grand Junction Ecological Services office at the above address, or contacting the above office by telephone, electronic mail, or facsimile. You also may make an appointment to view the documents at the above address during normal business hours. The documents also are available electronically on the World Wide Web at *http://mountain-prairie.fws.gov/species/birds/gunnisonsagegrouse/.*

Background

Under a Candidate Conservation Agreement with Assurances, participating landowners voluntarily implement conservation activities on their properties to benefit species that are proposed for listing under the ESA, candidates species, or other sensitive species. Candidate Conservation Agreements with Assurances encourage private and other non-Federal property owners to implement conservation efforts and reduce threats to unlisted species by assuring them they will not be subjected to increased property-use restrictions if the species is listed in the future under the ESA. Application requirements and issuance criteria for enhancement of survival permits through Candidate Conservation Agreements with Assurances are found in 50 CFR 17.22(d) and 17.32(d).

On March 15, 2000, the Service found that listing the Gunnison sage-grouse under the ESA may be warranted, and initiated a review of the species' status. The Gunnison sage-grouse currently occupies about 8.5 percent of its historic range in southwestern Colorado and southeastern Utah. The species now persists in seven fragmented populations in Colorado and one population in Utah. The largest remaining population is located in Gunnison County, Colorado, which is currently estimated at 2,443 individuals (about 76 percent of the entire population). The total population in Colorado is currently estimated at 3,046 individuals. With the additional 152 individuals in Utah, the best information currently available suggests a total population of 3,198 individuals.

The 2005 Gunnison Sage-Grouse Rangewide Conservation Plan and the Service's 2004 Candidate Notice of Review have identified threats that contribute to the current and future status of the species. These include—habitat loss, fragmentation, and degradation; disease (*e.g.,* West Nile virus); predation; lack of existing regulatory protection; drought; disturbance to adults; juveniles (*e.g.,* off-highway-vehicles, construction projects, dogs, noise); low genetic diversity; and competition for habitat from other species. The 2005 Gunnison Sage-Grouse Rangewide Conservation Plan also estimates that about 46 percent of the currently occupied habitat in Colorado and Utah is in non-Federal ownership. The CDOW and Service do not believe a viable population of Gunnison sage-grouse can be assured in the long term by implementing conservation efforts on Federal lands only. The fact that nearly one-half of the currently occupied habitat is privately owned, combined with the low potential for the long-term species viability on Federal lands alone, emphasizes the need to encourage and actively promote conservation efforts by private landowners.

Consequently, the CDOW has developed an Agreement for the

Gunnison sage-grouse in cooperation with the Service, and has applied to the Service for a permit under section 10(a) of the ESA (16 U.S.C. 1531 et seq.), which would authorize future incidental take of the Gunnison sage-grouse by the CDOW and cooperating landowners. The CDOW and the Service believe approval of the Agreement is necessary to promote implementation of conservation measures on non-Federal lands. The CDOW and the Service believe implementation of the Agreement will make a significant contribution to the long-term viability of the species, which may help defend that Federal listing is not warranted. Without the Agreement, the CDOW and the Service are concerned that the population of the Gunnison sage-grouse in Colorado may continue to decline. Further decline of the species could trigger listing under the ESA, which could provide a disincentive to private landowners for conservation of the species on private lands. The lack of conservation efforts on private lands could reduce the potential for successfully achieving long-term viability for the species.

Under the Agreement and permit, Participating Landowners would provide certain Gunnison sage-grouse habitat protection of enhancement measures on their lands. These measures would be primarily those identified in the 2005 Gunnison sage-grouse Rangewide Conservation Plan, but additional conservation practices could be determined throughout the 20-year period of the Agreement. Protection and enhancement measures will be directed towards Gunnison sage-grouse lek, nest, roost, and/or winter habitat. If the Gunnison sage-grouse is listed under the ESA, and after a Participating Landowner has provided the agreed-upon habitat conditions for the specified period of time, the permit would authorize incidental take of Gunnison sage-grouse as a result of the non-Federal landowner's agricultural or industrial related activities (*e.g.,* crop cultivation, crop harvesting livestock grazing, farm equipment operation, commercial/residential development).

We are providing this notice pursuant to section 10(c) of the ESA and implementing regulations for the National Environmental Policy Act (40 CFR 1506.6). We will evaluate the permit application, associated documents, and comments submitted thereon to determine whether the permit application meets the requirements of section 10(a) of the ESA and National Environmental Policy Act regulations. The Service also will evaluate whether the issuance of the Agreement complies with section 7 of the ESA by conducting an intra-Service section 7 consultation on the issuance of the permit. If we determine that all requirements are met, we will sign the Agreement and issue an enhancement of survival permit under section 10(a)(1)(A) of ESA to the CDOW for take of Gunnison sage-grouse incidental to otherwise lawful activities in accordance with the terms of the Agreement. We will not make our final decision until after the end of the 60-day comment period and we will fully consider all comments received during the comment period.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1521 *et seq.*) and the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Dated: June 10, 2005.

Ralph O. Morgenweck,

Regional Director, Denver Colorado.

[FR Doc. 05–13247 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–964–1410–HY–P; AA–38080, F–21916, F–22864, F–21944, F–21978, F–21979, F–21973, F–21949, F–21954 (BSA–7); AK–964–1410–HY–P; F–22285, F–22290, F–22269, F–22214, F–22341 (NAA–8)]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decisions approving lands for conveyance.

SUMMARY: As required by 43 CFR 2650.7(d), notice is hereby given that fourteen appealable decisions approving lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Bering Straits Native Corporation and NANA Regional Corporation, Inc. for lands located in the vicinity of Norton and Kotzebue Sounds, Alaska. Notice of the decisions will also be published four times in the Nome Nugget.

DATES: The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decisions shall have until August 5, 2005 to file an appeal.

2. Parties receiving service of the decisions by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, subpart E, shall be deemed to have waived their rights.

ADDRESSES: Copies of the decisions may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Dina Torres by phone at 907–271–3248, or by e-mail at *Dina_Torres@ak.blm.gov.*

Dina L. Torres,

Land Law Examiner, Branch of Adjudication II (964).

[FR Doc. 05–13291 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK963–1410–HY–P; F–14946–A, F–14946–B, F–14946–D; BSA–3]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: As required by 43 CFR 2650.7(d), notice is hereby given that an appealable decision approving lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Teller Native Corporation. The lands are located in U.S. Survey No. 8892, T. 4 S., R 36 W., T. 5 S. R. 37 W., and T. 5 S., R. 40 W., Kateel River Meridian, in the vicinity of Teller, Alaska, and contain 6,596.51 acres. Notice of the decision will also be published four times in the *Nome Nugget.*

DATES: The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decision shall have until August 5, 2005 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, subpart E, shall be deemed to have waived their rights.

ADDRESSES: A copy of the decision may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION, CONTACT: Jennifer L. Noe, by phone at (907) 271–3169, or by e-mail at *jennifer_noe@ak.blm.gov.* Persons who

use a telecommunication device (TTD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8330, 24 hours a day, seven days a week, to contact Ms. Noe.

Jennifer L. Noe,

Realty Specialist, Branch of Adjudication 964.

[FR Doc. 05–13290 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–930–5420–EU–L029; AA–85442]

Notice of Application for Recordable Disclaimer of Interest for Lands Underlying Chilkoot River and Chilkoot Lake in Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The State of Alaska has filed an application for a recordable disclaimer of interest from the United States in certain lands underlying the Chilkoot River and Chilkoot Lake.

DATES: Comments on the State of Alaska's application will be accepted until October 4, 2005. Interested parties may submit comments on the BLM Draft Navigability Report on or before September 6, 2005.

ADDRESSES: Send comments to the Chief, Branch of Lands and Realty, BLM Alaska State Office, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Jack Frost at (907) 271–5531, or the Public Information Center, (907) 271–5960, Alaska State Office, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599, for copies of the draft report, or you may visit the BLM recordable disclaimer of interest Web site at *http://www.ak.blm.gov/.*

SUPPLEMENTARY INFORMATION: On May 12, 2004, the State of Alaska filed an application for a recordable disclaimer of interest pursuant to Section 315 of the Federal Land Policy and Management Act and the regulations contained in 43 CFR subpart 1864 for lands underlying Chilkoot River and Chilkoot Lake (AA–85442). A recordable disclaimer of interest, if issued, will confirm the United States has no valid interest in the subject lands. The notice is intended to notify the public of the pending application and the State's grounds for supporting it. The State asserts that this river and lake is navigable; therefore, under the Equal Footing Doctrine and Submerged Lands Act of 1953, ownership of these lands underlying the river and lake automatically passed from the United States to the State of Alaska (the State) at the time of statehood in 1959. The State also asserts, in those instances where it is the upland owner, and the water body is non-navigable, the State received title to the submerged lands under state law.

The State's application (AA–85442) is for the bed of the Chilkoot River and all interconnecting sloughs between the ordinary high water lines of the left and right banks from its origin at the Ferebee Glacier terminus within Section 8, T. 27 S., R. 57 E., Copper River Meridian (CRM), Alaska, through and including Chilkoot Lake, to all points of confluence with Lutak Inlet within T. 29 S., R. 59 E., CRM. The State did not identify any known adverse claimant or occupant of the affected lands.

A final decision on the merits of the application will not be made before October 4, 2005. During the 90-day period, interested parties may comment on the State's application (AA–85442) and supporting evidence. Interested parties may comment on the evidentiary evidence presented in the BLM's Draft Navigability Report on or before September 6, 2005.

Comments, including names and street addresses of commenters, will be available for public review at the BLM's Alaska State Office (see address above), during regular business hours 8 a.m. to 3:45 p.m., Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to hold your name or address from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comments. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses will be made available for public inspection in their entirety.

Dated: June 3, 2005.

Carolyn Spoon,

Chief, Branch of Lands and Realty.

[FR Doc. 05–13292 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Docket No. OR–010–1020–PK; HAG 05–0159]

Meeting: Resource Advisory Council—Southeast Oregon

AGENCY: Bureau of Land Management (BLM), Lakeview District.

ACTION: Meeting notice for the Southeast Oregon Resource Advisory Council (SEORAC).

SUMMARY: The SEORAC will hold a conference call for all members on Monday August 8, 2005 at 10 a.m. Pacific standard time. The conference call is open to the public. Members of the public in the Lakeview area may attend the meeting in person in the Abert Rim Conference Room, Lakeview Interagency Office, 1301 South G Street, Lakeview, Oregon 97630.

The meeting topics to be discussed include: Approval of past meeting minutes, an update on off-highway vehicle regulations, new wild horse and burro information, and an update on grazing regulations. There may also be a report concerning stewardship, and an update on the Tri-RAC meeting planned for November 6 to 8, 2005.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the SEORAC conference call may be obtained from Pam Talbott, contact representative, Lakeview Interagency Office, 1301 South G Street, Lakeview, Oregon 97630 (541) 947–6107, or *ptalbott@or.blm.gov.*

Dated: June 28, 2005.

M. Joe Tague,

Associate District Manager.

[FR Doc. 05–13207 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–200–1120–PH]

Notice of August Resource Advisory Council Meeting To Be Held in Twin Falls District, Idaho

SUMMARY: This notice announces the intent to hold a Resource Advisory Council (RAC) meeting in the Twin Falls District of Idaho on Tuesday, August 9, 2005. The meeting will be held in the Conference Room at the Burley BLM Fire Building, 3600 South Overland Avenue, in Burley, Idaho.

SUPPLEMENTARY INFORMATION: The Twin Falls District Resource Advisory Council consists of the standard fifteen members residing throughout south central Idaho. Meeting agenda items will include updates on the Proposed Cotterel Mountain Wind Power Project, Blaine County Travel Plan, proposed seeding projects in the Burley Field Office Area, a recommendation regarding issuance of a weed free feed program on Idaho BLM lands, and a report from the Blaine County Airport

Re-location sub-group. Other potential topics may also arise.

FOR FURTHER INFORMATION CONTACT: Sky Buffat, Twin Falls District, Idaho, 2536 Kimberly Road, Twin Falls, Idaho 83301, (208)735–2068.

Dated: June 28, 2005.

Howard Hedrick,

Twin Falls District Manager.

[FR Doc. 05–13241 Filed 7–5–05; 8:45 am]

BILLING CODE 4310–GG–P

INTERNATIONAL TRADE COMMISSION

Agency Form Submitted to OMB for Review

AGENCY: United States International Trade Commission.

ACTION: In accordance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Commission has submitted a request for approval of surveys to the Office of Management and Budget for review.

Purpose of Information Collection: The forms are for use by the Commission in connection with analysis of the effectiveness of Section 337 remedial exclusion orders, instituted under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337).

Summary of Proposal:

(1) *Number of forms submitted:* two.

(2) *Title of form:* USITC Survey Regarding Outstanding section 337 Exclusion Orders.

(3) *Type of request:* new.

(4) *Frequency of use:* survey, single data gathering, scheduled for 2005.

(5) *Description of responding firms:* complainants that obtained exclusion orders from the Commission following investigations under Section 337 that remain in effect at the time of the survey.

(6) *Estimated number of responding firms:* 54.

(7) *Estimated number of hours to complete the forms:* 54.

(8) Information obtained from the firm that qualifies as confidential business information will be so treated by the Commission and not disclosed in a manner that would reveal the individual operations of a firm.

DATES: To be assured of consideration, written comments must be received not later than thirty (30) days after publication of this notice.

Additional Information or Comment: Copies of the forms and supporting documents are posted on the Commission's Internet server at *http://www.usitc.gov* or may be obtained from Lynn I. Levine, Director, Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone, (202) 205–2560. Comments about the proposals should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Room 10102, Washington, DC 20503.

Attention: Desk Officer for the International Trade Commission. All comments should be specific, indicating which part of the survey is objectionable, describing the concern in detail, and including specific suggested revisions or language changes. Copies of any comments should be provided to Robert Rogowsky, Director, Office of Operations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, who is the Commission's designated Senior Official under the Paperwork Reduction Act.

Hearing impaired individuals are advised that information on this matter can be obtained by contacting our TTD terminal (telephone no. (202) 205–1810). General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

By order of the Commission.

Issued: June 29, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–13235 Filed 7–5–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–468]

Economywide Simulation Modeling: Technical Analysis of the Doha Round

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

DATES: *Effective Date:* June 24, 2005.

SUMMARY: Following receipt on May 25, 2005 of a request from the United States Trade Representative (USTR) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332 (g)), the Commission instituted investigation No. 332–468, Economywide Simulation Modeling: Technical Analysis of the Doha Round.

FOR FURTHER INFORMATION CONTACT: Project manager William Donnelly (202–205–3225 or *william.donnelly@usitc.gov*) Office of Economics, or deputy project manager David Ingersoll (202–205–2218 or *dave.ingersoll@usitc.gov*) Office of Industries, U.S. United International Trade Commission, Washington, DC 20436. General information concerning the Commission may be obtained by accessing its Internet server (*http://www.usitc.gov*). For information on legal aspects of the investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of Public Affairs (202–205–1819 or *margaret.olaughlin@usitc.gov*).

Background: As requested by the USTR, the Commission will provide an economy-wide analysis of the economic effects of selected prospective results of the World Trade Organizations (WTO) Doha Round of trade negotiations. Specifically, the Commission will provide the following in its report:

(1) Changes in production, consumption, trade, and prices that may be associated with the Doha Round, with regional and sectoral aggregations appropriate to illustrate those changes; and

(2) The trade liberalization scenarios associated with those regional and sectoral aggregations.

As requested, the Commission will provide those estimates, to the extent possible, for scenarios that reflect a range of possible outcomes with respect to market access for all products and trade-distorting domestic assistance programs and export subsidies related to agriculture, to be informed by the ''July package'' agreed to by the WTO's General Council on August 1, 2004.

The USTR stated that the Administration is conducting an environmental review of WTO multilateral trade negotiations known as the Doha Round and that the Commission's report would assist the Trade Policy Staff Committee (TPSC) in conducting an environmental review. For information and background on USTR environmental reviews, see *http://www.ustr.gov/Trade_Sectors/Environment/Section_Index.html.*

As requested, the Commission will provide its report not later than 10 months after receipt of the request, or by March 27, 2006. The USTR has directed that the Commission mark or identify as ''confidential'' the Commission's analytical products, as well as associated working papers in this investigation. The letter also stated that USTR considers the Commission's analytical products to be inter-agency memoranda that will contain pre-decisional advice subject to the deliberative process privilege. Accordingly, the Commission does not plan to issue a public report.

Written Submissions: The Commission does not plan to hold a public hearing in connection with the preparation of this report. However, interested persons are invited to submit written statements concerning the matters to be addressed in the report. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. To be assured of consideration by the Commission, written statements relating to the Commission's report should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on November 30, 2005. All written submissions must conform with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8). Section 201.8 of the rules requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential business information (CBI) must be deleted (see the following paragraph for further information regarding CBI). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *ftp://ftp.usitc.gov/pub/reports/electronic_filing_handbook.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000 or edis@usitc.gov).

Any submissions that contain CBI must also conform with the requirements of section 201.6 of the Commission's rules (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages clearly be marked as to whether they are the ''confidential'' or ''nonconfidential'' version, and that the CBI be clearly identified by means of brackets. All written submissions, except for CBI, will be made available for inspection by interested parties.

The Commission may include any CBI received in the confidential report it sends to the USTR. Should the Commission at a later date make its report available to the public, any CBI received by the Commission in this investigation will not be published in that report in a manner that would reveal the operations of the firm supplying the information.

The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Issued: June 29, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–13234 Filed 7–5–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. Nos. 701–TA–430B and 731–TA–1019B]

Hard Red Spring Wheat From Canada; Notice and Scheduling of Remand Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: The U.S. International Trade Commission (the Commission) hereby gives notice of proceedings in the remand investigation ordered by a binational panel established under Article 1904 of the North American Free Trade Agreement (NAFTA) in Hard Red Spring Wheat from Canada, Inv. Nos. 701–TA–430B and 731–TA–1019B (Final).

FOR FURTHER INFORMATION CONTACT: Christopher J. Cassise, Office of Investigations, telephone 202–708–5408 or Michael Diehl, Esq., Office of the General Counsel, telephone (202) 205–3095, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

SUPPLEMENTARY INFORMATION:

Background

In October 2003, the Commission determined, by a two-to-two vote, that an industry in the United States was materially injured by reason of subject imports of hard red spring wheat from Canada. On June 7, 2005, a binational panel formed under Article 1904 of the NAFTA issued a decision in its review of the Commission's determination. The panel remanded the determination to the Commission with an order to take further action consistent with its instructions. The Commission is directed to issue its remand determination within 90 days of the issuance of the Panel's decision, *i.e.*, by September 6, 2005.

Reopening the Record

In order to assist it in making its determination on remand, the Commission is reopening the record in this investigation to seek additional information with respect to certain of the instructions provided by the panel.

Participation in the Remand Proceedings

Only those interested parties who were parties to the original investigations (*i.e.*, persons listed on the Commission Secretary's service list) may participate in this remand proceeding. No additional filings with the Commission will be necessary for these parties to participate in the remand proceeding. Business proprietary information (BPI) obtained during the remand proceeding will be governed, as appropriate, by the administrative protective order (APO) issued in the original investigations. (Parties who participated in the original investigation, if no longer covered by the APO, are directed to contact the Commission Secretary.)

Written Submissions

Information obtained during the remand investigation will be released to the parties under the administrative protective order (''APO'') issued in the original investigations on or about July 19, 2005. The remand staff report will be placed in the nonpublic record on August 1, 2005, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules. Parties that are participating in the remand proceedings may file comments on or before August 8, 2005 with respect to how the record, as supplemented, bears on the issues presented by the panel's remand instructions.

No additional factual information may be included in such comments. Comments shall not exceed 30 pages of textual material, double-spaced and single-sided, on stationery measuring 8½ x 11 inches.

All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain business proprietary information (BPI) must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (Nov. 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or updated BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Parties are also advised to consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subpart A (19 CFR part 207) for provisions of general applicability concerning written submissions to the Commission.

Authority: This action is taken under the authority of the Tariff Act of 1930, title VII.

Issued: June 29, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–13236 Filed 7–5–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–05–026]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 14, 2005 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–1092 and 1093 (Preliminary) (Diamond Sawblades and Parts Thereof from China and Korea)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on or before July 18, 2005; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before July 25, 2005.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: June 30, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–13391 Filed 7–1–05; 2:14 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act; Native American Employment and Training Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, and section 166(h)(4) of the Workforce Investment Act (WIA) (29 U.S.C. 2911(h)(4), notice is hereby given of the next meeting of the Native American Employment and Training Council as constituted under WIA.

Time and Date: The meeting will begin at 9 a.m. e.d.t. (eastern daylight time) on Thursday, July 14, 2005, and continue until 5 p.m. e.d.t. that day. The period from 3 p.m. to 5 p.m. e.d.t. on July 14 will be reserved for participation and presentation by members of the public. The meeting will reconvene at 9 p.m. e.d.t. on Friday, July 15, 2005, and adjourn at approximately 12 p.m. e.d.t. on that day.

Place: All sessions will be held at the Crowne Plaza Hotel, 1800 Market Street, Philadelphia, Pennsylvania.

Status: The meeting will be open to the public. Persons who need special accommodations should contact Ms. Athena Brown on (202) 693–3737 by July 7, 2005.

Matters to be Considered: The formal agenda will focus on the following topics: (1) Strategic Planning for Economic Development Report; (2) UI Wage Study-Discussion of Preliminary Findings; (3) Follow-up Issues on Technical Assistance; (4) Follow-up on Resolutions; (5) Timeline for Implementation of Common Measures; and (6) Proposed Changes to Section 166 Reporting (NAWIA).

FOR FURTHER INFORMATION CONTACT: Ms. Athena Brown, Chief, Division of Indian and Native American Programs, Office of National Programs, Employment and Training Administration, U.S. Department of Labor, Room C–4311, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Telephone: (202) 693–3737 (VOICE) (this is not a toll-free number) or (202) 693–3841.

Signed at Washington, DC, this 29th day of June, 2005.

Emily Stover DeRocco,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 05–13216 Filed 7–5–05; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act; Meeting

TIME AND DATE: 9:30 a.m. Tuesday, July 12, 2005.

PLACE: NTSB Board Room, 429 L'Enfant Plaza, SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED: 7727, Highway Accident Report—Motorcoach Median Crossover and Collision with the Sport Utility Vehicle, Hewitt, Texas, February 14, 2004 (HWY–03–MY–022).

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

Individuals requesting specific accommodations should contact Ms. Carolyn Dargan at (202) 314–6305 by Friday, July 8, 2005.

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.ntsb.gov.*

FOR MORE INFORMATION CONTACT: Vicky D'Onofrio, (202) 314–6410.

Dated: July 1, 2005.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. 05–13377 Filed 7–01–05; 1:49 pm]

BILLING CODE 7533–01–M

PENSION BENEFIT GUARANTY CORPORATION

Pendency of Request for Approval of Special Withdrawal Liability Rules; Service Employees International Union Local 25 and Participating Employers Pension Trust

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of pendency of request.

SUMMARY: The Pension Benefit Guaranty Corporation (''PBGC'') has received a request from the Service Employees International Union Local 25 and Participating Employers Pension Trust for approval of a plan amendment providing for special withdrawal liability rules. Under section 4203(f) of the Employee Retirement Income Security Act of 1974 and the PBGC's regulation on Extension of Special Withdrawal Liability Rules, a multiemployer pension plan may, with PBGC approval, be amended to provide for special withdrawal liability rules similar to those that apply to the construction and entertainment industries. Such approval is granted only if the PBGC determines that the rules apply to an industry with characteristics that make use of the special rules appropriate and that the rules will not pose a significant risk to the PBGC. This notice advises interested persons of the pendency of this request and invites public comment.

DATES: Comments must be submitted by August 22, 2005.

ADDRESSES: All written comments (at least three copies) should be mailed or delivered to: Office of the Chief Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026. Copies of the request for approval and any comments may be obtained by writing to the PBGC's Communications and Public Affairs Department at Suite 240 at the above address or by visiting that office or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.) Copies of the PBGC's regulation on Extension of Special Withdrawal Liability Rules (29 CFR part 4203) and of the originating request for approval may be accessed through the PBGC's Web site (*http://www.PBGC.gov*).

FOR FURTHER INFORMATION CONTACT: Frank Anderson, Attorney, Office of the Chief Counsel (22500), Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; telephone 202–326–4020. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4020).

SUPPLEMENTARY INFORMATION:

Background

Under section 4203(a) of ERISA, a complete withdrawal from a multiemployer plan generally occurs when an employer permanently ceases to have an obligation to contribute under the plan or permanently ceases all covered operations under the plan. Under section 4205 of ERISA, a partial withdrawal generally occurs when an employer (1) reduces its contribution base units by seventy percent in each of three consecutive years, or (2) permanently ceases to have an obligation to contribute under one or more but fewer than all collective bargaining agreements under which the employer has been obligated to contribute under the plan, while continuing to perform work in the jurisdiction of the collective bargaining agreement of the type for which contributions were previously required or transfers such work to another location, or (3) permanently ceases to have an obligation to contribute under the plan for work performed at one or more but fewer than all of its facilities, while continuing to perform work at the facility of the type for which the obligation to contribute ceased.

Although the general rules on complete and partial withdrawal identify events that normally result in a diminution of the plan's contribution base, Congress recognized that, in certain industries and under certain circumstances, a complete or partial cessation of the obligation to contribute does not normally weaken the plan's contribution base. For that reason, Congress established special withdrawal rules for the construction and entertainment industries.

For construction industry plans and employers, section 4203(b)(2) of ERISA provides that a complete withdrawal occurs only if an employer ceases to have an obligation to contribute under a plan and the employer either continues to perform previously covered work in the jurisdiction of the collective bargaining agreement, or resumes such work within five years without renewing the obligation to contribute at the time of resumption. Section 4203(c)(1) of ERISA applies the same special definition of complete withdrawal to the entertainment industry, except that the pertinent jurisdiction is the jurisdiction of the plan rather than the jurisdiction of the collective bargaining agreement. In contrast, the general definition of complete withdrawal in section 4203(a) of ERISA defines a withdrawal to include permanent cessation of the obligation to contribute regardless of the continued activities of the withdrawn employer.

Congress also established special partial withdrawal liability rules for the construction and entertainment industries. Under section 4208(d)(1) of ERISA, ''[a]n employer to whom section 4203(b) (relating to the building and construction industry) applies is liable for a partial withdrawal only if the employer's obligation to contribute under the plan is continued for no more than an insubstantial portion of its work in the craft and area jurisdiction of the collective bargaining agreement of the type for which contributions are required.'' Under section 4208(d)(2) of ERISA, ''[a]n employer to whom section 4203(c) (relating to the entertainment industry) applies shall have no liability for a partial withdrawal except under the conditions and to the extent prescribed by the [PBGC] by regulation.''

Section 4203(f) of ERISA provides that the PBGC may prescribe regulations under which plans in other industries may be amended to provide for special withdrawal liability rules similar to the rules prescribed in section 4203(b) and (c) of ERISA. Section 4203(f)(2) of ERISA provides that such regulations shall permit the use of special withdrawal liability rules only in industries (or portions thereof) in which the PBGC determines that the characteristics that would make use of such rules appropriate are clearly shown, and that the use of such rules will not pose a significant risk to the insurance system under Title IV of ERISA. Section 4208(e)(3) of ERISA provides that the PBGC shall prescribe by regulation a procedure by which plans may be amended to adopt special partial withdrawal liability rules upon a finding by the PBGC that the adoption of such rules is consistent with the purposes of Title IV of ERISA.

The PBGC's regulation on Extension of Special Withdrawal Liability Rules (29 CFR part 4203) prescribes procedures whereby a multiemployer plan may ask PBGC to approve a plan amendment that establishes special complete or partial withdrawal liability rules. The regulation may be accessed on the PBGC's Web site (*http://www.PBGC.gov*).

Request

The PBGC has received a request from the Service Employees International Union Local 25 and Participating

Employers Pension Trust (''Local 25 Plan'') for approval of a plan amendment providing for special withdrawal liability rules. A copy of the originating request, and PBGC's summary of the actuarial reports that the plan provided, may be accessed on the PBGC's Web site (*http://www.PBGC.gov*). A copy of the complete filing may be requested from the PBGC Disclosure Officer. The fax number is 202–326–4042. It may also be obtained by writing the Disclosure Officer, PBGC, 1200 K Street, NW., Suite 240, Washington, DC 20005.

In brief, the Local 25 Plan, a multiemployer plan covering the commercial building cleaning and security industry in Chicago, represents that the industry has characteristics similar to those of the construction industry. The plan has adopted an amendment prescribing special withdrawal liability rules, which, if approved by the PBGC, would be effective as of September 30, 2002. Under the proposed amendment, complete withdrawal of an employer would occur only under conditions similar to those described in ERISA section 4203(b)(2), or certain other conditions including a mass withdrawal. Partial withdrawal of an employer would occur only under conditions similar to those described in ERISA section 4208(d)(1). The request includes actuarial data to support the plan's contention that the amendment will not pose a significant risk to the insurance system under Title IV of ERISA.

Comments

All interested persons are invited to submit written comments concerning the pending request to the PBGC at the above address by August 22, 2005. All comments will be made a part of the record. Comments received will be available for public inspection at the address set forth above.

Issued in Washington, DC, on this 27 day of June, 2005.

Vincent K. Snowbarger,

Acting Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 05–13201 Filed 7–5–05; 8:45 am]

BILLING CODE 7708–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Leucadia National Corporation to Withdraw its Common Stock, $1.00 par value, from Listing and Registration on the Pacific Exchange, Inc.

[File No. 1–05721]

DATES: June 29, 2005.

On June 14, 2005, Leucadia National Corporation, a New York corporation (''Issuer''), filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') [1] and 12d2–2(d) thereunder,[2] to withdraw its common stock, $1.00 par value (''Security''), from listing and registration on the Pacific Exchange, Inc. (''PCX'').

The Board of Directors (''the Board'') of the Issuer approved a resolution on May 26, 2005 to withdraw the Security from listing and registration on PCX. The Issuer stated the reason the Board decided to withdraw the Security from PCX because: (1) The Security currently trades on the New York Stock Exchange, Inc. (''NYSE'') and PCX; (2) the primary exchange for trading of the Security is NYSE; and (3) a de minimus amount of trading the Security is effected through PCX. Accordingly, the Board determined that it is in the best interest of the Issuer and its shareholders to withdraw the Security from listing and registration on PCX.

The Issuer stated in its application that it has complied with applicable rules of PCX by complying with all applicable laws in effect in the State of New York, the state in which the Issuer is incorporated, and by providing PCX with the required documents governing the withdrawal of securities from listing and registration on PCX.

The Issuer's application relates solely to the withdrawal of the Security from listing on PCX and shall not affect its continued listing on NYSE or its obligation to be registered under Section 12(b) of the Act.[3]

Any interested person may, on or before July 25, 2005 comment on the facts bearing upon whether the application has been made in accordance with the rules of PCX, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

- Send an e-mail to *rule-comments@sec.gov*. Please include the File Number 1–05721 or;

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303. All submissions should refer to File Number 1–05721. This rule number should be included on the subject line if e-mail is used. To help us 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/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–13233 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–M

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

[File No. 1–07598]

Issuer Delisting; Notice of Application of Varian Medical Systems, Inc. To Withdraw its Common Stock, $1.00 Par Value, and Associated Preferred Stock Purchase Rights, From Listing and Registration on the Pacific Exchange, Inc.

June 29, 2005.

On June 14,2005, Varian Medical Systems, Inc., a Delaware corporation (''Issuer''), filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 12d2–2(d) thereunder,[2] to withdraw its common

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

stock, $1.00 par value, and associated preferred stock purchase rights (''Securities''), from listing and registration on the Pacific Exchange, Inc. (''PCX'').

On May 19, 2005, the Board of Directors (''Board'') of the Issuer approved resolutions to withdraw the Securities from listing and registration on PCX. The Issuer stated in its application that the Securities are listed on both the New York Stock Exchange, Inc. (''NYSE'') and PCX. The Issuer stated that the Board's reason for requesting withdrawal of the Securities is the belief by the Board and Issuer that the benefits of being listed on PCX's are outweighed by the added administrative burdens and expenses.

The Issuer stated in its application that it has complied with PCX rules by complying with all applicable laws in effect in the state of Delaware, the state in which the Issuer is incorporated, and by filing with PCX the required documents governing the withdrawal of securities from listing and registration on PCX.

The Issuer's application relates solely to the withdrawal of the Securities from listing on PCX and shall not affects continued listing on the NYSE or its obligation to be registered under Section 12(b) of the Act.[3]

Any interested person may, on or before July 25,2005, comment on the facts bearing upon whether the application has been made in accordance with the rules of PCX, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/delist.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include the File Number 1–07598 or;

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–9303.

All submissions should refer to File Number 1–07598. This file number should be included on the subject line if e-mail is used. To help us 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/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 05–13232 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–M

[3] 15 D.S.C. 78*1*(b).

[4] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of St. George Metals, Inc.; Order of Suspension of Trading

July 1, 2005.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of St. George Metals, Inc. (Pink Sheets symbol: ''SGGM''), a Nevada corporation. Questions have been raised about the adequacy of publicly available information concerning, among other things, St. George Metals' assets and liabilities, mining and other business activities, stock issuances, and corporate management. Since the fiscal year ending January 31, 2003, St. George Metals has been delinquent in its periodic filing obligations under Section 13(a) of the Securities Exchange Act of 1934.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period from 9:30 a.m. EDT, July 1, 2005, through 11:59 p.m. EDT, on July 15, 2005.

By the Commission.

Johathan G. Katz,

Secretary.

[FR Doc. 05–13329 Filed 7–5–05; 11:48 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51932; File No. SR–NASD–2005–076]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Fees for NASD Members Using the New Testing Facility

June 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 16, 2005, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq.[3] Nasdaq has designated this proposal as one establishing or changing a due, fee, or other charge imposed by Nasdaq under Section 19(b)(3)(A)(ii) of the Act,[4] and Rule 19b–4(f)(2) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is filing this proposed rule change to simplify the fee schedule for connectivity and testing fees for NASD members wishing to access the Nasdaq Testing Facility (''NTF''). Nasdaq will implement the change to NASD Rule 7050(d) on or about August 1, 2005. The text of the proposed rule change is below. Proposed new language is in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has made minor technical changes to this notice with Nasdaq's consent. Telephone conversation between Katherine A. England, Assistant Director, Jan Woo, Attorney, Division of Market Regulation, Commission, and Eric Lai, Assistant General Counsel, Nasdaq, dated June 23, 2005.

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

[5] 17 CFR 240.19b–4(f)(2).

italics; proposed deletions are in [brackets].

* * * * *

7000. CHARGES FOR SERVICES AND EQUIPMENT

7050. Other Services

(a)–(c) No change.

(d) Nasdaq Testing Facility

(1) Subscribers that conduct tests of their *Nasdaq access protocols connection (which includes* computer-to-computer interface (CTCI), NWII application programming interface (API), Financial Information Exchange (FIX) interface, *and Nasdaq Information Exchange (QIX) interface)* or market data vendor feeds through the Nasdaq Testing Facility (NTF) shall pay the following charges:

$285/hour	For [an] Active Connection *testing using current Nasdaq access protocols*[CTCI/NWII API/FIX testing] during the normal operating hours of the NTF;
$75/hour	[For an Idle Connection for CTCI/NWII API/FIX testing during the normal operating hours of the NTF, unless such an Idle Connection is over a dedicated circuit;]
No Charge	For [an] Idle Connection *testing using current Nasdaq access protocols* [for CTCI/NWII API/FIX testing if such an Idle Connection is over a dedicated circuit during the normal operating hours of the NTF];
$333/hour	For *Active Connection* [CTCI/NWII API/FIX] testing *using current Nasdaq access protocols* [(for both Active and Idle Connections)] at all times other than the normal operating hours of the NTF.

(2)(A) An ''Active Connection'' commences when the user begins to send and/or receive a transaction to and from the NTF and continues until the earlier of disconnection or the commencement of an Idle Connection.

(B) An ''Idle Connection'' commences after a Period of Inactivity and continues until the earlier of disconnection or the commencement of an Active Connection. If a Period of Inactivity occurs immediately after subscriber's connection to the NTF is established and is then immediately followed by an Idle Connection, then such Period of Inactivity shall also be deemed a part of the Idle Connection.

(C) A ''Period of Inactivity'' is an uninterrupted period of time of specified length when the connection is open but the NTF is not receiving from or sending to subscriber any transactions. The length of the Period of Inactivity shall be such period of time between [5]*10* minutes and [10]*60* minutes in length as Nasdaq may specify from time to time by giving notice to users of the NTF.

(3)–(5) 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, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the fees for the NTF are assessed based on Active Testing, where the user is sending and receiving transactions, and Idle Testing, where the user is connected to the NTF, but not sending or receiving transactions. The current fees for Active Testing and Idle Testing are $285 per hour and $75 per hour respectively. The proposed rule change simplifies the NTF fee schedule by eliminating the Idle Testing fees and modifying the parameters for Active Testing. Nasdaq believes that the proposed rule change will make the NTF services more cost-effective for Nasdaq's customers.

Nasdaq's customers have historically accessed the NTF through dial-up connections using either Nasdaq's computer-to-computer interface (CTCI) or the NWII application programming interface (API). As Nasdaq transitions to new technology (*i.e.*, FIX and QIX) [6], Nasdaq believes that users will increasingly access the NTF using high bandwidth Internet or Extranet connections that are ''always on''. The Idle Testing fee was originally designed to discourage customers from needlessly taking a limited number of dial-up connections when no testing was being performed. Some NTF users have created automated connection mechanisms that automatically access the NTF on a periodic basis. These firms sometimes unknowingly maintain idle connections and only discover the problem after days or weeks of idly connecting to the NTF. By eliminating the Idle Testing fee, these users will only be charged when Active Testing occurs, and will not be charged for idle connections.

In addition to eliminating fees for Idle Testing, Nasdaq proposes to change the time period for when an Idle Connection commences from five to 10 minutes in length to 10 to 60 minutes in length. Initially, the period during which a connection needs to remain inactive before it will be deemed idle will be 60 minutes. Nasdaq, however, reserves the right to adjust this time within a range of 10 to 60 minutes by giving notice of the change to NTF subscribers. The proposed rule change also clarifies that the fee schedule for access to the NTF applies to all Active Connection testing regardless of the Nasdaq access protocols used to access the NTF. Thus, the new modified NTF fee schedule will also apply to QIX and other access protocols that Nasdaq may offer in the future.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,[7] in general, and Sections 15A(b)(5) [8] of the Act, in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. By modifying the NTF pricing structure to be more responsive to subscriber needs

[6] FIX (Financial Information Exchange) and QIX (Nasdaq Information Exchange) are new messaging protocols that are used by customers to communicate with Nasdaq's systems. *See* Securities Exchange Act Release Nos. 48387 (August 21, 2003), 68 FR 51619 (August 27, 2003) (SR–NASD–2003–117); 48452 (September 5, 2003), 68 FR 53767 (September 12, 2003) (SR–NASD–2003–118); and 51170 (February 9, 2005), 70 FR 7988 (February 16, 2005) (SR–NASD–2005–002).

[7] 15 U.S.C. 78*o*–3.

[8] 15 U.S.C. 78*o*–3(b)(5).

and market demands, Nasdaq believes the proposed rule supports efficient use of existing systems and ensures that the charges associated with such use are allocated equitably. The proposed rule change will apply to NASD members seeking access to the NTF. This fee schedule is identical to the new fee schedule that Nasdaq proposes to charge persons that are not NASD members that also seek access to the NTF.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq 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 rule change establishes or changes a due, fee, or other charge imposed by the NASD, it has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(2) [10] 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 proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASD–2005–076 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2005–076. 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. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. 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–NASD–2005–076 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3536 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51933; File No. SR–NASD–2005–075]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Fees for Non-Members Using the New Testing Facility

June 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 16, 2005, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq.[3] Nasdaq filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [4] and Rule 19b–4(f)(6) thereunder,[5] which renders the proposed rule change effective upon filing with the Commission.[6] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is filing this proposed rule change to simplify the fee schedule for connectivity and testing fees for persons that are not NASD members wishing to access the Nasdaq Testing Facility (''NTF''). Nasdaq will implement the change to NASD Rule 7050(d) on or about August 1, 2005.

The text of the proposed rule change is below. Proposed new language is in *italics;* proposed deletions are in [brackets].

* * * * *

7000. CHARGES FOR SERVICES AND EQUIPMENT

7050. Other Services

(a)–(c) No change.

(d) Nasdaq Testing Facility

(1) Subscribers that conduct tests of their *Nasdaq access protocols*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has made minor technical changes to this notice with Nasdaq's consent. Telephone conversation between Katherine A. England, Assistant Director, Jan Woo, Attorney, Division of Market Regulation, Commission, and Eric Lai, Assistant General Counsel, Nasdaq, dated June 23, 2005.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6).

[6] Nasdaq provided the Commission with written notice of its intention to file the proposed rule change on June 14, 2005. The Commission received Nasdaq's submission, and asked Nasdaq to file the instant proposed rule change, pursuant to Rule 19b–4(f)(6) under the Act. 17 CFR 240.19–4(f)(6).

connection (which includes computer-to-computer interface (CTCI), NWII application programming interface (API), Financial Information Exchange (FIX) interface, *and Nasdaq Information Exchange (QIX) interface)* or market data vendor feeds through the Nasdaq Testing Facility (NTF) shall pay the following charges:

$285/hour	For [an] Active Connection *testing using current Nasdaq access protocols* [CTCI/NWII API/FIX testing] during the normal operating hours of the NTF;
[$75/hour]	[For an Idle Connection for CTCI/NWII API/FIX testing during the normal operating hours of the NTF, unless such an Idle Connection is over a dedicated circuit;]
No Charge	For [an]Idle Connection *testing using current Nasdaq access protocols* [for CTCI/NWII API/FIX testing if such an Idle Connection is over a dedicated circuit during the normal operating hours of the NTF];
$333/hour	For *Active Connection* [CTCI/NWII API/FIX] testing *using current Nasdaq access protocols* [(for both Active and Idle Connections)] at all times other than the normal operating hours of the NTF.

(2)(A) An ''Active Connection'' commences when the user begins to send and/or receive a transaction to and from the NTF and continues until the earlier of disconnection or the commencement of an Idle Connection.

(B) An ''Idle Connection'' commences after a Period of Inactivity and continues until the earlier of disconnection or the commencement of an Active Connection. If a Period of Inactivity occurs immediately after subscriber's connection to the NTF is established and is then immediately followed by an Idle Connection, then such Period of Inactivity shall also be deemed a part of the Idle Connection.

(C) A ''Period of Inactivity'' is an uninterrupted period of time of specified length when the connection is open but the NTF is not receiving from or sending to subscriber any transactions. The length of the Period of Inactivity shall be such period of time between [5]*10* minutes and [10]*60* minutes in length as Nasdaq may specify from time to time by giving notice to users of the NTF.

(3)–(5) 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, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the fees for the NTF are assessed based on Active Testing, where the user is sending and receiving transactions, and Idle Testing, where the user is connected to the NTF, but not sending or receiving transactions. The current fees for Active Testing and Idle Testing are $285 per hour and $75 per hour respectively. The proposed rule change simplifies the NTF fee schedule by eliminating the Idle Testing fees and modifying the parameters for Active Testing. Nasdaq believes that the proposed rule change will make the NTF services more cost-effective for Nasdaq's customers.

Nasdaq's customers have historically accessed the NTF through dial-up connections using either Nasdaq's computer-to-computer interface (CTCI) or the NWII application programming interface (API). As Nasdaq transitions to new technology (*i.e.*, FIX and QIX) [7], Nasdaq believes that users will increasingly access the NTF using high bandwidth Internet or Extranet connections that are ''always on''. The Idle Testing fee was originally designed to discourage customers from needlessly taking a limited number of dial-up connections when no testing was being performed. Some NTF users have created automated connection mechanisms that automatically access the NTF on a periodic basis. These firms sometimes unknowingly maintain idle connections and only discover the problem after days or weeks of idly connecting to the NTF. By eliminating the Idle Testing fee, these users will only be charged when Active Testing occurs, and will not be charged for idle connections.

In addition to eliminating fees for Idle Testing, Nasdaq proposes to change the time period for when an Idle Connection commences from five to 10 minutes in length to 10 to 60 minutes in length. Initially, the period during which a connection needs to remain inactive before it will be deemed idle will be 60 minutes. Nasdaq, however, reserves the right to adjust this time within a range of 10 to 60 minutes by giving notice of the change to NTF subscribers. The proposed rule change also clarifies that the fee schedule for access to the NTF applies to all Active Connection testing regardless of the Nasdaq access protocols used to access the NTF. Thus, the new modified NTF fee schedule will also apply to QIX and other access protocols that Nasdaq may offer in the future.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,[8] in general, and Section 15A(b)(5) [9] of the Act, in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. By modifying the NTF pricing structure to be more responsive to subscriber needs and market demands, Nasdaq believes the proposed rule supports efficient use of existing systems and ensures that the charges associated with such use are allocated equitably. The proposed rule change will apply to non-members (usually service bureaus) seeking access to the NTF. This fee schedule is identical to the new fee schedule that Nasdaq proposes to charge NASD members seeking access to the NTF.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq 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.

[7] FIX (Financial Information Exchange) and QIX (Nasdaq Information Exchange) are new messaging protocols that are used by customers to communicate with Nasdaq's systems. *See* Securities Exchange Act Release Nos. 48387 (August 21, 2003), 68 FR 51619 (August 27, 2003) (SR–NASD–2003–117); 48452 (September 5, 2003), 68 FR 53767 (September 12, 2003) (SR–NASD–2003–118); and 51170 (February 9, 2005), 70 FR 7988 (February 16, 2005) (SR–NASD–2005–002).

[8] 15 U.S.C. 78*o*–3.

[9] 15 U.S.C. 78*o*–3(b)(5).

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: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) [10] of the Act and Rule 19b–4(f)(6) thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov. Please include File Number SR–NASD–2005–075 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2005–075. 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. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq.

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–NASD–2005–075 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3537 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51931; File No. SR–NASD–2005–052]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change and Amendments No. 1 and No. 2 Thereto Relating to Honorarium for Arbitrators Deciding Discovery-Related Motions

June 28, 2005.

I. Introduction

On April 14, 2005, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly owned subsidiary, NASD Dispute Resolution, Inc. (''NASD Dispute Resolution''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to an honorarium for arbitrators deciding discovery-related motions. On April 29, 2005, NASD Dispute Resolution submitted Amendment No. 1 to the proposed rule change. On May 6, 2005, NASD Dispute Resolution submitted Amendment No. 2. The proposed rule change, as amended, was published for comment in the **Federal Register** on May 19, 2005.[3] The Commission received one comment on the proposal. For the reasons discussed below, the Commission is approving the proposed rule change, as amended.

II. Description of the Proposed Rule Change

A. Description of the Proposal

In 2002, NASD Dispute Resolution conducted arbitrator focus groups across the country. One of the consistently raised concerns was the amount of time and effort invested by chairpersons in reviewing and deciding various discovery motions, especially in situations in which the motions are decided without a hearing (*i.e.*, on the papers). Also, Dispute Resolution staff has found that the current lack of compensation for deciding such motions has made it more difficult to recruit current arbitrators to become chairpersons. Currently, arbitrators are not compensated for deciding discovery motions on the papers. Arbitrators are compensated, however, when they conduct pre-hearing conferences to hear arguments from parties regarding discovery motions.

NASD, therefore, proposed to adopt a rule to compensate arbitrators in the amount of $200 (the same amount that is paid for an arbitrator to participate in a pre-hearing conference regarding discovery) to decide discovery motions on the papers. The new rule language states that NASD will pay arbitrators an honorarium of $200 to decide a discovery-related motion without a hearing session. For purposes of this rule, a discovery-related motion and any replies or other correspondence relating to the motion will be considered to be a single motion. If more than one arbitrator considers a discovery-related motion, each arbitrator will receive $200. The panel will allocate the cost of the honoraria as part of the eventual arbitration award. The rule will not apply to simplified cases administered under Rules 10203 and 10302.

B. Comment Summary

The proposal was published for comment in the **Federal Register** on

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 51693 (May 12, 2005), 70 FR 28972 (May 19, 2005) (the ''Notice'').

May 19, 2005.[4] We received one comment letter on the proposal which suggested that compensation to arbitrators should be based on units of time required to decide discovery motion on the papers and also proposed several alternatives for improving the arbitration process.[5] In response to the Greenberg Letter, the NASD states that ''NASD concluded that variable fee structures based on such factors as the number or complexity of motions or the time spent by an arbitrator in deciding a discovery-related motion on the papers could result in unlimited costs for the parties.''[6] The NASD therefore concluded that ''a set fee would be the most efficient way to compensate arbitrators for the additional work in deciding discovery-related motions, while keeping costs to the parties at reasonable and predictable levels.''[7] The NASD indicated that the remaining items in the Greenberg Letter were beyond the scope of the proposed rule change.[8]

III. Discussion and Findings

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the provisions of Sections 15A(b)(5)[9] and 15A(b)(6)[10] of the Act, which require, among other things, that the NASD's rules provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system that the NASD operates or controls, and that NASD 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. The Commission believes that the proposed rule change, as amended, accomplishes these goals by encouraging arbitrators to decide discovery-related motions on the papers without the need for a pre-hearing conference (while keeping costs to the parties at reasonable and predictable levels), thereby expediting the pace of arbitrations, which should reduce the time between the filing of an arbitration claim and the rendering of an award.

IV. Conclusions

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[11] that the proposed rule change, as amended (SR–NASD–2005–052), be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3542 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[4] *See* Notice, *supra* note 3.

[5] *See* letter from Les Greenberg, Law Offices of Les Greenberg, to Jonathan G. Katz, Secretary, Securities and Exchange Commission, received May 31, 2005 (''Greenberg Letter'').

[6] *See* letter from Mignon McLemore, Associate Chief Counsel, NASD, to Lourdes Gonzalez, Assistant Chief Counsel, Division of Market Regulation, Commission, dated June 24, 2005.

[7] *Id.*

[8] *Id.*

[9] 15 U.S.C. 78o–3(b)(5).

[10] 15 U.S.C. 78o–3(b)(6).

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51935; File No. SR–NASD–2005–066]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change Relating to Amendments to NASD Rule 3011 and the Adoption of New Related Interpretive Material

June 29, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 23, 2005, the 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 NASD. 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

NASD is proposing to amend NASD Rule 3011 and adopt new related interpretive material (''IM''), to (1) require each member to conduct the independent test of its anti-money laundering program on an annual basis, with the exception of certain types of firms, which would be allowed to test every two years; (2) clarify the persons not considered to be independent for purposes of Rule 3011(c), and therefore not eligible to conduct the test; and (3) require a member to review and update, if necessary, the accuracy of the member's anti-money laundering compliance person information on a quarterly basis. The text of the proposed rule change is available on NASD's Web site (*http://www.nasd.com*), at NASD's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statuory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD 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. NASD 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

Financial institutions, including broker-dealers, must develop and implement anti-money laundering (''AML'') programs pursuant to the Bank Secrecy Act,[3] as amended by Section 352 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001 (''PATRIOT Act'').[4] Consistent with Treasury regulation 31 CFR 103.120 under the Bank Secrecy Act, NASD Rule 3011 requires that each member develop and implement a written AML program and specifies the minimum requirements for those programs.

Independent Testing

One of the AML program requirements is that firms independently test their AML programs. Testing allows a member to review and assess the adequacy of the firm's AML program and the firm's degree of compliance with its written procedures. Test results alert members to any deficiencies in their AML programs, thereby allowing them to take appropriate corrective action or disciplinary action as the situation may warrant. The independent test report also is an important tool for regulators during their examinations of firms for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Currency and Foreign Transactions Reporting Act of 1970 (commonly referred to as the Bank Secrecy Act), 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5330.

[4] Pub. L. 107–56, 115 Stat. 272 (2001).

AML compliance to, among other things, ensure that the firms are following up with corrective action when such tests discover AML program deficiencies.

Frequency of Testing

Neither the Bank Secrecy Act nor Rule 3011 currently specifies the frequency of independent testing, and members have asked NASD for guidance on this issue. Given the important role that testing plays in a firm ensuring that its AML program is effective in preventing money laundering activities from occurring at or through the firm and, in order to assure that member AML programs are serving their regulatory purposes, the proposed rule change would require in most instances that firms test their AML programs at least annually (on a calendar-year basis). Certain firms, however, because of their business models and activities may be able to test on a less frequent basis. Therefore, the proposed rule change would allow members that do not execute transactions for customers or otherwise hold customer accounts or act as an introducing broker with respect to customer accounts to test at least once every two years (on a calendar-year basis), rather than on an annual basis. Examples of these types of firms may include firms that engage solely in proprietary trading or that conduct business only with other broker-dealers. In either case, the proposed rule change establishes a minimum requirement, and members should undertake more frequent testing than required if circumstances warrant.

Establishing Independence

Rule 3011(c) allows the independent testing of a firm's AML program to be conducted by either member personnel or by a qualified outside party. Some firms may find it more cost effective to use appropriately trained firm personnel. In this regard, members have asked for guidance on how to sufficiently maintain the independence of any internal personnel conducting the test. The proposed rule change would require the person conducting the independent test to have a working knowledge of the applicable Bank Secrecy Act requirements and related implementing regulations. The proposed rule change further clarifies that, to ensure sufficient separation of functions for independence purposes, the testing cannot be conducted by the AML compliance person(s) designated in Rule 3011, by any person who performs the AML functions being tested, or by any person who reports to any of these persons.

Recognizing that these limitations may effectively prevent a small firm from using appropriate internal personnel to conduct the tests, the proposed rule change would allow tests to be conducted by persons who report to either the AML compliance person or persons performing AML functions if (1) the member has no other qualified personnel to conduct the test; (2) the member establishes written policies and procedures to address potential conflicts that can arise from allowing the test to be conducted by a person in the reporting chain (*e.g.*, anti-retaliation procedures); (3) to the extent possible, the results of the test are reported to someone senior to the person to whom the test conductor reports; and (4) the member documents its rationale, which must be reasonable, for determining that it has no other alternative than to comply in this manner.[5] In addition, if the person does not report the results to a person senior to the AML compliance person or persons performing AML functions, the member must document a reasonable explanation for not doing so.

Consistent with SEC and NASD recordkeeping requirements, the member would need to retain a copy of the documented rationale, which would be reviewed by NASD examiners to assess whether the member's rationale reasonably supports its determination.

NASD engaged in extensive discussions with the New York Stock Exchange, Inc. (''NYSE'') to coordinate this proposed rule change regarding independent testing of AML compliance programs. To the extent possible, NASD and the NYSE have tried to develop consistent approaches with variations where necessary to account for the differences in NASD and NYSE membership, namely, differences in firm size, types of businesses conducted, and overall business models.

AML Compliance Person—Review and Update of Contact Information

Paragraph (d) of Rule 3011 requires that each member designate and identify to NASD the member's AML compliance person(s) and notify NASD of any changes to the compliance person(s)' contact information. NASD requires this information to, among other things, facilitate the efforts of the Financial Crimes Enforcement Network, pursuant to Section 314(a) of the PATRIOT Act and its implementing regulations, in requesting information from financial institutions about persons suspected of engaging in money laundering or terrorist activities.

Given the important role of the AML compliance person in ensuring effective communication for purposes of identifying money-laundering and terrorist financing activities, NASD believes that members should review and update the AML compliance person information periodically to ensure its accuracy. As such, the proposed rule change would require that each member conduct a review and update, if necessary, of its AML compliance person information within 17 business days after the end of each calendar quarter.[6] Quarterly reviews and updates are consistent with NYSE requirements.[7]

The proposed rule change also would clarify that the AML compliance person must be an associated person of the member. As noted in Section 2 of this filing, NASD will announce the effective date of the proposed rule change in a *Notice to Members* to be published no later than 60 days following Commission approval. The effective date will be not more than 30 days following publication of the *Notice to Members* announcing Commission approval.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, which requires, among other things, that NASD rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to

[5] This exception is primarily intended to accommodate small firms. For example, assume that all of a small firm's employees, even those who do not perform any AML functions, report to the firm's AML compliance person who is also the sole compliance officer of the firm. The member could elect to use qualified internal personnel who do not perform AML functions to conduct the independent test, even though they report to the AML compliance officer, provided all of the conditions set forth in proposed IM–3011–1(c)(3) have been met.

[6] This proposed schedule is consistent with a member's quarterly FOCUS reporting schedule, as well as with a member's business continuity plan requirement to review and update emergency contact information on a quarterly basis (*see* NASD Rule 3520(b)). Similarly, the proposed schedule is consistent with the requirement to review and update a member's Executive Representative designation and contact information (*see* NASD Rule 1150) and to designate a person to receive notifications relating to continuing education, and the need to review and update such designation and contact information (*see* NASD Rule 1120(a)(7)). When members file their FOCUS reports each quarter, they are reminded of the need to review and update this information on the NASD Contact System.

[7] In Information Memo Number 02–41 (Aug. 30, 2002), the NYSE stated that its members should review and/or update on a quarterly basis (*i.e.*, March, June, September, and December) the information furnished on its Electronic Filing Platform, including information regarding the member's or member organization's AML compliance person.

protect investors and the public interest. NASD believes that the proposed rule change is designed to accomplish these ends by requiring members to conduct periodic tests of their AML compliance programs, preserve the independence of their testing personnel, and ensure the accuracy of their AML compliance person information.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD 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

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. The Commission particularly urges commenters to consider the proposed rule change in light of a similar but not identical proposed rule change by the NYSE.[8]

Specifically, the NASD and NYSE proposals differ in who would be permitted to serve as a firm's designated AML compliance contact person (''AML Officer''). The NYSE proposal would, subject to certain restrictions, permit the AML Officer to be an employee of a parent, affiliate, or subsidiary of a member. As discussed above, the NASD proposal, however, would require the AML Officer to be an ''associated person of the member,'' as that term is defined in Article I(dd) of the NASD By-Laws. Serving as an AML Officer, by itself, would not make a person an associated person of an NASD member. What issues, if any, would arise from the application of both standards regarding who can serve as an AML Officer at firms that are dual members of the NASD and NYSE?

The NASD and NYSE proposals also differ in who would be permitted to perform the independent testing function for AML compliance. Primarily to accommodate smaller firms, the NASD proposal would permit an employee who reports to a person who performs the functions being tested and/or reports to the AML Officer to perform the independent testing, if, among other requirements, the member has no other qualified internal personnel to conduct the test and the member creates a written policy to address conflicts. The NYSE proposal, however, would not permit an employee who reports to a person who performs the functions being tested or reports to the AML Officer to perform the independent testing. How would these standards, if adopted, affect the AML program of dual members of the NASD and NYSE? Firms are invited to discuss how this would affect their specific operations.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASD–2005–066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2005–066. 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. Copies of such filing will also be available for inspection and copying at the principal office of NASD.

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 the File Number SR–NASD–2005–066 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3543 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[8] The text of the proposed rule change is available on the NYSE's Web site (*www.NYSE.com*), at the NYSE's principal office, and at the Commission's Public Reference Room.

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51929; File No. SR–NASD–2005–083]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Definition of ''Non-Professional'' and Use of TRACE Transaction Data

June 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 23, 2005, the National Association of Securities Dealers, Inc. (''NASD'') 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 NASD. NASD filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

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

NASD is proposing to amend the definition of ''Non-Professional'' in NASD Rule 7010(k)(3)(C)(i), relating to Transaction Reporting and Compliance Engine (''TRACE'') transaction data and fees, and add new NASD Rule 7010(k)(3)(A)(iv) to clarify that a natural person who receives and uses TRACE transaction data for his or her personal, non-commercial use will not be charged a TRACE market data professional fee for such use. The text of the proposed rule change is available on NASD's Web site (*http://www.nasd.com*), at NASD's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD 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. NASD 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

NASD seeks to make minor clarifying changes to the definition of ''Non-Professional'' in NASD Rule 7010(k)(3)(C)(i) and to add new NASD Rule 7010(k)(3)(A)(iv). The purpose of the proposed rule change is to restructure NASD Rule 7010(k) to reflect more clearly a recently approved rule change to permit natural persons actively engaged in providing financial services or employed in the financial services industry who do not fall within the definition of ''Non-Professional'' to access TRACE transaction data solely for personal, non-commercial purposes and not be liable for professional TRACE transaction data fees.

Background. NASD recently made minor clarifying amendments to the defined term ''Non-Professional'' in NASD Rule 7010(k)(C)(3)(i) to make explicit in the rule that persons who are otherwise excluded from the definition of ''Non-Professional,'' such as registered persons employed by a broker-dealer or an investment adviser, should not be liable for professional fees for TRACE market data when such persons access the TRACE data solely for their personal, non-commercial use.[5] The amendments became effective June 1, 2005.

Proposal. The definition of ''Non-Professional'' is used in various NASD rules. NASD is concerned that defining the same term differently among NASD Rules will create confusion and inefficiencies both for the industry and NASD. For the purpose of maintaining uniformity among definitions, eliminating confusion among industry professionals who must apply the multiple provisions, and creating efficiencies for regulatory data searches and data retrieval, NASD is proposing to amend the defined term ''Non-Professional'' in NASD Rule 7010(k)(3)(C)(i). This amendment would reverse some of the minor clarifying amendments previously made but would conform it to other NASD provisions also defining ''Non-Professional'' and preserve the previously approved rule change providing natural persons who are affiliated with or employed by the securities or commodities industry or other parts of the financial services industry[6] access to TRACE transaction data without paying professional TRACE data fees when using the data solely for personal, non-commercial use.

To effect the restructuring rule change, NASD proposes specific minor clarifying changes to NASD Rule 7010(k)(3)(C)(i) that are set forth in the proposed rule text. The proposed amendments reverse some but not all of the minor clarifying changes recently incorporated in the Rule.[7] NASD also proposes to amend NASD Rule 7010(k)(3)(A) to add subparagraph (iv), providing:

> A natural person otherwise subject to market data fees under Rule 7010(k)(3)(A) is not subject to such fees when he or she accesses TRACE transaction data solely for his or her personal, noncommercial use.

Together, the proposed amendments continue to make clear that a natural person who is registered in one of several capacities as a securities or commodities professional, or performs similar functions but is not required to be registered due to an exemption, or is an employee of certain financial services businesses, may access TRACE transaction data free of professional TRACE data charges if the natural person uses such data solely for personal, non-commercial uses. These changes also would maintain conformity among various NASD provisions in which the term ''Non-Professional'' is defined.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[8] which requires, among other things, that NASD 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, and Section 15A(b)(5) of the Act,[9] which requires, among other things, that NASD rules provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system that NASD operates or controls.

NASD believes that continuing to provide access to TRACE data to persons who are using TRACE market data solely for personal, non-commercial use is consistent with the NASD's goals to promote corporate bond market transparency, and would not adversely affect the use and distribution of TRACE data for the protection of investors and in furtherance of the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change would result in any burden on competition that is not

[5] *See* Securities Exchange Act Release No. 51611 (April 26, 2005), 70 FR 22735 (May 2, 2005) (order approving File No. SR–NASD–2005–026); NASD *Notice to Members* 05–37 (May 2005). For example, a registered representative of a broker-dealer is not liable for fees charged professionals in those instances where the registered representative accesses the TRACE transaction data solely for personal, non-commercial use, such as when the registered representative accesses TRACE data at home to obtain information about bonds held in his or her personal account.

[6] Such financial services industry affiliations are described fully in NASD Rule 7010(k)(3)(C)(i) in current subparagraphs (a) through (d), to be renumbered as subparagraphs (a) through (c).

[7] NASD is not revising recently adopted amendments to NASD Rule 7010(k)(3)(C)(i)(d) (to be renumbered as NASD Rule 7010(k)(3)(C)(i)(c)). Prior to amendment, NASD Rule 7010(k)(3)(C)(i)(d) excluded from ''Non-Professional'' persons employed by a bank, insurance company, or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt if such persons used TRACE transaction data for other than personal, noncommercial use. The revisions added that ''other employees'' of such organizations who use TRACE transaction data for other than personal, non-commercial use also are not ''Non-Professionals.''

[8] 15 U.S.C. 78o–3(b)(6).

[9] 15 U.S.C. 78o–3(b)(5).

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

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, and NASD provided the Commission with written notice of its intent to file the proposed rule change at least five days prior to the filing date, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11] NASD complied with this pre-filing requirement.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. NASD has asked the Commission to waive the 30-day operative delay to clarify an existing policy regarding TRACE market data fees applicable to professionals and to reverse expeditiously recent rule amendments to the definition of ''Non-Professional'' in Rule 7010(k)(3) regarding the TRACE policy to avoid industry confusion. The Commission hereby grants this request and designates the proposal to be operative upon filing with the Commission.[12] The Commission believes that maintaining conformity among definitions in NASD's rules and reducing fees for non-professional use of TRACE transaction data are consistent with the protection of investors and the public interest.

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.[13]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NASD–2005–083 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File No. SR–NASD–2005–083. 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. Copies of such filing will also be available for inspection and copying at the principal office of NASD. 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–NASD–2005–083 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3544 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] *See* 15 U.S.C. 78s(b)(3)(C).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51934; File No. SR–NYSE–2005–36]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change To Amend Rule 445

June 29, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Exchange Act'') [1] and Rule 19b–4 [2] thereunder, notice is hereby given that on May 23, 2005, the New York Stock Exchange, Inc. (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or the ''Commission'') the proposed rule changes 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 changes from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Changes

The Exchange proposes to amend Rule 445 (''Anti-Money Laundering Compliance Program'') to establish: (1) Timeframes within which the required independent testing function must be performed; (2) qualification and independence standards for those who conduct such testing function; and (3) jurisdictional requirements pertaining to AML Officers (as defined below). The text of the proposed rule change is available on the NYSE's Web site (*http://www.NYSE.com*), at the NYSE's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

Summary

The proposed rule change consists of amendments to Rule 445 (''Anti-Money Laundering Compliance Program'') to establish that the ''independent testing'' requirement of the Rule must be conducted, at minimum, on an annual calendar-year basis by members and member organizations that conduct a public business, or every two years if no public business is conducted. The amendments also establish a standard to determine who is adequately qualified and sufficiently independent to conduct the required testing. Further, they clarify that each person designated to implement and monitor an Anti-Money Laundering Program must either be an employee of the member or member organization for which they are designated or, with the prior approval of the Exchange, an employee of a parent, affiliate, or subsidiary of the member or member organization. Employees of a parent, affiliate, or subsidiary of a member or member organization who are designated to implement and monitor Anti-Money Laundering Programs must consent to the jurisdiction of the Exchange and the member or member organization must acknowledge their responsibility to supervise them as employees.

Background and Detail

Rule 445, which became effective on April 24, 2002,[3] requires each member organization and each member not associated with a member organization to develop and implement an anti-money laundering (''AML'') program consistent with ongoing obligations pursuant to Treasury regulation 31 CFR 103.120 under the Bank Secrecy Act,[4] as amended by the United and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001.[5]

The prescribed AML program obligations include the development of internal policies, procedures and controls; the designation of a person to implement and monitor the day-to-day operations and internal controls of the program (commonly referred to as an ''AML Officer''); ongoing training for appropriate persons; and an independent testing function for overall compliance.

Neither the Bank Secrecy Act nor Rule 445 currently specifies: (1) Timeframes within which the independent testing function must be performed, (2) qualification and independence standards for those who conduct such testing function, or (3) jurisdictional requirements pertaining to AML Officers. In order to provide interpretive clarity to the text, the following amendments to Rule 445 are proposed.

Timeframes for Independent Testing

The proposed amendments would require that independent testing of AML programs be conducted, at a minimum, on an annual (calendar-year) basis by members or member organizations that conduct a public business, or every two years if no public business is conducted (*i.e.*, if the member or member organization engages solely in proprietary trading, and/or conducts business only with other broker-dealers). The Exchange believes these timeframes are reasonable in that they require more frequent testing of AML programs designed to monitor a public business, which is likely more susceptible to money laundering schemes than strictly proprietary business. Further, the one-year time frame for testing is consistent with standard industry practice in that it is similar to generally accepted guidelines for conducting tests in the context of, for instance, general audits and branch office visits. However, the proposed amendments make clear that more frequent testing should be conducted if circumstances warrant (*e.g.*, should the business mix of the member or member organization materially change; in the event of a merger or acquisition; in light of systemic weaknesses uncovered via testing of the AML program; or in response to any other ''red flags'').

Qualification and Independence Standards for Testing

With regard to who is adequately qualified and sufficiently independent to conduct the independent testing function, the proposed amendments would require that testing be conducted by a designated person with a working knowledge of applicable requirements under the Bank Secrecy Act and its implementing regulations. Such person need not be an employee of the member or member organization since the responsibility being delegated is essentially an auditing function and, as such, it would not be unusual or ineffective for it to be performed by an independent outside party. As noted below, the proposed amendments require that the day-to-day responsibilities for monitoring operations and internal controls of AML programs be performed by a person fully subject to the supervision of the member or member organization for which they are designated, and to the jurisdiction of the Exchange.

The proposed amendments do not preclude an employee of the member or member organization from conducting the required independent testing of the AML program; however the proposed ''independence'' standard would prohibit testing from being conducted by a person who performs the functions being tested, or by the designated AML compliance officer, or by a person who reports to either. This standard is designed to promote the independence, and thus the integrity, of the testing function by insulating it from the day-to-day administration of the activities being tested. It also serves to remove the testing function from the supervisory structure of the member or member organization, thus eliminating the possibility that a person might not candidly report shortcomings in a system designed by their supervisor for fear of reprisal.

Jurisdiction Over AML Officers

The proposed amendments clarify that the person or persons designated to implement and monitor a member's or member organization's Anti-Money Laundering Program (commonly referred to as an AML Officer, as previously indicated) must either be an employee of the member or member organization for which they are designated or, with the prior approval of the Exchange, an employee of a parent, affiliate or subsidiary of the member or member organization.

The rationale behind the proposal to allow employees of parents, affiliates and subsidiaries to be designated AML Officers of members and member organizations is the recognition that AML programs may be integrated into, and extend throughout, the corporate family. Accordingly, a person acting as an AML Officer for both a member organization and the member organization's parent bank would be better situated to see the ''big picture'' (*i.e.*, to monitor the movements of funds

[3] See Securities Exchange Act Release No. 45798 (April 22, 2002); 67 FR 20854 (April 26, 2002) (SR–NYSE–2002–10).

[4] Currency and Foreign Transactions Reporting Act of 1970 (commonly referred to as the Bank Secrecy Act), 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5330.

[5] Pub. L. 107–56, 115 Stat. 272 (2001).

and securities throughout the corporate structure and, thus, be better able to identify and understand AML issues across the range of such structure). The ability to situate AML Officers where they can be most effective gives members and member organizations the flexibility to integrate their AML program into the larger corporate structure to achieve a more global perspective, and thus a more comprehensive and effective AML program.

The prior written approval of the Exchange is required if the designated AML Officer is other than an employee of the member or member organization. Further, each such person must execute an attestation, acceptable to the Exchange, consenting to the supervision of each member or member organization for which they are designated and to the jurisdiction of the Exchange. A proposed example of such an attestation is included in Exhibit 3 of the proposed rule change, which is available on the NYSE's Web site (*http://www.NYSE.com*), at the NYSE's principal office, and at the Commission's Public Reference Room, under the heading ''AML Officer Consent to Jurisdiction.'' In addition, the member or member organization must execute an agreement, acceptable to the Exchange, acknowledging their responsibility to supervise, as an employee for all regulatory purposes, each such person designated by them. A proposed example of such an agreement is included in Exhibit 3 of the proposed rule change under the heading ''Acknowledgement of Supervisory Responsibility over AML Officer.''

2. Statutory Basis

The proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with the requirements of Sections 6(b)(5)[6] of the Exchange Act. Section 6(b)(5) requires, among other things, that the rules of an 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 national market system, and in general, to protect investors and the public interest. NYSE believes that the proposed rule change is designed to accomplish these ends by requiring members to conduct periodic tests of their AML compliance programs, preserve the independence of their testing personnel, and ensure the accuracy of their AML compliance program.[7]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange 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 Exchange Act. The Commission particularly urges commenters to consider the proposed rule change in light of a similar but not identical proposed rule change by the National Association of Securities Dealers, Inc. (''NASD'').[8]

Specifically, the NYSE and NASD proposals differ in who would be permitted to serve as an AML Officer. As discussed above, the NYSE proposal would, subject to certain restrictions, permit the AML Officer to be an employee of a parent, affiliate, or subsidiary of a member. The NASD proposal, however, would require the AML Officer to be an ''associated person of the member,'' as that term is defined in Article I(dd) of the NASD By-Laws. Serving as an AML Officer, by itself, would not make a person an associated person of an NASD member. What issues, if any, would arise from the application of both standards regarding who can serve as an AML Officer at firms that are dual members of the NYSE and NASD?

The NYSE and NASD proposals also differ in who would be permitted to perform the independent testing function for AML compliance. Primarily to accommodate smaller firms, the NASD proposal would permit an employee who reports to a person who performs the functions being tested and/or reports to the AML Officer to perform the independent testing, if, among other requirements, the member has no other qualified internal personnel to conduct the test and the member creates a written policy to address conflicts. The NYSE proposal, however, would not permit an employee who reports to a person who performs the functions being tested or reports to the AML Officer to perform the independent testing. How would these standards, if adopted, affect the AML program of dual members of the NYSE and NASD? Firms are invited to discuss how this would affect their specific operations.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2005–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NYSE–2005–36. 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

[6] 15 U.S.C. 78f(b)(5).

[7] Statement regarding NYSE beliefs is based on statements by the NYSE during a conference call with the staff of the Division of Market Regulation on June 27, 2005.

[8] The text of the proposed rule change is available on the NASD's Web site (*http://www.nasd.com*), at the NASD's Office of the Secretary, and at the Commission's Public Reference Room.

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. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE.

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 the File Number SR–NYSE–2005–36 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3539 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51937; File No. SR–PCX–2005–31]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Notice of Filing of Proposed Rule Change and Amendments No. 1, 2, and 3 Thereto To Permit Lead Market Makers To Operate From a Remote Location

June 29, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 15, 2005, the Pacific Exchange, Inc. (''PCX'' 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 Exchange submitted Amendments No. 1, 2, and 3 on May 27, 2005,[3] June 6, 2005,[4] and June 22, 2005,[5] respectively. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX is proposing to amend PCX trading rules in order to allow OTP Holders and OTP Firms who conduct Lead Market Making activity to do so whether on the trading floor or from a remote location. The text of the proposed rule change is set forth below. Additions are in *italics*; deletions are in brackets.

Rules of the Pacific Exchange, Inc.

Rule 6 Options Trading

Rule 6.32(a). A Market Maker is an individual who is registered with the Exchange for the purpose of making transactions as a dealer-specialist on the Floor of the Exchange or, in the case of a Remote Market Maker *or a Lead Market Maker*, through the facilities of the Exchange in accordance with the provisions of this subsection. Registered Market Makers are designated as specialists on the Exchange for all purposes under the Securities Exchange Act of 1934 and the Rules and Regulations thereunder. Except as provided in subsection (c) below, only transactions that are initiated on the Floor of the Exchange or executed through the facilities of the Exchange [by a Remote Market Maker] will count as Market Maker transactions for the purposes of Rule 6.32. A Market Maker on the Exchange must be either a Lead Market Maker, a Remote Market Maker, a Supplemental Market Maker, or a Floor Market Maker.

(1) A Lead Market Maker is a registered Market Maker who makes transactions as dealer-specialist [while] on [the Floor of] the Exchange and who meets the qualification requirements of Rule 6.82(b).

(2)–(4)—No change.

(b) Market Makers and Floor Brokers effecting transactions as Market Makers are instructed that, except as specified in subsection (c) below, only transactions that are initiated on the Floor of the Exchange or[, in the case of a Remote Market Maker,] through the facilities of the Exchange by that person shall count as Market Maker transactions and be entitled to special margin treatment, pursuant to the net capital requirements of Rule 15c3–1 under the Securities Exchange Act of 1934 and Regulation T of the Board of Governors of the Federal Reserve system. Accordingly, any position established for the account of a Market Maker [other than a Remote Market Maker] which has been ''entered [from off the floor] *through an OTP Firm acting as a Floor Broker*'' must be placed in the Market Maker's investment account and be subject to applicable customer margin.

(c) A Market Maker may enter opening orders from off the Floor of the Exchange for execution by Floor Brokers and receive special margin treatment for such orders during any calendar quarter, provided that such Market Maker executes in person *or through a facility of the exchange*, and not through the use of orders, at least 80% of his or her total transactions during that calendar quarter. This provision, if applicable, shall supersede the 60% in-person requirement of Rule 6.37. In addition, the [off-floor] orders executed by a Floor Broker for which a Market Maker received market-maker treatment shall be consistent with a Market Maker's duty to maintain fair and orderly markets and in general shall be effected for the purpose of hedging, reducing the risk of, or rebalancing open positions of the Market Maker. Remote Market Makers may enter opening orders from off the Floor of the Exchange for execution by Floor Brokers and receive special margin treatment for them as long as the entry of such orders is consistent with the Remote Market Maker's duty to maintain fair and orderly markets and such orders are entered for the purpose of hedging, reducing the risk of, or rebalancing open positions of the Remote Market Maker.

(d)–(e)—No change.

Rule 6.33–6.35(h)(3)—No Change.

Rule 6.35(h)(4) at no time will a Remote Market Maker concurrently trade or quote the same option issue as a Remote Market Maker *or Lead Market Maker* who is a Nominee for the same OTP Holder or OTP Firm.

Rule 6.36(a). Required of Each OTP Holder. No Market Maker may make any transaction on the floor of the Exchange or, in the case of a Remote Market Maker *or a Lead Market Maker*, through the facilities of the Exchange unless there is in effect a Letter of Guarantee which has been issued for such OTP Holder or OTP Firm by a Clearing Member and approved by the Options Clearing Corporation and the Exchange. An OTP Holder or OTP Firm may not have more than one such Letter in effect at the same time except for the purpose of facilitating the transfer of that OTP Holder or OTP Firm's Market Maker account from one Clearing Member to another or unless the Exchange determines otherwise.

Rule 6.36(b)–6.37(c)—No Change.

Rule 6.37(d) In-Person Requirements for Market Makers [(other than Remote

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[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] CFR 240.19b–4.

[3] Amendment No. 1 makes clarifying changes to the purpose statement and rule text. Amendment No. 1 replaces the original rule filing in its entirety.

[4] Amendment No. 2 makes a technical correction to the rule text in Exhibit 5.

[5] Amendment No. 3 clarifies how a Lead Market Maker will garner their guaranteed trade allocations to the PCX by adding the words ''via the PCX Plus system'' at the end of the second paragraph in the purpose statement. Amendment No. 3 also eliminates the deletion of PCX Rule 6.37(f)(1).

Market Makers who are not present on the Trading Floor)]. In order to meet the obligations of this rule, and in the interest of a fair and orderly market, an adequate number of Market Makers must be available throughout each trading session. In acknowledgement thereof, the following minimum in-person trading requirements shall be in effect: At least 60% of a Market Makers transactions must be executed by the Market Maker in-person or through an approved facility of the exchange [, while he is present on the Options Trading Floor of the Exchange]. Orders executed for a Market Maker through a Floor Broker will not be credited toward the 60% requirement. A failure to comply with this 60% in-person trading requirement may result in a fine pursuant to Rule 10.13; however, if aggravating circumstances are present, formal disciplinary action may be taken pursuant to Rule 10.4.

Rule 6.37(e)—Rule 6.37 Commentary .02—No Change.

Rule 6.37 Commentary .03(a)—When a Market Maker other than a Remote Market Maker *or a Lead Market Maker operating from off the trading floor*, displays a market on the screen that is the best market in that crowd, the Market Maker is obligated to ensure that its market is removed from the screen when the Market Maker leaves the crowd.

Rule 6.37 Commentary .04—Rule 6.81—No Change.

Rule 6.82(a). General Provisions

(1) Lead Market Maker Defined. A Lead Market Maker (''LMM'') is an individual or entity that has been deemed qualified by the *Exchange* [Options Allocation Committee] for the purpose of making transactions on [the Options Floor of] the Exchange in accordance with the provisions of Rule 6.82. Each LMM or nominee thereof must be registered with the Exchange as a Market Maker. Any OTP Holder or OTP Firm registered as a Market Maker with the Exchange is eligible to be qualified as an LMM. [Remote Market Makers are not eligible to act as LMMs from a location off the trading floor.]

Rule 6.82(a)(2)–(c)(4)—No Change.

Rule 6.82(c)(5) Be [present at the trading post] accessible throughout every business day and, in addition, designate an approved LMM to act as a back-up LMM and notify Book Staff of such designation;

Rule 6.82(c)(6)–(g)—No Change.

Rule 6.82(h)(1)—*Reserved*. [LMM Performance of Order Book Official Functions.

(a) The LMM may, subject to the approval of the Exchange, perform all functions of the Order Book Official (''OBO'') in designated option issues pursuant to Rules 6.51 through 6.59.

(b) The Exchange shall make personnel available to assist the LMM as the LMM shall reasonably require in performing the OBO function. The Exchange may charge the LMM a reasonable fee for such use of Exchange personnel.

(c) Subject to the review of two Trading Officials or the Exchange, the LMM shall resolve trading disputes upon request of any party to such dispute.

(d) The LMM shall disclose Book information to OTP Holders or OTP Firms upon request, pursuant to Rule 6.57.

(e) If the Exchange decides to reallocate an issue to the Market Maker system pursuant to Section (f)(2) of this Rule, the terminated LMM may receive a share of the net Book revenues, not to exceed one-half, for any period specified by the Exchange up to a maximum of five years. Such award shall take into account the length of time of LMM service, the LMM's capital commitment, efforts expended as LMM and any other relevant factors.]

Rule 6.82(h)(2)–(h)(3)—No Change.

Commentary:

.01 It shall be the duty of the Exchange to promulgate and recommend to the Board of Directors rules and policies with regard to the [Options Floor] *trading* activities of the LMM.

[.02 LMMs who perform the function of an Order Book Official pursuant to Rule 6.82(h) shall maintain ''minimum net capital'' as provided in SEC Rule 15c3–1, and shall also maintain a cash or liquid asset position of at least $500,000, plus $25,000 for each issue over 5 issues for which they perform the function of Order Book Official.]

* * * * *

Rule 7.1. Unless otherwise ruled by the Board of Directs, the Exchange shall be open for the transactions of business daily except on Saturdays and Sundays. The hours at which trading sessions shall open and close shall be established by the Board of Directors.

Dealings upon the Exchange shall be limited to the hours during which the Exchange is open for the transaction of business. No OTP Holder or OTP Firm shall make any bid, offer or transaction upon the Floor or in the case of Remote Market Makers *or Lead Market Makers operating from off the Floor*, through the facilities of the Exchange before the official opening of the Exchange and loans of securities may be made after those hours.

Commentary:

.01 The Board of Directors has resolved that transactions may be effected on the Options Floor of the Exchange or in the case of Remote Market Makers *or Lead Market Makers operating from off the Floor*, through the facilities of the Exchange until 1:02 p.m. for equity options and until 1:15 p.m. for index options at which time no further transactions may be made.

.02—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 filing is to modify the Exchange trading rules in order to allow OTP Holders and OTP Firms who conduct Lead Market Making activity to do so whether on the trading floor or from a remote location. Currently, the PCX rules require a Lead Market Maker be physically present on the trading floor in order to conduct Lead Market Maker activities. With the roll out of PCX Plus, the Exchange's electronic trading system, the Exchange seeks to introduce a platform by which Lead Market Makers may either be present on the trading floor or may serve their role from a remote location.

To permit a Lead Market Maker to work from remote locations, the Exchange is proposing to modify its trading rules to remove the current restrictions that require a Lead Market Maker to be physically present on the trading floor. The proposed changes will not affect any rights of the Lead Market Maker. They will retain their guaranteed participation allowances and opportunities to participate in open outcry should they choose to work from the physical trading floor. For those Lead Market Makers who choose to conduct their business from remote locations, they will not be able to inure

the benefits of the current open outcry strategies and will be granted their guaranteed participation rights solely based upon the size and price that they disseminate via the PCX Plus System.

In order to allow Lead Market Makers to operate from a remote location, the Exchange is proposing a number of changes to its Rules. First, PCX Rule 6.32 is being amended to add Lead Market Makers to the definition of who may make transactions through the facilities of the Exchange. This change will allow Lead Market Makers who are not physically present on the trading floor to perform the duties and obligations from a remote location. Language in PCX Rule 6.32 is also being changed to allow for trades executed by a Lead Market Maker through a facility of the Exchange, in addition to in-person trades, to be eligible to receive market maker margin. Presently only Lead Market Maker trades that are executed on the floor of the Exchange or those that meet the criteria of PCX Rule 6.32(c) are eligible for market maker margin. Under the proposal, a Lead Market Maker acting from a remote location would still be required to meet all of the obligations of a Lead Market Maker as stated in PCX Rule 6.82 and therefore the PCX believes such LMMs should be entitled to market maker margin on all qualified trades.

Second, the Exchange is proposing to eliminate the prohibition in PCX Rule 6.82(a)(1) that Remote Market Makers are not eligible to act as Lead Market Makers from a location off the trading floor. This change is necessary to permit Lead Market Makers to operate from a remote location and to eliminate any uncertainty that may exist in interpreting PCX Rules. A firm that operates at the PCX can have different employees who function as Remote Market Makers and Lead Market Maker, however under the proposed new rules these individuals are prohibited from trading the same option issues.[6] Without eliminating this restriction, PCX Rule 6.82(a)(1) would prohibit a PCX firm from having different employees functioning as both a Remote Market Maker and a Lead Market Maker from off the trading floor. Firms would be only allowed to have an employee in one of these categories and thus this would restrict a firm's ability to operate remotely and in turn reduce the amount of liquidity available to the PCX markets.

Fourth, as part of allowing Lead Market Makers to operate from a remote location, the Exchange is proposing to eliminate PCX Rule 6.82(h)(1). This rule currently allows the Lead Market Maker to perform Order Book Official functions. Since an Order Book Official is only present on the trading floor (PCX Plus does not contain a functionality similar to that which is performed by an Order Book Official), this function is not needed should a Lead Market Maker choose to operate from a remote location. The Exchange represents that at this time no Lead Market Maker is currently performing the functions of an Order Book Official nor has any Lead Market Maker expressed an interest in doing so. The Exchange further represents that for those individuals who continue to trade via open outcry on the trading floor, the Exchange will provide the necessary staff to effectively supervise trading.

Finally, the Exchange notes that provisions of the PCX Rules that permit Lead Market Makers to perform certain functions that require them to be physically present on the trading floor (*i.e.* PCX Rule 6.82(h)(3)) will only be permitted should the Lead Market Maker remain physically present on the trading floor. These functions will not be permitted should the Lead Market Maker decide to operate from a remote location.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(5) of the Act[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of change, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change, as amended, will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

[6] *See* Proposed PCX Rule 6.35(h)(4).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

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 Exchange consents, the Commission will:

(A) By order approve such 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, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an E-mail to *rule-comments@sec.gov.* Please include File Number SR–PCX–2005–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission/ Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–PCX–2005–31. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml.*) Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing also will be available for inspection and copying at the principal office of the PCX. 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–PCX–2005–31 and should be submitted on or before July 27, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–3538 Filed 7–5–05; 8:45 am]

BILLING CODE 8010–01–P

[9] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Request Approval From the Office of Management and Budget (OMB) of One New Public Collection of Information

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the FAA invites public comment on one public information collection which will be submitted to OMB for review and approval.

DATES: Comments must be received on or before September 6, 2005.

ADDRESSES: Comments may be mailed or delivered to the FAA at the following address: Ms. Judy Street, Room 613, Federal Aviation Administration, Standards and Information Division, APF–100, 800 Independence Ave., SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Street at the above address or on (202) 267–9895.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Therefore, the FAA solicits comments on the following collection of information in order to evaluate the necessity of the collection, the accuracy of the agency's estimate of the burden, the quality, utility, and clarity of the information to be collected, and possible ways to minimize the burden of the collection in preparation for submission to renew the clearance of the following information collection.

2120–XXXX, International Survey of Human Factors Status in Maintenance Organizations, The Civil Aerospace Medical Institute (CAMI) will collect the information on behalf of the Federal Aviation Administration's (FAA) Aviation Safety (AVS) organization. Organizations that are approved to conduct aircraft maintenance are certified and regulated under 14 CFR part 145, or international equivalent (henceforth referred to as part 145). Part 145 organizations will receive an invitation via e-mail to complete a web-based survey. The information collected will be used to assess what companies have done, are doing or are planning to do regarding the human factors elements of part 145. A partial list of subjects includes training, error management, fatigue management, and additional human factors metrics. Additionally, respondents will be asked to describe their organization's support of their human factors program. CAMI will be responsible for the logistical details associated with collecting and processing the responses. The current estimated annual reporting burden is 1,500 hours.

Issued in Washington, DC, on June 29, 2005.

Judith D. Street,

FAA Information Collection Clearance Officer, ABA–20.

[FR Doc. 05–13267 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2005–34]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions 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 any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before July 26, 2005.

ADDRESSES: You may submit comments identified by DOT DMS Docket Number FAA–2005–21317 by any of the following methods:

- Web site: *http://dms.dot.gov*. Follow the instructions for submitting comments on the DOT electronic docket site.
- Fax: 1–202–493–2251.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Susan Lender (202) 267–8029 or John Linsenmeyer (202) 267–5174, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on June 29, 2005.

Anthony F. Fazio,

Director, Office of Rulemaking.

Petitions for Exemption

Docket No.: FAA–2005–21317.

Petitioner: Prism Helicopters Inc.

Section of 14 CFR Affected: 14 CFR 43.3(g).

Description of Relief Sought: Prism Helicopters Inc. (Prism) seeks an exemption that would allow a Prism pilot to remove and reinstall the helicopter cabin/cockpit doors on the MD500D (369D) and the AS 350B2. The removal and reinstallation would require no tools. The pilot would have satisfactorily completed an approved training program and be authorized in writing to perform each task. The certificate holder would have written procedures available to the pilot to evaluate accomplishing the task.

[FR Doc. 05–13269 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2005–35]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions 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 any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before July 26, 2005.

ADDRESSES: You submit comments (Identified by DOT DMS Docket Number FAA–2005–21615 or FAA–2005–20857) by any of the following methods:

- Web site: *http://dms.dot.gov*. Follow the instructions for submitting comments on the DOT electronic docket site.
- Fax: 1–202–493–2251.
- Mail: Docket Management Facility; US Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Madeleine Kolb (425) 227–1134, Transport Airplane Directorate, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SE, Renton, WA 98055–4056; or John Linsenmeyer (202) 267–5174, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on June 29, 2005.

Anthony F. Fazio,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2005–21615.

Petitioner: Empresa Brasileira de Aeronáutica S.A. (Embraer).

Section of 14 CFR Affected: 14 CFR 25.1549(c).

Description of Relief Sought: Petitioner seeks a time-limited exemption for the Embraer ERJ 190–100 airplane from 14 CFR § 25.1549(c), which requires a precautionary range displayed on a required propulsion system instrument.

Docket No.: FAA–2005–20857.

Petitioner: The Boeing Company.

Section of 14 CFR Affected: 14 CFR 21.325(b)(3).

Description of Relief Sought: Petitioner requests that the FAA reconsider its petition for exemption permitting issuance of export airworthiness approvals for Class II and Class II products from suppliers in India, Greece, South Korea, and Turkey.

[FR Doc. 05–13270 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2005–36]

Petitions for Exemption; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of disposition of prior petition.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption, part 11 of title 14, Code of Federal Regulations (14 CFR), this notice contains the disposition of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

FOR FURTHER INFORMATION CONTACT: Kenna Sinclair (425) 227–1556, Transport Airplane Directorate, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SE., Renton, WA 98055–4056; or John Linsenmeyer (202) 267–5174, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

Issued in Washington, DC, on June 29, 2005.

Anthony F. Fazio,

Director, Office of Rulemaking.

Disposition of Petitions

Docket No.: FAA–2005–20583.

Petitioner: Dassault Aviation.

Sections of 14 CFR Affected: 14 CFR 91.613(b) and 135.170(c).

Description of Relief Sought/Disposition: Relief from the requirements for material in compartment interiors for Dassault Model Mystere-Falcon 20 and Mystere-Falcon 200 series airplanes.

Denial of Exemption, 06/24/2005, Exemption No. 8573.

[FR Doc. 05–13271 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Sussex County, Delaware

AGENCIES: Federal Highway Administration (FHWA) and the Delaware Department of Transportation (DelDOT).

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed highway improvement project in eastern Sussex County, Delaware.

FOR FURTHER INFORMATION CONTACT: Mr. Robert F. Kleinburd, Realty and Environmental Program Manager, Federal Highway Administration, Delaware Division, J. Allen Frear Federal Building, 300 South New Street, Room 2101, Dover, DE 19904; Telephone: (302) 734–2966; or Mr. Donald Plows, P.E., Project Manager, Delaware Department of Transportation, 800 Bay Road, P.O. Box 778, Dover, DE 19903; Telephone: (302) 760–2524. DelDOT Public Relations office (800) 652–5600 (in DE only) or (302) 760–2080.

SUPPLEMENTARY INFORMATION: The Federal Highway Administration (FHWA), in cooperation with the Delaware Department of Transportation

(DelDOT), will prepare an Environmental Impact Statement (EIS) to consider additional north-south capacity either as a new facility on new alignment or widened existing facility, west of Coastal Highway (SR 1). The project study limits are generally bound by Old Landing Road (CR 274) to the south, Red Mill Pond at SR 1 to the north, SR 1 to the east and Love Creek to the west. Access limitations will be considered during the course of the study. Because of the potential for a new alignment alternative, access restrictions and the resulting potential for significant impacts on the human and natural environment, the FHWA has determined that an EIS is the appropriate documentation for any corridor changes that may be selected.

The study of transportation changes in eastern Sussex County was introduced in the DelDOT sponsored State Route 1 Grid Study, 1999. As part of the Phase I recommendations, a network of secondary road connections was proposed. As part of the State Route 1 Grid Study, Phase II, a recommendation to create a new roadway connection between SR 1 west of Five Points, south to Route 9 was made. The new roadway connection was proposed to meet one of the new secondary road connections of the Phase I study, creating a new roadway corridor west of Plantation Road from Route 1 north of Five Points to south of Old Landing Road.

Subsequent to the SR 1 Grid Study, DelDOT and Sussex County jointly conducted the SR 1 Land Use & Transportation Study (LUTS), August 2003. The stated objective of this study was ''* * * to effectively address joint interests in the transportation systems and land use for the Rehoboth/Lewes area.'' The SR 1 LUTS overall objectives were to increase the mobility of area residents by developing alternative roadway links and connections; provide a variety of ways to travel; reduce congestion; improve safety, maintain the character of the study area, and gain public acceptance of the study recommendations. The centerpiece long-term recommendation of the SR 1 LUTS was a new controlled access parkway west of Route 1 that would run from northwest of Five Points to Country Club Road (CR 273).

A program of public involvement and coordination with Federal, State, and local agencies has been initiated. Both agency and public involvement will continue throughout project development. Comments are being solicited from appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. Public scoping meetings will be held. Additional informational meetings will be scheduled during the course of the study. In addition, a formal public hearing will be held after the draft EIS has been prepared. Public notice will be given of the time and place of the scoping meetings, and the formal public hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing on the draft EIS.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA or DelDOT at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued by: June 29, 2005.

Raymond J. McCormick,

Division Administrator, Federal Highway Administration, Dover, Delaware.

[FR Doc. 05–13240 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration, DOT.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking renewal of the following currently approved information collection activities. Before submitting these information collection requirements (ICRs) for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than September 6, 2005.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 17, Washington, DC 20590, or Mr. Victor Angelo, Office of Support Systems, RAD–20, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB control number 2130–0544.'' Alternatively, comments may be transmitted via facsimile to (202) 493–6230 or (202) 493–6170, or e-mail to Mr. Brogan at *robert.brogan@fra.dot.gov,* or to Mr. Angelo at *victor.angelo@fra.dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292) or Victor Angelo, Office of Support Systems, RAD–20, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6470). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law No. 104–13, section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR Part 1320, require Federal agencies to provide 60-days notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being

collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.*, permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(I)–(iv); 5 CFR 1320.8(d)(1)(I)–(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a ''user friendly'' format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below is a brief summary of the currently approved ICRs that FRA will submit for clearance by OMB as required under the PRA:

Title: Passenger Equipment Safety Standards.

OMB Control Number: 2130–0544.

Abstract: The information gained from daily inspections is used to detect and correct equipment problems so as to prevent collisions, derailments, and other occurrences involving railroad passenger equipment that cause injury or death to railroad employees, railroad passengers, or to the general public; and to mitigate the consequences of any such occurrences, to the extent that they can not be prevented. The information provided promotes passenger train safety by ensuring requirements are met for railroad equipment design and performance; fire safety; emergency systems; the inspection, testing, and maintenance of passenger equipment; and other provisions for the safe operation of railroad passenger equipment.

Affected Public: Businesses.

Respondent Universe: 22 railroads.

Frequency of Submission: On occasion; annually.

REPORTING BURDEN

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost
216.14—Special Notice For Repairs: Passenger Equip..	22 railroads	9 forms	5 minutes	1 hour	$34
238.7—Waivers	22 railroads	9 waivers	2 hours/25 hours	64 hours	2,176
238.15—Movement of Passenger Equip. w/power brake defects: Limitations on movement found during Class I/IA Brake Test.	22 railroads	1,000 tags/cards	3 minutes	50 hours	2,250
—Limitations on movement of passenger equip. in passenger service that becomes defective en route after Class I/IA brake test.	22 railroads	288 tags/cards	3 minutes	14 hours	630
—Conditional Requirement: Notifications.	22 railroads	144 Notifications	3 minutes	7 hours	315
238.17—Movement of Passenger Equip. w/Other than Power Brake Defects: Defects Developed En Route.	22 railroads	200 tags/cards	3 minutes	10 hours	300
—Special Requisites For Movement of Equipment w/Safety Appliance Defects.	22 railroads	76 tags/cards	3 minutes	4 hours	120
—Notifications	22 railroads	38 notifications	30 seconds	19 minutes	10
238.19—Reporting and Tracking Defective Passenger Equipment: Updated List.	1 railroad	1 update	1 hour	1 hour	34
238.21—Special Approval Procedure: Petitions For Alternative Std.	22 railroads	1 petition	16 hours	16 hours	544
—Petitions For Alternative Compl.	22 railroads	1 petition	120 hours	120 hours	4,080
238.21—Petitions For Special Approval of Pre-Revenue Service Acceptance Plan.	22 railroads	2 petitions	40 hours	80 hours	2,720
—Comments	Unknown	8 comments	1 hour	80 hours	440
238.103—Fire Safety: Equipment Design (New Equip.).	9 equipment manufacturers.	7.2 equip. designs	540 hours	3,888 hours	198,720
—Subsequent Modifications	9 equipment manufacturers.	7.2 equip. designs	60 hours	432 hours	43,200
—Existing Equipment: Fire Safety Analysis.	9 equipment manufacturers.	18 analyses	30 hours	540 hours	54,000
—Equipment Transfers: New Analysis.	9 equipment manufacturers.	1 analysis	20 hours	20 hours	2,000
238.107—Inspection, Testing, and Maintenance Plan: Annual Reviews.	22 railroads	22 reviews	60 hours	1,320 hours	44,880
238.109—Training, Qualification, and Designation Prog.—Training Employees Who Perform Mechanical Insp.	7,500 employees; 100 trainers.	2,500 employees trained/100 instructors.	1.33 hours	3,458 hours	103,075
—Recordkeeping	22 railroads	2,500 records	3 minutes	125 hours	4,250
238.111—Pre-Revenue Service Acceptance Testing Plan: Equipment Previously Used in Revenue Service.	9 equipment manufacturers.	7.2 plans	16 hours	115 hours	7,705
—Equipment Not Previously Used in Revenue Service.	9 equipment manufacturers.	7.2 plans	192 hours	1,382 hours	138,200

REPORTING BURDEN—Continued

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost
—Subsequent Orders	9 equipment manufacturers.	7.2 plans	60 hours	432 hours	33,762
238.203—Static End Strength: Grandfathering of Non-Complaint Equipment.	22 railroads	1 petition	100 hours	100 hours	5,500
—Comments	Unknown	3 comments	20 hours	60 hours	3,300
238.237—Automated Monitoring	22 railroads	22 documents	2 hours	44 hours	1,496
—Display Regarding Defective Alerter/Deadman Control.	22 railroads	100 tags	3 minutes	5 hours	225
238.303—Exterior Calendar Day Inspection of Equip..	22 railroads	25 notices	1 minute	.50 hour	23
—Defective Dynamic Brakes on MU Locomotive.	22 railroads	50 tags/cards	3 minutes	3 hours	135
—Defective Dynamic Brakes on Conventional Locos.	22 railroads	50 tags/cards	3 minutes	3 hours	135
—Records	22 railroads	2,017,756 records	1 minute	33,629 hours	1,143,386
238.305—Interior Calendar Day Mechanical Insp.: Tagging Req.	22 railroads	540 tags	1 minute	9 hours	324
—Records	22 railroads	1,866,904 records	1 minute	31,115 hours	1,057,910
238.307—Periodic Mechanical Inspection of Pass. Cars: Notification of Alternative Intervals.	22 railroads	5 notifications	5 hours	25 hours	850
—Non-Complying Conditions	22 railroads	200 notices	2 minutes	7 hours	238
—Records	22 railroads	56,462 records	2 minutes	1,882 hours	63,988
—Reliability Assessments Concerning Alt. Inspection Interval.	22 railroads	5 documents	100 hours	500 hours	17,000
238.311—Single Car Test: Movement to Nest Forward Location.	22 railroads	25 tags	3 minutes	1 hour	36
238.315—Class IA Brake Test	22 railroads	365,000 communications.	3 seconds	304 hours	0
—Communication Signal Tests	22 railroads	365,000 tests	15 seconds	1,521 hours	51,714
238.317—Class II Brake Test: Communication Signal System Test.	22 railroads	365,000 tests	15 seconds	1,521 hours	51,714
238.431—Brake Test: Analysis	1 railroad	1 analysis	40 hours	40 hours	1,360
238.437—Emergency Comm.	3 car manufacturers	3 sets of instruction + 25 decals.	25 hours/10 min.	79 hours	2,670
238.441—Emergency Roof Location	3 car manufacturers	3 sets of instruction + 25 placards.	25 hours/60 min.	100 hours	3,300
238.445—Automated Monitoring	1 railroad	10,000 alerts/alarms	10 seconds	28 hours	0
—Self-Tests: Notific.	1 railroad	21,900 notifications	20 seconds	122 hours	0

Total Responses: 5,076,058.

Estimated Total Annual Burden: 83,257 hours.

Status: Regular Review.

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC on June 29, 2005.

D.J. Stadtler,

Director, Office of Budget, Federal Railroad Administration.

[FR Doc. 05–13186 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Environmental Impact Statement for the East Contra Costa BART Extension, California

AGENCY: Federal Transit Administration, U.S. Department of Transportation.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Federal Transit Administration (FTA) and the San Francisco Bay Area Rapid Transit District (BART) intend to prepare a joint Environmental Impact Statement (EIS) pursuant to the National Environmental Policy Act (NEPA) and Environmental Impact Report (EIR) pursuant to the California Environmental Quality Act (CEQA) for proposed transit service to eastern Contra Costa County. The project would extend service from the existing BART terminus station at Pittsburg/BayPoint, through the communities of Pittsburg, Antioch, Brentwood, and Oakley, to a new terminus in Byron. The corridor generally follows State Route 4 through the eastern part of the county. As an extension of BART service into Eastern Contra Costa County, the project, commonly referred to as ''eBART,'' is intended to improve travel in the increasingly congested State Route 4 corridor by providing direct coordinated connections to the BART system. An earlier planning and feasibility study completed in 2002 evaluated a wide range of alternatives and recommended an innovative transit service concept, which employs light-weight, self-propelled rail cars known as Diesel Multiple Units (DMUs) on right-of-way to be acquired from the Union Pacific Railroad. Service with DMUs is intended to provide a seamless connection to the existing BART service but at a much lower cost.

The EIS/EIR will evaluate the DMU alternative (the Proposed Action) and will also evaluate a no build alternative, a bus rapid transit alternative, and a conventional BART extension to Hillcrest Avenue in Antioch. Other alternatives may also surface during the scoping process. Based on the presentation of the Proposed Action, project alternatives, and breadth of the environmental analysis described below, please let us know of your views regarding the scope and content of the EIS/EIR. Your suggestions can be communicated at the scoping meeting or via email or letter to the contact person identified below.

DATES: *Comment Due Date:* Written comments regarding the scope of alternatives and impacts to be considered should be sent to BART by August 20, 2005. *Scoping Meeting:* A public scoping meeting is scheduled for Antioch, July 19, 2005 at 7 p.m. at the Dallas Ranch Middle School, and a second public scoping meeting is scheduled for Brentwood, July 20, 2005 at 7 p.m. at the Brentwood Council Chamber. See **ADDRESSES** below.

ADDRESSES: *Written comments* on project scope should be sent to Ms. Ellen Smith, San Francisco Bay Area Rapid Transit District, 300 Lakeside Drive, 16th floor, Oakland, CA 94612. An information packet describing the purpose of the project, the proposed alternatives, the impact areas to be evaluated, the citizen involvement program, and the preliminary project schedule will be made available at the scoping meeting. Others may request the scoping materials or to be placed on the mailing list to receive further information as the project continues by contacting Ms. Ellen Smith at BART at (510) 287–4758 and at the above address.

The scoping meetings will be held at: Dallas Ranch Middle School, 1401 Mt. Hamilton Drive, Antioch, CA 94531, Transit access is via Tri Delta Route 380.

Brentwood Council Chamber, 734 3rd Street, Brentwood, California 94513, Transit access is via Tri Delta Routes 300 and 391.

The buildings for the scoping meetings are accessible to persons with disabilities. People with special needs should call Ellen Smith at least 72 hours prior to the scoping meeting at the number listed in **ADDRESSES.**

FOR FURTHER INFORMATION CONTACT: Ms. Lorraine Lerman, Community Planner, FTA Region IX, 201 Mission Street, Suite 2210, San Francisco, CA 94105. Phone: (415) 744–3115. Fax: (415) 744–2726. Information about the project can also be obtained from the project Web site, *http://www.ebartproject.org.*

SUPPLEMENTARY INFORMATION: FTA and BART invite interested individuals, organizations, and federal, state, and local agencies to participate in defining the alternatives to be evaluated in the EIS/EIR and identifying any significant environmental issues related to the alternatives. The meeting is also being advertised in the *San Francisco Chronicle, Contra Costa Times, Concord Transcript, Southeast Antioch News, Ledger Dispatch, Brentwood News, and Oakley News.* During scoping, comments should focus on identifying specific environmental impacts to be evaluated and suggesting alternatives that have fewer environmental impacts while achieving the objectives noted below under Purpose and Need. Comments should focus on the issues and alternatives for analysis, and not on a preference for a particular alternative. Individual preference for a particular alternative should be communicated during the comment period for the Draft EIS/EIR.

I. Description of Study Area, Project Background and Scope

The planning and development of transportation improvements within the State Route 4 East Corridor has been ongoing since the late 1980s. These efforts have led to the widening of State Route 4 from Willow Pass Road in Concord to Railroad Avenue in Pittsburg. Plans and studies to continue the highway widening through the Loveridge Road interchange are underway under the direction of the Contra Costa Transportation Authority (CCTA). In addition, the BART extension to Pittsburg/Bay Point opened in 1996. The station serves over 10,000 persons entering and exiting the BART system each weekday.

In 2001, BART and CCTA commenced the *State Route 4 East Corridor Transit Study* to explore a series of alternative transit improvements. (The study is available at the project Web site: *http://www.ebartproject.org* in the Library section under ''2002 Feasibility Study.'') This feasibility study, steered by a Policy Advisory Committee of elected and appointed local officials and a BART Board representative, started with a long list of nearly 20 potential types of transit and transportation improvements. Among these alternatives were continuation of existing BART service in the median of State Route 4 to Hillcrest Avenue; continuation of existing BART service in the median of State Route 4 to Loveridge Road and then to Hillcrest Avenue using the Union Pacific line; extension of transit services using Bus Rapid Transit technology; extension of transit services using commuter rail; and expansion of express bus service by Tri Delta Transit District, the local transit operator. Through an iterative process of screening and refinement, involving public discussions, engineering and cost evaluations, and ridership estimates, the long list of alternatives was winnowed down to eight viable alternatives referred to as Packages A through H. The Packages can be found on the project Web site in the *State Route 4 East Corridor Transit Study.*

The study culminated in 2002 with a unanimous recommendation by the Policy Advisory Committee, and direction from both the BART and CCTA Boards, to proceed to environmental analyses and preliminary engineering. The highest rated transit alternative was DMU service in an alignment in the State Route 4 median between the Pittsburg/BayPoint BART Station and Loveridge Road, and then to Byron via the Union Pacific Mococo Line, with single track service between the Hillcrest and Byron stations. This alternative was Package C–1 in the feasibility study, and is now the Proposed Action. This 23-mile corridor was proposed to include five transit stations. The recommended rail technology involves trains using light-weight, self-propelled rail cars known as Diesel Multiple Units (DMUs). Passengers on the DMUs would transfer to the existing BART line, ideally with a short walk across or along the BART platform. A train storage yard and maintenance facility was proposed east of Hillcrest Avenue. As proposed, the eBART project would include new grade separations in Antioch at Somersville Road, A Street, and Hillcrest Avenue. Also, local bus service offered by Tri Delta Transit District would be modified to eliminate routes that duplicate eBART service, synchronize headways with eBART schedules, and redefine routes to feed eBART stations.

In 2004, local voters passed Regional Measure 2 and Measure J in Contra Costa County, supporting a local sales tax increase for transportation improvements. In addition, on March 23, 2005, the Metropolitan Transportation Commission approved the use of funds from Regional Measure 2 for additional study of transit service improvements in the East Contra Costa Corridor. In response to these developments, FTA and BART are now embarking on an EIS/EIR for the eBART project.

II. Purpose and Need

The East Contra Costa County study area is the fastest growing portion of the San Francisco Bay Region. Between the years 2000 and 2025, an additional 40,000 households and 63,000 jobs are expected to be added in the East County. This growth in population and jobs portend a dramatic increase in traffic delay and congestion on State Route 4, the primary access route to this part of the Bay Area, with associated impacts on environmental resources including air quality and energy. Given the foreseeable growth in the eastern portion of the County, highway improvements alone cannot keep pace with the travel demand or address environmental impacts associated with motor vehicle travel.

The purpose of the Proposed Action, is to improve travel along the State Route 4 East corridor with direct, coordinated connections to the existing BART system. In light of the regional and local need for an improved transit connection, the Proposed Action objectives are the same as those identified in the 2002 East County corridor study:

- Improve transportation service;
- Maximize access to transit system;
- Maximize connectivity and seamlessness of transit system, both from home to transit and from one form of transit to another;
- Promote transit-oriented land use initiatives and policies;
- Maximize economic benefits and financial feasibility;
- Balance short, medium, and long-term strategies to provide continual improvements in transit services; and
- Protect or enhance the environment.

In particular, as the first new extension proposed since BART adopted its System Expansion Policy in 1999, the eBART project purpose incorporates BART's goal of enhancing ridership by coordinating transit projects with local land use planning. Jurisdictions within the eBART corridor will commit to a process intended to attain a corridor-wide ridership target. The target is to be achieved by adopting transit supportive land uses and making access improvements at transit stations. Ridership Development Plans incorporating land use changes and access improvements are to be completed and adopted by the cities and the County. BART, the cities, and the County will enter into a Memorandum of Understanding describing BART's intent to move forward with the environmental review process and the corridor communities' intent to engage in the planning and implementation programs to achieve BART's ridership goals.

III. Alternatives

As noted above, the Proposed Action is the provision of DMU service in an alignment in the State Route 4 median between the Pittsburg/BayPoint BART Station and Loveridge Road, and then to Byron via the Union Pacific Mococo Line, with single track service between the Hillcrest and Byron stations. Specific alternatives to the Proposed Action are expected to evolve during the environmental review process and in response to the public scoping process. While a number of alternatives were discussed and evaluated as part of the earlier planning/feasibility study, project alternatives expected to be evaluated in the EIS/EIR include:

- A No Build, or No Project, Alternative that considers the consequences of not extending rail transit services beyond the Pittsburg/BayPoint BART Station. This alternative would involve continuation of the existing Tri Delta Transit District and implementation of additional express bus service from East County communities to BART;
- A Bus Rapid Transit Alternative that considers technical and operational transit improvements using buses in the same alignment as the DMU project (freeway median and railroad right of way). The system seeks to emulate the service levels provided by a fixed guideway rail system. Amenities would be provided at stations, and portions of the route could be constructed with exclusive transit lanes or other transit preferential treatments in order to bypass areas of localized traffic congestion; and
- A conventional BART Alternative that using BART vehicles and systems in the same alignment as the DMU project (freeway median and railroad right of way). This alternative would consist of an extension of the electrically-powered, exclusive-use right of way BART system with one station at Hillcrest Avenue and a yard facility.

IV. Probable Effects

The purpose of the EIS/EIR is to fully disclose the social, economic, and environmental consequences of building and operating eBART in advance of any decisions to make substantial financial or other commitments to its implementation. The EIS/EIR will explore the extent to which the project alternatives result in potentially significant social, economic, and environmental effects and identify appropriate actions to reduce or eliminate these impacts. Issues that will be investigated in the EIS/EIR include transportation, traffic, and circulation effects; land use compatibility and consistency with locally adopted plans including the Regional Transportation Plan, the Transportation Improvement Plan and the State Implementation Plan; potential effects on local businesses and employment; disturbance to sensitive visual and cultural resources; effects of noise and vibration; geologic and hydrology effects; potential disturbance to sensitive wildlife and vegetation species and habitats; air and noise emissions from project-related construction and operation; public health and safety concerns related to exposure to hazardous materials; community service and utility demand; direct or indirect effects to public parklands, significant historic resources, or wildlife refuges; and environmental justice concerns from any disproportionate impacts of the project alternatives on low-income or ethnic minority neighborhoods.

Among the list of potential issues identified above, several will definitely warrant detailed investigation based on an environmental reconnaissance performed by BART as part of the previous planning/feasibility study completed in 2002:

- Consistency with local general plans for potential land use conflicts;
- Potential disturbance to surface waters, since the corridor traverses the Contra Costa Canal, Kirker Creek, Los Medanos Waterway, Markley Creek, the Mokelumne Aqueduct, Marsh Creek, Main Canal, Kellogg Creek, the Byron-Bethany Irrigation Canal, and unnamed drainages;
- Potential flood hazards related to overflowing of Kirker Creek, Marsh Creek, Kellogg Creek, and an unnamed drainage north of Lone Tree Way;
- Potential disturbance to seasonal wetlands and freshwater marsh areas, including several seasonal wetlands east of the existing BART station and south of State Route 4, a large wetland complex approximately 1 mile further east along State Route 4, several creeks and drainages between Loveridge Road and Hillcrest Avenue, a large wetland complex at the bend of Highway 160, and numerous drainages and irrigation ditches south of Oakley;
- Potential disturbance to federally and state listed threatened and endangered species and their habitats;
- Potential public health hazards from exposure to soil and/or groundwater contamination associated with highway and railroad operations, as well as agricultural activities;

• Given the extensive industrial and commercial development in the corridor, historic resources evaluation and a high potential to encounter historic archaeological resources; and

• Potential impacts to nearby sensitive receptors to air and noise emissions.

V. FTA Procedures

A Draft EIS/EIR for eBART will be prepared following FTA policy and all federal laws, regulations, and executive orders affecting project development, including but not limited to the regulations of the Council on Environmental Quality and FTA implementing guidance implementing NEPA (40 CFR parts 1500–1508, and 23 CFR part 771), the Clean Air Act, section 404 of the Clean Water Act, Executive Order 12898 regarding environmental justice, the National Historic Preservation Act, the Endangered Species Act, and section 4(f) of the Department of Transportation Act to the maximum extent practicable during the NEPA process.

After its publication, the Draft EIS/EIR will be available for review and comment by interested public members and local, state, and federal agencies, and public hearings will be held on the Draft EIS/EIR. The Final EIS/EIR will consider the comments received during the Draft EIS/EIR public review and will identify the preferred alternative. Additional opportunities for public involvement have been and will continue to be provided throughout all phases of project development. FTA and BART must approve the Final EIS/EIR prior to making any decisions regarding the project.

Issued on: June 29, 2005.

Leslie T. Rogers,

Regional Administrator.

[FR Doc. 05–13268 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2005–20455, Notice 2]

Spyker Automobielen B.V.; Grant of Application for a Temporary Exemption From Federal Motor Vehicle Safety Standards No. 108, and 208; and Part 581 Bumper Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Grant of Application for a Temporary Exemption from Federal Motor Vehicle Safety Standard No. 208, and Part 581 Bumper Standard. Partial Grant of Application for a Temporary Exemption from Federal Motor Vehicle Safety Standard No. 108.

SUMMARY: This notice grants the Spyker Automobielen B.V. (''Spyker'') application for a temporary exemption from the requirements of S4.1.5.3 and S14 of Federal Motor Vehicle Safety Standard (FMVSS) No. 208, *Occupant crash protection,* and Part 581 *Bumper Standard.* This notice also partially grants the Spyker application for a temporary exemption from FMVSS No. 108, *Lamps, reflective devices, and associated equipment.* The exemptions apply to the Spyker C8 vehicle line. In accordance with 49 CFR Part 555, the basis for the grant is that compliance would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard.[1] While the exemption from FMVSS No. 208 and Part 581 will be effective for a period of three years, the exemption from FMVSS No. 108 is limited to the first 10 Spyker C8 vehicles imported and sold in the United States.

The National Highway Traffic Safety Administration (NHTSA) published a notice of receipt of the application on March 29, 2005, and afforded an opportunity for comment.[2]

DATES: The exemption from FMVSS No. 208, and Part 581, *Bumper standard,* is effective from June 15, 2005 until June 15, 2008. The exemption from FMVSS No. 108 applies to not more than 10 Spyker C8 vehicles sold in the United States.

FOR FURTHER INFORMATION CONTACT: George Feygin in the Office of Chief Counsel, NCC–112, (Phone: 202–366–2992; Fax 202–366–3820; E-Mail: *George.Feygin@nhtsa.dot.gov).*

I. Background

Spyker is a small publicly traded Dutch vehicle manufacturer established in 2002. Spyker manufactures hand-built high-performance automobiles similar to vehicles manufactured by Ferrari, Lamborghini, Saleen, and other high-performance vehicle manufacturers.[3] Spyker has manufactured approximately 50 model C8 vehicles, and has back orders approaching 80 vehicles.[4]

To date, Spyker has been unable to develop compliant bumpers and air bags for the C8 and has requested a three-year exemption from the applicable air bag and bumper requirements in order to develop compliant bumpers and air bags. The petitioner anticipates that the funding necessary for these compliance efforts will come from immediate sales of Spyker C8 in the United States. These sales would amount to approximately 50 model C8 vehicles per year.

If the exemption is granted, Spyker has indicated that it would be able to sell fully compliant vehicles by 2008. If the exemption is denied, Spyker has indicated that the company would be in danger of going out of business.

II. Why Spyker Needs a Temporary Exemption

Spyker indicates that it has invested significant resources into making the C8 compliant with applicable Federal regulations. However, because of the limited resources as well as the fluctuating value of the U.S. dollar, the petitioner argues that it cannot bring the C8 into compliance with FMVSS No. 208 and Part 581 without generating immediate U.S. sales revenue. The petitioner indicates that it is experiencing substantial economic hardship. Specifically, the company's consolidated balance sheet shows a net loss of €1,245,000 (≈ $1,527,868)[5] in 2002; a net loss of €4,216,000 (≈ $5,173,889) in 2003; and a net loss of €4,912,000 (≈ $6,028,022) in 2004. This represents a cumulative net loss for a period of 3 years of €10,373,000 (≈ $12,729,778). Since Spyker is a publicly traded company, their financial information is available to the public.[6]

In short, the petitioner indicates that the cost of making the C8 compliant with FMVSS No. 208 and Part 581 is beyond the company's current capabilities. Spyker thus requests a three-year exemption in order to develop compliant bumpers and advanced air bags. The petitioner anticipates the funding necessary for these compliance efforts will come from immediate sales of the C8 in the United States.

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[1] To view the petition and other supporting documents, please go to: *http://dms.dot.gov/search/searchFormSimple.cfm* (Docket No. NHTSA–2005–20455).

[2] *See* 70 FR 15987.

[3] For more information on Spyker, see *http://www.spykercars.com/.*

[4] *http://www.spykercars.com/meta/investors/pdf/Financieel/first_halfjaar_report_2004.pdf.*

[5] All dollar values are based on an exchange rate of € = $1.23 as of 6/5/2005.

[6] See *http://www.spykercars.com/meta/investors/pdf/Financieel/Annual_Report_2004.pdf* and *http://www.spykercars.com/meta/investors/pdf/Financieel/spyker_anual_report_2003.pdf.*

III. Why Compliance Would Cause Substantial Economic Hardship, and How Spyker Has Tried in Good Faith To Comply with the Applicable Requirements

The petitioner contends that it cannot attain profitability unless it receives a temporary exemption for the C8. Specifically, Spyker offers the following projections as a consequence of grant or denial of their petition:

Net profit	2005	2006	2007
If exemption is granted	≈(−$3,500,000)	≈$500,000	≈$6,000,000
If exemption is denied	≈(−$6,000,000)	≈(−$6,000,000)	≈(−$6,000,000)

In short, a grant of the petition would amount to ≈ $3 million in potential revenue that would be used to develop a fully complaint vehicle. Spyker indicates that absent this revenue stream, the company would be precluded from developing a fully compliant vehicle and its long term-viability would be in question.

In an effort to develop a fully compliant vehicle, Spyker turned to other companies for technical assistance. Spyker's supplementary petition indicates that its compliance efforts are being directed by Lotus Engineering.[7] However, the petitioner states that the Spyker's current assets cannot support air bag development, and that testing expenses, as well as re-engineering and re-design delays would bankrupt the company.

Spyker indicates that it has experienced great difficulty in finding suppliers willing to provide air bag systems to an ultra low-volume manufacturer. For example, the company has been in discussions with Siemens Restraint Systems and TNO in order to develop and produce air bags. However, these efforts have not yet produced the necessary results. The petitioner indicates that it now plans on concentrating its efforts on designing advanced air bags that become mandatory in 2006.

Spyker indicates that it failed to design compliant bumpers for the C8. The petitioner argues that the only viable method for bringing the C8 into compliance with Part 581 is to re-engineer the front end of the vehicle. The petitioner states that it cannot bear these costs at this time. However, Spyker indicates that if it were able to sell C8 in the U.S. for the next 3 years, it would be able to redesign the vehicle such that it would incorporate complaint bumpers.

Finally, in a supplement to their petition, Spyker has indicated that their vehicle may not comply with S7 of the requirements of FMVSS No. 108.[8] Subsequent to filing this supplement, however, Spyker indicated that it would be able to meet the headlighting requirements of FMVSS No. 108 for all but the first ten vehicles imported into the U.S. On May 16, 2005, George Feygin from the NHTSA Office of Chief Counsel met with Victor R. Muller, the Chief Executive Officer of Spyker. At the meeting, Mr. Muller explained that Spyker was able to resolve the lighting issue, and all but the first 10 C8 vehicles will have compliant lighting. Mr. Muller further indicated that retrofit headlamps would be made available for the first ten vehicles imported into U.S.

IV. Why an Exemption Would Be in the Public Interest

The petitioner put forth several arguments in favor of a finding that the requested exemption is consistent with the public interest. Specifically:

1. The petitioner argues that Part 581 is not a safety standard, but a standard designed to reduce costs associated with minor impacts.
2. With respect to air bags, the petitioner argues that the vehicles are designed with a ''frontal crush structure and occupant protection cell for use as a race vehicle.'' Specifically, the occupants are positioned in a protective ''cell'' with the main chassis structure surrounding them. Further, The C8 will meet the injury criteria specified in FMVSS 208 S4.2.3 when tested with belted dummies.
3. The vehicle would be equipped with labels reminding drivers to buckle up. Specifically, in addition to the labels required on exempted vehicles under 49 CFR Part 555, Spyker would place an additional label on the instrument panel informing occupants of the exemption and the need to buckle up.
4. Spyker's engineering analysis shows that at impact speeds of less than 5 mph, there is no damage to the C8's safety equipment (other than license plate lights).
5. The likelihood of minor damage is very low. The vehicle costs in excess of $200,000, and it is reasonable to assume that it would not be subject to normal ''wear-and-tear'' associated with typical bumper impacts.
6. Spyker does not anticipate selling more than 200 vehicles for a period of 3 years covered by the requested exemption. Thus, the impact of the exemption is expected to be minimal.
7. Spyker argues that granting the exemption would be consistent with the Agency's previous decisions.[9]
8. Spyker argues that granting the exemption would increase choices available to the U.S. driving population in the high-performance vehicle segment.
9. Spyker argues that granting the exemption would increase jobs in the U.S. associated with sales and maintenance of the C8.
10. Finally, because of its price and exclusivity, the petitioner anticipates that the C8 would not be used extensively.

V. Comments Regarding the Spyker Petition

The agency received two comments from David H. Nguyen and David Smith in response to the notice of the application.

Mr. Nguyen indicated support for granting the petition for the following reasons. First, because of the limited number of cars that would be sold and the limited exemption period, the overall safety impact will be negligible. Second, most buyers of exotic automobiles such as those produced by Spyker do not use their vehicles on a daily basis for transportation due to practical considerations such as comfort and utility. As a result, the C8 would be driven considerably less than the average vehicle. Mr. Nguyen estimated that, based on Fatality Analysis Reporting System (FARS) data, the exemption would not result in any additional fatalities. Third, Mr. Nguyen suggested that the C8, which is already being sold in Europe, is reasonably safe because it complies with the European

[7] *See* Docket No. NHTSA–2005–20455–8.

[8] See Docket No. NHTSA–2005–20455–9.

[9] *See* 69 FR 5658 (February 5, 2004); 69 FR 3192 (January 22, 2004); 64 FR 6736 (February 10, 1999).

Union safety requirements. Finally, Mr. Nguyen stated that there is strong societal interest in having unique vehicles available for sale and use in the U.S.

Mr. Smith indicated that he was against granting of the exemption. First, Mr. Smith suggested that Spyker cars are already being offered for sale in the U.S. Second, Mr. Smith expressed concerns that if Spyker is indeed experiencing economic harm, it would be unable to meet potential obligations related to recalls and early warning notifications. Third, Mr. Smith noted that Spyker has failed to provide proof that the C8 complies with other applicable requirements.

VI. The Agency's Findings

Spyker is typical of small volume manufacturers who have received temporary exemptions in the past on hardship grounds. With limited resources, the petitioner developed a high-priced automobile for a specialty market. In evaluating Spyker's current situation, the agency finds that to require immediate compliance with FMVSS No. 208 and the bumper standard would cause petitioner substantial economic hardship, and could even result in the company going out of business.

The agency concludes that the Spyker application for a temporary exemption demonstrates that the company has made a good faith effort to bring the C8 into compliance with applicable air bag and bumper requirements. Spyker has also demonstrated the requisite financial hardship.

Traditionally, the agency has found that the public interest is served by affording consumers a wider variety of motor vehicles. In this instance, denial of the petition is likely to put Spyker out of business in the U.S. and cause the company to lose approximately $3,000,000 in potential profits.

The term of this exemption will be limited to three years and the agency anticipates that the C8 will be sold in very limited quantities. In total, we anticipate that Spyker will sell not more than 150 vehicles. We anticipate that with the help of revenues derived from U.S. sales, Spyker will be able to introduce a fully compliant vehicle by the time this exemption expires.

While we disagree with Mr. Nguyen's suggestion that compliance with the European Union motor vehicle safety standards means that a vehicle need not meet applicable FMVSSs, we agree that this exemption will have negligible impact on motor vehicles safety because of the limited number of vehicles sold and because each vehicle is likely to travel on public roads only infrequently.

In respect to Mr. Smith's comments, we first note that a temporary exemption does not excuse vehicle manufacturers from applicable notification and remedy requirements. This is the case with all manufacturers that have previously obtained temporary exemptions on financial hardship grounds. Second, we note that Spyker is not required to show proof that it complies with other applicable requirements. Instead, under 49 U.S.C. Chapter 301, the manufacturers are required to self-certify that their vehicles and equipment meet applicable requirements. Finally, the agency is aware that several Spyker vehicles were temporarily imported in the U.S. for display purposes and for EPA certification. Along with Immigration and Customs Enforcement, the agency has taken appropriate steps to insure that no Spyker vehicles were sold in the U.S. prior to issuing our decision on the petition.

Because the Spyker C8 will be manufactured in limited quantities and because each vehicle is likely to be operated only on a limited basis, the agency finds that this exemption will likely have a negligible impact on the overall safety of U.S. highways. The agency notes that the vehicle subject to this petition complies with all applicable Federal motor vehicle safety standards.

In consideration of the foregoing, it is hereby found that compliance with the requirements of S4.1.5.3 and S14 of FMVSS No. 208, *Occupant crash protection,* and 49 CFR Part 581 *Bumper Standard* would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard. It is further found that the granting of an exemption would be in the public interest and consistent with the objectives of traffic safety.

In accordance with 49 U.S.C. 30113(b)(3)(B)(i), Spyker C8 is granted NHTSA Temporary Exemption No. EX 05–2, from S4.1.5.3 and S14 of § 571.208 and 49 CFR part 581, *Bumper Standard.* The exemption shall remain in effect until June 15, 2008. In accordance with 49 U.S.C. 30113(b)(3)(B)(i), not more than 10 Spyker C8 vehicles are exempted from S7 of § 571.108.

Authority: 49 U.S.C. 30113; delegations of authority at 49 CFR 1.50. and 501.8.

Issued on: June 29, 2005.

Jeffrey W. Runge,

Administrator.

[FR Doc. 05–13250 Filed 7–5–05; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34713]

BG & CM Railroad—Acquisition and Operation Exemption—Great Northwest Railroad, Inc

BG & CM Railroad (BG & CM), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire and operate approximately 76.2 miles of rail line owned by Great Northwest Railroad, Inc. (GNR) in Nez Perce, Clearwater, and Lewis Counties, ID as follows: (1) From milepost 132.7 east of Lewiston to milepost 61.9 (end of line), at or near Kooskia; (2) from milepost 0.0 at Spalding to milepost 1.0 near Spalding;[1] and (3) from milepost 0.0 at Orofino to milepost 3.5 at Konkolville.

BG & CM certifies that its projected revenues will not exceed those that would qualify it as a Class III rail carrier, and that its annual revenues will not exceed $5 million.

The transaction was expected to be consummated on June 13, 2005, the effective date of the exemption (7 days after the exemption was filed).

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34713, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Charles H. Montange, 426 NW 162nd St., Seattle, WA 98177.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 28, 2005.

[1] Pursuant to *BG & CM Railroad, Inc.—Exemption from 49 U.S.C. Subtitle IV*, STB Finance Docket No. 34399, served Oct. 17, 2003, *clarified Camas Prairie Railnet, Inc.—Abandonment—in Lewis, Nez Perce, and Idaho Counties, ID (Between Spalding and Grangeville, ID),* STB Docket No. AB–564 (STB served May 3, 2004), BG & CM previously acquired and operated an extension of this segment (milepost 1.0 near Spalding to the end of the line at milepost 66.8 near Grangeville) as a contract carrier. BG & CM's status as a contract rather than a common carrier between milepost 1.0 and milepost 66.8 will not change as a result of this filing.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–13294 Filed 7–5–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–254 (Sub-No. 8X)]

Providence and Worcester Railroad Company—Abandonment Exemption—in Providence County, RI

On June 16, 2005, Providence and Worcester Railroad Company (P&W), filed with the Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon approximately 4.79±miles of its lines of railroad, in Providence County, RI. The lines proposed for abandonment include: (1) a portion of P&W's branch line, known as the East Providence Branch (EP Branch), extending from the switch at milepost 5.53± near Dunnellen Road south to the end of the track at milepost 9.84± near Whipple Avenue in East Providence, a distance of approximately 4.31± miles; and (2) a portion of P&W's branch line, known as the East Junction Branch (EJ Branch), extending from milepost 0.48± at the north side of Dexter Road south to its connection with the EP Branch at milepost 0.0 north of Waterman Avenue in East Providence, a distance of approximately 0.48± miles. The lines traverse U.S. Postal Service Zip Codes 02914, 02915, and 02916. P&W states that there are no active stations or terminals on the portions of the lines proposed for abandonment.

The lines do not contain federally granted rights-of-way. Any documentation in P&W's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by October 4, 2005.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,200 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than July 26, 2005. Each trail use request must be accompanied by a $200 filing fee. See 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–254 (Sub-No. 8X) and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001; and (2) Amy Silverstein, Esq., Providence and Worcester Railroad Company, 75 Hammond Street, Worcester, MA 01610; and (3) Edward D. Greenberg, Esq., Galland, Kharasch, Greenberg, Fellman & Swirsky, P.C., 1054 Thirty-First Street, NW., Washington, DC 20007–4492. Replies to the petition are due on or before July 26, 2005.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary), prepared by SEA, will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: June 29, 2005.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–13295 Filed 7–5–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Financial Management Service; Proposed Collection of Information: Annual Letters—Certificates of Authority (A) and Admitted Reinsurer (B)

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice and Request for comments.

SUMMARY: The Financial Management Service, 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 a continuing information collection. By this notice, the Financial Management Service solicits comments concerning the ''Annual Letters—Certificates of Authority (A) and Admitted Reinsurer (B).''

DATES: Written comments should be received on or before September 6, 2005.

ADDRESSES: Direct all written comments to Financial Management Service, 3700 East West Highway, Records and Information Management Program Staff, Room 135, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Rose Miller, Surety Bond Branch, 3700 East West Highway, Room 632F, Hyattsville, MD 20782, (202) 874–6850.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below:

Title: Annual Letters—Certificates of Authority (A) and Admitted Reinsurer (B).

OMB Number: 1510–0057.

Form Number: None.

Abstract: This letter is used to collect information from companies to determine their acceptability and solvency to write or reinsure federal surety bonds.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 347.

Estimated Time Per Respondent: 39.75 hours.

Estimated Total Annual Burden Hours: 13,793.

Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget 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.

Dated: June 22, 2005.

Vivian L. Cooper,

Director, Financial Accounting and Services Division.

[FR Doc. 05–13184 Filed 7–5–05; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8379

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 8379, Injured Spouse Claim and Allocation.

DATES: Written comments should be received on or before September 6, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland Internal Revenue Service, room 6512, 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 Larnice Mack at Internal Revenue Service, room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at (*Larnice.Mack@irs.gov*).

SUPPLEMENTARY INFORMATION:

Title: Injured Spouse Claim and Allocation.

OMB Number: 1545–1210.

Form Number: 8379.

Abstract: Form 8379 is used by a non-obligated spouse to request the non-obligated spouse's share of a joint income tax refund that would otherwise be applied to the past due obligation owed to a state or Federal agency by the other spouse. The IRS uses the information provided by the injured spouse on Form 8379 to determine the proper allocation of the joint refund.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 300,000.

Estimated Time Per Response: 1 hour, 47 minutes.

Estimated Total Annual Burden Hours: 531,000.

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: June 27, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3507 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 8109, 8109–B and 8109–C

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 Forms 8109 and 8109–B, Federal Tax Deposit Coupon, and Form 8109–C, FTD Address Change.

DATES: Written comments should be received on or before September 6, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland Internal Revenue Service, room 6512, 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 Larnice Mack at Internal Revenue Service, room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at (*Larnice.Mack@irs.gov*).

SUPPLEMENTARY INFORMATION:

Title: Federal Tax Deposit Coupon (Forms 8109 and 8109–B) and FTD Address Change (Form 8109–C).

OMB Number: 1545–0257.

Form Number: 8109, 8109–B, and 8109–C.

Abstract: Federal tax deposit coupons (Forms 8109 and 8109–B) are used by taxpayers to deposit certain types of taxes at authorized depositaries or in certain Federal Reserve Banks. Form

8109–C, FTD Address Change, is used to change the address on the FTD coupon. The information on the deposit coupon is used by the IRS to monitor compliance with the deposit rules and insure that taxpayers are depositing the proper amounts within the proper time periods with respect to the different taxes imposed by the Internal Revenue Code.

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, farms, not-for-profit institutions, and Federal, state, local or tribal governments.

Estimated Number of Responses: 62,513,333.

Estimated Time Per Respondent: 2 minutes.

Estimated Total Annual Burden Hours: 1,841,607.

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: June 27, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3508 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8693

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 8693, Low-Income Housing Credit Disposition Bond.

DATES: Written comments should be received on or before September 6, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland Internal Revenue Service, room 6512, 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 Larnice Mack at Internal Revenue Service, room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at (*Larnice.Mack@irs.gov*).

SUPPLEMENTARY INFORMATION:

Title: Low-Income Housing Credit Disposition Bond.

OMB Number: 1545–1029.

Form Number: 8693.

Abstract: Section 42(j)(6) of the Internal Revenue Code states that when a taxpayer disposes of a building (or an interest therein) on which the low-income housing credit has been claimed, the taxpayer may post a bond in lieu of paying the recapture tax if the building continues to be operated as a qualified low-income building for the remainder of the compliance period. For 8693 is used to post a bond under Code section 42(j)(6) to avoid recapture of the low-income housing credit.

Current Actions: There are no changes being made to the Form 8693 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations and individuals.

Estimated Number of Respondents: 1000.

Estimated Time Per Respondent: 1 hour, 41 minutes.

Estimated Total Annual Burden Hours: 1,690.

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: June 27, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3510 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4361

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 4361, Application for Exemption From Self-Employment Tax for Use by Ministers. Members of Religious Orders and Christian Science Practitioners.

DATES: Written comments should be received on or before September 6, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6512, 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 Larnice Mack at Internal Revenue Service, room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at (*Larnice.Mack@irs.gov*).

SUPPLEMENTARY INFORMATION:

Title: Application for Exemption From Self-Employment Tax for Use by Ministers, Members of Religious Orders and Christian Science Practitioners.

OMB Number: 1545–0168.

Form Number: 4361.

Abstract: Form 4361 is used by ministers, members of religious orders, or Christian Science practitioners to file for an exemption from self-employment tax on certain earnings and to certify that they have informed the church or order that they are opposed to the acceptance of certain public insurance benefits.

Current Actions: There are no changes being made to Form 4361 at this time.

Type of Review: Extension of a current OMB approval.

Affected Public: Individuals or households.

Estimated Number of Respondents: 10,270.

Estimated Time Per Respondent: 59 minutes.

Estimated Total Annual Burden Hours: 10,168.

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: June 27, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3511 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–209831–96]

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–209831–96 (TD 8823), Consolidated Returns—Limitations on the Use of Certain Losses and Deductions.

DATES: Written comments should be received on or before September 6, 2005 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Consolidated Returns—Limitations on the Use of Certain Losses and Deductions.

OMB Number: 1545–1237.

Regulation Project Number: REG–209831–96.

Abstract: Section 1502 provides for the promulgation of regulations with respect to corporations that file consolidated income tax returns. These regulations amend the current regulations regarding the use of certain losses and deductions by such corporations.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

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: June 23, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3512 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–LTC

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–LTC, Long-term Care and Accelerated Death Benefits.

DATES: Written comments should be received on or before September 6, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland Internal Revenue Service, room 6512, 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 Larnice Mack at Internal Revenue Service, room 6512, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at (*Larnice.Mack@irs.gov*).

SUPPLEMENTARY INFORMATION:

Title: Long-Term Care and Accelerated Death Benefits.

OMB Number: 1545–1519.

Form Number: 1099–LTC.

Abstract: Under the terms of Internal Revenue Code sections 7702B and 101g, qualified long-term care and accelerated death benefits paid to chronically ill individuals are treated as amounts received for expenses incurred for medical care. Amounts received on a per diem basis in excess of $175 per day are taxable. Code section 6050Q requires all such amounts to be reported.

Current Actions: There are no changes being made to form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, individuals or households, not-for-profit institutions, and state, local or tribal governments.

Estimated Number of Responses: 79,047.

Estimated Time Per Response: 14 minutes.

Estimated Total Annual Burden Hours: 18,181.

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: June 27, 2005.

Glenn Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3513 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 99–26

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 Revenue Procedure 99–26, Secured Employee Benefits Settlement Initiative.

DATES: Written comments should be received on or before September 6, 2005 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 revenue procedure should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Secured Employee Benefits Settlement Initiative.

OMB Number: 1545–1653.

Revenue Procedure Number: Revenue Procedure 99–26.

Abstract: Revenue Procedure 98–26 offers employers alternative 50 percent settlement options to settle cases in which they accelerated deductions for accrued employee benefits secured by letter of credit, bond, or other similar financial instruments. The purpose of this settlement initiative is to provide options for taxpayers and the IRS to expeditiously resolve these cases, thereby avoiding litigation of the cases in the future.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time Per Respondent: 20 hours.

Estimated Total Annual Burden Hours: 2,000.

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: June 24, 2005.

Paul Finger,

IRS Reports Clearance Officer.

[FR Doc. E5–3515 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 9779, 9779(SP), 9783, 9783(SP), 9787, 9787(SP), 9789, 9789(SP) and 12252

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 Forms 9779, 9779(SP), 9783, 9783(SP), 9787, 9787(SP), 9789, 9789(SP) and 12252, Electronic Federal Tax Payment System (EFTPS).

DATES: Written comments should be received on or before September 6, 2005 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 forms and instructions should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Electronic Federal Tax Payment System (EFTPS).

OMB Number: 1545–1467.

Form Number: Forms 9779, 9779(SP), 9783, 9783(SP), 9787, 9787(SP), 9789, 9789(SP) and 12252.

Abstract: These forms are used by business and individual taxpayers to enroll in the Electronic Federal Tax Payment System (EFTPS). EFTPS is an electronic remittance processing system that the Service uses to accept electronically transmitted federal tax payments. EFTPS (1) establishes and maintains a taxpayer data base which includes entity information from the taxpayers or their banks, (2) initiates the transfer of the tax payment amount from the taxpayer's bank account, (3) validates the entity information and selected elements for each taxpayer, and (4) electronically transmits taxpayer payment data to the IRS.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, and state, local or tribal governments.

Estimated Number of Respondents: 4,471,000.

Estimated Time Per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 766,613.

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: June 28, 2005.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E5–3516 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Area 7 Taxpayer Advocacy Panel (Including the States of Alaska, California, Hawaii, and Nevada)

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Area 7 committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel (TAP) is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. The TAP will use citizen input to make recommendations to the Internal Revenue Service.

DATES: The meeting will be held Thursday, July 28, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Peterson O'Brien at 1–888–912–1227, or 206–220–6096.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Area 7 Taxpayer Advocacy Panel will be held Thursday, July 28, 2005 from 12:30 p.m. Pacific Time to 1:30 p.m. Pacific Time

via a telephone conference call. The public is invited to make oral comments. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or 206–220–6096, or write to Mary Peterson O'Brien, TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174 or you can contact us at *http://www.improveirs.org.* Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Mary Peterson O'Brien. Ms. O'Brien can be reached at 1–888–912–1227 or 206–220–6096.

The agenda will include the following: Various IRS issues.

Dated: June 28, 2005.

Martha Curry,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. E5–3509 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Ad Hoc Committee of the Taxpayer Advocacy Panel

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Ad Hoc Committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The TAP will be discussing issues pertaining to lessening the burden for individuals. Recommendations for IRS systemic changes will be developed.

DATES: The meeting will be held Monday, August 1, 2005.

FOR FURTHER INFORMATION CONTACT: Mary O'Brien at 1–888–912–1227, or 206 220–6096.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Ad Hoc Committee of the Taxpayer Advocacy Panel will be held Monday, August 1, 2005 from 4 p.m. Eastern Time to 5 p.m. Eastern Time via a telephone conference call. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or 206–220–6096, or write to Mary O'Brien, TAP Office, 915 2nd Avenue, MS W–406, Seattle, WA 98174 or you can contact us at *http://www.improveirs.org.* Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Mary O'Brien. Ms O'Brien can be reached at 1–888–912–1227 or 206–220–6096.

The agenda will include the following: Various IRS issues.

Dated: June 28, 2005.

Martha Curry,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. E5–3514 Filed 7–5–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Submission for OMB Review; Comment Request—Thrift Financial Report: Schedules PD and VA

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OTS has solicited public comments on the proposal and is now providing a summary of those comments as well as final notice of the proposed revisions to this information collection.

On April 29, 2004, OTS, together with the Office of the Comptroller of the Currency (OCC), Board of Governors of the Federal Reserve System (Board), and Federal Deposit Insurance Corporation (FDIC) (collectively the agencies), requested public comment for 60 days (69 FR 23502) on proposed revisions to the instructions for the Thrift Financial Report (TFR), which are currently approved collections of information. After considering the comments received, OTS has adopted the proposed instructional revisions and also will add new items to the TFR based on suggestions by commenters. In addition, on April 26, 2005, OTS requested public comment for 60 days (70 FR 21494) on other proposed revisions to the TFR. OTS received no comments on these additional revisions and has adopted the revisions as proposed. OTS is submitting the adopted revisions to OMB for review and approval.

DATES: Submit written comments on or before August 5, 2005.

ADDRESSES: Send comments to OMB and OTS at these addresses: Mark Menchik, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, DC 20503, or e-mail to *mmenchik@omb.eop.gov;* and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, send facsimile transmissions to (202) 906–6518, send e-mails to *infocollection.comments@ots.treas.gov,* or hand deliver comments to the Guard's Desk, east lobby entrance, 1700 G Street, NW., on business days between 9 a.m. and 4 p.m. All comments should refer to ''TFR: Schedules PD and VA, OMB No. 1550–0023.'' OTS will post comments and the related index on the OTS Internet site at *http://www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *publicinfo@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the submission to OMB, contact Marilyn K. Burton, OTS Clearance Officer, at *marilyn.burton@ots.treas.gov,* (202) 906–6467, or facsimile number (202) 906–6518, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552. You can obtain a copy of the September 2005 Thrift Financial Report form from the OTS Web site at *http://www.ots.treas.gov/resultsort.cfm?catNumber=275&dl=33&edit=1.*

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. OTS has requested OMB approval to revise the currently approved collections of information identified below.

The effect of the proposed revisions on the reporting requirements of these information collections will vary from institution to institution, depending on the institution's involvement with the types of activities or transactions to which the proposed changes apply. OTS expects that the reporting changes that relate to certain securitized U.S. government-guaranteed or -insured residential mortgage loans will primarily affect the small percentage of institutions that service or securitize and service these loans. The revisions to the TFR dealing with acquired loans with evidence of deterioration of credit quality since origination, including

acquisitions of such loans in business combinations accounted for using the purchase method, will generally apply only to the limited number of institutions that are involved in purchase business combinations or that engage in purchases of loans with credit quality problems as a business activity. OTS estimates that implementation of these reporting changes will result in a small increase in the current reporting burden imposed by the TFR for those institutions involved with these activities and transactions. The following burden estimates include the effect of the proposed revisions.

Title: Thrift Financial Report.

OMB Number: 1550–0023.

Form Number: OTS 1313.

Statutory Requirement: 12 U.S.C. 1464(v) imposes reporting requirements for savings associations. Except for selected items, these information collections are not given confidential treatment.

Type of Review: Revision of currently approved collections.

Affected Public: Savings associations.

Estimated Number of Respondents and Recordkeepers: 880.

Estimated Burden Hours per Respondent: 36.4 burden hours.

Estimated Frequency of Response: Quarterly.

Estimated Total Annual Burden: 128,128 burden hours. Because some of these changes will not affect all savings associations that file the TFR, the burden hours reflected above will vary from institution to institution.

Abstract: All OTS-regulated savings associations must comply with the information collections described in this notice. OTS collects this information each calendar quarter, or less frequently if so stated. OTS needs this information to monitor the condition, performance, and risk profile of the savings association industry.

Current Actions

I. Overview

On April 29, 2004, OTS, together with the agencies, jointly published a notice (69 FR 23502) soliciting comments for 60 days on proposed revisions to the Call Report and the TFR. This joint notice requested comments on two proposed instructional changes, one of which would affect how institutions report certain information in the TFR, but the notice did not propose to change the report forms themselves. The proposal affecting the TFR would change and clarify the reporting requirements related to certain U.S. Government-guaranteed or -insured residential mortgage loans backing Government National Mortgage Association (GNMA) securities that meet certain delinquency criteria and are subject to servicer or seller/servicer buy-back provisions, *i.e.,* ''GNMA loans.'' These clarifications involved the reporting of GNMA loans as delinquent and the balance sheet classification of real property backing a delinquent GNMA loan on which an institution has foreclosed.

OTS received six comments on the April 2004 proposals pertaining to TFR changes: Four from savings associations, one from a thrift holding company, and one from a trade group whose members include savings associations.

OTS has considered these comments and has decided to proceed with the instructional revisions pertaining to mortgage loans subject to buy-back provisions, but with the addition of new items to the TFR Schedule PD on which savings associations report information on past due and nonaccrual loans.[1] This decision is discussed below.

In addition, on April 26, 2005, OTS published a notice (70 FR 21494) requesting comments on proposed revisions to the TFR in response to Statement of Position 03–3, Accounting for Certain Loans or Debt Securities Acquired in a Transfer (SOP 03–3), which was issued by the American Institute of Certified Public Accountants. SOP 03–3 applies to loans acquired in fiscal years beginning after December 15, 2004. OTS proposed to add three items to the TFR relating to loans within the scope of SOP 03–3. OTS also proposed a revision to the TFR instructions to explain how the delinquency status of loans within the scope of SOP 03–3 should be determined for purposes of disclosing past due loans in the TFR.

OTS received no comments in response to its April 2005 proposal, and has decided to proceed with the SOP 03–3 changes as proposed.

OTS will implement the proposed TFR changes as of the September 30, 2005, report date, except for the revisions pertaining to foreclosed properties backing delinquent GNMA loans. Nonetheless, as is customary for TFR changes, if the information to be reported in accordance with the revised reporting requirements is not readily available, institutions are advised that they may report reasonable estimates of this information for the report date when the proposed changes first take effect, *i.e.*, September 30, 2005. With respect to the reporting of foreclosed properties backing GNMA loans, institutions should report these properties in their TFR in accordance with their existing reporting policies for such properties through the December 31, 2005, report date. Effective with the March 31, 2006, report date, all institutions should report these properties as real estate owned on the balance sheet and disclose the amount in a new subitem that will be added to the TFR schedule in which information on the composition of real estate owned is reported.

II. Revisions to the Thrift Financial Report

A. GNMA Buy-Back Option

Under the GNMA Mortgage-Backed Securities Guide, the issuer of GNMA securities has the option to repurchase individual Federal Housing Administration (FHA), Department of Veterans Affairs/Veterans Administration (VA), and Farmers Home Administration (FmHA) mortgage loans backing the securities when these GNMA loans meet certain delinquency criteria. Because of this option, if and when individual loans that have been accounted for as sold in accordance with Statement of Financial Accounting Standards No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities (FAS 140), later meet GNMA's specified delinquency criteria and are eligible for repurchase, FAS 140 requires these individual delinquent GNMA loans to be brought back onto the seller/servicer's books as assets, along with an offsetting liability. This rebooking of the GNMA loans is required regardless of whether the seller/servicer intends to exercise the buy-back option.

OTS and the other federal banking agencies jointly proposed that all delinquent rebooked GNMA loans (including those for which the institution is taking steps to foreclose on the real estate collateral at the time of repurchase, but for which the sheriff's sale has not yet taken place) should be reported as past due on TFR Schedule PD, Consolidated Past Due and Nonaccrual Assets, and on Call Report Schedule RC–N—Past Due and Nonaccrual Loans, Leases, and Other Assets, in accordance with their contractual terms. As part of this change, the agencies proposed to eliminate an existing provision in the TFR and Call Report instructions that permits institutions not to report

[1] The other federal banking agencies joining OTS in the April 2004 proposal intend to follow a similar course of action with respect to U.S. government-guaranteed or -insured residential mortgage loans backing GNMA securities subject to buy-back provisions in the future, beginning with the June 2005 Call Report.

delinquent GNMA loans that are repurchased when they are ''in foreclosure status'' at the time of repurchase as past due loans in TFR Schedule PD or in Call Report Schedule RC–N, provided the government reimbursement process is proceeding normally. In proposing this reporting change, the agencies noted that delinquent rebooked GNMA loans would also be reported as supplemental items in TFR Schedule PD and in Call Report Schedule RC–N, which disclose amounts for past due loans wholly or partially guaranteed or insured by the U.S. Government. These items supplement the main body of the past due loans schedule by providing information that enables users of the TFR and Call Report to determine the amount of an institution's total delinquent loans that are not protected by a U.S. Government guarantee or insurance.

In addition, the agencies proposed that, when an institution forecloses on real estate backing a delinquent GNMA loan that it has rebooked as an asset, it should report the property as ''real estate owned'' and not as an ''other asset'' on the TFR and Call Report balance sheets. The foreclosed property should be reported in this manner beginning at the time of foreclosure until it has been sold, transferred to HUD, or otherwise disposed of.

OTS received six comments addressing the portion of the April 2004 proposal on GNMA loan reporting issues. With one exception, commenters disagreed with the agencies' proposed reporting treatment for past due GNMA loans and foreclosed property. One commenter did ''not object to the proposal that all delinquent rebooked GNMA loans should be treated consistently and reported as past due'' in the schedule for past due loans, observing that users of this schedule ''will have a method to identify the amount of loans that are not guaranteed by the U.S. Government.'' However, this commenter did not favor the proposed treatment of foreclosed property.

Delinquency Reporting

With respect to delinquency reporting, five commenters did not support reporting rebooked past due GNMA loans in the main body of TFR Schedule PD. These commenters recommended that if these delinquent loans must be reported in this schedule, they should be reported only in a Memorandum section of the schedule and should not be aggregated with other past due loans. They favored segregated reporting for the GNMA loans because these loans have a different risk profile than other past due loans due to their guarantees or insurance. These commenters stated that reporting these delinquent rebooked GNMA loans with the other past due loans will skew analytical ratios used to evaluate credit risk, which will lead to misinterpretation of the past due data and cause banks and savings associations to have to respond to questions regarding these data. One commenter specifically suggested that if the agencies decided to proceed with the proposed inclusion of delinquent rebooked GNMA loans in the body of the past due schedule, ''a separate line should be added for past due GNMA loans.'' Nevertheless, this commenter also expressed concern that the agencies' proposed past due reporting treatment in Schedule PD and Schedule RC–N would produce disparities between the TFR and Call Report past due schedules and the past due reporting by public banking organizations in their filings with the Securities and Exchange Commission (SEC).

OTS does not believe that the agencies' proposal to include delinquent rebooked GNMA loans in the body of the past due schedule should lead to inconsistencies in the disclosure of these loans in the TFR and Call Report and in SEC filings. Accounting staff members in the SEC's Division of Corporation Finance prepared guidance on ''Current Accounting and Disclosure Issues in the Division of Corporation Finance'' dated November 30, 2004, and updated on March 4, 2005. Both versions of this guidance discuss ''Accounting for Loans or Other Receivables Covered by Buyback Provisions,'' including, but not limited to, loans securitized through GNMA.[2] (See Section II.K.1. of the SEC staff's November 2004 guidance, which was carried forward without revision to Section II.N.1. of the March 2005 guidance.) The SEC staff's discussion of this topic states the following concerning loans, including GNMA loans, that have been ''re-recognized,'' *i.e.*, rebooked as assets in accordance with FAS 140:

> In the event that loans re-recognized by the transferor have the risk elements contemplated by Item III.C.1. of Industry Guide 3 (*i.e.*, nonaccrual, past due, restructured), the amount of such loans should be included in the disclosures required by that Item. Supplemental disclosures may be made to facilitate understanding of the aggregate amounts reported pursuant to Item III.C.1. These disclosures may include, for example, information as to the nature of the loans, any guarantees, the extent of collateral, or amounts in process of collection. For example, if a loan re-recognized by a transferor is accruing, but it is contractually past due 90 days or more as to principal or interest, that loan should be included in the disclosure required by Item III.C.1(b) even if the loan is guaranteed through a government program, such as the Veterans Administration (VA) or Federal Housing Authority (FHA).

As recognized by the SEC staff, delinquent rebooked GNMA loans are to be included in the aggregate past due disclosures required by Industry Guide 3. However, public banking organizations may provide supplemental disclosure of the fact that these loans are guaranteed or insured by the U.S. Government to assist users in understanding the aggregate amounts of past due loans. The agencies' proposal for reporting past due rebooked GNMA loans in TFR Schedule PD and Call Report Schedule RC–N parallels the SEC staff's guidance because these schedules include items that permit the ''supplemental disclosure'' of the amount of past due loans wholly or partially guaranteed or insured by the U.S. Government. Nevertheless, the agencies and other users of the supplemental Schedule PD and Schedule RC–N items on past due government-guaranteed or -insured loans would benefit from having delinquent rebooked GNMA loans identified separately from other past due government-guaranteed or -insured loans, especially for institutions that service or sell and continue to service a significant volume of GNMA loans.

Accordingly, OTS has decided to proceed with the agencies' original proposal that would require rebooked GNMA loans that are past due to be reported in the main body of TFR Schedule PD and in memoranda items PD195, PD295, and PD395, ''Loans and Leases Reported in PD115–PD380 That Are Wholly or Partially Guaranteed by the U.S. Government, Agency, or Sponsored Entity.'' However, based on suggestions from commenters, effective September 30, 2005, OTS will add to TFR Schedule PD new memoranda items PD192, PD292, and PD392 for ''Loans and Leases Reported in PD115–PD380 That Are Held for Sale'' and PD196, PD296, and PD396 in which savings associations would report ''Guaranteed Portion of Other Loans and Leases Included in PD195–PD395 (Exclude Rebooked 'GNMA Loans'). OTS will also add new memoranda items PD197, PD297, and PD397 to Schedule PD effective September 30, 2005, in which savings associations

[2] This guidance can be accessed at *http://www.sec.gov/divisions/corpfin/acctdis030405.htm.*

would report ''Rebooked 'GNMA Loans' Repurchased or Eligible for Repurchase Included in PD195–PD395.'' [3] [4]

OTS notes that savings associations that originate and hold FHA, VA, and FmHA mortgage loans in their loan portfolios, rather than securitizing and selling them in the form of GNMA securities, currently report these loans as past due in the main body of TFR Schedule PD if and when these loans become delinquent. These past due loans are also reported in existing TFR Schedule PD memoranda items PD195, PD295, and PD395 for past due loans wholly or partially guaranteed or insured by the U.S. Government. The reporting treatment of these guaranteed and insured loans in Schedule PD will not change.

Foreclosed Real Estate

Commenters on the portion of the agencies' April 2004 proposal on GNMA loans objected to the proposed balance sheet classification of foreclosed real estate collateral backing delinquent GNMA loans as ''real estate owned.'' Commenters recommended that institutions report such real estate as ''other assets'' because they do not believe that institutions are exposed to the underlying risk of the real estate, despite the foreclosure, due to the insurance or guarantee by the U.S. Government. They also observed that, in contrast to foreclosed real estate arising from other types of loans, institutions do not intend to sell foreclosed properties resulting from GNMA loans in order to recover the value of these assets. Instead, institutions look to their claim on the U.S. Government for recovery.

OTS has reviewed and considered these comments. As stated in the April 2004 proposal, the U.S. Department of Housing and Urban Development (HUD), the federal entity that administers the GNMA program, cannot accept a foreclosed property nor can the government guarantee or insurance be honored until all legal actions related to the foreclosure process have been completed. Commenters confirmed that certain conditions must be met before a property can be conveyed to HUD. While these conditions normally will be met, whether they will ultimately be met for an individual property is not known at the time of foreclosure. For example, the servicing guide for VA loans indicates the circumstances in which foreclosed property would not be conveyed, including when the VA issues ''no-bid'' advice (because the VA's cost of paying its guarantee is less than its estimated cost of taking possession of the property and selling it) and when there has been a failure to follow the regulations upon which the VA's guarantee is based.

Although the existence of insurance or a guarantee from the U.S. Government on a particular foreclosed loan will aid in determining whether the carrying value of the asset is recoverable, it does not determine the classification of the asset upon foreclosure. Because an institution's claim against the U.S. Government is effectively conditional until all the conditions have been met for the conveyance of a foreclosed property to HUD, the asset resulting from an institution's foreclosure on a delinquent GNMA loan has more of the characteristics of real estate than a receivable from the U.S. Government. Accordingly, the agencies believe that, for TFR and Call Report balance sheet purposes, it is more appropriate to view this asset as real estate owned than as a receivable at foreclosure.

The agencies recognize that the more common practice is for institutions that foreclose on delinquent GNMA loans to report the resulting asset as an ''other asset'' rather than ''real estate owned'' on the TFR and Call Report balance sheets. In this regard, some commenters recommended that if the agencies concluded that these assets should not be reported as ''other assets,'' there should be separate disclosure of these assets in the TFR and Call Report because of the difference in their risk profile compared to other types of foreclosed real estate. OTS sees merit in enabling institutions with foreclosed properties from GNMA loans to distinguish the amount of these properties from other foreclosed properties. Therefore, OTS will delay the implementation date for institutions to report foreclosed real estate from GNMA loans as ''other real estate owned'' on the balance sheet until the March 31, 2006, report date. OTS will also add to TFR Schedule SC a new line, SC429, ''U.S. government-guaranteed or -insured real estate owned,'' to enable institutions to disclose the amount of such real estate effective with the March 2006 TFR. Until then, *i.e.*, through the December 31, 2005, report date, institutions should continue to report these foreclosed properties in their TFRs in accordance with their existing reporting policies for such properties.

B. Loans Within the Scope of SOP 03–3

SOP 03–3 applies to ''purchased impaired loans,'' *i.e.*, loans [5] that a savings association has purchased, including those acquired in a purchase business combination, when there is evidence of deterioration of credit quality since the origination of the loan and it is probable, at the purchase date, that the savings association will be unable to collect all contractually required payments receivable. To assist OTS in understanding the relationship between the allowance for loan and lease losses and the carrying amount of the loan portfolios of those savings associations that include purchased impaired loans, OTS proposed to add three items to the TFR. All three of these items represent information included in the disclosures required by SOP 03–3. OTS proposed to add three memorandum items to TFR Schedule VA, Consolidated Valuation Allowances and Related Data, related to purchased impaired loans held for investment: [6] (1) the outstanding balance,[7] (2) the recorded investment (carrying amount before deducting any loan loss allowances) as of the report date that are included in Schedule SC, and (3) the amount of post-acquisition loan loss allowances that is included in the total amount of the allowance for loan and lease losses as of the report date.

OTS also stated that it planned to revise the instructions to Schedule VA to explain how purchased impaired loans should be reported in this schedule. SOP 03–3 does not prohibit placing loans on nonaccrual status and any nonaccrual purchased impaired loans should be reported accordingly in Schedule PD—Consolidated Past Due

[3] See the OTS website at *http://www.ots.treas.gov/resultsort.cfm?catNumber=275&dl=33&edit=1* for the revised TFR Schedule PD effective September 30, 2005.

[4] In addition, if a savings association services but did not originate mortgage loans backing a GNMA security, *i.e.*, where the savings association was not the transferor of the loans that have been securitized, the servicing savings association should also include any government-guaranteed or -insured mortgage loans that it has purchased out of the securitization in Schedule PD, lines PD195–PD395 and PD197–PD397, even if the savings association was not required to record the delinquent loans as assets prior to purchasing the loans.

[5] As defined in SOP 03–3, the term ''loans'' includes ''debt securities.''

[6] Loans held for investment are those loans that the savings association has the intent and ability to hold for the foreseeable future or until maturity or payoff. Thus, the outstanding balance and carrying amount of any purchased impaired loans that are held for sale would not be reported in these proposed memorandum items.

[7] Outstanding balance as defined in SOP 03–3 is the undiscounted sum of all amounts, including amounts deemed principal, interest, fees, penalties, and other under the loan, owed to the savings association at the report date, whether or not currently due and whether or not any such amounts have been charged off by the savings association. However, the outstanding balance does not include amounts that would be accrued under the contract as interest, fees, penalties, and other after the report date.

and Nonaccrual Assets. For those purchased impaired loans that are not on nonaccrual status, savings associations should determine the loans' delinquency status in accordance with the contractual repayment terms of the loans without regard to the purchase price of (initial investment in) these loans or the amount and timing of the cash flows expected at acquisition. As previously mentioned, OTS received no comments in response to its April 2005 proposed reporting revisions related to SOP 03–3.

Accordingly, the OTS will adopt as proposed the remaining changes to the September 2005 TFR published in the **Federal Register** on April 29, 2004 (69 FR 23502), and April 26, 2005 (70 FR 21494).

III. Request for Comment

All comments will become a matter of public record. Written comments are invited on:

(a) Whether the proposed revisions to the TFR collections of information are necessary for the proper performance of OTS functions, including whether the information has practical utility;

(b) The accuracy of OTS estimates of the burden of the information collections as they are proposed to be revised, 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 information collections 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.

Dated: June 30, 2005.

By the Office of Thrift Supervision.

Richard M. Riccobono,

Acting Director.

[FR Doc. 05–13286 Filed 7–5–05; 8:45 am]

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Federal Register

Wednesday,
July 6, 2005

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1325–IFC]

RIN 0938–AN58

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that require the implementation of a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning January 1, 2006, physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price system.

DATES: *Effective date:* The amendments to § 414.906(c); § 414.908(b), (c), (d), and (e); § 414.910, and § 414.912(a) are effective on July 6, 2005. All other amendments are effective September 6, 2005.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1325–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments*. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1325–IFC, P.O. Box *8013*, Baltimore, MD 21244–*8013*.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lia Prela, (410) 786–0548.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in further considering issues and developing policies. You can assist us by referencing the file code CMS–1325–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Information on the competitive acquisition program, including a copy of this interim final rule with comment period, can be found on the CMS homepage. You can access this data by going to the following Web site: *http://www.cms.hhs.gov/providers/drugs/compbid*.

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents.

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In addition, because of the many organizations and terms to which we refer by acronym in this interim final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below.

Alphabetical List of Acronyms Appearing in the Interim Final Rule With Comment Period

ABN—Advanced Beneficiary Notice
ASP—Average sales price
AWP—Average wholesale price
BBA—Balanced Budget Act of 1997, Pub. L. 105–33
CAP—Competitive Acquisition Program
CERT—Comprehensive Error Rate Testing
CFR—Code of Federal Regulations
CMS—Centers for Medicare & Medicaid Services (formerly Health Care Financing Administration)
COBC—Coordination of Benefits Contractor
DAW—Dispense as written
DME—Durable medical equipment
DMERC—Durable medical equipment regional carrier
DOJ—Department of Justice
EAC—Estimated acquisition cost
ESRD—End-stage renal disease
FAR—Federal Acquisition Regulation
FDA—Food and Drug Administration
GAO—Government Accountability Office
GPOs—Group Purchasing Organizations
GPO Access—Government Printing Office Access
HCPCS—Healthcare Common Procedure Coding System
HHS—Health and Human Services
HIC—Health Insurance Number
HIPAA—Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
ICD–9—International Classification of Diseases—Ninth Edition
IVIG—Intravenous immune globulin
LCDs—Local coverage determinations
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MSN—Medical summary notice
NDC—National Drug Code
OIG—Office of Inspector General
OPPS—Outpatient prospective payment system
PPAC—Practicing Physicians Advisory Council
PIN—Provider identification number
PSCs—Program Safeguard Contractors
RAC—Recovery Audit Contractor
RFA—Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354)
RFI—Request for information
RTI—Research Triangle Institute
UPIN—Unique provider identification number
WAC—Wholesale acquisition cost

I. Background

A. Covered Drugs and Biologicals

Medicare Part B currently covers a limited number of prescription drugs. For the purposes of this interim final rule with comment period, the term ''drugs'' will hereafter refer to both drugs and biologicals. Currently covered Medicare Part B drugs generally fall into three categories: Drugs furnished incident to a physician's service, drugs administered via a covered item of durable medical equipment (DME), and drugs covered by statute.

1. Drugs Furnished Incident to a Physician's Service

Injectable or intravenous drugs as well as non-injectable or non-intravenous drugs are administered incident to a physician's service as specified under section 1861(s)(2)(A) of the Social Security Act (the Act). Under the ''incident-to'' provision, the physician must incur a cost for the drug, and must bill for it. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173, enacted on December 8, 2003) revised the ''incident-to'' provision, permitting payment of ''incident-to'' drugs under the CAP even though the physician participating in the CAP would not, in fact, incur a cost for the drug or actually bill for the drug. The Act limits ''incident-to'' coverage to drugs that are not usually self-administered. Examples include injectable drugs used in connection with the treatment of cancer (such as epoetin alpha), intravenous drugs used to treat cancer (such as paclitaxel and docetaxel used to treat breast cancer), injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy, infliximab or other similar products used to treat rheumatoid arthritis, rituximab or other similar products used to treat non-Hodgkin's lymphoma, and Dermagraft or other similar products used to treat skin ulcers.

2. Durable Medical Equipment (DME) Drugs

DME drugs are administered through a covered item of DME, such as a nebulizer or pump. Two of the most common drugs in this category are the inhalation drugs albuterol sulfate and ipratropium bromide.

3. Statutorily Covered Drugs and Other Drugs

Drugs specifically covered by statute include—immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities (for example, iron dextran, vitamin D injections); and osteoporosis drugs.

4. Types of Providers

Types of providers and suppliers that are paid based on the current ASP system for all or some of the Medicare covered drugs they furnish include the following: physicians and certain non-physician practitioners, pharmacies, DME suppliers, hospital outpatient departments, and ESRD facilities.

5. Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are outside of the scope of this interim final rule include—drugs furnished during an inpatient hospital stay (except clotting factor); drugs paid under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

B. Revised Drug Payment Methodology

The MMA revised the drug payment methodology by creating a new pricing system based on a drug's Average Sales Price (ASP). The MMA also provides for a program beginning in 2006 to give physicians a choice between—(1) Obtaining these drugs from vendors selected through a competitive bidding process; or (2) directly purchasing these drugs and being paid under the ASP system.

Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Act, manufacturers submit to us the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance. The WAC is defined, with respect to a drug or biological, as the

manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

C. Competitive Acquisition Program (CAP)

Section 303(d) of the MMA provides for an alternative payment methodology for most Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(d) of the MMA amends Title XVIII of the Act by adding a new section 1847B, which establishes a competitive acquisition program for the acquisition of and payment for competitively biddable Part B covered drugs and biologicals furnished on or after January 1, 2006.

Beginning January 1, 2006, physicians will have a choice between—(1) Obtaining these drugs from entities selected to participate in the CAP in a competitive bidding process; or (2) acquiring and billing for Part B covered drugs under the ASP system. The provisions for acquiring and billing for drugs through this new system, as well as additional information about this new drug payment system are described in this interim final rule.

The CAP may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP. However, the CAP has other purposes than the potential to achieve savings. The competitive acquisition program provides opportunities for physicians who do not wish to be in the business of drug acquisition. Engaging in drug acquisition may require physicians to bear financial burdens such as employing working capital and bearing financial risk in the event of non-payment for drugs. The CAP is designated to reduce this financial burden for physicians. In addition, physicians who furnish drugs often cite the burden of collecting coinsurance on drugs, which can represent a substantial dollar amount to a beneficiary and physicians' practice. The competitive acquisition program eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.

D. Requirements for Issuance of Regulations

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. We intend to publish the final rule within the 3-year timeframe established under section 902 of the MMA.

II. Provisions of the March 4, 2005 Proposed Rule and Our Summary of and Responses to Public Comments

We received approximately 570 timely pieces of correspondence containing multiple comments in response to the March 4, 2005 proposed rule. Summaries of the public comments and our responses are set forth in the various sections of this preamble under the appropriate heading.

A. Policy for the CAP

1. General Overview of the CAP

In the March 4, 2005 proposed rule, we discussed the activities to implement the CAP that need to be completed before January 1, 2006, including—designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and other activities specified in section 1847B of the Act.

The statute provides some flexibility in the development of the CAP by requiring an appropriate ''phase-in'' of the program and providing the Secretary with the discretion to select appropriate categories of drugs and appropriate geographic areas for the program. Section 1847B(a)(1)(B) of the Act states that for purposes of implementing the CAP, ''the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.'' Additionally, the statute states that the competitive acquisition areas for the CAP on which contracts are to be awarded (and vendors chosen) are ''appropriate geographic regions established by the Secretary.''

We also briefly discussed the activities we had initiated to enable us to implement the statutory provisions of section 1847B of the Act including:

- The award of a contract to Research Triangle Institute (RTI) to obtain information and develop alternatives regarding the implementation of a drug and biological competitive bidding program.
- Convening a Special Open Door Listening Session on April 1, 2004, to gather input and allow interested parties to hear and be heard by other members of the healthcare industry.
- Establishment of an electronic mailbox, *MMA303DDrugBid@cms.hhs.gov,* for interested parties to submit comments on the CAP program before the issuance of the March 4, 2005 proposed rule.
- Issuance of a Request for Information (RFI) on December 13, 2004 to assess public interest in bidding on contracts to supply drugs and biologicals for the CAP.

Comment: A few commenters referenced the discussion in the proposed rule concerning the activities that we initiated to implement the statute. These commenters questioned the fact that we only received 15 responses from the issuance of an RFI, given the number of Medicare beneficiaries, specialty groups (particularly oncology), State organizations, and providers that could be impacted by the proposed rule. Another commenter commended us for acknowledging the need to gather information and obtain industry input through informal processes and encouraged us to continue to solicit input from the public through formal and informal means, while an additional commenter implored us to give serious consideration to the comments on the proposed rule from affected specialty societies.

Response: The discussion in the March 4, 2005 proposed rule provided examples of activities and resources we used to establish the framework for the proposed rule. The reference to 15 responses was specific to the RFI that we issued on December 13, 2004, which was vendor interest specific. As mentioned in the March 4, 2005 proposed rule, our contractor, RTI, also consulted with groups and organizations, including medical specialty organizations and a national oncology practice to obtain input concerning establishment of a CAP program. As with any rulemaking process, we have given serious consideration to the comments from both specialty groups as well as individuals on the proposed rule.

Comment: Some commenters were supportive of the proposal for the CAP, with several commenters stating that the current buy and bill reimbursement system has created undue barriers. These commenters believe the CAP would at least provide an alternative to buy and bill arrangements for consumers and providers, by simplifying the reimbursement process.

Response: As discussed in the March 4, 2005 proposed rule, and also later in this preamble, participation in the CAP is voluntary on the part of the physician. As pointed out by commenters, implementation of the CAP provides an alternative to the current buy and bill system. To the extent that a physician or physicians' group believes that the CAP is not a viable alternative to the current buy and bill system, that physician or physicians' group can continue to use the current system and not elect to participate in the CAP.

Comment: Many commenters believe that we should beta test the CAP or have a limited trial period or phase-in of some sort, to confirm the quality of the CAP before full implementation. These commenters expressed concern that introducing the CAP system, particularly given the short timeframe, without any formal testing or analysis is risky to patient care because it is a dramatic potential change to the current system. Some commenters referenced the Government Accountability Office's (GAO) final report assessing the durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) competitive bidding demonstrations that suggests that further demonstrations be conducted for the DMEPOS before implementation. These commenters believe the GAO report supports taking a slower approach for implementing the CAP for Part B drugs. The commenters suggested that a slower approach would allow us to refine our application and vendor selection process. Other commenters, while cognizant of the January 2006 effective date, suggested we delay the effective date of the CAP to allow us to fully structure the CAP to meet congressional objectives and benefit physicians without compromising beneficiary access to drug therapies and treatment. In addition, commenters argued that the introduction of Part D beginning in 2006 may cause significant stress to providers and beneficiaries, and introducing the CAP at the same time could create confusion.

Response: Although we understand the concerns of the commenters, we believe the regulatory framework established through this rulemaking provides a firm basis for implementing the CAP program in January 2006. We recognize that the timeframe for implementation is ambitious but we believe that it is important to provide the physicians' community with an alternative to the current buy and bill system as soon as possible. In addition, the statute also requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. The use of a designated carrier for processing vendor claims is one of the approaches we will be using to ensure a smooth implementation. Other aspects of the CAP discussed later in the preamble also provide information on how we are addressing the implementation of CAP within this restricted timeframe. Additionally, the Congress did not intend this to be a demonstration, but instead established the CAP as an operational program.

We recognize that the Medicare community will be faced with many new challenges and options in 2006. We will be working to ensure that providers and beneficiaries are aware of these new choices and programs and that the transition is as smooth as possible.

Comment: One commenter requested that we continue to issue guidance to further clarify and refine the CAP requirements. The commenter also encouraged us to continue our efforts to educate and seek input through venues such as the ''Open Door'' sessions.

Response: We agree that it is important to continue our educational efforts and obtain feedback from the provider community and plan to convene special ''Open Door'' sessions as part of the implementation of the CAP. Additional discussion of this important aspect of the CAP is provided later in the preamble.

Comment: A few commenters expressed concern that we were limiting the CAP to oncology drugs.

Response: As discussed in the proposed rule, we were considering several alternative approaches to phasing in the CAP with respect to drug categories, one of which was initially including only all oncology drugs. The specific drug categories for the CAP that will be effective January 1, 2006 are discussed in detail later in this section of the preamble.

Comment: A number of commenters raised concerns about maintaining the safety of the drug delivery system or ''medication pipeline,'' particularly in light of the frequent changes in the disease status of certain patient populations (for example, cancer patients).

Response: We understand the commenters concerns, and, as discussed in more detail later in the preamble, we have established financial and quality standards to ensure that reputable and experienced vendors are chosen to participate in the CAP. We have also indicated that under the dispute resolution requirements, issues connected with drug quality will be given top priority.

Comment: One commenter stated that private insurers have tried models similar to the CAP and all of them have resulted in minimal savings but increased administrative overhead and patient inconvenience.

Response: We are mindful of the points that the commenter raised concerning private insurers attempts at similar models and have sought to address these points in establishing the CAP as reflected in the requirements we are establishing concerning the operational aspects of CAP (section II.B of this interim final rule) as well as those discussed in the CAP contracting process (section II.C of this interim final rule).

Other Comments

We also received many comments concerning: Payment for drug administration services, infusion services, and evaluation and management services for cancer patients; the chemotherapy demonstration project; price controls for drugs; and the new Medicare Part D Prescription Drug Program. These issues were outside the scope of this rulemaking, and, therefore, we will not be responding to these comments as part of this interim final rule.

Comment: Several commenters contended that our proposed rule did not satisfy all the requirements of the Administrative Procedure Act (APA). In particular, these commenters pointed out that the proposed rule did not include a specific proposal about the drug categories that would be adopted in the initial implementation of the CAP, or a specific proposal about the competitive acquisition areas that would be established. The commenters contended that the proposed rule therefore did not provide sufficient factual detail and rationale to permit interested parties to comment meaningfully. These commenters contend that CMS must either publish a second proposed rule providing specific proposals on these issues, or at least present our decisions about these matters in the context of an interim final regulation with opportunity for public comment. Other commenters recommended that we implement the

CAP through the issuance of an interim final rule. This would provide an extended opportunity for public comment and facilitate the approval of required program modifications.

Response: We do not believe that our proposed rule failed to satisfy the requirements of the APA. In our March 4, 2005 proposed rule, we presented specific options concerning the drug categories and competitive acquisition areas that we were considering for adoption in the final rule. We also discussed the advantages and disadvantages of each option to provide a basis for informed comment, and we received several comments on these options. These comments addressed in detail the options that we discussed, and addressed the specific considerations that we had discussed. The commenters offered specific recommendations and proposals based on the options that we had presented. The comments themselves thus are convincing evidence that our proposed rule provided adequate basis for meaningful comment from interested parties. Although we do not believe that we are required under the provisions of the APA to publish another proposed rule with more specific proposals, as requested by some commenters, we are exercising our discretion and publishing this rule as an interim final rule to allow our provisions to take effect and to provide the public with the opportunity to comment on our final provisions. We believe that additional public comment on this new and complex program would be valuable. We especially welcome comments on issues related to phasing in the program. For example, we describe below how we have decided to exercise our statutory authority to determine and phase in categories of drugs under the CAP. We specifically invite comments on the further development of appropriate drug categories after this initial stage of implementing the program. We also welcome comments on other issues regarding the CAP program.

Regulations

In the March 4, 2005 rule, we proposed to codify the requirements and provisions for the CAP in regulations at 42 CFR Part 414, Subpart K. We proposed to revise the heading for subpart K to read ''Payment for Drugs and Biologicals under Part B''; amend existing sections and section headings; and add new definitions and sections to set forth the proposed requirements with respect to the CAP. Specifically, we proposed to make the following changes:

- Revise existing § 414.900, which sets forth the basis and scope for subpart K;
- Revise § 414.900(b)(ii) to clarify that the hepatitis vaccine referred to in this paragraph is the hepatitis ''B'' vaccine;
- Add new § 414.906 through § 414.920 to address requirements with respect to payment under the CAP; and
- Revise § 414.902 to add definitions pertaining to the new CAP addressed in new § 414.906 through § 414.920.

We did not receive comments on the proposed organization of subpart K or the proposed changes to § 414.900, which sets forth the basis and scope for subpart K or § 414.900(b)(ii). Therefore, we finalize them as proposed. Specific comments pertaining to the proposed definitions for the CAP as well as proposed sections § 414.906 through § 414.920 are addressed later in this preamble.

2. Categories of Drugs To Be Included Under the CAP

Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from vendors rather than purchasing and billing for those drugs themselves. The statute, therefore, most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service. For example, under the mechanisms described in the statute:

- Only physicians are expressly given an opportunity to elect to participate in the CAP.
- The second sentence of section 1847B(a)(1)(A) of the Act explicitly indicates that such section shall not apply in the case of a physician who elects section 1847A of the Act to apply.
- Physicians who elect to obtain drugs under the CAP make an annual selection of the contractor through which drugs will be acquired and delivered to the physician under Part B.
- Section 1847B(a)(3)(A) of the Act specifically applies the CAP to drugs and biologicals that are prescribed by a physician who has elected the CAP to apply.
- Payment for drugs furnished under the CAP is conditioned upon drug administration.
- The requirement for submission of information that will be used by in the contract for collection of cost sharing applies to physicians.
- The primary site for delivery of drugs furnished under the CAP is the physician's office.
- The statute requires the Secretary to make available to physicians on an ongoing basis a list of CAP contractors.
- The statute explicitly defines a ''selecting physician'' to be one who has elected the CAP program to apply.

Section 1847B(a)(1)(B) of the Act specifically requires the Secretary to establish categories of drugs that will be included in the CAP, and requires the Secretary to phase-in the program with respect to these categories, as the Secretary determines to be appropriate. Section 1847B(a)(1)(D) of the Act further authorizes the Secretary to exclude competitively biddable drugs and biologicals from the competitive bidding system if the application of competitive bidding to those drugs and biologicals—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs and biologicals.

Finally, the statute defines the term ''competitively biddable drugs and biologicals'' for purposes of the CAP as ''a drug or biological described in section 1842(o)(1)(C) of the Act and furnished on or after January 1, 2006.'' As discussed in the March 4, 2005 proposed rule, the drugs described in section 1842(o)(1)(C) of the Act include most drugs paid under Medicare Part B and not otherwise paid under cost-based or prospective payment basis. Medicare Part B covered vaccines, drugs infused through a covered item of DME, and blood and blood products (not including clotting factor and intravenous immune globulin (IVIG)) are not included under this definition because they are expressly excluded from section 1842(o)(1)(C) of the Act. The statutory definition of ''competitively biddable drugs'' therefore includes drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). Although the statutory definition includes all these categories of drugs, as noted above, the specific mechanisms described under section 1847B of the Act relate to the provision of and the payment for drugs provided incident to a physician's service. Given our concerns about the clear direction of the statute that the election to participate in this program rests with physicians, in the proposed rule we indicated that we do not believe it is possible to include drugs other than those administered as incident to a physician's service as part of this program. However, we also recognized that the statute provides a potentially broader definition of ''competitively biddable drugs and

biologicals'' in section 1847B(a)(2)(A) of the Act. We, therefore, requested comments on whether, in the light of these mechanisms, the CAP is properly restricted under the statute to drugs administered incident to a physician's service.

We also solicited comments on how an expansion of the drugs covered under this program might work, given that the option to participate clearly rests with the physician.

Comment: Many commenters supported our proposal to restrict the CAP, at least initially, to drugs administered incident to a physician's service. Some of these commenters endorsed the more restrictive reading of the statute, under which the CAP is properly restricted to drugs administered incident to a physician's service. A congressional commenter advised that the intent of the Congress was to include all physician injectable drugs within the CAP. Other commenters expressed the view that the statute would allow the program to include drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). However, some of these commenters also supported restricting the program, at least initially, to drugs administered incident to a physician's service as an appropriate exercise of the Secretary's authority to phase-in the drug categories established under the CAP. A few commenters supported including some categories of drugs administered through DME or drugs usually dispensed by pharmacies in the CAP, either initially or at an early stage of implementing the program. These commenters generally cited the statutory definition of ''competitively biddable drugs,'' which in and of itself is broad enough to include drugs administered incident to a physician's service, drugs administered through DME (with the exception of DME infusion drugs), and some drugs usually dispensed by pharmacies. Some of these commenters acknowledged that the general statutory structure of the program, which defines acquisition mechanisms applicable only to physicians, raises practical and/or legal issues about including drugs administered through DME and drugs usually dispensed by pharmacies within the program.

Response: We continue to believe that, given the clear direction of the statute that the election to participate in this program rests with physicians, it is not advisable to include drugs other than those administered as incident to a physician's service as part of this program. As we discuss further below, we, therefore, will implement the CAP initially for a broad range of drugs administered incident to a physician's service. However, we will continue to consider whether the statute allows extension of the program to Part B drugs that are administered through DME or dispensed by pharmacies. We will continue to analyze whether drugs other than those administered as incident to a physician's service can be included in the CAP within the parameters of the statute. At the same time, we have no present plans to expand the program beyond the class of drugs administered incident to a physician's service. If we were to determine that it was warranted to expand the program beyond the category of drugs furnished incident to a physician's service, we would first publish a proposed rule and allow for public comment before proceeding, as necessary.

The March 4, 2005 proposed rule included discussions on the merits of several options for defining the drug categories to be included within the CAP, as well as for phasing in the program with respect to drug categories. These are summarized below:

Drugs Furnished Incident to a Physician's Service

Under this option, all drugs furnished incident to a physician's service would be included in the CAP. The majority (more than 80 percent) of Medicare Part B drug expenditures are for drugs furnished incident to a physician's service, such as chemotherapy drugs. Therefore, it is important to include all drugs furnished incident to a physician's service to provide an alternative to physicians who did not want to purchase drugs directly. It may also provide more opportunity for realizing savings to the program than some other options.

Phasing in CAP Drugs by Physician Specialty

Another option would be to phase-in the program by implementing the CAP initially for a limited set of drugs that are typically administered by a single physician specialty, such as a set of drugs commonly furnished by oncologists. Drugs commonly furnished by additional specialties could be included over the next few years of the program. Drugs typically furnished by oncologists constitute a large portion of the Part B drug market. Drugs typically administered by other physician specialties represent smaller portions of physician-administered drugs. A basic decision with respect to a phase-in for drugs administered in physician offices would be whether to begin implementation of the program only with drugs typically administered by oncologists, or with some set of drugs that other specialties (for example, urology) tend to administer.

A few of the alternative approaches that could be used to phase-in the CAP with respect to drug categories discussed in the proposed rule were:

- Initially include all drugs typically administered by oncologists within the program.
- Begin with some set of the drugs that are typically administered in physician offices by other specialties (for example, drugs typically administered by urologists).
- Implement the CAP for all Part B drugs that are furnished incident to a physician's service.

We stated that we were actively considering all these options, and encouraged comments on all the options that we have discussed. We also welcomed recommendations of other options for consideration that could be adopted. We especially encouraged comments from physicians concerning their preferences about how a phase-in should be designed and more generally how the categories of drugs under the CAP should be structured.

Comment: Many commenters (especially from the oncology community) recommended beginning the phase-in with drugs that are typically used by some specialty that is less drug-intensive than oncology. However, many other commenters recommended beginning a phase-in with oncology drugs, on the grounds that doing so would provide much of the potential benefit of the CAP immediately. Other commenters, including some members of the oncology community, recommended inclusion of all physicians' drugs within the program immediately, in order to provide an alternative method of obtaining drugs for all physicians. A congressional commenter recommended that the program start with a sufficiently large category of drugs to provide a sufficiently sized market for vendors and that the program ramp up quickly to include all physician-administered Part B drugs.

Response: We have been convinced by the commenters that it is feasible and appropriate to implement the CAP initially for the broad range of drugs administered incident to a physician's service. As we discuss in more detail

below, in response to these comments, we have identified a set of 169 drugs that are most commonly administered incident to a physician's service for inclusion in the initial stage of the CAP. We have not included drugs with very low volumes of billing by physicians because we believe including such drugs at this time would impose a greater burden on vendors, and undercut the goal of providing a sufficiently sized market. As described in further detail below, in response to concerns raised by commenters we have also not included certain drugs whose patterns of use do not make them suitable for inclusion under the CAP. For example, certain vaccines, such as tetanus and diphtheria vaccines, are most commonly used in emergency situations. These drugs are therefore poorly suited for the normal ordering and billing procedures contemplated by the CAP statute. Physicians often will not be in the position to submit to their approved CAP vendor in advance a patient-specific order for these drugs. Although section 1847B(b)(5) of the Act outlines special rules to allow approved CAP vendors to resupply drugs used in emergency situations, we do not believe that it is advisable to include within the CAP drugs for which this special mechanism will be routinely employed, at least during this initial stage of implementing the program. (It is important to note that the statute specifically excludes pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine from the CAP.) As we discuss in response to the specific comments below, we have also not included, at least initially, certain types of drugs that pose special issues. For example, we have not included drugs that pose special implementation issues such as some controlled substances and orphan drugs.

Comment: One commenter asked about the status of opioid medications administered intrathecally through implanted variable-rate infusion devices (for example, Prialt®). The commenter notes that historically, when these pain medications have been furnished by physicians in their offices, they have been covered and billed through the local carriers as drugs administered incident to physicians' services, rather than as drugs infused through covered durable medical equipment billed through the DMERCs. In the light of this, the commenter requested that we confirm specifically that those medications will be eligible for the CAP, at least once the program is fully phased in.

Response: We agree in principle that opioid medications administered intrathecally through implanted variable-rate infusion devices could be included under the CAP, when they are administered by physicians in their offices incident to their services. In the specific case of Prialt®, we have not been able to include the drug in this initial phase of the CAP because it is very new and has not yet been assigned a code. (We discuss treatment of new drugs in greater detail below.) However, our analysis has suggested that some pain medications may be inappropriate for inclusion in the CAP, at least in the initial stage. Specifically, we are concerned that the special recordkeeping and other requirements that apply to Schedule II, III, and IV controlled substances would make inclusion of these drugs in the CAP problematic. Under the CAP, the approved CAP vendor retains title to the drug, even after it is shipped to the physician, which may make it more difficult to ensure compliance with the special rules for controlled substances. We, therefore, are not including Schedule II, III, and IV controlled substances in the initial stage of implementing the CAP. We welcome comments on the implications of these special requirements for including these drugs in the CAP during later stages of implementation.

Comment: Several commenters recommended that we exclude orphan drugs from the CAP. (''Orphan drug'' is defined by FDA, under 21 CFR 316.3(b)(10), as a ''drug intended for use in a rare disease or condition as defined in section 526 of the Federal Food, Drug, and Cosmetic Act.'') These commenters pointed out that orphan drugs often pose access challenges. Specifically, one commenter noted that vendors may not be able to provide orphan drugs adequately in a timely manner. The same commenter noted that CMS has provided a special exception for payment of orphan drugs in the outpatient prospective payment system.

Response: We agree with the commenters that access problems provide a sound reason for not including some orphan drugs from the CAP, at least in the initial stages of the program. However, we do not believe that it is necessary to decline to include all orphan drugs from the program, even in this initial stage of implementation. This is because many orphan drugs are not approved exclusively for the treatment of orphan indications, but they are also approved for other non-orphan indications that affect broader groups of the public. In contrast, other orphan drugs are approved exclusively for the treatment of orphan indications. The latter group of orphan drugs poses much more severe access issues than other orphan drugs precisely because their use is generally limited to relatively rare orphan indications. As one commenter noted, we provide special payment consideration under the outpatient prospective payment system (OPPS) to this latter set of orphan drugs. Specifically, we designate drugs that meet the following criteria as single indication orphan drugs under the OPPS:

- The drug is designated as an orphan drug by the FDA and approved by the FDA only for treatment of only one or more orphan conditions(s); and
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s).

In this interim final rule, we, therefore, are not including those orphan drugs that meet the above criteria within the CAP, at least during the initial stage of implementing the program. Under these criteria, the following drugs are not included, at least for the initial stage of CAP:

J0205 (Injection, Alglucerase, per 10 units);
J0256 (Injection, Alpha 1-proteinase inhibitor, 10 mg);
J9300 (Gemtuzumab ozogamicin, 5mg);
J1785 (Injection, Imiglucerase, per unit);
J2355 (Injection, Oprelvekin, 5 mg)
J3240 (Injection, Thyrotropin alpha, 0.9 mg);
J7513 (Daclizumab, parenteral, 25 mg);
J9010 (Alemtuzumab, 10 mg);
J9015 (Aldesleukin, per single use vial);
J9017 (Arsenic trioxide, 1 mg);
J9160 (Denileukin diftitox, 300 mcg); and
J9216 (Interferon, gamma 1–b, 3 million units).

We welcome comments on whether these drugs should be included in the CAP during later stages of implementation.

Comment: Several commenters also recommended that we not include contrast agents within the CAP. Some of these commenters recommended permanent exclusion of contrast agents from the program. Others recommended that we phase-in these agents during later stages of implementing the CAP. Contrast drugs are used only in diagnostic imaging tests. The commenters cited various reasons for excluding contrast agents. These included the difficulty of determining appropriate categories for these products, fast pace of change in this

field, and the rapid changes in coding and payment for these products. These changes may not yet be well understood among physicians, and this may hamper their ability to select the vendor that provides the most appropriate contrast agents for their patients.

Response: We agree with the commenters that the rapid pace of change in this field, in conjunction with major changes in coding and payment in recent years, may pose special possibilities for confusion during the initial stage of the CAP. We, therefore, are not including contrast agents under the CAP during this initial stage of implementing the program. We, however, will consider including them as we refine and develop the drug categories under the program in future stages of implementation.

Comment: Several commenters requested that CMS clarify whether carriers' least costly alternative (LCA) policies would apply under the CAP. Most of these commenters maintained that those policies should not be applied under the CAP. For example, one commenter argued that substituting one manufacturer's price for another is inconsistent with a system of establishing prices for HCPCS codes on the basis of submitted bids. Others pointed out that it would be administratively difficult to apply LCA policies within the CAP claims processing system.

Response: As we note in section II.B of this interim final rule, least costly alternative policies are established by our contractors. Nothing in this interim final rule is intended to disrupt the longstanding ability of contractors to apply this policy under section 1862(a)(1)(A) of the Act. Section 1862(a)(1)(A) provides that notwithstanding any other provision in the Medicare statute (that is, including section 1847B), no payment may be made under Part A or Part B for any expenses incurred for items and services that are not reasonable and necessary. Medicare carriers establish local coverage determinations (LCDs), under which coverage for a particular drug is limited to the coverage level for its least costly alternative. As stated in the March 2005 proposed rule, physicians who submit claims under the CAP must comply with applicable LCDs.

However, we acknowledge that the existence of LCA policies, and the fact that they will apply under the CAP just as they apply outside the CAP, have obvious implications for the provision of certain drugs under the CAP. If a carrier applies an LCA policy to a particular drug, the approved CAP vendor's claim for that drug, when ordered by a participating CAP physician in that carrier's jurisdiction, would be subject to LCA. We are aware of one instance in which every carrier has applied the ''least costly alternative'' policy to a drug that would otherwise meet the criteria outlined in this section for inclusion in the CAP. Every carrier has applied an LCA policy to injectable forms of leuprolide (not, however, to leuprolide implant). Under these polices, claims for leuprolide are paid at the level of its least costly alternative (goserelin). We are implementing the CAP initially through a single, broad drug category and a single, national competitive acquisition area; therefore, because leuprolide is subject to LCA policies in all carrier jurisdictions, its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes that we describe below, and regardless of the geographic location (and local carrier jurisdiction) of the participating CAP physician. For this reason, we have decided to exercise our authority under 1847B(a)(1)(B) not to include leuprolide in this initial stage of implementing the CAP. This decision is based on our authority under the CAP statute, and does not affect the applicability of LCA policies to leuprolide. We welcome comments on how to deal with this issue in later stages of implementing the program.

Comment: We received a number of comments recommending that we exclude blood clotting factors and intravenous immune globulin (IVIG) from the CAP. A number of these commenters recommended that we employ the authority under section 1847B(a)(1)(D) of the Act to exclude these products on the grounds that their inclusion within the program would not result in significant savings or would have an adverse impact on access. Many of these commenters also argued that IVIG is implicitly excluded from the CAP by section 1842(o)(1)(E)(ii) of the Act (section 303(b)(1)(E)(ii) of the MMA), which provides that the payment for IVIG ''in 2005 and subsequent years'' is the amount determined under the ASP system. Some commenters also pointed to the Conference Report on the MMA, which states that ''[c]ompetitively biddable drugs and biologicals exclude IVIG products and blood products.'' Other commenters contended that IVIG is inappropriate for inclusion under the CAP because it is frequently not administered incident to a physician's services. A number of commenters also pointed out that hemophilia patients commonly receive treatment with blood clotting factor at special treatment centers, or self-administer blood clotting factor at home. As in the case of IVIG, these commenters contended that blood clotting factor is therefore inappropriate for inclusion in a program intended and designed primarily for drugs administered incident to a physician's services.

Response: In this interim final rule, we continue to rely solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories. Using this authority, we have not included blood clotting factors or IVIG within the CAP. If we were to consider including blood clotting factors or IVIG, we would first publish a proposed rule and seek public comment.

We are also exercising our statutory authority to establish and phase-in drug categories in deciding not to include other immune globulins from the CAP in this initial stage of implementing the program. As in the case of tetanus and diphtheria vaccines, these products are commonly used in emergency situations, and are therefore poorly suited for the normal ordering and billing procedures contemplated by the CAP statute. We do not believe that it is advisable to include within the CAP drugs for which the special emergency mechanism will be routinely employed, at least during this initial stage of implementing the program. In addition, immune globulins are considered by some to belong to the category of blood products, which are explicitly excluded under the definition of competitively biddable drugs (see section 1847B(a)(2)(A) of the Act). Although we do not necessarily agree that immune globulins are properly classified as blood products within the meaning of the statute, we will not include them in our initial drug category in order to provide opportunity for further comment on whether they should properly be excluded on a permanent basis.

Comment: Numerous members of the mental health community (physicians, representatives of mental health clinics, and other mental health professionals) have requested inclusion of physicians' injectable psychiatric medications (for example, long-acting anti-psychotic drugs) in the initial phase-in of the CAP.

These commenters contend that including these medications within the CAP would enhance access to treatments of proven therapeutic value to a very vulnerable population. Some commenters specifically requested inclusion of these drugs in the CAP in order to make it more feasible for community mental health centers (CMHCs) to acquire and provide these therapies for their patients. Other commenters also noted that coinsurance for these drugs can be approximately 50 percent (in contrast to the 20 percent coinsurance for other Part B drugs) under the mental health limit (section 1833(c) of the Act, § 410.155 of our regulations).

Response: We will include drugs commonly billed incident to the services of psychiatrists in this initial stage of implementing the CAP. The single drug category that we are establishing for this initial stage of the program does in fact include many of the drugs that commenters specifically recommended for inclusion in the CAP. However, it is important to note that, under the statutory structure of the CAP as we are implementing it, CMHCs themselves will not be able to elect to participate in the CAP for provision of Part B drugs. This is because, as we have noted before, the specific mechanisms described under section 1847B of the Act as we have implemented them relate to the provision of and the payment for drugs provided incident to a physician's service. Therefore, only physicians are eligible to elect participation in the CAP for provision of the drugs that they administer incident to their services.

The issue of the appropriate coinsurance for mental health drugs in the light of the mental health limit provision is outside the scope of this regulation.

Comment: Several commenters asked for clarification of how codes for drugs that are not otherwise classified (NOC codes, including codes J3490, J3590, J7199, J7599, J7699, J7799, J9999, and Q0181) would be treated for purposes of the CAP.

Response: We do not believe that it would be appropriate to include the drugs billed under these codes within the CAP. Bidding and determination of payment for these codes would present insurmountable problems and pose unwarranted risks for potential vendors under the CAP. These are codes into which new drugs are assigned before receiving an appropriate permanent code. Some new drugs are assigned to these codes on a temporary basis, and each code thus represents a shifting collection of miscellaneous, unrelated products. It is not feasible for potential vendors to develop meaningful bids on these codes, given the fact that the codes represent such disparate products and that the specific drugs assigned to these codes are constantly changing.

Comment: Some commenters recommended that we establish narrowly defined drug categories. These commenters argued that broader categories would place a greater burden on vendors, who would have to bid and supply all drugs within broad categories. However, other commenters strongly supported the establishment of drug categories that are broadly defined to include all the drugs typically administered by a given medical specialty. These commenters argued that broadly defined categories would simplify the program for vendors, physicians, and the agency. Specifically, broad categories would allow most physicians to be able to choose one CAP vendor to meet all their Part B drug needs. One commenter in particular recommended establishing a single category including all Part B drugs administered incident to a physician's services. This commenter argued that such a broad category would make the CAP most accessible to all physicians, and allow vendors to bid on a wide array of products, give them a wider market, and allow for greater flexibility in designing their bids.

Response: We are persuaded that establishing relatively broad categories of drugs is the most appropriate and feasible approach for implementing the CAP, at least in the initial stage. We agree with the commenters that broad categories will promote greater access to the program for physicians, and provide vendors with flexibility in designing their bids. Broad categories will also, as noted by a number of commenters, allow most physicians to meet all (or almost all) their Part B drug needs.

We are also convinced by the arguments for establishing one broad category, at least for this initial stage of implementing the CAP. Such a broad category would make the CAP most accessible to all physicians. It would also allow vendors to bid on a wide array of products, give them a wider market, and provide them with greater flexibility in designing their bids. We, therefore, believe that employing a single category for the broad range of drugs administered incident to a physician's service is an appropriate measure, at least for the initial stage of implementing the CAP. We intend this single drug category as an interim measure, for this initial stage of implementing the program. We believe that establishing a single, broad drug category in this initial stage of implementing the CAP is an appropriate exercise of the Secretary's authority under the statute to establish categories of competitively biddable drugs and to phase-in the program with respect to those categories. We expect to phase-in multiple drugs categories, probably defined around the drugs commonly used by physicians' specialties (for example, urology, rheumatology), as we refine and develop the CAP. We welcome comments on how to develop and refine multiple drug categories for later stages of implementing the program.

As described below, we are therefore providing in this interim final rule for the establishment of a single category consisting of 169 drugs commonly provided incident to physicians' services. This broad category incorporates drugs commonly used by a wide range of specialties that bill for Part B drugs. The category also incorporates approximately 85 percent of physicians' Part B drugs by billed charges. In response to commenters' concerns, we have elected not to include at this time certain low volume drugs, as described further below.

The procedure that we used to select drugs for CAP bidding employed multiple sources of data to find Part B-covered drugs that are used in sufficient quantities by a variety of Part B-administering physicians. We believe that the broad drug category that we have developed through this procedure should tend to increase the interest of potential vendors and physicians in participating by making it more likely that (1) the fixed costs of being a vendor can be covered across the broad array of Part B physician-administered drugs that are included; (2) the impact of spoilage can be reduced; and (3) physicians electing can select one vendor to provide all, or almost all, of the Part B drugs that they administer. We derived our basic utilization data (restricted to physicians' specialties administering drugs in an office setting) from 2003 claims, the most recent available data. We supplemented these data with data on 2004 Medicare Part B drug utilization in office settings extracted from the Part B Extract and Summary System (BESS) to provide volume data on new drugs.

In the light of these considerations, we employed the following specific steps to develop a single category of the drugs most commonly used incident to a physician's services:

(1) We determined the claims volume for all Part B drugs in calendar year 2003. We did so by counting, in the claims from both the 100 percent carrier

and DMERC SAFs for 2003, the number of separate claims on which each Part B drug HCPCS appeared as a line item. If a particular HCPCS appeared multiple times on a single claim (for example, if the dates of service for the claim spanned more than a single day), this claim would only count once toward the HCPCS' claim count. We also tabulated separate counts for a number of physicians' specialties, specifically:

- Oncology specialties (including hematology, hematology/oncology, medical oncology, surgical oncology, urology, gynecology/oncology, and interventional radiology).
- Ophthalmology.
- Psychiatry (psychiatry, addiction medicine, and neuropsychiatry).
- Rheumatology.
- We determined separate counts for each of these specialties in order to be able to ensure that a broad spectrum of the Part B drugs used by physicians was included in this initial drug category for the CAP. In some cases (oncology, rheumatology) we included a separate count for the specialty because of the significance of drug billing by physicians in the specialty relative to overall billing for Part B drugs. In other cases (psychiatry, ophthalmology), we included distinct counts in order to respond adequately to comments specifically recommending the drugs commonly billed by those specialties for inclusion in the program. By specifically considering these drugs, we are responding to comments from member of these specific specialties in favor of including these drugs under the CAP. In addition, many of these drugs are highly specialized and unlikely to be present in the utilization data for other specialties. (Many other specialties are represented in this analysis because the drugs they commonly administer are also furnished by specialties that are specifically included. For example, most drugs commonly billed by urologists are also commonly billed by oncologists.) Finally, we tabulated a count for all other specialties not specifically identified above.

(2) We determined the proportion of each specialty group's claims on which each Part B drug appears. Once the claim counts from step (1) were computed, they were divided by the total number of claims submitted by the specialty groups for Part B drugs in an office setting. (Note that the sum over all drugs of these proportions will generally exceed 1.0 because multiple drugs can appear on the same claim.) Table 1 below shows these total claim counts, along with the number of Part B drug line items and total allowed Part B drug charges for each specialty group for drugs administered in an office setting.

TABLE 1.—CLASS & LINE ITEM VOLUME AND ALLOWED CHARGES FOR THE SPECIALTY GROUPS IN 2003

Specialty group	Number of claims	Number of line items	Allowed charges
Oncology	7,311,248	14,628,558	$5,647,268,606
Opthalmology	169,061	178,604	154,720,837
Psychiatry	43,752	55,599	3,626,108
Rheumatology	952,381	1,211,630	404,027,916
All other specialties	12,034,708	15,448,287	1,369,525,241

(3) We then extracted utilization and allowed charge data for each Part B drug in 2004 from BESS. Using BESS, information on utilization (HCPCS units) and total allowed charges for each Part B drug HCPCS code administered in an office setting were extracted. (For codes in the range 90200 through 90799 we retained only those CPT codes for vaccines and immune globulins; the other codes in that range were eliminated because they represent drug administration. We included all HCPCS J-codes. We also included HCPCS Q-codes corresponding to Part B drugs. We also excluded blood product HCPCS P-codes because of the statutory exemption of blood products from the CAP.) The resulting BESS output files were merged to create a single 2004 utilization file.

(4) We then crosswalked 2003 and 2004 Part B drug HCPCS to 2005 HCPCS. We did this in order to account for updates of the HCPCS codes. Specifically, several HCPCS codes from 2003 and 2004 were updated to 2005 codes in the Part B drug utilization data from steps (2) and (3). In most cases, this merely required changing the old HCPCS code to the new code and converting the units of service. However, two drugs required special treatment. In the case of lidocaine (which was formerly J2000, and is now J2001), the unit of service changed from 50 cc to 5 ml, and the NDCs included in the new code suggested a significant change in the mode of administration. In the case of octreotide acetate (which was formerly J2352 and Q4053, and is now J2353 and J2354), a new distinction was made between the depot and non-depot formulations that did not appear, from utilization data and NDC lists, to have been made previously. For these drugs, we summed the allowed charges, and imputed the number of claims to be the maximum of the number of claims for the old HCPCS.

(5) We merged the crosswalked drug utilization data for 2003 and 2004 by the 2005 HCPCS. The data from step (4) for the 2003 and utilization data were merged by the 2005 HCPCS.

(6) We then identified the drugs that we have determined not to include in the CAP drug category at this time. (We have discussed the reasons for not including most of these drugs above.) The types of drugs that are not included in the CAP drug category are:

- Clotting factors and immune globulins.
- Drugs administered through durable medical equipment.
- HCPCS used for erythropoietin administered to ESRD patients.
- HCPCS used for specific drugs administered in hospital outpatient departments and covered by section 1861(s)(2)(B) of the Act (codes Q2001 through Q2022).
- Orally-administered anti-cancer and anti-emetics.
- Orphan drugs that meet the criteria to be single indication orphan drugs for purposes of OPPS, as discussed above.
- Controlled substances on Schedules II, III, IV, and V.
- Tissues (for example, dermal, metabolically active, etc.). (Tissues are not considered drug products, and do not appropriately belong under the category of physician administered drugs that we have devised in response to the comments.)
- Influenza, pneumococcal, hepatitis B, tetanus, and diphtheria vaccines.
- Not otherwise classified (NOC) drugs (HCPCS J3490, J3590, J7199, J7599, J7699, J7799, J9999, and Q0181).
- Leuprolide

(7) We identified drugs to be included in our initial CAP category using the utilization data described above. Specifically, in order to be included in

the category, a drug needed to satisfy at least one of the following conditions:

- Be identified as an oncolytic, chemotherapy adjunct, anti-emetic, hematologic, or have a HCPCS in the J9000 series (except for J9999, which is excluded as a NOC code).
- Appear on more than 0.1 percent of claims for the oncology or all other specialty groups.
- Appear on more than 1 percent of claims for the ophthalmology, psychiatry, or rheumatology specialty groups.
- Have more than $250,000 in allowed charges in office settings in 2004 and be identified as an antibacterial, antifungal, antiparasitic, antidote, or cardiovascular agent.
- Have more than $1 million in allowed charges in office settings in 2004.

In addition to satisfying one of the above conditions, a drug must also satisfy both of the following conditions:

- Not be on the list specified in step (6) above of drugs that are not included in the CAP drug category.
- Have more than $50,000 in allowed charges in office settings in 2004 (another measure designed to avoid including very low volume drugs in this initial category).

We employed the criteria above to ensure that our single drug category would include a broad spectrum of the Part B drugs billed by physicians generally and by various physicians' specialties in particular. Our intent was to provide the physician with a single source for drugs (that is, the approved CAP vendor) that would be able to furnish the majority of drugs used in a practice regardless of the practice specialty or the diversity of prescribing patterns in that practice. Furthermore, we intended to provide the physician with choice and flexibility within groups of drugs that might be used by different specialties for the treatment of various conditions. This list of drugs is intended to accommodate a variety of physician practice patterns and a variety of specialties with the understanding that many drugs, for example, anti-emetics, are used by more than one specialty.

As noted above, we believe that in many cases, there is significant overlap in the types of Part B drugs administered by most physician specialties, including oncology. For this reason, we decided that oncolytics, chemotherapy adjuncts, anti-emetics, hematologics, and drugs having a HCPCS in the J9000 series (except for J9999), should be included in the CAP even if they did not meet the specialty claims percentage thresholds described in step (7) above. We believe that these drugs should be included in the CAP (so long as they meet the baseline claims volume threshold specified above and are not on the list specified in step (6) above). We believe it is necessary to include these drugs, even at lower volumes, because they may often be used in conjunction with one another, both by oncologists and by physicians in many other specialties.

However, for other drugs, we looked at claims volume in the aggregate of all specialties except those identified below to determine a threshold that would allow for a sufficiently sized market for vendors, while at the same time making the CAP a meaningful alternative for most physician specialties. At the same time, in response to specific comments about specialties where there is not significant overlap between small but highly utilized groups of drugs, the drugs that physicians in those specialties use, and drugs commonly used by other physician specialties, we identified psychiatry, ophthalmology, and rheumatology as specialties whose drugs claim threshold should be different. In order to lessen the inventory burden for vendors, we wanted to minimize the number of drugs included in the CAP that are billed in very low volumes, so we have applied a $50,000 minimum threshold for all drugs that otherwise would be included in the CAP (see step (7) above).

We determined separate counts for several specialties, in order to be able to ensure that a broad spectrum of the Part B drugs used by physicians was included in this initial drug category for the CAP. In some cases (oncology), we included a separate count for the specialty because of the significance of drug billing by these physician specialists relative to overall billing for Part B drugs. In other cases (psychiatry, ophthalmology, and rheumatology), we included distinct counts in order to respond adequately to comments specifically recommending the drugs commonly billed by those specialties for inclusion in the program, which, as noted above, are not frequently used by physicians in other specialties. As we have discussed above, we agree with the comment that we should include within this initial stage of the CAP drugs that provide a sufficiently large market for the program to be viable for vendors. For this reason, we decided not to include most very low volume drugs in this initial drug category. However, because overall volume of billing for Part B drugs varies widely from one physician category to another, we determined that the threshold for determining ''low volume'' had to vary somewhat among the specialties that we have separately identified in this analysis. In this context, we have determined that the low volume threshold should be relative to the size of the specialty and the overall volume of billing for Part B drugs by the specialty: The universe of Part B drugs billed by oncologists is roughly comparable to those in all other specialties in the aggregate and is much larger than the universe of Part B drugs billed by ophthalmology, psychiatry, or rheumatology. Specifically, the overall volume of billing for Part B drugs by oncologists is very high, while the overall volume of billing for Part B drugs by psychiatry and ophthalmology is relatively low. The same percentage threshold for these specialties would therefore yield very different numbers of claims for exclusion. We therefore determined that it would be appropriate to establish different percentage thresholds for including drugs billed by these specialties in the CAP. We accordingly set the percentage threshold for the oncology and all other specialty groups at 0.1 percent of claims submitted by the specialty. We set the threshold for ophthalmology, psychiatry, and rheumatology, at 1.0 percent of claims. A low percentage threshold (0.1 percent) for oncology claims (and claims for the other specialty category) is appropriate in relation to the overall high numerical volume of billing by oncologists for Part B drugs: a higher percentage threshold for this specialty would exclude some relatively high volume drugs from the category. Conversely, a similarly low percentage threshold for psychiatric drugs would not be appropriate because it would allow some very low volume drugs into the CAP. A higher percentage threshold in this case is necessary to exclude some very low volume drugs from the CAP. We decided on these specific percentage thresholds after examining various alternative levels (for example, 0.01 percent) and different combinations of levels (for example, 0.1 percent for oncology drugs, 0.01 percent for ophthalmology and psychiatry). After examining a number of alternatives, we determined that these levels strike an appropriate balance: they are high enough to prevent truly low volume drugs from being included in the category, and low enough to incorporate within the category a truly broad spectrum of the Part B drugs commonly billed by physicians. When we considered cutting the list off at a higher threshold (for example, 1.0 percent) for oncology drugs (and the

''other specialty'' category), we realized that numerous commonly billed drugs would have been excluded. Similarly, when we considered a lower threshold (for example, 0.1 percent) for ophthalmology, psychiatry, and rheumatology, we realized that many drugs billed in small numbers would be included.

Finally, we set several other thresholds based on claims volume that we believe would be appropriate for balancing the goal of providing approved CAP vendors with a sufficiently sized market with that of allowing physicians to obtain a broad array of drugs through the CAP. For this reason, we determined that a $250,000 threshold would be appropriate for drugs identified as an antibacterial, antifungal, antiparasitic, antidote, or cardiovascular agents. These drugs are often used by particular specialties like infectious disease or cardiology, but many of these drugs may be used by other specialties, and the $250,000 threshold ensures that only those drugs of this type that are commonly used are included in the CAP. Finally, for the same reasons, we believe that any drug that otherwise meets the criteria for inclusion in the CAP (as specified above), but does not meet one of the other four specific criteria outlined in step (7) above, should be included if the volume of claims for the drug is significant. We have set that threshold at $1 million. The result of performing this methodology is a list of 169 drugs. Table 2 gives the percentage of total allowed charges for Part B drugs for each of the five specialty groups shown in Table 1.

TABLE 2.—PERCENT OF 2003 TOTAL ALLOWED CHARGES ACCOUNTED FOR BY THE CAP BIDDING DRUGS

Oncology	84.92
Ophthalmology	99.97
Psychiatry	46.14*
Rheumatology	99.29
Other specialties	80.57
All non-oncology specialties	86.00
All physicians (in office)	85.20

* **Note:** Our data on drug billing by psychiatrists showed a high proportion (53 percent) of allowed charges for Rho D immune globulin, which is not included in our single drug category for the reasons discussed above. The drugs that we have included represent 97.94 percent of allowed charges for all other drugs commonly used by psychiatrists.

Using these steps, we have identified a list of 169 drugs for inclusion in our single drug category. We show the list of these drugs in Addendum A. These drugs represent a large proportion of the 440 drugs billed incident to physicians' services in our Part B billing data. More importantly, they represent about 85 percent of the charges for all the Part B drugs billed by physicians. We also have revised the definition of ''CAP drug'' in the regulations at § 414.902 to clarify that the provisions of the CAP program apply to drugs that we have included in the drug category.

Comment: Several commenters noted that, in light of the congressional intent to provide physicians with an alternative method for obtaining the Part B drugs that they use, it would be especially appropriate to incorporate into the CAP at an early stage of implementation those drugs that have been identified as posing acquisition problems for physicians under the ASP system.

Response: The methodology that we described above does not specifically account for those drugs. However, we have reviewed the resulting list of 169 drugs against a list that we have maintained of drugs that have been reported to us as posing access problems for physicians under the ASP system. Most of the drugs on that list appear in the drug category that we are establishing for this initial phase of implementing the CAP. These include:

J7050 Normal Saline 250 mL
J9245 Melphalan/Alkeran 50 mg
J2430 Pamidronate
J2920 Methylprednisolone
J2930 Methylprednisolone
J7317 Sodium Hyaluronate
J7320 Hylan G-F 20
J9310 Rituximab
J1750 Iron Dextran 50 mg Injection
J2405 Odansetron 1 mg Injection

To account for the drug category that we are adopting in this interim final rule with comment period, we have revised the proposed regulations at § 414.902 to specify that CAP drugs are those physician-administered drugs or biologicals furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Vendor Implications

We pointed out that the categories established for physicians to select would be the same categories that would be open for bids by potential vendors. Vendors would not be able to submit bids on only some of the HCPCS codes in the category, and physicians would not be able to elect to acquire only some of the HCPCS codes in that category from the approved CAP vendor. Note that in § 414.902 the proposed definition for ''approved vendor'' at § 414.902 has been revised to ''approved CAP vendor'' and clarified to specifically reference 1847B of the Act.

In addition, it is important to keep in mind that HCPCS codes can often describe products represented by multiple National Drug Codes (NDC). For example, the drug cyclophosphamide is manufactured by a number of different pharmaceutical companies and has multiple NDC codes.

In proposed § 414.908(d), we indicated that vendors will not be required to provide every National Drug Code associated with a HCPCS code. Section 1847B(b)(1) of the Act states that ''in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.'' However, we also proposed that vendors be required to provide potential physician participants in the competitive acquisition program the specific NDCs within each HCPCS code that they will be able to provide to the physician. Potential vendors would also need to provide this same information to us as part of the bidding application. This information would be provided to physicians who request it no later than the beginning of the election period during which the physician chooses whether to participate in the CAP and, if so, selects a vendor.

Comment: Many commenters supported our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. Many of these commenters urged us to resist any recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. Many other commenters expressed opposition to any attempt by the agency to establish a formulary as an element of implementing the CAP. A few commenters representing potential vendors did make such a recommendation. Other commenters recommended that we establish a more stringent standard, such as: requiring that vendors offer at least one drug for each distinctive treatment or therapy represented within a HCPCS code; requiring that vendors be required to offer at least one formulation (that is, at least one NDC) for each single-source drug that falls within the same HCPCS code; or requiring that vendors be required to provide all available FDA-approved drugs within a HCPCS code. Finally, some commenters recommended that information about which specific NDC codes vendors will

be offering be made generally available, perhaps through the CMS Web site, and not merely made available to physicians upon request.

Response: In this interim final rule, we are finalizing our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. At the same time, we do not believe that it is advisable or feasible to require vendors to provide all available FDA-approved drugs within a HCPCS code. We are concerned that such a requirement may exclude vendors who are unable to provide even one drug in a category, unduly limiting the number of vendors that would participate in the program. We also do not believe that it is advisable to establish a standard requiring that vendors offer at least one drug for each distinctive treatment or therapy represented within a HCPCS code. Such a provision would be difficult to distinguish from establishing the type of formulary that many commenters opposed. Consistent with the requirement of 1847B(b)(1) of the Act, we have therefore decided to finalize our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. We believe that the program will provide a strong incentive for vendors to include a broad selection of drugs within individual codes. It will be difficult for vendors to attract business from physicians under the program if the choice among drugs within specific codes is unduly restrictive. We expect that this incentive will be sufficient to prompt vendors to offer a wide range of drugs, including multiple NDCs within a single drug code, and thus protect physicians' ability to choose the most medically appropriate therapies for their patients. In addition, our decision to include our proposed ''furnish as written'' provision in this interim final rule should provide protection for physicians in those cases when an approved CAP vendor does not offer the specific drug or formulation that is medically necessary for a patient. (See section II.B of this interim final rule.) In addition, in this interim final rule, we are finalizing our proposed policy that vendors will be required to provide to potential physician participants in the CAP the specific NDCs within each HCPCS code that they will be able to provide to the physician. We are not accepting the recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. The statute expressly requires that for multiple source drugs, a competition be conducted for the acquisition of at least one drug per billing code within the category. Thus, the statute does not contemplate a formulary. Finally, we agree with the suggestion that the specific NDC codes vendors will be offering be made generally through our Web site. By October 1, 2005, we will make available, on the CAP web page, a directory of the approved CAP vendors and the specific NDC numbers these vendors will be providing.

We also note that we have revised the definition of approved vendor at § 414.902 to read ''approved CAP vendor'' and we have specifically referenced 1847B of the Act.

Comment: A number of commenters asked us to clarify that, if the CAP is phased in by physicians' specialty, physicians of any specialty will still be able to obtain drugs initially included in the program from a CAP vendor.

Response: We stated in the proposed rule (70 FR 10750) that ''if we choose to phase-in the CAP by restricting the program initially to drugs typically administered by members of one specialty, all physicians who administer the drugs selected would still be eligible to elect to obtain these drugs through the CAP and to select a vendor of these drugs. For example, if we choose to phase-in the program initially with drugs typically administered by oncologists, participation in the CAP would not be restricted to oncologists: non-oncologists who prescribe these drugs would still be eligible to elect the CAP and to select a vendor from which to obtain these drugs.'' In this interim final rule, we are establishing one broad category of drugs commonly furnished incident to a physician's services for the initial stage of implementing the program. Physicians of any specialty are eligible to elect the CAP and to select a vendor from which to obtain these drugs. As we refine and expand the program, and expand our single category into multiple drug categories, we will maintain the policy that any physician, regardless of specialty, who administers the drugs in a specific category, may elect to obtain those drugs through the CAP in accordance with the statute and implementing regulations.

Finally, in the proposed rule, we emphasized that, in framing these options, we relied solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories. Although we did not propose to rely at this time on the Secretary's authority under section 1847B(a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals, we proposed to set forth the circumstances for which we may exclude competitively biddable drugs and biologicals (including categories of drugs) from the CAP at § 414.906(b) of our regulations. In this interim final rule, we continue to rely solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories.

3. Competitive Acquisition Areas

Definition of Competitive Acquisition Areas

Section 1847B(a)(1)(A)(i) of the Act provides that, under the competitive acquisition program (CAP), competitive acquisition areas are established for contract award purposes. Section 1847B(a)(2)(C) of the Act further defines the term ''competitive acquisition area,'' for purposes of the CAP, as ''an appropriate geographic region established by the Secretary.'' Section 1847B(b)(1) of the Act also requires that the Secretary conduct a competition among entities for the acquisition of at least one competitively biddable drug within each billing and payment code within each category of competitively biddable drugs for each competitive acquisition area. Finally, section 1847B(b)(3) of the Act states that the Secretary may limit (but not below two) the number of qualified entities that are awarded contracts for any competitively biddable drug category and competitive acquisition area.

Under this statutory scheme, competitive acquisition areas (that is, the geographic areas the contractor would be responsible for serving) have an important role in the CAP. These areas constitute the geographic boundaries within which entities will compete for contracts to provide competitively biddable drugs.

As explained in the March 4, 2005 proposed rule, the definition of these areas will be a crucial factor in determining—the number of entities that bid for contracts; the number of entities that are ultimately awarded these contracts; the level of savings from the successful bids; and the efficiency with which the system delivers competitively biddable drugs to physicians.

Because the statute grants the Secretary broad discretion in defining competitive acquisition areas under the CAP, we discussed several factors that must be considered in defining competitive acquisition areas for competitively biddable drugs and biologicals, including how promptly physicians need drugs provided to their practices if distribution capacity varies geographically, as well as aspects of vendors and their distribution systems, such as:

- Current geographic service areas;
- Density of distribution centers, distances drugs and biologicals are typically shipped, and costs associated with shipping and handling;
- The relationships between vendors and their suppliers (manufacturers, wholesalers, etc.); and
- State licensing laws that may preclude vendors from operating in a State are to be taken in account. These factors can affect the price of supplying drugs to different regions as well as the size of the market in which vendors are allowed or able to operate.

Section 1847B(a)(1)(B) of the Act specifically requires the Secretary to phase-in the CAP with respect to the categories of drugs and biologicals in the program, in such a manner as the Secretary determines to be appropriate. We believe that this provision, particularly in conjunction with the statutory definition of ''competitive acquisition area'' (''an *appropriate* geographic region *established by the Secretary*'') (emphasis added), provides broad authority for the Secretary to phase-in the CAP with respect to the geographical areas in which the program will be implemented.

In the proposed rule, we identified several basic options for defining the competitive acquisition areas required under the CAP along with possible advantages and disadvantages for these options. The specific options discussed included: establishing a national competitive acquisition area; establishing regional competitive acquisition areas; and establishing statewide competitive acquisition areas.

We requested comments on all the options that we have discussed and also welcomed recommendations of other options for consideration but stated that defining competitive acquisition areas, at least initially, on the basis of a level no smaller than the States is the most feasible approach.

Comment: Many commenters addressed these two related issues: (1) Whether to implement the CAP immediately on a national scale, or to phase-in the program by beginning in one or more smaller areas; and (2) whether to establish a national competitive acquisition area, regional competitive acquisition areas, or statewide competitive acquisition areas on a permanent basis.

Commenters were divided about whether to implement the CAP nationally on January 1, 2006, or to phase-in the program by beginning on a more limited scale. Those commenters in favor of immediate national implementation emphasized congressional intent to establish a national program or the importance of providing physicians immediately with an alternative method for procuring drugs. Commenters in favor of a geographic phase-in argued that the CAP should be tested on a smaller scale in order to ensure that major implementation issues are solved before extending the program nationally. These commenters were divided on how to begin a geographic phase-in. Most of the commenters in favor of a phase-in endorsed beginning on a state or regional level. Some commenters specifically recommended beginning the program on a limited geographic basis in one or more of the most highly populated States, such as California, New York, or Texas. Other commenters recommended implementing the program initially with a few vendors serving a nationwide area.

Some commenters recommended establishing a single, national acquisition area on a permanent basis. Other commenters supported either State-based or regional acquisition areas on a permanent basis. Supporters of State areas emphasized that the licensing requirements operate at the State level, and that State-based areas would permit participation by smaller vendors. Supporters of regional areas pointed to the regional administration of other Medicare programs. Others pointed out that vendors may not bid to provide drugs for some small, low population states if the acquisition areas are established on a statewide basis.

Response: We are persuaded by those commenters who advocated national implementation of the CAP beginning January 1, 2006. We agree with these commenters that it is important to provide an alternative to the ''buy-and-bill'' method of drug acquisition for physicians as widely and quickly as possible. We have therefore decided to implement the program for the broad drug categories that we have previously described on a nationwide basis January 1, 2006.

We also agree with those commenters who recommended initially implementing the program in a single, nationwide competitive acquisition area for several reasons. First, in a single national area, the number of Medicare beneficiaries and physicians is sufficiently large to encourage vendors to participate. In addition, starting with a nationwide competitive acquisition area allows additional time to consider whether smaller, regional competitive acquisition areas should consist of single States or multiple States. Also, implementing the program initially in a single nationwide area would impose less administrative burden on potential bidders than other options, because each applicant would be submitting bids for contracts to cover one geographic area. Finally, implementing a nationwide competitive acquisition area initially allows us to develop and evaluate the administrative structures of the new program in conjunction with the relatively smaller number of vendors that can operate on a national level before extending the program to the larger number of vendors that might operate on a State or regional level, while still providing all physicians the opportunity to participate from the outset. It is important to note that we received 15 responses to our December 13, 2004 Request for Information. All these responders expressed an interest in participating in the CAP. Most of these responders indicated a willingness to provide selected Part B drugs on a nationwide basis. We therefore believe that implementing the CAP initially in a single nationwide competitive acquisition area will allow for an appropriate level of competition among vendors to provide drugs for physicians.

We also agree with those commenters who supported phasing in the CAP. We agree with these commenters that phasing in the CAP would give us the opportunity to test and refine the administrative apparatus with a limited number of vendors before expanding the program to allow larger numbers of vendors to participate. Most of the commenters in favor of a phase-in recommended implementing the program initially on a limited geographic scale, such as one or more States or regions of the country. However, a few commenters supported an alternative phase-in approach that we discussed in the proposed rule. As we stated there, one way to phase-in the program is to begin with the limited number of vendors that can deliver drugs on a nationwide basis: ''the program could be phased in by initially employing a national competitive acquisition area. This would limit participation in the program initially to those vendors that could compete to bid and supply drugs nationally, to the

exclusion of the vendors that could bid and supply drugs on a regional or State basis. Under such a phase-in plan, the definition of competitive acquisition area would ultimately be established on the basis of regions, States, or some other smaller geographic area, which might expand the number of vendors that could bid to participate in the program.''

In this interim final rule, we are establishing a single, national distribution area for the initial stage of the CAP. This national distribution area will embrace the 50 States, the District of Columbia, Puerto Rico, and U.S. territories. In order to participate in this initial stage of the program, vendors will need to be appropriately licensed in all 50 States and the District of Columbia (as well as Puerto Rico and the U.S. territories). It is important that, as we discuss in section 2.C.1 of this interim final rule, vendors submitting bids to participate in the program may employ subcontractors, including vendors that operate on a State-wide or regional basis, to provide for distribution of drugs across the nationwide area that we are establishing. Under this phase-in plan, we expect that the definition of competitive acquisition areas will ultimately be established on the basis of regions, States, or some other smaller geographic area, which we expect to increase the number of vendors that could bid to participate in the program. We will consider how to establish smaller competitive acquisition areas (regional or State-based) as this initial phase of implementation proceeds. We welcome additional comments in response to this interim final rule on how to proceed with the development of smaller competitive acquisition areas for later stages of implementing the program. We anticipate that our final plan for those areas will not only allow smaller, State-based or regional vendors to compete for contracts under the CAP, but also preserve the opportunity for large vendors to participate in the program on a nationwide basis.

B. Operational Aspects of the CAP

1. Statutory Requirements Concerning Claims Processing

Section 1847B(a)(3)(A) of the Act sets forth specific requirements that have a direct impact on the administrative and operational parameters for instituting a CAP. This section of the statute requires the following: (1) Vendors participating in the CAP bill the Medicare program for the drug or biological supplied, and collect any applicable deductibles and coinsurance from the Medicare beneficiary. (For purposes of the preamble the term ''vendor'' means the term ''contractor'' as referred to in the statute.) (2) Any applicable deductible and coinsurance may not be collected unless the drug was administered to the beneficiary. (For purposes of the preamble the term ''drug'' refers to drugs and biologicals.) (3) Medicare can make payments only to the vendor, and these payments are conditioned upon the administration of the drug.

The statute requires the Secretary to provide for a process for adjustments to payments when payment was made for the drugs, but they were not actually administered to the beneficiary. The Secretary is also required to provide a process by which physicians submit information to vendors for purposes of the collection of applicable deductible or coinsurance. Payment may not be made for competitively biddable drugs supplied to a physician who has elected to participate in the CAP unless the vendor supplying the drugs has a contract to provide them in that geographic area and the physician receiving them has elected the vendor to supply that category of drug in that geographic area.

Section 1847B(b)(4)(E) of the Act requires that the vendor supply drugs directly only to the selecting physicians and not directly to individuals, except under circumstances and settings where the individual currently receives drugs in his or her home or another non-physician office setting, as provided by the Secretary. In addition, the vendor may not provide drugs to a physician participating in the CAP unless the physician submits a written order or prescription, and any other data specified by the Secretary, to the vendor.

However, the statute also makes it clear that the physician is not required to submit an order (prescription) for individual treatments of a drug or biological, and that the statute is not intended to change a physician's flexibility to choose whether to write a prescription for a single treatment or a course of treatments. In certain sections of the proposed rule, we used the term ''prescription'' and the term ''order'' interchangeably. Section 1847B of the Act uses the term ''prescription'' but does not define it. For purposes of the CAP, we proposed to interpret the term to include a written order submitted to the vendor.

We also noted that section 1847B(b)(4)(E) of the Act, in requiring that vendors deliver drugs only upon receipt of a ''prescription,'' expressly indicates that the statute does not ''require a physician to submit a prescription for each individual treatment'' or ''change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.'' As we stated in the proposed rule, it is not our intention to restrict the physician's flexibility when ordering drugs from a CAP vendor.

Resupplying Inventory

Section 1847B(b)(5) of the Act requires the Secretary to establish rules under which drugs acquired under the CAP may be used to resupply inventories of these drugs administered by physicians. The statute contains four criteria that must be met in order for the physician to use this provision: the drugs are required immediately; the physician could not have anticipated the need for the drugs; the vendor could not have delivered the drugs in a timely manner; and the drugs were administered in an emergency situation.

Comment: One commenter stated that the statutory requirement to provide for a process of adjustments to payments in cases where payment was made for a drug that was not actually administered to the beneficiary was unnecessary and should be removed or clarified since under the proposed claims processing system payment to the vendor would not be made until administration was verified, unless CMS adopted the partial payment methodology.

Response: We agree with the commenter that generally the claims processing system we are adopting in this interim final rule makes it less likely that we will need to recover payments made in error to vendors for drugs that were not actually administered to the beneficiary, because we will not pay the vendor until the drug administration claim has been processed. However, it is still possible that claims filing and processing errors could occur and that as a result, a vendor could be paid in error. In that event, we will use existing overpayment recovery processes to recover claims payments made in error. Therefore, we are retaining the language at § 414.906(d).

Comment: Some commenters requested that we define the term prescription and/or order in the final rule preamble and regulations. Other commenters stated that because the statute uses the word prescription, CMS does not have the authority to redefine the term to mean an order. Several commenters characterized the drug order process described in the proposed rule as the filling of a prescription for a patient, and stated that only a licensed pharmacist may fill a prescription under State and Federal law. Another

commenter noted that ''prescription'' and ''order'' have very different meanings in the marketplace, with prescription being associated with precise pharmacy rules, and order being more commonly used to describe a distribution system. Some commenters requested that CMS define the program as either a pharmacy program or a distribution program and use consistent language within the regulation. Other commenters felt that there was no doubt that the statute required CMS to define the patient-specific drug order as a prescription and that CMS should consistently describe it as such.

Response: As we stated in the proposed rule, the statute uses the term prescription but does not define it. Further, the process envisioned in the statute contains elements more commonly consistent with orders as well as elements usually associated with prescriptions. We do not believe that the Congress intended us to abide by a rigid definition of a prescription. We note that CAP vendors must comply with State licensing requirements in all cases, and that our definition of prescription as used in the statute is not meant in any way to override those requirements. For purposes of this interim final rule, we will define the CAP drug ordering process as a prescription order and will add a definition of the term to the regulations text at § 414.902. For purposes of the CAP, we define a prescription order as a written order submitted by the physician to the vendor in accordance with the requirements of the CAP. (The discussion of whether CAP requires a drug distributor's license or a pharmacy license is dealt with in more detail in section II C, the CAP contracting process.)

Comment: One commenter believed that it was a violation of physician flexibility to require that in the case of a multiple source drug, vendors supply only one drug within each billing and payment code within each category.

Response: Section 1847B(b)(1) of the Act explicitly states the requirement, and we will implement it as stated in the statute: ''In the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.''

Comment: Another commenter believes that CAP vendors should be prohibited from acting differently than the drug distributors or wholesalers with which the physician currently does business. That is, the vendor should be prohibited from exercising the responsibilities of a physician or a pharmacist with regard to drug interactions, appropriate dosing, or other issues such as substituting drugs in the physician's order.

Response: We expect vendors to perform their responsibilities consistent with applicable State law and this interim final rule. To the extent that the vendor is required by State law to include a pharmacist in the CAP process or to act as a pharmacy, the vendor may be required to discuss possible drug interactions or to perform other duties commonly performed by pharmacies. Although the CAP legislation does not require these activities as part of the CAP, neither does it excuse vendors from any applicable requirements under State law.

Comment: Some commenters supported the resupply criteria. Others, including an association of cancer centers, expressed concern about the strict requirements for physician compliance with the criteria for the resupply provision described in section 1847B(b)(5) of the Act and requested that CMS liberalize the provisions.

Response: The four criteria that govern the resupply option are contained in section 1847B(b)(5) of the Act, as specified above. The statute also states that the physician may use drugs and biologicals obtained from a CAP vendor to resupply drugs and biologicals that he or she has taken from his or her own stock to treat the beneficiary if the physician can demonstrate to us that all four of the criteria have been met. Because the criteria and the responsibility to comply with all of them are statutory, we do not have the authority to change them, or to allow that some of them be optional. However, we interpret ''timely manner,'' for purposes of the resupply provisions of the CAP, to mean the ability to meet emergency delivery standards for timely delivery as defined in § 414.902. That is, if the vendor could not have delivered the drugs to the physician to respond to the patient's clinical need for the drug under the emergency delivery process, then the vendor could not have delivered the drug in a timely manner for purposes of the resupply provisions. Further, we interpret the term ''emergency situation,'' for purposes of the resupply provisions of the CAP, to mean a situation that in the physician's clinical judgment requires immediate treatment of the patient. We have made some technical changes to these definitions in § 414.902. (These comments are further addressed in the claims processing/operational overview section that follows).

Comment: Some commenters suggested that in an emergency situation, the physician should be given the option of using the drug replacement option or of billing for the replacement drug using the ASP methodology.

Response: We believe that the Congress created the emergency resupply provision to address situations when a physician participating in the CAP would need immediate access to drugs but would not have the time to obtain them from the vendor. This provision allows a physician to treat the patient in situations that comply with the four criteria specified in the Act, and then obtain replacement drugs from the CAP vendor. This provision specifies that the physician obtain replacement drugs from the CAP vendor and thus does not allow the physician to bill under ASP in this situation.

2. Proposed Claims Processing and Operational Overview

To comply with the statutory requirements described above, in the March 4, 2005 rule, we proposed to implement a claims processing system that would enable selected vendors to bill the Medicare program directly, and to bill the Medicare beneficiary and/or his or her third party payor after verification that the physician has administered the drug. We set forth the proposed requirements for payment under the CAP at § 414.906 of our regulations. For the initial implementation of the CAP, we discussed our plan to designate one Medicare fee-for-service claims processing carrier to process all drug vendors' Medicare claims (and referred to this entity as the designated carrier.) Physicians who elect to participate in the program will continue to bill their local Medicare fee-for-service claims processing carrier for physicians' services.

Comment: One commenter supported CMS' plan to make a single designated carrier responsible for processing drug vendor claims. However, the commenter encouraged CMS to move toward having the Part B carriers process both the physician's claim and the drug vendor's claim at some point. The commenter also suggested that CMS consider aligning the CAP areas with the claims processing jurisdictions that CMS will adopt for the Medicare Administrative Contractors.

Response: We will continue to evaluate the operation of the CAP and will conduct the evaluation in the context of the implementation of Medicare contracting reform.

Roles of the Contractor

We proposed that both the designated carrier and the physician's local carrier would be charged with keeping track of the physician's vendor selection and making sure that the physician is administering drugs provided by the vendor with whom he or she has elected to participate. This process also would involve our central claims processing system.

The March 4, 2005 rule (70 FR 10754) also discussed the proposed operational structure for the CAP and the relationship and responsibilities of the participating CAP physician and approved vendor with respect to the ordering, delivery, and administration of the CAP drug and the payment aspects associated with the CAP drug. A summary of this proposed operational structure follows.

Ordering the CAP Drugs

We proposed that when a physician who has elected to participate in the CAP prepares an order for a drug to be administered to a Medicare beneficiary, the physician would provide basic information about the beneficiary and the beneficiary's third party insurance to the drug vendor. In addition, the physician would check that he or she was planning to use the drug consistent with any local coverage determination policies (LCDs), just as he or she would do now if obtaining a drug under the current payment methodology.

We proposed that the order transmitted between the physician and the drug vendor could occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order.

Comment: Several commenters stated that the drug ordering process outlined in the proposed rule will make it difficult for the physician to treat a patient on the patient's first visit to the office, which will necessitate at least a 1-day delay in treatment. If the patient's condition changes and a different drug or a different amount of the same drug is needed, delays could occur and additional work by the physician's staff to work with the vendor to make the necessary revisions may be necessary. The commenters requested that CMS try to incorporate more flexibility into the drug ordering process.

Response: The CAP drug ordering process must be considered in the context of the statutory requirements of a patient-specific drug ordering process, the requirement that payment to the vendor requires verification that the drug was administered, and the requirement that the vendor bill the Medicare program and the beneficiary or the beneficiary's third party insurance. We have defined delivery timeframes at § 414.902 in such a way that the physician should be able to obtain needed drugs quickly, since the vendor is required to provide routine delivery within two business days, and emergency delivery within one business day. The vendor may be required to ship drugs more quickly if the integrity of the product requires it. If the vendor's routine and emergency delivery processes would not enable the physician to obtain the drug quickly enough for a particular patient, the physician will have the option of obtaining the drug order under the emergency replacement process if the situation complies with the four criteria governing this process specified in the statute. There could be some rare occasions when the physician is unable to obtain a drug to treat a patient at the desired time. In that case, the physician could choose to refer the patient to another health service provider or hospital outpatient department for immediate treatment, or to ask the patient to return to the office for treatment on another day. Physicians may already face this prospect under the buy and bill methodology currently in effect. We hope that these situations will be rare under either the CAP or the ASP system. Physicians who find that the CAP requirements and advantages do not fit the needs of their practice have the option to continue to obtain Part B drugs for their practice under the ASP system rather than electing to participate in the CAP. Note that we have made a technical revision to the proposed definition of designated carrier and local carrier under § 414.902 to specifically reference ''CAP'' rather than ''Part B Competitive Acquisition Program''.

Comment: Some commenters asked for more information on how the carriers would apply coverage policies under the CAP, and whether CMS was planning to change its process for determining if drugs were covered for off-label uses. The Practicing Physicians Advisory Council (PPAC) recommended that CMS require CAP vendors to provide drugs for off-label use when evidence supports such use. In these cases, PPAC suggested that vendors could use established CMS processes for determining medical necessity.

Response: Determinations of medical necessity are made by the Medicare carriers and are not made by suppliers, such as the approved CAP vendor. As we stated in the proposed rule, the local carrier will be responsible for adjudicating the physician's claim for drug administration and checking that the claim is compliant with all local coverage determinations (LCDs). If the local carrier determines that the claim is not compliant with an LCD, the local carrier will deny the physician's claims for administering the drug and send a message to the CMS central claims processing system that the drug vendor's claim for the drug is also not payable. The local carrier will enforce its LCDs because they govern the rules in effect where the drug was administered. The designated carrier's LCDs would not play a role in determining whether the vendor's claim was payable except in its carrier jurisdiction if it is acting as a local carrier in that jurisdiction. It is not our intention to change our policy on the carrier's authority to make decisions about whether a particular medication will be covered. Under the CAP, the local carrier will continue to exercise the same process it currently uses for determining if a drug is payable. Similar to the scenario we have outlined for enforcement of the local carrier's LCDs, we anticipate that the local carrier will review a drug prescribed and make a decision about whether the physician's claim for administering the drug and the vendor's claim for the drug is payable under those circumstances. The local carrier will notify our central claims processing system about its decision, and the vendor's claim will be paid or denied accordingly. If payment for the drug administration claim is denied, the physician will have a responsibility to appeal the denial. As noted in section II.B.3 of this interim final rule, the vendor also may appeal the denial of the drug claim. The vendor also can ask the designated carrier for assistance under the dispute resolution process in making sure the physician's appeal was filed properly or in determining other steps that the vendor can take to resolve the situation. (For a more detailed discussion of this, see the section on dispute resolution at the end of this section.)

Comment: Some commenters requested guidance about how the Comprehensive Error Rate Testing Program (CERT) and the Recovery Audit Contractor Demonstration would apply to the CAP.

Response: We anticipate that the CERT Program will apply to the CAP claims, but the process for doing so has not been determined at this point. The Recovery Audit Contractor (RAC) Demonstration will not apply to the CAP, because there is an explicit exemption in the demonstration for claims that are adjudicated under special processing rules. Claims

processed for drugs provided under the CAP receive special treatment relative to the balance of Part B claims.

Comment: A commenter suggested that the final rule address the steps necessary for a non-CAP physician to refer a patient for treatment to a participating CAP physician.

Response: If a non-participating CAP physician refers a patient to a participating CAP physician, the participating CAP physician will treat the beneficiary as he or she would any other patient, because the decision to participate in the CAP is made at the physician level rather than on a beneficiary-by-beneficiary basis. The participating CAP physician would need to provide the same education about the CAP to the beneficiary referred by the non-participating CAP physician as he or she did for his or her regular patients. If the participating CAP physician needs to provide a drug to the referred patient and the drug is a CAP drug, the drug may be obtained from the approved CAP vendor. If it is medically necessary that the patient receive a specific formulation of a drug not available from the approved CAP vendor, the physician may obtain the drug under the ''Furnish As Written'' provision. Finally, if the drug the patient needs is not one that is included in the CAP category the physician would buy the drug and bill for it under the normal ASP system.

Comment: Several commenters requested guidance about whether the vendor would be able to refuse to ship an order if the vendor believed it was inconsistent with an LCD or if the designated carrier had denied payment for the drug previously for some other reason. Some commenters stated that the vendor should be prevented from substituting its decision making for that of the physician by refusing to ship an ordered drug or changing the dose of a particular drug.

Response: If the vendor believes a drug order is not consistent with an LCD, the vendor may call the physician to discuss the order and try to determine why the physician believes it will be covered under the local carrier's LCD. If the physician declines to change the order, but the vendor still believes the local carrier will not cover the drug, the vendor may ask the beneficiary to sign an Advanced Beneficiary Notice (ABN). Because approved CAP vendors will be Medicare suppliers, they will have the same right to issue ABNs that any other Medicare supplier has. A signed ABN would make the beneficiary liable to pay for the drug if the carrier denied the claim. However, in the event the vendor is not successful in collecting an ABN from the beneficiary, and the physician refuses to change the order, the vendor will still be required to provide the drug to the physician under its contract with us. If the claim for the drug administration is denied, the physician would be required to pursue an appeal of the denial with the local carrier. The vendor also may appeal the denial of the drug claim. If the claim ultimately remains unpaid, the vendor may ask the designated carrier for assistance under the dispute resolution process. (This process is described in more detail in the section on dispute resolution (section II.B.3 of this interim final rule).)

We are requiring the vendor to deliver the drug to ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process. In addition, the local carrier's coverage determination (rather than the designated carrier's) must apply in the local carrier's jurisdiction so that the same coverage policies are in force in an area regardless of whether a drug is paid for under the CAP or under the ASP system. The only exception to this policy is that if the beneficiary does not pay his or her cost sharing in certain circumstances, the vendor may refuse to ship additional drugs to the participating CAP physician for that beneficiary. For more information on this process, please see the discussion of beneficiary cost sharing later in this section.

Comment: One commenter requested that CMS clarify whether the local carrier may also apply its least costly alternative policy to the claim submitted under the CAP, despite the establishment of pre-determined CAP reimbursement rates.

Response: Least costly alternative policies are established by our contractors. Nothing in this interim final rule is intended to disrupt the longstanding ability of contractors to apply this policy under section 1862(a)(1)(A) of the Act. Section 1862(a)(1)(A) provides that notwithstanding any other provision in the Medicare statute (that is, including section 1847B of the Act), no payment may be made under Part A or Part B for any expenses incurred for items and services that are not reasonable and necessary. Medicare carriers establish local coverage determinations (LCDs), under which coverage for a particular drug is limited to the coverage level for its least costly alternative. If there is an LCD on a particular drug that contains a least costly alternative provision, and the drug is included in the CAP, when the participating CAP physician orders that drug, the drug claim will be paid subject to the LCA policy, rather than the CAP-established price. Both the physician and the drug vendor should be aware of any LCDs that are in effect in a particular jurisdiction. When ordering drugs we ask that the physician be mindful of the fact that the vendor's claim for drug payment will be dependent on the local carrier's coverage policies, including least costly alternative policies. As stated above, under its contract with us, the vendor would need to ship an ordered drug if the vendor believes it will receive a reduced payment because of a carrier payment policy. The vendor may call the physician to discuss the order, but if the physician confirms the order, the vendor must ship it. (The vendor would have the same right to collect an ABN from the beneficiary in this situation, as described elsewhere in this section. In addition, the vendor could appeal the drug claim denial. Further, the vendor may ask the designated carrier for assistance under the dispute resolution process.)

Comment: Some commenters support our proposal that the CAP order may be initiated via a Health Insurance Portability and Accountability Act (HIPAA) compliant phone call or fax with a follow-up written order. The vendor could begin filling the order but wait to finalize shipment until the written order is received. These commenters believe that this process would provide drugs to patients more quickly than if the vendor is required to wait until it has a written order in hand before it begins preparing the order. Additionally, one commenter asked that we clarify that electronic transmission of the drug order between the physician and vendor would be permitted.

Response: We appreciate that commenters supported our proposal. Both the participating CAP physician and the approved CAP vendor will be enrolled Medicare suppliers. As noted elsewhere, the approved CAP vendor will be a covered entity for purposes of the HIPAA rules. If a participating CAP physician meets the criteria under the HIPAA rules, he or she may also be a covered entity. Covered entities must comply with HIPAA privacy and security requirements. Where transmission of protected health information via electronic means would be permitted under the HIPAA privacy and security rules, covered entities may do so. The CAP statute and these implementing regulations are not intended to affect the manner in which HIPAA-compliant communications may occur.

Comment: One commenter requested clarification as to how, if at all,

physicians will be required to incorporate e-prescribing technologies if ordering drugs currently under the Part B program or acquiring drugs through the CAP.

Response: The MMA electronic prescription program provisions apply to the electronic prescription of Medicare Part D drugs for Part D enrolled individuals, not specifically Part B drugs. The MMA provides that not later than one year after the promulgation of final standards for Medicare Part D drugs for Part D enrolled individuals, prescription and certain other related information transmitted electronically can only be transmitted according to the adopted final standards. The Medicare Prescription Drug Benefit final rule (70 FR 4198, January 28, 2005) states that Part D sponsors that participate in the Part D program are required to support and comply with adopted electronic prescription standards. Physicians would not be required to write prescriptions electronically and therefore their participation in Part D electronic prescription drug programs would be voluntary. Those physicians that decide to prescribe Part D drugs electronically, however, would be required to comply with the adopted final standards. We proposed a foundation set of final standards in February 2005 (70 FR 6256, February 4, 2005) and hope to finalize those standards and require compliance by January 2006, when the Medicare Part D prescription drug benefit begins. We will also monitor the program as it develops to determine if some aspects of it could be adapted for use in the CAP drug ordering process.

Content of the CAP Drug Order

We proposed that the physician would transmit the following specific information to the CAP drug vendor from whom he or she has elected to receive drugs. (Abbreviated information could be sent for repeat patients.)

- Date of order
- Beneficiary name
- Physician identifying information: Name, practice location, group practice information (if applicable), PIN and UPIN, Drug name
- Strength
- Quantity ordered
- Dose
- Frequency/instructions
- Anticipated date of administration
- Beneficiary Medicare information/ Health insurance (HIC) number
- Supplementary Insurance information (if applicable)
- Medicaid information (if applicable)
- Shipping address
- Additional Patient Information: date of birth, allergies, Height/Weight/ ICD–9.

We specifically requested comments on this proposed information as well as any additional information that might be necessary.

Comment: We received several comments about the proposed content of the physician's order. Some commenters stated that the proposed items duplicate those submitted on a claim for service and do not reflect the information typically included in a drug order or prescription. *Other* commenters were concerned about compliance with HIPAA guidelines and requested that unnecessary patient-specific information be deleted from the order form. Commenters also stated that the detailed list of order information should be needed only for the initial order for a new patient. They noted that subsequent orders could be greatly abbreviated.

Response: The statute provides that we must establish a process for the sharing of applicable deductible and coinsurance information between the participating CAP physician and the approved CAP vendor. The participating CAP physician is also required to submit a prescription order to the approved CAP vendor to order drugs for an individual patient. The order form information that we proposed in the proposed rule contains information necessary to comply with both of those requirements. It is not possible to link beneficiary-specific information from our claims processing system with the physician's order before the drug vendors compiling the information necessary to prepare the drug order and return it to the physician because it is not possible for a provider to query the system and obtain beneficiary billing information. Allowing suppliers and providers to obtain beneficiary specific information from the Medicare claims processing system could be a violation of beneficiary privacy rules. In addition, the statute specifies that this information will be provided by the physician. The HIPAA guidelines allow the sharing of beneficiary-specific information necessary for treatment purposes. Without needed information, the approved CAP vendor will be prevented from completing the drug order accurately and providing the drug to the participating CAP physician so that the required treatment can be administered to the patient. We are specifying in our regulations that the participating CAP physician will be required to provide the approved CAP vendor complete patient information only for the initial order, or when the information changes (for example, the patient develops a new drug allergy). The approved CAP vendor will specify which information is necessary on a follow-up order.

Comment: One commenter stated that the physician may be uncertain when the patient will be receiving his or her treatment, and thus it may not be possible to determine the anticipated date of treatment with any accuracy. This commenter recommended instead that CMS allow the physician to specify a range of dates when the treatment may be administered.

Response: We agree with the commenter that it may not be feasible for a physician to establish in advance an exact date for drug administration. We will specify that providing the vendor with a range of dates over a 7-day period will be sufficient. We have selected the 7-day timeframe based on our understanding that many of the drugs included in the CAP are used in a treatment regimen that repeats on a weekly basis. The 7-day time period is intended to provide the physician with flexibility to shift the specific date of administration of needed drugs within a specified period without overlapping the next treatment period. When the approved CAP vendor submits its claim for the drug, the vendor will be instructed to include the first day in the 7-day period as the date of service. Because the vendor will not know the actual date the drug is administered before submitting its claim, the date of service will not be used to match the approved CAP vendor's claim with the participating CAP physician's claim. Instead, as described later in this section, a unique number will be used to match the claims.

Comment: Some commenters recommended that CMS eliminate the ''Additional Patient Information'' (date of birth, allergies, height, weight, ICD–9 codes) specified in the potential list of data elements. Information related to height and weight would be used by the physician to determine the dose, and the ICD–9 would be included on the physician's claim form, so the physician would not need to provide it. The commenters stated that this type of information was not typically included in a drug order and that the CAP vendor should not use the information to perform pharmacy functions.

Response: Based on our decisions regarding the approved CAP vendor's ability to break up shipments in appropriate circumstances, our conclusion that approved CAP vendors may directly appeal the denial of their

drug claims, and the fact, with limited exceptions, that approved CAP vendors must ship CAP drugs upon receipt of a prescription order, we believe it is important for approved CAP vendors to have the information specified above. For example, ICD–9 information may help an approved CAP vendor assess whether it should seek to obtain an ABN from the beneficiary. Dosing information will help an approved CAP vendor determine whether it can appropriately split a prescription order into separate shipments. Patient date of birth is required by the Medicare claims processing system and is a required field on the claim form.

Comment: Another commenter noted that because the proposed order form information requested the frequency with which the drug was to be given, the physician was being required to submit a treatment and delivery schedule that would be difficult to comply with for some individuals, such as ''snowbirds'' who obtain their drugs from multiple locations.

Response: The expected frequency of drug administration is needed so that the approved CAP vendor can determine how often the drug will be administered, the amount of drug to ship at one time and the appropriate timing of the shipments. Should the participating CAP physician need to deviate from the anticipated schedule, that can be accommodated. However, if the change in the administration schedule will require the approved CAP vendor to ship more drugs, or ship them on a different schedule, the participating CAP physician will need to inform the approved CAP vendor.

Comment: Another commenter pointed out that a physician may have several practice locations and that it is important that a physician's practice location be included in the information that the physician will provide to the vendor. (Additional elements of this comment are addressed in the section below on shipping.)

Response: A physician's practice location and his or her shipping address are both included as required data elements in the CAP drug order.

Comment: One commenter suggested that the order form should also include beneficiary contact information (phone number, billing address) and credit card information to enable the vendor to collect the beneficiary's coinsurance.

Response: We will add beneficiary's address and phone number to the required list of data elements to enable the approved CAP vendor to mail the bill to the beneficiary and to call him or her should there be an error in mailing to correct the address. The statute requires that we develop a process for the sharing of information between the participating CAP physician and the approved CAP vendor related to the payment of deductible and coinsurance. We have interpreted this to mean beneficiary contact information, Medicare information, and third party insurance information. We will not ask the physician to collect the beneficiary's credit card information and share it with the vendor because it is not information necessary to complete the drug ordering process, nor is it part of any supplemental insurance coverage that the beneficiary may have. Should the beneficiary choose to pay his or her share of the coinsurance via a credit card, he or she can provide that information directly to the approved CAP vendor after receiving a bill.

Comment: One commenter requested that CMS begin using the National Provider Identifier (NPI) as soon as possible, but not later than May 2007 (the implementation date of the NPI).

Response: We plan to adopt the National Provider Identifier for use by the CAP as soon as it is available.

In this interim final rule, we have made revisions to the required list of drug order information. We are adding that ''a range of dates not to exceed 7 days'' may be noted if the physician is uncertain of the specific date the drug will be administered. In addition, we are adding beneficiary's address and phone number; physician's shipping address, the National Provider Identifier, and patient's gender to the list. The information on patient's gender is required for claim submission and was inadvertently omitted from the list in the proposed rule.

The required list of drug order information will be the following:

- Date of order
- Beneficiary's name, address, and phone number
- Physician's identifying information: Name, practice location/shipping address, group practice information (if applicable), PIN and UPIN (NPI when available)
- Drug name
- Strength
- Quantity ordered
- Dose
- Frequency/instructions
- Anticipated date of administration (Range of dates not to exceed 7 days)
- Beneficiary Medicare information/ Health insurance (HIC) number
- Supplementary Insurance info (if applicable)
- Medicaid info (if applicable)
- Additional Patient Information: date of birth, allergies, Height/Weight/ ICD–9 code
- Gender

In the March 4, 2005 rule, we proposed that the participating CAP physician could place an order for a beneficiary's entire course of treatment at one time, but that the approved CAP vendor could split the order in to appropriately spaced shipments. The approved CAP vendor would create a separate prescription order number for each shipment and the physician would track each prescription order number separately and place the appropriate prescription order number(s) on each drug administration claim. The physician would have the ability to modify the course of treatment and submit a separate prescription order as necessary.

Comment: Many commenters supported our proposal that the physician should be able to place one order for the entire course of treatment because it reduces the burden of CAP ordering on both physicians and vendors. However, some commenters supported, while others opposed, our proposal that the vendor, at its discretion, could split the order into different shipments. Those opposed were concerned that some shipments might not arrive timely and needed treatment could be delayed to the beneficiary. Another commenter stated that the vendor should not be allowed to ship more than one visit's drugs at one time, because many physicians' practices will not have the space to store additional inventory.

Response: We plan to implement our proposal and allow the approved CAP vendor to split shipments. We believe the commenters' concerns regarding potential delays in split orders are adequately addressed by the routine and emergency delivery timeframes discussed elsewhere in this interim final rule because the approved CAP vendor will still be required to deliver the initial dose of the drug within two business days for routine delivery or one business day for emergency delivery. Delivery timeframes are discussed in more detail later in this section. We will require that if the approved CAP vendor opts to split shipments, the approved CAP vendor must notify the physician in writing that it is a split shipment and of the schedule for delivering subsequent shipments. We will also require that incremental shipments must arrive at least two business days before they are expected to be administered to a patient (as noted on the prescription order). The two-business-day time period is consistent with the routine delivery timeframe, and should ensure that the physician has sufficient time to obtain

the drugs under the emergency delivery timeframe in the event that they are not delivered within the routine delivery timeframe. In response to the commenters who were concerned that physicians may not have the space to store an entire course of treatment and wanted drugs shipped incrementally, we will allow the physician to specify to the approved CAP vendor whether or not he or she can accommodate larger shipments based on a prescription order for a course of treatment, if the approved CAP vendor desires to do so. The participating CAP physician could also control the amount of drugs that were shipped by ordering smaller quantities of drugs at one time.

Comment: Another commenter requested clarification of whether one prescription order number will be assigned for each patient or whether multiple prescription order numbers will be assigned (that is, one for each drug). These commenters proposed that each drug should have a separate prescription order number, which would include a unique patient identification number. This number should be attached to the drug to decrease the possibility of patient billing errors.

Response: We will require that each dose of a drug must have a separate prescription order number in order to facilitate claim matching and approved CAP vendor payment. The prescription order number will be unique to a dose of a drug to be administered to a particular beneficiary in one setting. It will include an approved CAP vendor specific identification number, the HCPCS code for the drug, and a randomly generated number. The beneficiary information will be provided by the HIC number that will be entered separately on the claim form. Because of privacy concerns we are not making the HIC number part of the prescription order number.

Drug Vendor's Prescription Order Process

In the proposed rule, we specified that the approved CAP vendor would receive the prescription order from the physician, check the physician's CAP eligibility from a list provided by the designated carrier and verify the beneficiary's Medicare eligibility with the designated carrier.

After those checks were completed, the approved CAP vendor would generate a prescription order number that would include the approved CAP vendor's assigned identification number and the drug HCPCS code. The approved CAP vendor would assemble the prescription order and prepare it for shipping. The approved CAP vendor would ship the drug to the participating CAP physician using a delivery method specified by its contract with us.

Comment: One commenter requested additional information on the process that the vendor will use to verify the patient's Medicare eligibility with the designated carrier.

Response: We anticipate that the approved CAP vendor will contact the designated carrier by telephone to verify that the beneficiary has current Part B coverage. As well as being able to verify the beneficiary's coverage the carrier may also know whether another insurer is primary to Medicare.

Comment: One commenter requested clarification on whether the vendor would ship and bill drugs at the HCPCS level or the NDC level. The commenter believes that bidding, ordering and claims processing should all occur at either the NDC level or the HCPCS level.

Response: Drug ordering and claims processing will occur at the HCPCS level. Billing will occur at the HCPCS level, as occurs currently for Part B drugs. The drugs being furnished by the vendor will be identified at the NDC level during the bidding process. We intend for the approved CAP vendors to be able to furnish CAP drugs in a manner that minimizes waste, reshipping and risk of diversion. Noting that section 1847B of the Act states that competition shall occur, for multiple source drugs, for ''at least one competitively biddable drug * * * within each billing and payment code within each category,'' we encourage approved CAP vendors to submit bids in a manner that will provide them with flexibility in terms of providing more than one package size or formulation within a HCPCS code that contains multiple NDCs. The approved CAP vendor will be required to specify the NDCs that it will be providing for a particular HCPCS code for multi-source drugs. This information will be available to the physician when he or she chooses to participate in the CAP and may be used by the physician when selecting an approved CAP vendor.

Comment: Some commenters suggested that CMS develop a contingency plan for use in cases where the CAP runs into ongoing operational challenges that significantly delay drug delivery to oncologists and jeopardizes timely treatment of cancer patients. Under these procedures, commenters recommended that CMS consider permitting physicians to temporarily revert to billing under the ASP system.

Response: Should a drug delivery problem develop with one of our approved CAP vendors, we will work with the approved CAP vendor through the designated carrier's dispute resolution process to promptly restore dependable service. If, despite all of our efforts to resolve the problem, we were to make a decision to terminate an approved CAP vendor for failure to comply with its contractual obligations, we would allow the affected physicians to switch to another approved CAP vendor who could assume the workload. Those physicians would also be given the option to revert to billing under the ASP system for the remainder of the year. In addition in situations where the emergency restocking criteria apply, the physician could use his or her own inventory and get a replacement from the vendor.

Submitting Prescription Order Number

Once a shipment is received from the approved CAP vendor, the participating CAP physician would store the drug until the date of drug administration. When the drug is administered to the beneficiary, the physician or his or her staff will place the prescription order number for each drug administered on the claim form submitted to the regular Part B carrier. Similarly, when the approved CAP vendor bills Medicare for the drug it shipped to the physician, it will place the relevant prescription order number on the claim form submitted to the designated carrier. We note that the electronic version of the Medicare carrier claim form has space for a series of prescription numbers, which we have not used previously for Part B drugs.

In the proposed rule, we stated that vendors and physicians who elect to participate in the CAP will need to be capable of submitting these prescription order numbers to us in their claims processing systems. If physicians and potential vendors are not already billing other payors using prescription numbers, they will need to work with their internal information systems staff or practice management software vendors to make the necessary changes to submit these data elements to Medicare in a manner consistent with HIPAA transaction guidelines for capturing prescription numbers.

Comment: One commenter indicated that to accommodate the new data element, his claims processing software would need to be modified. Another commenter requested that CMS issue billing instructions that instruct physicians regarding the appropriate HIPAA compliant fields on the 837 and CMS 1500 forms to use in submitting the prescription order number on their claims.

Response: As stated in the proposed rule, we are aware that our proposed claims processing system will require some physicians to modify their claims processing software if they do not already have the capability to submit claims with prescription numbers. After publication of the interim final rule, we will issue billing instructions with guidance about the appropriate fields on our electronic and paper claim form to use in billing.

Claims Processing Methodology

Our claims processing methodology will use the prescription order number to match the two claims and authorize payment to the approved CAP vendor. Payment to the approved CAP vendor will be dependent upon the filing of the drug administration claim by the physician, and the physician's claim being approved for payment by our claims processing system.

Comment: Some commenters stated that requiring the physician to put the prescription number on the claim form will complicate the billing process for the physician. In addition, one commenter believes that a separate billing process will be required for drugs billed under the emergency replacement process (discussed below), and that the physician will also require another process for drugs billed under the ''furnish as written'' methodology (discussed below). They suggested that in order to reduce physicians' cost, CMS should simplify the process so that one billing system could be used for all CAP drugs.

Response: We are aware that adding the prescription order number to the claim form will be an additional activity required for physicians who elect to participate in the CAP. Under the CAP program as we are implementing it, the use of the prescription order number is necessary to allow our claims processing system to match the physician's claim for administering the drug with the approved CAP vendor's claim for the drug. The physician's process for billing a drug administration claim for a CAP drug acquired through the regular ordering process and one acquired through the emergency replacement process will be essentially the same, except that the physician will add an additional modifier to the claim form indicating that the drug was acquired under the emergency replacement provision. The modifier is necessary to enable the carrier to identify the replacement claims. For drugs that the participating CAP physician acquires under the ''furnish as written'' process, the physician will bill for the drug and the administration under the ASP system that he or she currently uses. In these situations, the physician will place a modifier on his claim form that will allow him to bill for both the drug and the administration in that circumstance.

''Furnish As Written''

We proposed to allow the physician to obtain a drug under the ASP system in ''furnish as written'' cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and that formulation is not provided by the approved CAP vendor. This situation closely parallels dispense as written (DAW) prescription orders that are used in retail pharmacies or other locations where a prescription is written and the physician wants the pharmacist to fill the prescription with a particular brand of the drug. In cases when the approved CAP vendor does not furnish a specific formulation of a drug or a product defined by the product's NDC number, and the physician has determined that it is medically necessary to use another brand of product within the HCPCS or an NDC that is not being furnished by the approved CAP vendor, the physician could purchase the product for the beneficiary and bill Medicare for it using the ASP system. The physician would be instructed to place a ''furnish as written'' modifier on his or her claim form and bill his or her Medicare carrier for the drug and the administration fee. The modifier would alert the carrier to allow the physician to bill under the ASP system in this case. We proposed that the physician's carrier would, at times, conduct a post payment review of the use of the ''furnish as written'' modifier. If the carrier determined that the physician had not complied with ''furnish as written'' requirements and that a specific NDC or brand name drug was not medically necessary, the carrier could deny the claim for the drug and the administration fee.

We established this method of alternative payment for a competitively biddable drug under proposed § 414.906(c)(2)(ii) of our regulations.

Comment: Commenters were generally in favor of the ''furnish as written'' proposal. However, some commenters who support the ''furnish as written'' provision felt it should be simplified and made easier for physicians to use or that CMS should create other options for the physician to accommodate clinical differences among patients who are on the same treatment regimen. Other commenters were concerned that the ''furnish as written'' option might be overused and subject to gaming by some physicians and manufacturers who were seeking a way to opt out of the CAP when it was financially favorable.

Response: We are implementing the ''furnish as written'' option as described in the proposed rule. The ''furnish as written'' option is intended to be used only occasionally in limited circumstances where a patient's medical condition requires a particular formulation of a drug at the NDC level—it is not intended to be used in routine situations as a means to circumvent the normal CAP ordering process. An example of a situation when the ''furnish as written'' option would be appropriate is where a participating CAP physician is treating a patient with a documented allergy to certain excipients or preservatives who requires a specific formulation of a product that the approved CAP vendor does not furnish as a part of its CAP contract. In this case, documentation of the allergy is a justification to use another product. However, this documentation must be maintained in the patient's medical record. Use of the ''furnish as written'' modifier will permit the physician to bill under the ASP system in this limited circumstance even though the physician has elected to participate in the CAP. Physicians who believe the ''furnish as written'' provision and the emergency replacement provision along with the drugs available through the regular CAP drug ordering process will not meet their patients' clinical needs may choose to continue billing under the ASP system rather than electing to participate in the CAP.

Comment: One commenter requested that CMS provide more guidance on what is meant by the term ''specific formulation.''

Response: A patient known not to respond appropriately to a certain formulation of a product may require a specific formulation of a product that is still within the same HCPCS, but not furnished under the approved CAP vendor's CAP contract because the approved CAP vendor submitted a bid to provide a different NDC within the HCPCS code. Documentation of treatment failure or adverse effects from specific formulations may provide justification to use another product (for example, if an approved CAP vendor was contracted to provide HCPCS code, J9260, which represents the drug Methotrexate Sodium). Several different manufacturers produce this drug, and it may be formulated with or without a preservative. Each product within HCPCS code J9260 has a specific NDC number. If the physician determines that it is medically necessary to administer the preservative-free

methotrexate injection for the patient, but the approved CAP vendor did not offer that product's NDC, the physician would be able to purchase the specific drug for the patient and bill for it under the ASP system by using the ''furnish as written'' modifier.

Comment: Another commenter asked whether the vendor might be able to discontinue providing a drug mid-year if it discovered that the CMS CAP payment amount was not covering its costs. Other commenters asked what would happen if a CAP vendor had trouble obtaining a CAP drug or it became unavailable.

Response: Once a vendor elects to participate in the CAP and decides for a multi-source drug which formulation of the drug (NDC) to provide within a HCPCS code, the approved CAP vendor will not be able to switch NDCs mid-year should the price increase. However, as discussed in further detail in section C.3 below, the statute provides for adjustments to the reimbursement for CAP drugs in certain circumstances in response to changes in the approved CAP vendor's reasonable net acquisition costs.

Mid-year changes will only be allowed should an NDC become unavailable or go through a period of short supply. We expect that the need for substitutions or changes will occur rarely. Although we would like to incorporate flexibility into this process so that an approved CAP vendor may react quickly to substitute an appropriate product, we are concerned that an unrestricted substitution process could have negative consequences. Although many multi-source products can be considered therapeutically equivalent, in some situations, differences in packaging, preservatives, fillers and dissolution rates for powders that require reconstitution may have clinical impact on the beneficiary and work flow impact on those who are preparing and administering the drug. If a vendor is facing a situation where a certain CAP NDC cannot be supplied, but a comparable product can be sent and the approved CAP vendor is willing to accept payment for that product at the CAP rate, the approved CAP vendor must contact the physician's office in order to have the office approve the substitution. This procedure is intended to be used occasionally and is not intended to justify a situation where an approved CAP vendor repeatedly calls a physician to seek approval for a less costly item. If the physician and the approved CAP vendor are unable to resolve short term issues around drug availability and substitution on their own, they may ask the designated carrier's dispute resolution staff for assistance.

In a situation where an item becomes unavailable for an extended period of time (more than 2 weeks), the approved CAP vendor must identify a replacement product or products, obtain CMS approval to do a long-term substitution from the designated carrier's medical director, and notify all physicians who have elected to receive CAP drugs from that approved CAP vendor in writing of the change. Payment for the substituted drug will be at the CAP bid price; the vendor may seek price adjustment at the following annual price adjustment period. Physicians who have elected to participate with that approved CAP vendor will be notified before such a change is made.

We request comments on refinement and alternatives to the short and long term substitution processes.

Comment: Other commenters stated that a physician who uses the ''furnish as written'' methodology to obtain needed drugs for his or her patients may be charged more by a non-CAP wholesaler because its volume has declined because of the physician's participation in the CAP. They propose instead that the physician be reimbursed for his or her actual acquisition costs of the drug instead of paying them under the ASP system.

Response: We do not have the statutory authority to allow physicians to be paid their actual acquisition costs for Part B drugs in this situation. Physicians have the choice of obtaining drugs under the ASP system or of obtaining them from the approved CAP vendor. The occasional need to purchase drugs outside of the CAP and which approved CAP vendor to select will need to be factored into the physician's decision to participate in the program. If an approved CAP vendor provides many of the drugs at the NDC level that a physician routinely uses, the physician should need to rely on the ''furnish as written'' provision rarely.

Comment: Some commenters questioned why the carrier would be conducting a retroactive review of the physician's use of the ''furnish as written'' option, because that would permit the physician to buy and bill the drugs under the ASP system. The commenters asserted that because physicians' ASP claims are not routinely reviewed by the carrier, physicians' use of this provision in the CAP should not be either. Another commenter stated that if the physician's use of the ''furnish as written'' modifier was denied on the basis of post payment review, this could trigger an obligation to appeal on the part of the physician. Some commenters stated that although physicians are accustomed to supporting medical necessity of their orders, historically this has not involved a comparison of clinical appropriateness of one drug within a HCPCS code with that of another.

Response: The statute is clear that for multiple source drugs, the approved CAP vendors are required to supply at least one drug NDC in each HCPCS code. It is also clear that physicians must elect the CAP for an entire drug category. As such, we believe it is appropriate to ensure physicians employ a ''furnish as written'' instruction only when medically necessary. As a result, it is important that physicians document the necessity of a particular formulation of a drug in the medical record. If the physician's use of the ''furnish as written'' option is denied by the local carrier, it will be up to the physician as to whether to appeal because payment to the approved CAP vendor will not be affected.

Comment: Some commenters from physicians' groups and some commenters from potential vendors have expressed an interest in the vendor's providing the needed drug in a ''furnish as written'' situation. Many of the physician commenters suggested that the vendor should be required to provide different formulations of a drug other than the one bid, while some potential vendors have suggested that they be given the option to provide it.

Response: As indicated above, we are implementing the ''furnish as written'' provision described in the proposed rule, but we have moved it as an element to § 414.908(a)(3) as this placement is more appropriate. The CAP statute and section 1861(s)(2)(A) of the Act, as amended by Section 303(i) of the MMA, contemplate that approved CAP vendors can submit claims and be paid for drugs only when they are provided through the CAP. Thus, we do not believe the commenter's proposal to allow the approved CAP vendor to provide the drug under the CAP in ''furnish as written'' situations is feasible.

Timeframes for Routine and Emergency Shipment

Section 1847B (b)(2)(A)(i)(II) of the Act requires that approved CAP vendors have sufficient capacity to acquire and deliver drugs in a timely manner within the geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days each week. However, the statute does not provide specific definitions of these timeframes. In addition, as noted previously, the

statute requires that the approved CAP vendor may not provide drugs to a participating CAP physician unless the physician submits a written prescription order to the approved CAP vendor.

We proposed that a CAP prescription order could be initiated by telephone and followed up with a written order. We proposed that the delivery time period would begin when a drug order was received by the approved CAP vendor and would end at the time of delivery to the physician's office or other intended setting. We proposed that routine shipments of drugs furnished under the CAP would occur within a one- to two-business-day time period and that the duration of the delivery time period must not exceed the drug's stability in appropriate shipping containers and packaging. Emergency drug orders would need to be furnished on the next day for orders received by the approved CAP vendor before 3 p.m. (approved CAP vendor's local time). We requested comment on how to define timely delivery for routine and emergency drug shipments and on the feasibility of requiring a shorter duration for routine delivery of CAP drugs and of providing same-day deliveries for orders received for emergency situations.

Comment: Comments on the definition of an appropriate timeframe for deliveries defined a relatively narrow potential timeframe. The shortest recommended timeframes were daily, or up to twice daily deliveries for emergencies, while the longest timeframes were three to five business days. Most comments suggested a one- or two-business-day timeframe for delivery in routine cases and overnight delivery for emergencies. The relatively short turn around time assumed a ''clean'' order—one without patient safety, logistical, or payment problems. One comment suggested category-specific timeframes.

Response: At the program's start, we plan to implement a two-business-day timeframe for routine deliveries and a one business day timeframe for emergency deliveries, except for deliveries to certain U.S. territories in the Pacific, as discussed below. However, these timeframes shall not exceed the drug's stability in appropriate shipping and packaging as defined by manufacturer's labeling, drug compendia, or specialized drug stability references used in the practice of pharmacy or drug distribution. If drug stability necessitates a shorter shipping timeframe, or specialized shipping conditions, the approved CAP vendor must comply with them. For example, some drugs may require insulated packaging and/or cold-packs to prevent exposure to temperature extremes during shipping. Furthermore, we are aware that some drug products are shipped by express carriers in such conditions and are marked ''perishable.''

The delivery timeframe begins when a complete CAP prescription order is transmitted from the participating CAP physician to the approved CAP vendor. The participating CAP physician may begin this process with a phone call to the approved CAP vendor, but must follow-up with a written prescription order within 8 hours for routine deliveries. For emergency deliveries, a telephone order must be immediately followed with a written prescription order. If the participating CAP physician does not meet these deadlines for sending the written prescription order, the emergency or routine delivery timeframes are delayed accordingly until the written prescription order is received. The delivery timeframe ends when the drug is received at the participating CAP physician's office. A written prescription order may be transmitted by FAX, e-mail, or mail, subject to applicable HIPAA privacy and security requirements, and any applicable State pharmacy laws. As specified earlier, all communication between the physician and the approved CAP vendor must be conducted in accordance with applicable HIPAA privacy and security requirements, and with any applicable State pharmacy laws.

The approved CAP vendor is responsible for complying with the timeframes for routine and emergency delivery, as well as with the requirements for appropriate shipping conditions for drugs. If the participating CAP physician is dissatisfied with the vendor's compliance with the shipping timeframes or the manner in which drugs are being shipped, the physician should address the issue by means of the vendor's grievance procedure. If the two parties are unable to resolve the situation to their satisfaction they may ask the designated carrier's dispute resolution staff for assistance.

We believe that the two-business-day period for most routine prescription orders will provide an opportunity to resolve many common problems that can occur with transmitted drug orders, like legibility or poor transmission quality, simple clarification, etc. The two-business-day timeframe also provides a greater window of opportunity for approved CAP vendors and participating CAP physicians who are in different time zones to interact. The intent of the two-business-day timeframe is to balance the cost of shipping with potentially changing clinical requirements of a patient population and the requirement that needed drugs must be available promptly to the physician. The intent of the one-business-day timeframe for emergency deliveries is to accommodate the physician's need for more rapid delivery of drugs in certain clinical situations where the patient's rapidly changing condition requires it with the vendor's ability to ship the drug and have it delivered promptly in a nationwide delivery area. The emergency delivery option is not intended to be used routinely. It should be reserved for those situations when the patient's need for the drug could not have been accommodated under the routine delivery timeframe. At a minimum, under both the routine and emergency delivery timeframes, we expect vendors to accept new prescription orders until at least 5 p.m. (vendor's local time) on business days and we expect physicians to be able to take receipt of deliveries on business days until at least 5 p.m. (physician's local time). For emergency deliveries, we expect that the vendor will make the necessary adjustments in order to be able to prepare the drug for shipping and to deliver it the next business day. We note that the physician and the vendor will each need to be mindful of the time zones within which each are located. CAP participating physicians and approved CAP vendors operating in different time zones will need to be aware of cut-off times for placing orders and coordinate appropriately. We also point out that in some cases, two-business-day shipping may actually require several calendar days of transit during weekends and the commonly observed Federal holidays of New Years, Memorial Day, Independence Day, Labor Day, Thanksgiving, and Christmas. Some degree of coordination between the vendor and the physician's office will be required in those situations, and we stress that the drugs shipped must be packaged in a manner to preserve product integrity during shipping, for example to withstand temperature changes during shipping.

Specific examples appear below.

Example 1: The two-business-day timeframe for routine deliveries means that the physician's office may expect to receive a CAP prescription order on the second business day after it was placed. Therefore, an order received in the approved CAP vendor's office on a Monday by 5 p.m. (Vendor's local time) would arrive in the physician's office no later than Wednesday at 5 p.m. (physician's local time). Orders placed on Friday would arrive no later than

Tuesday. (Note: These orders must comply with the process specified above if the initial prescription order is placed by phone, the follow-up written prescription order must be received within 8 hours for routine deliveries.

Example 2: The one-business-day timeframe for emergency deliveries means that an order received in writing in the approved CAP vendor's office at 1 p.m. (approved CAP vendor's local time) on a Wednesday must be received by the physician in his or her office by 5 p.m. Thursday (physician's local time).

These are minimum standards, and nothing precludes the approved CAP vendor from using faster services and alternative delivery times (for example, Saturday delivery) when these services are available and appropriate. If an approved CAP vendor routinely offers faster shipping services, the approved CAP vendor should inform the physician of their availability.

We believe that the timeframes defined above, are practical and apply to the vast majority of situations that will be experienced at the program's implementation. However we anticipate that there will be occasional situations where a CAP vendor will not be able to furnish a drug to an office because the drug is needed sooner than the available delivery timeframes allow. In these situations, the vendor may elect to use the emergency resupply procedures described later in this section, if the situation complies with the relevant criteria.

The CAP was not designed to supply drugs that would be needed in emergencies such as acute care settings. However, we believe that even with a national program, an approved CAP vendor with multiple distribution points can provide turnaround in less than one to two business days in many situations.

Our discussions above reflect our anticipation that most shipments will occur within the continental United States. However, the initial CAP competitive acquisition area also includes Alaska, Hawaii, and the United States Territories. (We note that the United States territories in which Medicare pays for services are defined in § 400.200 of our regulations as the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.) We believe that shipping to Alaska, Hawaii and the eastern territories (that is, Puerto Rico and the U.S. Virgin Islands) within the timeframes described above is feasible, and we will require the vendor to ship to those areas within the standard routine and emergency timeframes. However, we are concerned that based on available information on shipping costs and delivery time periods, these timeframes may be too narrow for territories in the Pacific (that is, Guam, American Samoa, and the Northern Mariana Islands). Although the CAP drug vendor may be able to meet these timeframes in certain cases, the financial cost of doing so could greatly exceed the vendor's regular delivery costs. Therefore we are setting the standard delivery timeframes for the Pacific Territories, (Guam, American Samoa, and the Northern Mariana Islands) based upon delivery information available from commercial shippers, to be seven business days for routine delivery, and five business days for emergency delivery.

As we gain operational experience with CAP, we would like to explore being able to provide more rapid order turnaround, particularly in urgent situations. We are requesting comments on shortening the routine shipping timeframe to one business day and for requiring shorter shipping timeframes for emergency orders, especially the logistical and cost factors involved for same day or overnight delivery with early morning drop off. We are specifically interested in examples of circumstances when it would apply, who would be responsible for the cost of more rapid shipping methods, how unnecessary express shipping could be avoided, how approved CAP vendors who frequently missed timely delivery deadlines for same-day shipments would be sanctioned, and how those who abuse express shipments by seeking express delivery unnecessarily would be sanctioned. We ask that commenters address whether same day shipping can provide any real benefit to beneficiaries, or if overnight delivery with early morning drop-off is sufficient. We also welcome comment on the practicality of the timeframes set above for the Pacific territories and other areas outside of the continental United States. We seek input on whether the timeframes in general should be adjusted and whether the timeframe for delivery to the Pacific territories are reflective of current delivery timeframes used by other drug distributors shipping to those locations.

Comment: Some commenters stated that the CAP requirements should specify that the physician could return without penalty any drug that arrived in damaged condition or whose integrity the physician believes may have been compromised. The commenters requested that the approved CAP vendor not be allowed to require the physician to seek a remedy from the company that delivered the product.

Response: At the time a shipment of CAP drugs is received at the participating CAP physician's office, we expect that the individual who takes receipt of the order will be responsible for inspecting the external condition of the package(s) and will be given an opportunity not to accept the shipment on the basis of potential compromise of the product's integrity or damage during shipping. This initial inspection is not meant to be a final inspection, and we realize that some types of damage or compromise in integrity may only become apparent after the package is opened and the drug is being readied for use. A physician may return a drug product to the approved CAP vendor at any time if the product's integrity is in question. We recommend that returns of product on the basis of product integrity be coordinated with the approved CAP vendor so that the approved CAP vendor may take appropriate action to follow up on the reason for the breach of integrity. (Delivery requirements are also addressed in section II.C.2 of this interim final rule, ''Bidding Entity Qualifications.'')

Resupply Option for Emergency Situations

We proposed to implement the criteria specified in section 1847B(b)(5) of the Act that governs when in emergency situations, drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians. The four criteria contained in the Act are: (1) The drugs were required immediately. (2) The physician could not have anticipated the need for the drugs. (3) The approved CAP vendor could not have delivered the drugs in a timely manner. (4) The drugs were administered in an emergency situation. In section II.C.2.a. of this interim final rule, we requested comment on how to define timeframes for timely delivery, for emergency delivery, and for additional criteria we could use to define the replacement process.

We proposed that in emergency situations that met the criteria outlined above, the physician would treat the Medicare beneficiary with a drug from his or her own stock. After administering the drug to the beneficiary, the physician would prepare an order, identifying the drug as an emergency replacement for a drug already administered to the beneficiary. This notation could involve the use of a modifier to a HCPCS code, or another standardized means of incorporating the information into a claim. The approved CAP vendor would prepare the drug order, assign the unique transaction

identification (or prescription) number, and ship the replacement product to the physician. When the drug was received from the approved CAP vendor, the physician would return the drug to his stock. Both the physician and the approved CAP vendor would bill normally for the drug or its administration as applicable. We anticipated that the physician's carrier would, at times, conduct a post payment review of emergency drug replacement in order to determine whether physicians were complying with conditions for emergency drug replacement.

Comment: Some commenters were concerned that neither the statute nor the proposed rule defines ''emergency,'' and encouraged CMS to provide a definition in the final rule. They also questioned whether the definition of emergency would cover situations when the approved CAP vendor failed to deliver a needed drug within specified timeframes. Some commenters proposed that CMS define an emergency to allow any situation the physician felt required immediate attention would meet the criteria.

Response: We believe that the definition of emergency to be used in the emergency replacement provision should be one that enables the physician to use his or her clinical judgment to determine when his or her patient needs immediate treatment. We will define an emergency for purposes of this provision as a situation determined by the physician's clinical judgment to be an unforeseen situation and require prompt action or attention. Should the more expansive definition of the term appear to be causing overuse of this provision, we will consider adopting a more limited interpretation in the future. We will require that physicians ordering drugs under this provision continue to comply with the 14-day prompt filing requirement. The approved CAP vendor will provide a replacement drug from the same HCPCS category that it is providing in the CAP.

In determining whether the patient's need for the drug complies with the emergency replacement criteria, the physician will assess whether all of the criteria are applicable and will document the patient's medical record accordingly. If the approved CAP vendor's emergency delivery timeframe would result in delivery of the drug after the time necessary to meet the patient's clinical need, it shall be considered that the drug could not have been delivered timely. (Refer to the previous section on delivery times for more detail on the definition of routine and emergency deliveries.)

Comment: Another commenter expressed concern about enforcement, especially any documentation requirements for physicians using the emergency resupply provision.

Response: The process for billing for drugs ordered under the emergency resupply provision will be very similar to the regular CAP billing process, with an additional modifier that the physician will add to the claim. The physician will be expected to maintain documentation in the patient's medical record to verify that he or she complied with the criteria governing the resupply provision.

Comment: One commenter suggested that CMS design the CAP ordering process so that the physician could obtain extra doses of CAP drugs from the approved CAP vendor to keep in his or her inventory should the need arise to administer them to Medicare beneficiaries in an emergency situation. This process would be in addition to the process specified under the emergency resupply option.

Response: The statute does not directly address whether an alternative method for emergency drug replacement is permissible. However, it contemplates a beneficiary-specific order, and states that the approved CAP vendor shall not deliver drugs to the physician except upon receipt of the prescription order and such necessary data as may be required by the Secretary to carry out section 1847B of the Act. However, the statute provides for the replacement of drugs taken from a physician's own inventory in an emergency situation where the physician has administered drugs from his or her own stock. In that case, where the emergency resupply criteria are met, the participating CAP physician can replace the drugs that were used from his or her own inventory by means of an order to the approved CAP vendor. Although we recognize the commenters' concerns, we are also concerned about the potential for abuse if a stock of the approved CAP vendor's drugs was placed in physician's offices for use only by CAP patients in very limited circumstances. We believe because of potential program integrity and drug diversion concerns that the emergency replacement provision specified in the statute is the more appropriate way of providing needed drugs to beneficiaries when the patient's clinical condition does not allow time to obtain the drug from the approved CAP vendor.

Delivery of the CAP Drugs

As we specified in the proposed rule under § 414.906(a)(4) of our regulations, approved CAP vendors would deliver drugs directly to physicians in their offices. Although the statute allows us to provide for the shipment of drugs to other settings under certain conditions, we did not propose to implement the CAP in alternative settings at this time.

Comment: A commenter pointed out that a physician may have several practice locations. If the patient should change his or her site of treatment from the one to which the vendor originally shipped the drug, the physician will need an appropriate way of transporting the drugs from one location to another. Some potential vendors expressed concern that drugs could be improperly moved to an alternative location and that, as a result, spoilage and breakage could occur. They expressed concern that since the vendor retains ownership of the drug until it is administered to the beneficiary that they could be held liable if the drug deteriorates and is administered to the beneficiary in substandard condition.

Response: We recognize that a physician or group of physicians may maintain multiple office locations and, as a result, may desire to administer drugs to patients at any one of these multiple locations. Under the CAP, we will require the physician practicing individually, as well as the physician who is practicing as part of a group, to provide the address at which business will be conducted as part of the CAP election process. In the March 4, 2005 rule, we proposed that the vendor provide the ordered drugs to the address that the physician(s) specified on the election form. At this time, it is not a uniform requirement that physicians with multiple practice locations be issued a unique practice identification number (UPIN); therefore, in this interim final rule, we are expanding the reporting information on the election form to allow physicians to provide multiple addresses if they will be administering CAP drugs in multiple locations. We have also revised § 414.908(a)(3)(v) to add the physician's shipping address to the information that the physician will provide to the vendor on the prescription order. In response to the concern expressed by potential vendors about the possible damage to CAP drugs if they are transported by the physician, we will require that physicians must have CAP drugs shipped directly to the location at which they plan to administer them. The physician may not transport CAP drugs from one location to another. We are adding this requirement to the regulations at 414.908(a)(3)(xi). We understand that there may be occasions where a physician may currently transport drugs purchased under the

ASP system in order to administer them to Medicare beneficiaries in their homes. We seek comment on how this could be accommodated under the CAP in a way that addresses the product integrity concerns expressed by the potential vendors.

Storing the CAP Drugs

We proposed that the physician's office staff would receive the CAP drug(s) and store them until the time of administration. Although the statute discusses a patient-specific drug ordering process, it does not address the methods that may be used to store and inventory drugs in an office or clinic setting, or the potential burden associated with storing a patient's CAP drugs separately from other drugs. We believe that less burdensome alternatives to keeping separate inventories exist; however, any alternatives would be required to maintain program integrity and product integrity and to minimize the risk of diversion and medication errors. We do not believe that separate physical storage of CAP drugs is required. However, we proposed that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained. We requested comment on additional requirements that we should impose on maintaining CAP inventory.

We also proposed that if for some reason the drug could not be administered to the beneficiary on the expected date of administration, the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law. The notification would also serve to inform the vendor not to submit a claim for the drug. If the vendor and the physician agreed that the drug could be maintained in the physician's inventory for administration to another Medicare beneficiary at a later time, the physician would generate a new order form at that time. Included in the order would be a notation that the drug was being obtained from the physician's inventory of the vendor's drugs and that the vendor need not ship the drug.

Comment: Some commenters, responding to the suggestion that CAP drugs would not need to be separately physically maintained, indicated that this would not allow the physician's staff to determine visually the amount of stock on hand and for which patient it was intended. Another commenter stated that the physician would actually need three separate inventory areas (for non-CAP drugs, for CAP drugs and for CAP emergency drugs) and doing so would require additional storage space, and could increase the risk of drug administration and claims processing errors.

Response: As we stated in the proposed rule, the physician is required to keep track separately of each CAP drug obtained for each beneficiary. Beyond this requirement, each physician may decide the most feasible way for this to work within the confines of his or her practice. If the physically separate storage of the drugs under CAP works better, then the physician is free to store the CAP drugs separately. If space limitations are an issue or if the separate storage of CAP drugs imposes an additional untenable administrative burden or creates confusion, then the physician is not required to store the CAP drugs separately. The CAP drugs, even if they are not stored separately, must in some way be tracked separately, either electronically or on paper; however, this could be something as simple as an electronic spreadsheet.

Comment: One commenter supported allowing CAP vendors and physicians to enter into contracts that would allow the vendor to receive returns of drugs that were shipped but not administered to the beneficiary. Many commenters expressed safety concerns with returns of unused drugs, especially partly used multi-dose vials. Another commenter addressed the burden of asking the physician to notify the vendor about the change of administration plans and negotiate redirection of the unused drug. Another commenter pointed out that State pharmacy laws may not allow for redirection of unused drugs dispensed for one patient to another; some manufacturers do not allow the return of drugs when they are ordered through a distributor; and there may be potential discrepancies between State law, manufacturers' requirements, and the CAP. One commenter asked whether the vendor could require the physician to retain the drug and attempt to use it on another patient. Another commenter requested that we explain the process that is to be followed if the vendor requests that the physician return the drug, and whether the physician would be responsible for paying the return shipping cost. One commenter stated that communication between the vendor and the physician should be handled electronically when a drug was not administered and that we should implement an electronic system to facilitate this communication. One commenter stated that return on unused drugs should only be allowed when the box has not been opened, and no patient labels are attached. The commenter also stated that 11 States allow for ''reuse'' of unused drugs in very limited circumstances. Typically unused drugs are destroyed by physician or pharmacy staff. The commenter requested that any reference to this possibility be removed to avoid giving the impression that we favored such an option in conflict with State law in many States. The commenter proposed that the vendor be compensated for drugs that are not administered to patients and cannot be billed. Another commenter suggested that we include a statement in the final rule that makes it clear that physicians participating in the CAP would be allowed to use CAP drugs ''only'' for a patient for whom the drugs were dispensed and identified by the beneficiary's Medicare number.

Response: We defer to State law and regulations as well as manufacturers' requirements concerning the disposition of drugs that are not administered or drugs that are left over from an administration. Section 1847B(a)(3)(A)(iii) of the Act states that payment for CAP drugs is conditioned upon the administration of such drugs. Therefore, we do not have the authority to pay for CAP drugs that were not administered to the beneficiary. Please refer to section II.C of this interim final rule for a more complete discussion of our policy on drug wastage and the process for returning unused drugs. Special contracts between the vendor and the physician should not be necessary to provide for the return of unused drugs because the participating CAP physician election agreement and the approved CAP vendor's contract with CMS, as well as the requirements stated in the regulations, address this issue. We are requiring that when a physician does not administer a drug during the time frame specified on the order form, or administers a smaller amount of the drug than was originally ordered, that the physician must contact the vendor to discuss what to do. If it is permissible under state law, the drug is unopened, and both the physician and the vendor are in agreement, the physician may retain the drug for administration to another Medicare beneficiary. However, before the drug could be administered the physician would need to provide the vendor with a new prescription order for the drug, and the vendor would need to supply the physician with a new beneficiary specific prescription order number.

Comment: One commenter inquired whether a physician will be able to use the CAP if he or she is aware that another insurance is primary to Medicare. In addition, commenters asked that we explain what happens if

the physician is not aware, before administering the drug, that another insurance is primary. The commenters also wanted to know if the CAP requirements will be different if the beneficiary has a Medigap policy.

Response: Many beneficiaries have coverage in addition to Medicare. For instance, some beneficiaries have a Medigap policy or another type of supplemental insurance that covers costs that Medicare does not. Some beneficiaries have retiree coverage through a former employer that is secondary to Medicare, and such coverage is, for practical purposes, similar to supplemental coverage because it may cover costs Medicare does not. (See section on beneficiary coinsurance for more detail.) However, many beneficiaries have employer coverage that is primary to Medicare. In this instance, Medicare pays secondary. A beneficiary's additional coverage may have an effect on when or from whom an approved CAP vendor receives payment. However, the requirements under the CAP will not be different. When a beneficiary has supplemental or secondary insurance, the approved CAP vendor may bill such insurance as appropriate (that is, after payment from Medicare). Where Medicare is the secondary payer and not the primary payer for the beneficiary, the vendor would bill the primary insurer first, and bill Medicare second, as appropriate, in accordance with normal Medicare secondary payment rules.

Restricting Physicians to One Vendor

We requested comment on whether we should require that CAP-participating physicians obtain all categories of drugs that a particular approved CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he or she wishes to obtain from the vendor.

Comment: Several commenters supported allowing physicians to choose the categories of drugs they obtain from the CAP. Another commenter suggested that physicians should be required to obtain all drugs for all HCPCS within a designated specialty for their Medicare patients from the CAP vendor to increase billing accuracy, and reduce inventory and paperwork burden. Finally, several commenters suggested that physicians should be allowed to contract with multiple vendors for different categories of drugs.

Response: As indicated earlier in this preamble we are implementing CAP initially with one category that contains all CAP drugs. At a later point we plan to add additional categories of drugs. When there are additional categories from which to choose, physicians will be allowed to select the categories of drugs that they will obtain from the CAP. We will encourage physicians to select vendors in a manner that will minimize the number of vendors used by one practice, in an attempt to reduce potential billing errors and beneficiary confusion. Physicians will be limited to one vendor per category; however, it will be possible to select a different vendor for each category if the physician decides that it best meets his or her needs. Physicians billing under a group billing number will need to reach agreement among themselves on whether to participate in CAP and which vendor to select for each category. [See Section II.D of this interim final rule on physician election for more detailed information on this requirement.]

Administrative Burden

In the proposed rule, we indicated that we did not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system. The payment for clerical and inventory resources associated with buying and billing for drugs under the ASP system is bundled into the drug administration payment under the physician fee schedule. Taking these factors into account, we proposed not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program.

Comment: Some commenters disagree with our assessment of the clerical and inventory resources associated with participation in the CAP. They believe that the administrative cost of managing inventory would not be eliminated nor reduced proportionally based on drug volume decrease due to the CAP. They added that with the separate ordering process for CAP drugs requiring patient-specific orders, the number of individual orders would be higher with additional delivery times and likely increase waste. One commenter noted that oncologists often use an automated storage and inventory control system that automatically tracks the amount of each drug on hand. Instead of a bulk ordering system, the CAP will require a detailed patient-specific order. The commenters also pointed out that the billing processes would be similar but that the CAP claim form would require the prescription order number for each drug in addition to the HCPCS code. Keeping track of the prescription order number before administering the drug would also be a new activity. One physician also stated that his city requires that he pay tax at the time a drug is administered to a patient, and that he believed the CAP should compensate him for this cost.

Response: Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians. Again, as we have stated previously, a physician is free to a significant extent to design his or her practice so that the additional burden of participating under the CAP is as small as possible. CAP is a voluntary program, so if a physician finds it more burdensome, then he or she is under no obligation to participate. Although initially a physician's staff may have to make software changes to recognize the CAP system, this would be a one-time burden. Also, as we have stated previously, separate drug storage is not required—it is a suggested option if such a procedure makes it easier on the physician's practice to track the CAP drugs. Further, in the interest of easing the burden of information exchange to the extent possible, we are requiring at § 414.908(a)(3)(iii) that the physician provide the vendor with patient information for the initial order, or when the patient's information changes (for example, the patient develops a new drug allergy). The vendor would be able to specify which information is necessary on a follow-up order. (We note that some patient specific information such as date of birth and gender are required by the Medicare claims processing system. For additional information refer to Content of the Drug Order earlier in this section.

Drug Administration

We proposed that after administering the drug, the physician would submit a claim to his or her local carrier for drug administration. The claim would include the HCPCS code for the drug administered, the drug administration fee, the prescription code for each drug administered, and the date of service.

The local carrier would adjudicate the claim for drug administration and check that the physician was billing for appropriate drugs from the selected drug vendor, and that the claim was compliant with all local coverage determinations (LCDs). In general, if the physician's claim was inconsistent with an LCD, the local carrier would deny the claim for the drug administration and

would notify our central claims processing system that the drug vendor's claim for the drug would not be paid.

If the claim passes all local carrier edits, the local carrier would forward it to our CMS central claims processing system for additional editing and approval for payment.

We also proposed to require prompt claim filing for the drug administration on the part of physicians who elect to participate in the CAP in order to facilitate the match between the physician claim and the drug vendor claim so that drug administration can be verified. We proposed that in their CAP election agreements, physicians who choose to participate in the CAP would be required to agree to bill their claims within 14 calendar days of the date the drug was administered to the beneficiary, unless extenuating circumstances prevented them from filing the claim. (Statistics obtained from Medicare claims filing data indicated that more than 75 percent of physician's claims are currently filed within 14 days of the date of service.) We requested comment on how we should define the extenuating circumstances that should be considered for exceptions to the 14 calendar day time frame.

Comment: A commenter representing an organization of specialty distributors supported the timely filing of physician claims requirements in the proposed rule; however, the commenter noted that few procedures are proposed to augment physician compliance. The commenter supported development of an enforcement mechanism before the physician's dismissal from the program. Other commenters believe that it is burdensome for a physician to file a claim within 14 days after drug administration. One commenter asked for more detailed information about our data on physician claim filing because the statistics we cited are not reflective of their knowledge of small group practices and solo practitioners. They asserted that requiring CAP physicians to submit their claims within 14 days is too drastic a change from the 365 day current standard, and suggest that the requirement should be changed to 30 days. In response to our request for comment on extenuating circumstances that could be considered for exceptions to the 14 day filing requirement, the commenter stated that extenuating circumstances for claim filing requirements are already defined in Chapter 1 section 70.7 of the Medicare Claims Processing manual and that providers are allowed an extra 120 days in which to file claims in certain situations. They believe the same standards should be applied in the CAP.

Response: Concerning the 14-day requirement on physicians to file claims for drug administrations, we point out that the vendor's payment depends on the physician's administration of the drug that the vendor has already purchased and provided. We believe it is reasonable for the vendor to expect to be paid timely, and it is a benefit to the physician to be paid timely as well. The claim filing data we cited in the proposed rule were based on all physician claims where the place of service was the physician office, so it represented claims filed by all physician practices. Based on physicians' current claims filing practices, we believe that complying with this requirement will not be problematic for most physicians. We expect that physicians will take the requirement into account when they make a decision whether to participate in CAP and that before electing to participate they will have procedures in place that will enable them to meet the requirement on a routine basis if they are not already doing so. The local carrier may grant exceptions on rare occasions when due to extenuating circumstances the physician is unable to submit claims within 14 days. Such requests should not be granted on a routine basis. As physician billing practices increasingly become automated, we believe that this requirement will become less of a burden. We will ask the local carriers to periodically conduct a post payment review of participating CAP physicians' compliance with this requirement. If a vendor notes repeated non-compliance with this requirement on the part of a physician, the vendor may ask the designated carrier to assist in working with the physician to resolve this situation. Failure to comply with this requirement may be a factor taken into consideration in the designated carrier's recommendation to CMS about removing a participating CAP physician from the program.

Comment: One commenter noted that the proposed rule did not address how the patient newly eligible for the Medicare program during a course of treatment would be handled under the CAP. The commenter inquired whether the physician would be required to change the patient's therapy because the vendor might be offering a different NDC of a drug than the physician had been using previously.

Response: A physician that is treating a new Medicare patient is not required to change that patient's course of treatment merely because he or she may be participating in the CAP if the ''furnish as written'' conditions are met. If a patient becomes eligible for Medicare and the treating physician is participating in the CAP, and a particular formulation of a patient's drug is not available through the CAP, but is medically necessary, then the physician may obtain the drug through the ''furnish as written'' methodology and bill the local carrier for the drug under the ASP system.

Comment: Several commenters suggested that the CAP vendors and physicians should be able to enter into contracts or agreements that would allow them to work out details of doing business under the CAP such as how to handle drugs that were ordered and shipped but not administered. Other commenters proposed that we allow vendors and physicians to enter into contracts that would increase vendor financial incentives to participate in the CAP while at the same time reducing the physician's administrative burden. As an example, the commenter suggested allowing the vendor to bill for both the administration fee on behalf of the physician and the drug itself. In addition, another commenter asked if there are any restrictions concerning a physician using a CAP vendor for non-Medicare patients. Specifically, the commenter inquired whether a participating CAP physician could have an ancillary agreement with the approved CAP vendor to obtain drugs for his or her non-Medicare patients.

Response: This interim final rule does not prohibit approved CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services. However, parties to such arrangements must ensure that the arrangements do not violate the physician self-referral (''Stark'') prohibition (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), or any other Federal or State law or regulation governing billing or claims submission. For example, an agreement under which the approved CAP vendor provides billing services to a physician must comply with the Stark law, anti-kickback statute, and Medicare rules regarding billing agents (§ 447.10). On the other hand, an approved CAP vendor may not contract to furnish drugs at below market rates to a physician or a group for their private pay patients in exchange for the physician's or group's CAP business. For additional information on the Stark and anti-kickback statutes, parties may wish to consult the CMS and OIG Web sites.

Payment to Vendor

After shipping the drug to the physician, we proposed that the drug vendor could file a claim for the drug with the designated carrier no sooner than the expected date of administration. The claim form would contain the prescription number for each drug administered to the beneficiary on one calendar day, the unique provider identifier (UPIN) or (NPI when available) for the physician to whom the drug was supplied, and the expected date of service. The designated carrier would submit the claim to the central claims processing system after the claim had passed all edits. The central claims processing system would match the physician claim with the vendor claim using the prescription number.

As required by the statute, we proposed that the vendor would not be allowed to bill the beneficiary or his or her third party insurance, or both, for any applicable deductible and coinsurance until the Medicare carrier had verified that the physician administered the drug to the beneficiary, and final payment was made by the Medicare program. Proof that the drug was administered to the beneficiary would be established by the physician's claim being matched with the drug vendor's claim in the Medicare central claims processing system. After the two claims were matched, the claims processing system would notify the designated carrier to issue final payment to the vendor. We proposed that issuance of final payment by the Medicare program would serve as notification to the vendor that drug administration had been verified and that the vendor could proceed with billing the beneficiary or his or her third party insurance.

Comment: A specialty distributors association commented that every day that a vendor must wait for payment from Medicare and the beneficiary or his or her third party insurance represents additional working capital invested in the program by the CAP vendor and added inefficiencies to the Medicare program. Vendors may experience at least a 2-month delay in payment from the time the drug is shipped to the physician and payment is received from the Medicare program. The commenter stated that CAP vendors will not be able to assume the level of financial risk that was described in the proposed rule. They proposed a series of steps that we could take in the final rule to attempt to lessen the degree of risk that CAP vendors will assume. These include: Establishing a pre-review process to certify the medical necessity of a drug before the CAP vendor sends the order to the physician, creating risk corridors similar to those being used in the Part D program so that the vendor and CMS are sharing in the risks and benefits of the program, and implementing a process so that the CAP vendor could collect coinsurance from the beneficiary at the time the drug is administered. Commenters also expressed concern about the potential for low profit margins and delayed payment that exist in the CAP and suggested that we should provide additional financial safeguards for CAP vendors.

Response: Following is a response to the commenters' proposed suggestions about how to lessen the degree of risk that vendors will face in the CAP:

(1) Medicare contractors do not generally provide advance approval of potential claims. As stated previously both the participating CAP physician and the approved CAP vendor are expected to familiarize themselves with LCDs, NCDs, and other Medicare rules that may affect claims payment. If an approved CAP vendor encounters a circumstance where it believes that a prescription order is inconsistent with any of these things, the approved CAP vendor may work with the physician to amend the order. If the physician declines to change the order, but the approved CAP vendor believes the drug claim will not be paid by Medicare, the approved CAP vendor may issue an ABN to the beneficiary. If for some reason the vendor is unable to obtain a signed ABN from the beneficiary, the vendor still will have a responsibility under its CAP contract to ship the drug to the physician. (The only exception to this requirement is in the case of the beneficiary's failure to meet his or her obligation to pay deductible or coinsurance. This provision is described in more detail in the discussion of beneficiary coinsurance later in this section.)

We will include in the CAP contract a requirement that the vendor ship the drug in most situations because we believe that under the CAP program as it is being implemented, it would be inappropriate for the approved CAP vendor to interfere in the participating CAP physician's clinical decision making. If the payment for the drug is ultimately denied, then the physician will be required to appeal the drug administration claim denial. The approved CAP vendor may also appeal to the local carrier in accordance with the discussion of administrative appeals below in the dispute resolution section.

(2) We do not have the statutory authority under section 1847B of the Act to create risk corridors.

(3) We have designed the CAP payment system so that the vendor may bill the beneficiary and or his or her third party insurance when payment for the drug has been made by the CMS claims processing system. In order to ensure that this process happens as soon as possible, we are imposing a 14-day claim submission requirement on the physician. We have implemented this requirement because the statute requires that applicable deductible and coinsurance may not be collected unless the drug was administered to the beneficiary. Currently, we have no way of verifying drug administration other than by the matching of the physician's claim for drug administration with the vendor's claim for the drug. We seek comment on other ways that administration could be verified earlier in the process that minimize the burden on the approved CAP vendor, the participating CAP physician, and the beneficiary.

Partial Payment

Although we noted in the March 4, 2005 rule that we were not proposing to implement a system for partial claims payment, we requested comments on compelling reasons for making such a payment. We also sought comment on whether there are demonstrable, compelling reasons why we should consider making a partial payment to the vendor in cases where the drug administration claim is not received by our claims processing system within 28 calendar days of the anticipated date of administration and what the appropriate percentage of the partial payment should be.

We briefly described how such a partial payment methodology might work, if we decided to implement such an option. After the designated carrier made the partial payment, our claims processing system would continue to attempt to match the physician claim and the vendor claim for 90 days. We would not pay interest on interim payments. If a match of the two claims occurred, the vendor would receive Medicare payment for the remaining amount of money due on the claim. If no match between the two claims was made within 90 days, recovery of the amount already paid by Medicare would occur using normal Medicare overpayment recovery processes. After the Medicare program made the final payment, the vendor would be allowed to bill the beneficiary or the beneficiary's third party insurance, or both.

Comment: Some commenters supported partial payment of the vendor's claim at the time the drug is shipped to the physician, and 20 percent was suggested as an appropriate amount. Another commenter strongly opposed partial payment for the vendor because neither physicians nor pharmacies nor DME suppliers have ever received partial payment. The commenter expressed concern that the beneficiary would receive a bill on the partial payment.

Response: After further consideration of this issue, we will finalize the proposal to pay only when both the vendor claim for the drug and the physician's claim for administering the drug have been matched in the claims processing system. We believe that this is a more straightforward process and that it is a process that will assist in preserving the Medicare trust fund because it will not involve payment recovery if a claim is denied or a physician does not administer the drug.

Beneficiary Coinsurance

Comment: Some commenters stated that having the vendor collect the coinsurance adds further ''bureaucracy'' to patient care and introduces a middleman between the doctor/patient relationship.

Response: As stated in the proposed rule, the statute specifically requires that the vendors participating in the CAP collect any applicable deductible and coinsurance from the beneficiary. Therefore, we do not have any latitude in determining who collects the coinsurance.

Comment: A few commenters questioned our proposal to prohibit the vendor from billing for coinsurance until final payment of claim, stating this would be a significant change from current practice. The commenters believe delayed billing would increase risk of bad debt and increase collection-related efforts and costs and potentially risk solvency of the vendor and viability of program.

Response: We understand the concerns raised by the commenters; however, the statute specifies that the collection of any applicable deductible or coinsurance cannot occur until the drug is administered and that the vendor is responsible for billing the beneficiary for cost sharing. We note that Medicare allows for the collection of coinsurance at the time a service is delivered, however since the approved CAP vendor is not present at the time the drug is administered the vendor is unable to bill the beneficiary at that time. We agree that the delay in billing could increase the incidence of beneficiaries who are unable to meet their coinsurance obligations; however we note that (as explained in more detail below) approximately 80 percent of beneficiaries have supplemental insurance coverage which covers their Part B coinsurance. In order to help ensure more prompt payment to the vendor, we are requiring that the participating CAP physician must submit the claim for drug administration within 14 calendar days of the date of administration. In addition, the existing CMS coordination of benefits process provides for the automatic crossover of many Medicare beneficiaries' claims to their supplemental insurance provider after Medicare has paid its portion of the claim. For beneficiaries with supplemental insurance, their coinsurance obligation is usually met through the automatic coordination of benefit process, instead of requiring the beneficiary to pay the coinsurance at the time of service. We are currently consolidating the claims crossover process, on a national basis, to introduce standardization and efficiencies in a national crossover process that will automatically cross claims over to supplemental insurers/payers, including Medigap plans, employer retiree supplemental plans, TRICARE, and State Medicaid Agencies, for their use in calculating their financial liability after Medicare. Under this consolidated crossover process, supplemental insurers/payers will execute a national Coordination of Benefits Agreement with a single CMS contractor, the national Coordination of Benefits Contractor (COBC), for purposes of receiving Medicare crossover claims. We believe that the majority of supplemental insurers/payers will participate in the national consolidated crossover process due to the consistencies and efficiencies that result from a standard national process. Standardization of the crossover process thereby decreases the likelihood that beneficiaries' claims will not be crossed over.

Comment: Commenters raised concerns about the requirement that the approved CAP vendor collect the coinsurance for the drug from the beneficiary with respect to the following three major areas:

- *Effect on beneficiaries.* Under the current system, the physician often works with the beneficiary and social agencies to obtain payment, or in appropriate circumstances these costs may be born by the physician practice in cases of financial hardship as bad debt. Commenters expressed concern that vendors may use overly aggressive collection techniques, or no longer provide drugs for patients who are too far in arrears.
- *Effect on approved CAP vendors.* The inability of approved CAP vendors to collect coinsurance from beneficiaries could pose a major financial hardship to vendors. Collection of coinsurance may also be exacerbated due to the time delay between the dates of treatment and payment, as well as the approved CAP vendor's lack of a direct personal relationship with patients.
- *Clinical issues.* Failure to provide the drug due to nonpayment of coinsurance by the beneficiary may endanger patients and expose physicians to liability issues. Commenters stated that regardless of the patient/vendor dispute, this does not involve physician services, and failure of the vendor to provide the required drug could affect the physician's plan of treatment for the beneficiary.

Commenters recommended that the vendor should not be able to drop the physician from the CAP or withhold the shipping of the drugs due to nonpayment of the coinsurance.

Additionally, commenters suggested vendors be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual. The commenters recommended that assessment of these procedures should be part of our vendor evaluation process. If it is determined that vendors can refuse to deliver drugs because of coinsurance issues, commenters believe this must be made clear to physicians when they sign up for the CAP. As an alternative, other commenters recommended that when this occurs, physicians should be able to obtain drugs through the ASP system or be able to opt out of the CAP immediately. One commenter suggested that this option should also be available if the beneficiary's secondary insurance denies the claim.

The Practicing Physicians Advisory Council (PPAC) expressed similar concerns about the collection of coinsurance and recommended that we require selected CAP vendors be willing to advance credit for drugs to patients who are not able to pay the coinsurance.

Other commenters recommended that the final rule allow CAP vendors to refuse to distribute products to patients who have a prior history of failing to fulfill coinsurance obligations. This

would eliminate a significant amount of financial risk and uncertainty for vendors.

Response: We appreciate the commenters' concerns, and we address these concerns as outlined below:

• *Effect on beneficiaries.* With respect to commenters' concerns about the impact of the CAP on beneficiaries, the purpose of the CAP is to provide an alternative to physicians for obtaining Medicare Part B drugs and is not intended to have a negative impact on patient care. However, as part of their enrollment in Medicare, beneficiaries are obligated to pay the Part B deductible and coinsurance amounts, and this cost-sharing assists in controlling the over utilization of services. Information from the 2003 Medicare Current Beneficiary Survey shows that approximately 80 percent of fee-for service Medicare enrollees report that they have supplemental coverage that covers their Part B coinsurance obligations. Although we are uncertain of the level of coverage provided by these plans, we believe this supplemental coverage provides significant financial protection to many beneficiaries. However, we understand that there will be instances where a beneficiary may have difficulty in meeting the deductible or coinsurance payment. When this occurs under the current payment system, the physician often helps the beneficiary in finding assistance to meet this obligation or might choose not to pursue collection of the cost-sharing if the physician has made a good faith determination of financial need or reasonable collection efforts have failed.

In order to address these concerns, we are modifying the program requirements at § 414.914(g) to include a provision requiring vendors to provide information on sources of cost-sharing assistance available to beneficiaries on request. It is important to note that routine waiver of deductibles and coinsurance can violate the Federal anti-kickback statute, as well as the civil prohibition on offering inducements to beneficiaries at section 1128A(a)(5) of the Act. However, cost-sharing waivers are permitted under certain conditions for beneficiaries who are experiencing financial hardship. The assistance offered by the vendor must take the form of one of the following: a referral to a bona fide and independent charitable organization, implementation of a reasonable payment plan, and/or a full or partial waiver of the cost-sharing amount based on the individual financial need of the patient, provided that the waiver meets all of the requirements of paragraph (1) of 42 CFR 1003.101 (Definition of ''Remuneration''). The availability of waivers may not be advertised or be made as part of a solicitation; however, vendors may inform beneficiaries generally of the various categories of assistance noted in the preceding sentence. In no event may the vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers. We will evaluate the procedures that applicant vendors propose to implement to make cost-sharing assistance referrals as part of the approved CAP vendor application review process.

• *Effect on approved CAP vendors.* With respect to concerns about the potential impact on the approved CAP vendors, we will not require an approved CAP vendor to continue to provide CAP drugs for beneficiaries who do not pay their deductible or coinsurance. As noted previously, under the CAP contract, we are requiring vendors to ship ordered drugs to physicians in most situations. However, in the case of a beneficiary who fails to satisfy his or her cost-sharing obligations for CAP drugs ordered by a particular participating CAP physician, we will allow the vendor to refuse to make further shipments to that physician for that beneficiary in accordance with the provisions outlined below. The vendor may refuse to ship drugs to a physician for a beneficiary who has not met his or her coinsurance obligations, when the conditions outlined below are met, until the earlier of the end of the calendar year or the beneficiary's past due balance is paid in full. We will require that after receiving final payment by Medicare, the vendor must first bill any applicable supplemental insurance policy that the beneficiary may have. If there is a balance due after payment by the supplemental insurer, or if the beneficiary has no supplemental insurance, the vendor may proceed with billing the beneficiary.

As discussed previously, consistent with the requirements of section 1128A(a)(5) of the Act and § 414.914(g), at the time of billing, the vendor may inform the beneficiary generally of the types of cost-sharing assistance that may be available. If the beneficiary is unable to pay the coinsurance or deductible, he or she may request assistance from the vendor as described above. The vendor has an obligation to provide the information requested, and to take one of the actions specified in § 414.914(g). However, if the beneficiary has not requested financial assistance and if after a period of 45 days from the postmark date of the approved CAP vendor's bill to the beneficiary, the beneficiary's coinsurance obligation remains unpaid, the vendor may refuse to make further shipments of drugs to the physician for that beneficiary. We note that these provisions assume that the vendor bills the beneficiary after payment is received from Medicare and his or her supplemental insurance provider (if applicable.)

If the beneficiary requests cost-sharing assistance and the vendor refers the beneficiary to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait an additional 15 days from the postmark date of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance. If at the end of the 15-day time period the vendor has not received a cost-sharing payment (either from the charitable organization or from the beneficiary under the payment plan), the vendor may refuse to ship additional drugs to the physician on behalf of that beneficiary. Further, if the approved CAP vendor implements a reasonable payment plan, the vendor must continue to ship CAP drugs for the beneficiary, so long as the beneficiary remains in compliance with the payment plan.

Finally, if the vendor waives the cost-sharing in accordance with section 1128A(I)(6)(A) of the Act, 42 CFR § 1003.101, and § 414.914(g)(3) of these regulations, the vendor may not refuse to ship CAP drugs for the beneficiary. In instances where a beneficiary has failed to meet his or her obligation to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the drug, we will permit the participating CAP physician to opt out of that drug category for CAP. Note that for the initial implementation of the CAP, there is only one CAP drug category. Thus, a physician exercising this option will be opting out of the entire CAP program until the next opportunity to elect to participate. We are amending the regulations at § 414.908(a)(5) to include this provision. We seek comment on additional provisions that we should use to define these processes to protect the vendor and the beneficiary.

• *Clinical issues.* With respect to concerns raised that the inability of a beneficiary to make the coinsurance payment should not affect treatment, we believe the modifications we are making to require the vendor to provide information on sources available to a beneficiary who may be in need of assistance with his or her coinsurance payment as well as allowing the

physician to opt out of the CAP will assist in ensuring that the treatment is not affected.

Comment: One commenter questioned what is required from physicians for patients with Medigap or another type of supplemental insurance coverage.

Response: A high percentage of Medicare beneficiaries carry supplemental insurance such as a Medigap policy to cover deductible and coinsurance amounts, and the physician will provide this insurance information to the approved CAP vendor. The specific information that the physician must provide is discussed earlier in this section.

Comment: Another commenter requested that we implement processes to assist vendors in collecting beneficiary coinsurance, especially if the patient is deceased.

Response: We do not believe special provisions need to be made in this rule for beneficiaries who are deceased. If a beneficiary has died after receiving the CAP drug, but before he or she could pay the coinsurance amount to the vendor, the designated carrier would still process the approved CAP vendor's drug claim in accordance with the normal procedures outlined in these regulations, and the approved CAP vendor could bill the beneficiary's estate or the beneficiary's alternative insurance in accordance with CAP requirements. However, we would welcome further comments on this issue.

Comment: Commenters questioned whether vendors would be expected to bill Medicaid for coinsurance and deductible after billing Medicare in the case of dual eligible beneficiaries and the consequences to the beneficiary if Medicaid did not pay the coinsurance. Another commenter recommended that we require any vendors awarded the contracts to provide this prescription benefit with a coinsurance structure no higher than Medicaid.

Response: The CAP is an alternative to the current system for paying for Medicare Part B drugs. Because the coinsurance is a part of the Medicare total payment amount, we cannot establish a limit for this amount based on another payment system (that is, Medicaid). We have no authority to set coinsurance at anything other than 20 percent of the Medicare rate. If a beneficiary has supplemental insurance, the approved CAP vendor will bill the insurance provided by the beneficiary for the coinsurance amount. Medicaid payment rates and policies for dual eligibles will vary by State.

Comment: One commenter recommended that we establish a policy to reimburse vendors for part of the bad debt they experience when they are unable to collect in full the coinsurance and deductibles, similar to provisions for certain other providers. Alternatively, the commenters believe we should adjust the bid limit to take this issue into account.

Response: The bad debt policy referred to by the commenter is established by statute and regulations for specific provider types and is not applicable to the CAP program. We do not agree with the suggestion that we should adjust the proposed bid limit to account for the possibility that vendors will be unable to collect all coinsurance. Although the Medicare statute and regulations provide specific provisions to recognize and account for bad debt in the context of payments to hospitals and certain other provider types, there is no such provision in relation to the CAP. We therefore lack authority to provide for explicit recognition of bad debt in the mechanisms for bidding and determining payment amounts under the CAP.

Comment: One commenter stated that the CAP could result in beneficiaries returning to the physician's office more often and thus double the coinsurance amount. For example, a beneficiary undergoing chemotherapy may see the physician and have his or her laboratory results checked one day and, based on changes to the prescription, the physician will have to order a new drug and the beneficiary will have to return on another day to receive the drug.

Response: The statute and these regulations provide for situations in which a drug is needed immediately. If the criteria outlined in § 414.906(e) are met, the participating CAP physician can submit a prescription order to the approved CAP vendor to obtain a replacement for a drug from his own stock that was used to treat the beneficiary. The participating CAP physician is always free to do what is best for the beneficiary, but under CAP payment rules, payment is made for the CAP drug only when it is ordered from the vendor or the resupply or ''furnish as written'' criteria are met.

3. Dispute Resolution

Section 1847B of the Act is generally silent with regard to the treatment of disputes surrounding the delivery of drugs and the denial of drug claims. However, section 1847B(b)(2)(A)(ii)(II) of the Act does contain a reference to a grievance process which is included among the quality and service requirements expected of vendors.

As explained in the March 4, 2005 proposed rule, we gave substantial consideration to the applicability of the Medicare Part B administrative appeals process found at § 405.801 *et seq.* We believe the traditional Part B appeals process continues to be the appropriate dispute resolution process for beneficiaries and participating CAP physicians seeking review of drug administration claims that have been denied by the local carrier for any of the reasons described in § 405.803(a). Those reasons include the following: (1) Services were not a covered benefit; (2) The deductible was not met; (3) No evidence of acceptable payment; (4) Charges for services were unreasonable; and (5) Services furnished were not reasonable and necessary.

We also outlined reasons that we believed disputes raised by the approved CAP vendor regarding the nonpayment of a drug claim by the designated carrier cannot be adjudicated by application of the traditional Part B appeals process. First, the designated carrier's denial is based on the lack of a unique prescription ID number match in the central claims processing system. This reason does not meet any of the appeal criteria in § 405.803(a). Second, given the ministerial aspect of the designated carrier's prescription number matching task, an informal process focused on getting the underlying participating CAP physician's drug administration claim properly filed and adjudicated is a more effective remedy. Finally, we believed application of the proposed progressive alternative dispute resolution process described in the proposed rule represents a better use of program administration resources.

We encourage participating CAP physicians, beneficiaries, approved CAP vendors and the designated carrier to use informal communication to resolve service-related administration issues that occur in a delivery and payment system of this complexity. However, we recognized certain disputes will require the intervention of a neutral third party and established a proposed dispute resolution process § 414.916 which is summarized as follows.

a. Resolution of Vendor's Claim Denial

The participating CAP physician has control of the claim filed with the local carrier for drug administration services. In the proposed rule, we stated that the approved CAP vendor would not be a party to the appeal a physician may file if his or her drug administration claim is denied. We based this statement on the fact that the approved CAP vendor would possess little of the evidence required to substantiate the medical necessity requirements for administration of the drug. However, we

wish to clarify that the approved CAP vendor may appeal as a Medicare supplier under the Part B appeals rules at 42 CFR Part 405 and the online Medicare Claims Processing Manual, Chapter 29, §§ 20 and 60.4. Because the local carrier's initial determination regarding the drug administration claim is determinative of the CAP vendor's drug claim, we interpret that initial determination to be an initial determination regarding payment of the CAP vendor's drug claim for purposes of the Part B appeals regulations at 42 CFR 405. Thus, the CAP vendor is a party to any redetermination of the drug administration claim by the local carrier. In addition, any appeal from an initial determination regarding a claim for payment of a drug by the designated carrier should be filed with the local carrier. It is the local carrier, rather than the designated carrier, that possesses all information necessary to adjudicate an appeal from a denial of a claim for payment of a CAP drug. This information includes local coverage decisions, medical necessity determinations, and information regarding payment of drug administration claims. Thus, all parties, including the CAP vendor, will have 120 days from the date of receipt of an initial determination by the designated carrier regarding a claim for payment of a drug in which to file a request for a redetermination of that claim with the local carrier.

Accordingly, we have expanded the participating CAP physician's participation obligations to include support of the approved CAP vendor's appeal with documentation and written statements. Please see the comments and responses below.

The approved CAP vendor's drug product claim may be denied by the designated carrier if the participating CAP physician's drug administration claim is denied. In that event, the approved CAP vendor can not bill Medicare for the cost of a drug and can not bill the beneficiary for the appropriate deductible or coinsurance.

The approved CAP vendor will track its business with the individual participating CAP physicians who order drugs. We proposed that when an approved CAP vendor is not paid and the total dollar amount of the approved CAP vendor's loss exceeds an acceptable threshold, then the approved CAP vendor may ask the designated carrier to counsel the participating CAP physician on his or her obligation under the CAP election agreement to file a clean claim and pursue an administrative appeal in accordance with his or her CAP election agreement. We outlined the particulars of the proposed participating CAP physician's CAP election agreement in § 414.908(a)(3) of our regulations and we requested comment on the appropriate amount for the CAP vendor's loss threshold.

If problems persist, we proposed that the approved CAP vendor may request the designated carrier to review the situation and potentially recommend a suspension of the participating CAP physician's CAP election agreement. The designated carrier would gather and review the relevant facts, and make a recommendation to us on whether the physician has been filing his or her CAP administration claims in accordance with the requirements for CAP participation. We would review the recommendation of the designated carrier and, if necessary, gather additional information before deciding whether to suspend the participating CAP physician's election to participate in the CAP.

We proposed the suspension would last for a period not to exceed the end of the following CAP election cycle. Inasmuch as participating CAP physicians can elect to enroll every year for a 12-month period commencing in January, the suspension would end on one or another December thirty-first. We are clarifying that the participating CAP physician could enroll again a year from the next January first. Upon consideration of the situation where the participating CAP physician is suspended in the early months of the year, we have determined that the suspension may prove to be unnecessarily long. Accordingly, we have determined that a suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year. A suspension of less than 2 months would not have a meaningful impact. We indicated that the physician would be able to appeal our initial decision through the process articulated in proposed § 414.916.

Comment: Comments on the appropriate loss threshold that an approved CAP vendor would have to bear before requesting suspension of the participating CAP physician were varied. The potential vendor community indicated that it would prefer to have authority to exclude participating CAP physicians unilaterally. Physician commenters indicated that they would like a well-defined threshold with a high dollar and occurrence level.

Response: Regardless of whether a physician is participating in CAP, our primary concern is the welfare of the beneficiary and the implications of repeated drug administrations that are not in accordance with Medicare coverage policy. Our existing medical review safeguards and provider education efforts are as applicable to drug administration when the drug is provided by the approved CAP vendor as when it is purchased by the participating CAP physician. These existing mechanisms help ensure that our beneficiaries are receiving medically reasonable and necessary services and, as a consequence, will help ensure that the approved CAP vendors are able to be paid for drugs shipped to physicians. We also note that physicians, as a condition of participation in CAP, will have agreed to the claims, appeals filing, and CAP assignment requirements described in section II.D.1, ''Physician Election,'' of this interim final rule. This will also help to ensure that the approved CAP vendors are able to be paid for drugs shipped to physicians.

We emphasize that we believe many of the issues of concern raised by the potential vendors can either be resolved through cooperative interaction between the approved CAP vendor and the participating CAP physician or the dispute resolution efforts of the designated carrier without using the formal process for removal of physician from the CAP program. However, we recognize the need for such a process in the event the above efforts are unsuccessful just as we recognize the need to be able remove an approved CAP vendor from the CAP program if necessary.

We believe each CAP drug claim denial will require individual analysis to determine the cause. That review focuses on the depth of consideration the participating CAP physician gave to the pertinent Medicare coverage policy. If it turns out the physician knowingly ordered and administered a drug that is not covered, and the physician did not file a claim, or filed a frivolous claim to create the appearance of appropriate consideration of the coverage requirements, then the approved CAP vendor's request to initiate a suspension investigation may be well founded. Approved CAP vendors can not be expected to have no recourse in the event they are routinely shipping drugs for which they do not receive payment. However, participating CAP physicians should not be removed from the CAP program lightly. We think the ability of the approved CAP vendor to raise these issues to an independent party, the designated carrier, for investigation and a recommendation to us, provides a fair opportunity for the participating CAP

physician and the approved CAP vendor to submit evidence in support of continued participation in CAP or removal from the program. Our review of the recommendation adds another impartial step to the determination of whether to remove the participating CAP physician from the program. If we determine that the participating CAP physician should be removed from the CAP program, the ability of the participating CAP physician to request reconsideration and the potential for the involvement of an impartial hearing officer provides yet another level of safeguard against the improper removal of a physician from the CAP program. However, to take into account the legitimate business needs of the approved CAP vendor once a determination by us has been made that the participating CAP physician should have his or her CAP participation agreement suspended, the physician will be able to obtain drugs and bill for them under the ASP payment system until a final reconsideration determination is made. In response to comments, we have removed the last sentence of § 414.916(b)(3) which indicated a participating CAP physician could select another approved CAP vendor while a reconsideration was pending. The ability of the Director of the Center for Medicare Management to provide a final reconsideration of the matter is yet a potential fourth level of safeguard in this process. We believe this process strikes an appropriate balance between providing swift recourse for approved CAP vendors and the desire for a fixed threshold.

Given the impartial nature of the process for removing physicians from the CAP, and after consideration of all the related comments, we believe that institution of a fixed threshold would run counter to the desired outcome. We seek to have participating CAP physicians give careful consideration to Medicare coverage policy before ordering drugs. There will be cases when the cost of the denied drug is high, but the participating CAP physician researched and considered the applicable coverage policy as carefully as possible. Conversely, there will be cases where the cost of the denied drug is relatively low, but coverage was denied because the participating CAP physician did not consider whether the applicable coverage policy would support payment for the drug and its administration under the circumstances of the specific case. The approved drug vendor must be able to address a participating CAP physician who flouts coverage policy before a drug with a relatively high cost is denied. We will monitor the data trends carefully and may reexamine our dispute resolution process as we gain more experience under the CAP. Our final process is codified in § 414.916(b).

Comment: Some potential physicians commented and questioned the legal authority for the designated contractor to function in this capacity. One commented that the designated carrier is not qualified to make the recommendation discussed in § 414.916(b)(2)(i) because the recommendation amounts to a legal determination, and the regulation states no qualification for the individual designated carrier employee who develops that recommendation.

Response: As we noted in the proposed rule, section 1847B of the Act is generally silent with regard to the treatment of disputes surrounding the delivery of drugs and the denial of drug claims. However, section 1847B(b)(2)(A)(ii)(II) of the Act does contain reference to a grievance process which is included among the quality and service requirements expected of vendors. We believe that section 1847B(b)(2)(A)(ii)(II) of the Act, at a minimum, provides authority for this function of the designated contractor.

We have a longstanding history of working with contractors such as carriers and fiscal intermediaries, that employ individuals to make recommendations with respect to various operational and policy issues related to the administration of the Medicare program. The designated carrier will meet all of the qualifications that are applicable to our administrative contractors generally.

Specialty carriers perform a variety of functions to support programs that deliver benefits in a new or unique manner. As an example, the Durable Medical Equipment Competitive Acquisition demonstration carrier performed an alternative dispute resolution function similar to the function the designated carrier will perform here.

Therefore, we believe that both the designated carrier and its employees will be qualified to undertake the activities called for in this regulation.

Comment: Some commenters questioned the impartiality of the designated carrier and indicated a preference for the local carrier.

Response: We note that the designated carrier is not making the removal determination, but only providing a recommendation to us. The designated carrier has been selected from the pool of existing Part B carriers though the process used to select Title XVIII contractors. We will closely monitor the designated carrier's dispute resolution function with Government oversight staff experienced with other contractors that perform dispute resolution functions in the Medicare program.

Although we believe either the designated carrier or local carrier would function impartially, the designated carrier will have the most familiarity with the CAP program and there are administrative efficiencies that can be realized from consolidating this function. However, because the local carrier will possess valuable information to add to the process, the designated carrier will work closely with the local carrier as appropriate before making a recommendation.

Comment: Some potential physician commenters questioned the qualifications and impartiality of the hearing officer.

Response: We find the Director of the CMS Center for Medicare Management, the Center with oversight responsibility for the CAP program, to be abundantly qualified to make an appropriate unbiased selection of a hearing officer.

Comment: One commenter encouraged CMS to inform the participating CAP physician community that claims should be submitted timely and in compliance with local medical policies. This commenter suggested that CMS supply approved CAP vendors with coverage determination information prior to delivery of the drug and shift the financial risk to the participating CAP physician. The commenter also suggested that CMS regularly post the CAP claim denial rates of participating CAP physicians on a Web site in an effort to encourage participating CAP physicians to meet their obligation to file claims and appeals.

Response: As described earlier, the participating CAP physicians' claims and appeals filing expectations are described in section II.D.1, ''Physician Election,'' of this interim final rule. Approved CAP vendors should consult with the local carrier Web sites to familiarize themselves with LCDs. They should also review NCDs posted on the our Web site.

We do not believe it is appropriate to publish the names and claim denial rates of participating CAP physicians because approved CAP vendors will not have the authority to refuse to service participating CAP physicians who select them.

Comment: One commenter asked us to create a more meaningful way for the approved CAP vendor to appeal the local carrier's denial of the drug administration claim.

Response: As noted above, we have clarified that the approved CAP vendor has an independent right to appeal claims under existing Part B appeals rules. To assist approved CAP vendors in exercising these rights, we are including a new obligation in the participating CAP physician's CAP election agreement. The participating CAP physician must reasonably cooperate with the approved CAP vendor if the vendor chooses to appeal the local carrier's denial. Reasonable cooperation may include providing the approved CAP vendor with access to or copies of medical records, as appropriate, and written statements.

Comment: Several commenters were concerned that the process for determining whether a participating CAP physician should be removed from the CAP program would allow approved CAP vendors to pressure participating CAP physicians to alter their prescribing pattern and to intrude unacceptably on the participating CAP physician's clinical decision making.

Response: Please note the approved CAP vendor will be required under the terms of its CAP contract to ship the drug ordered by a participating CAP physician in most cases. The designated contractor will closely monitor the activities of approved CAP vendors and complaints from participating CAP physicians to ensure that no such inappropriate intrusion on physician clinical decision making occurs. Participating CAP physicians may address concerns of this type through the participating CAP physician/approved CAP vendor dispute resolution process described below and in § 414.917.

Comment: Several commenters suggested that, during the designated carrier's investigation into the participating CAP physician's compliance with his or her CAP election agreement, the designated carrier should be explicitly required to gather information from the participating CAP physician.

Response: The designated carrier will gather necessary information from the local carrier, the participating CAP physician and the approved CAP vendor. Section 414.916(b)(2)(ii) has been adjusted to explicitly include the physician among the sources of information the designated carrier must query during the investigation.

Comment: A commenter from a physician association believed that the participating CAP physician should be allowed to submit additional material to the record during the phase described in § 414.916(b)(3) when CMS makes a determination whether to suspend the participating CAP physician's CAP participation agreement.

Response: We agree. Section 414.916(b)(3) has been adjusted to require us to gather additional material from the participating CAP physician as appropriate.

Comment: Several commenters have suggested emphatically that CMS drop from the final rule the requirement that suspended physicians' names be published in the **Federal Register**. These commenters also requested that the final rule make clear that suspension of a CAP election agreement for denial of claims does not result in the physician becoming listed on the exclusion list under section 1128 of the Act.

Response: A suspension of a participating CAP physician's CAP election agreement or a termination of an approved CAP vendor's contract with us does not result per se in either party being excluded from participation in any Federal health care program. Such a decision only precludes the physician or vendor from participation in the CAP. Whether a participating CAP physician or vendor is excluded from all Federal health care programs under section 1128, 1128A, or any other exclusionary authority given to the Secretary under the Act, shall be based on a determination made by the Office of Inspector General of HHS, not by CMS through the § 414.916 or § 414.917 processes. We agree with the commenters' recommendation that we refrain from publishing the names of suspended physicians in the **Federal Register**, and this requirement has been removed.

Comment: One potential vendor suggested that vendors should not be required to enroll or re-enroll physicians who had been suspended from CAP at the conclusion of the suspension period.

Response: Physicians whose period of suspension from the CAP program has ended will be allowed to elect to participate in the CAP as described above, and could potentially select the same vendor that generated the suspension request. Section 1847B(a)(1)(A)(ii) of the Act states that each physician is given the opportunity annually to elect to obtain drugs under the CAP.

b. Resolution of Physicians' Drug Quality and Service Complaints

The proposed rule discussed how the participating CAP physician would use the approved CAP vendor's grievance process for drug quality or approved CAP vendor service issues and turn to the designated carrier for assistance in developing solutions. Based on comments from physicians, we have added § 414.917. This new section sets forth a process culminating in termination of the approved CAP vendor's contract for serious quality or service issues. It is described below in the responses to comments.

Comment: Several commenters suggested that CMS make approved CAP vendors indemnify participating CAP physicians for legal defense costs connected with ''adverse drug events'' when the participating CAP physician is ultimately exonerated.

Response: Individual participating CAP physicians and approved CAP vendors can seek legal advice from someone competent to provide such advice regarding the product liability laws and other laws applicable to financial liability associated with adverse drug events. We believe that addressing these complex issues is beyond the scope of this rule.

Comment: Several commenters requested that the final rule include a more definitive process for participating CAP physicians to employ for the resolution of service and drug quality issues. They requested a process that would include suspension of the vendor's right to participate in the CAP program.

Response: Issues connected with drug quality and approved CAP vendor service will be given a top priority. Both the approved CAP vendor and the designated carrier will be required to have qualified staff available to address drug quality and service complaints upon their receipt. Egregious drug safety issues should be brought to the designated carrier right away. For instance, evidence of counterfeit drugs would generate an immediate referral to the appropriate Federal, State, and local authorities, including the Department of Health and Human Services, Office of the Inspector General. The ultimate sanction for service and quality issues is suspension and/or termination of the approved CAP vendor's contract upon exhaustion of the reconsideration process set forth in § 414.917. This process is very similar to the process for removing participating CAP physicians, which is described above and in § 414.916.

When a participating CAP physician is dissatisfied with the drug quality or drug delivery performance of an approved CAP vendor, we expect the participating CAP physician to make a meaningful effort to resolve the issue with the approved CAP vendor informally, and then to use the approved CAP vendor's grievance procedure. The next step is to ask for

the designated carrier's assistance in developing a solution with cooperation from both parties. Failing resolution there, the participating CAP physician may ask the designated carrier to recommend to CMS that the approved CAP vendor's contract be suspended. CMS will act on that recommendation after gathering any necessary, additional information from the participating CAP physician and approved CAP vendor. The vendor may appeal our initial decision through the process articulated in § 414.917.

In response to these comments, we also believe that the process set forth in § 414.917 is the appropriate means for approved CAP vendors to seek a review of our suspension or termination of its CAP contract under § 414.914(a). We are specifying that this process will be available to approved CAP vendors who are dissatisfied with our determination to suspend or terminate the CAP contract for default. While the approved CAP vendor's appeal of our decision is pending, the approved CAP vendor's participation in the CAP would be suspended. We seek further comment about this issue.

In summary, § 414.916 and § 414.917 present several dispute resolution processes to treat program challenges experienced by beneficiaries, participating CAP physicians, and approved CAP vendors. The framework of the process for treating the approved CAP vendor's request to suspend the participating CAP physician's CAP election agreement has been changed in these ways:

- The participating CAP physician may now offer information to the designated carrier as it develops its recommendation on whether CMS should suspend the participating CAP physician's CAP election agreement;
- The participating CAP physician may now offer information to CMS as it makes its decision on whether to suspend the participating CAP physician's CAP election agreement; and
- CMS will not publish in the **Federal Register** the names of physicians whose CAP participation agreements have been suspended.

Section 414.917 has been added to create a process for termination of a vendor's CAP contract upon the request of a physician when service and quality issues cannot be resolved cooperatively.

We will ensure beneficiaries are educated on the avenues available to them to dispute billing issues. Approved CAP vendors may use the advance beneficiary notice (ABN) process if the approved CAP vendor reasonably expects its drug claims may be denied.

c. Resolution of Beneficiary Billing Issues

In the proposed rule, we specified that the beneficiary would receive a medical summary notice (MSN) from the local carrier indicating whether the physician's drug administration claim has been paid or denied. If the drug administration claim has been denied, the MSN would reflect a message instructing the beneficiary that no deductible or coinsurance may be collected for the drug. If the beneficiary receives a bill for coinsurance from the vendor, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. The designated carrier would first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file. If the approved CAP vendor requires targeted education on the subject of beneficiary billing, the designated carrier would initiate that effort.

Comment: Several commenters requested that CMS require every CAP MSN to include standard language clearly explaining the beneficiary grievance process and make clear that the CAP physician is not involved with billing for drug coinsurance amounts.

Response: We share the commenters' concern that beneficiaries should be provided with complete and timely information about the approved CAP vendor's grievance process. We support the commenters' interest in giving the beneficiary notice that the participating CAP physician is independent from the approved CAP vendor. We will consider these comments as the educational materials are finalized. All beneficiary education materials are focus-group tested to be certain they are understandable and communicate the intended message. We will require approved CAP vendors to provide participating CAP physicians with information on how beneficiaries, and participating CAP physicians, can each use their respective grievance processes when the approved vendors send introductory materials to the participating CAP physicians each autumn. It is unlikely the Medicare summary notice will be used to communicate about the beneficiary grievance process because there will exist no billing dispute until the approved CAP vendor actually bills the beneficiary. Information on the beneficiary grievance process will be more appropriately included with any bill the approved vendor may send to the beneficiary. We also will require all participating CAP physicians to distribute the CMS developed fact sheet to beneficiaries in the participating CAP physician's office. The fact sheet presents a good medium for distribution of information on the beneficiary grievance process, and information about the participating CAP physician's independence from the approved vendor.

Comment: Several commenters have requested that we describe whether and how an approved CAP vendor could deliver an ABN to a beneficiary.

Response: An ABN is the standard mechanism for advising beneficiaries of the cost of items and/or services for which they will be financially responsible. Generally, an ABN informs the beneficiary that, even though the service being delivered may be covered by Medicare in some situations, the issuer has reason to believe Medicare coverage policy will not support payment under the circumstances of the present case. For instance, an approved CAP vendor may reach the conclusion that the drug it is providing to the participating CAP physician for administration to the beneficiary would not be reasonable and necessary—and therefore will not be paid for by Medicare—after reviewing data on the prescription order and having follow-up communication with the participating CAP physician. The approved CAP vendor may request the participating CAP physician to deliver an ABN. If the participating CAP physician agrees to do so, then the physician will describe on the ABN both the administration services and the drug product, together with the estimated cost for each that the beneficiary must pay if he or she receives the drug.

If the participating CAP physician will not deliver an ABN on behalf of the requesting approved CAP vendor, then the approved CAP vendor may issue an ABN directly to the beneficiary before the item(s) or service(s) is received. For instructions and forms connected with ABNs, please visit this Web site: *http//www.cms.hhs.gov/medicare/bni.*

C. CAP Contracting Process

1. Quality and Product Integrity Aspects

Sections 1847B(b)(2), 1847B(b)(3), and 1847B(b)(4) of the Act address the issue of quality under the competitive acquisition process at both the product and approved CAP vendor level. We proposed to use the bid evaluation

process to ensure that these quality aspects are met.

a. Information To Assess and Ensure Quality

Sections 1847B(b)(2) and 1847B(b)(3) of the Act specifically require that approved CAP vendors meet financial and quality of care requirements aimed at assuring the stability and safety of the CAP program. Section 1847B(b)(2)(A) of the Act requires that approved CAP vendors have sufficient capacity to acquire and deliver drugs in a timely manner within the geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days each week. This section also requires that approved CAP vendors meet quality, service, financial performance, and solvency standards, which include having procedures for dispute resolution with physicians and beneficiaries regarding product shipment, and having an appeals process for the resolution of disputes. We proposed that CMS be allowed to suspend or terminate an approved CAP vendor's contract if the vendor falls out of compliance with any of these quality requirements. Section 1847B(b)(2)(B) of the Act states that the Secretary may refuse to award a contract, and may terminate a contract if the entity's license to distribute drugs (including controlled substances) has been suspended or revoked, or if the entity is excluded from participation in the Medicare or other Federal health care program under section 1128 or 1128A of the Act. In the proposed rule, we stated this requirement is enforced through the routine provider enrollment form monitoring process. We also specified that section 1847B(b)(3)(C) of the Act states that the ability to ensure product integrity must be included in the criteria for awarding approved CAP vendor contracts.

In the March 4, 2005 proposed rule, we stated that at a minimum, we wanted to define a set of overall financial and quality standards to ensure that reputable and experienced vendors are chosen to participate in the CAP. We believe that physicians would be reluctant to participate in the CAP if they had little confidence that the CAP vendors would be reliable and provide quality CAP products. We also stated that approved CAP vendors would be required to provide quality products in a timely manner.

Section 1847B(b)(4)(C) of the Act specifies that any contractor selected for this program ''shall (i) acquire all drugs and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and (ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.'' We proposed to include this requirement in the contracts signed between CMS and approved CAP vendors who are providing drugs or biologicals under this section. We solicited comments on what records or other evidence bidders would be required to furnish and approved CAP vendors would be required to maintain during the contract period.

Comment: Several commenters raised issues related to product integrity and vendors' distribution systems (for example, shipping and storage procedures). In addition, many commenters, including physicians, potential vendors, and a mix of other affected groups, associated high quality with appropriate access to care, avoiding delays in therapy, and beneficiary safety. Commenters did not perceive new or additional product integrity requirements as desirable, but requested that we provide a more specific description of product integrity and other quality requirements. One commenter noted that the criteria for assessing the adequacy of retail pharmacy networks under Tricare and the Part D rule (68 FR 4194) that will be implemented in 2006 exist and that these guidelines could be used to evaluate CAP vendors.

Response: The approved CAP vendors' ability to accurately furnish drug products in a timely manner will be vital to this program's success. Assessment of the bidding entity's ability to perform similar drug distribution tasks and the entity's financial status will occur through the Medicare Provider enrollment process and through a separate CAP Vendor Application. This form was made available for public comment and is pending OMB approval.

In an effort to ensure that the CAP provides high quality service and to protect the integrity of drugs furnished under the CAP, we proposed that the approved CAP vendor be a Medicare provider or supplier, and we proposed additional and more specific requirements on licensing, product integrity, and contract agreements. We plan to implement these requirements in this interim final rule. The proposed regulation and corresponding changes to sections § 414.908(b) and § 414.914(f) of the proposed regulation reflect these requirements. The Provider Enrollment and Vendor Application form process will collect the detailed information that will be used to assess a potential CAP vendor's capacity to acquire drugs, and the ability to provide quality products and service, timely and accurate shipping, use of a compliance plan, history of past experience, and evidence of appropriate State licensure. We believe that the requirements described above will not be improved by incorporating additional criteria intended to assess retail pharmacy networks because CAP vendors are expected to operate differently than retail pharmacy networks. In addition, we have determined that the CAP vendors will be considered suppliers for Medicare purposes.

Comment: Several commenters stated that in order to attract physician participation, quality requirements should be stringent, and approved CAP vendors should be held to very high standards for quality and performance. These commenters agreed that measures, up to and including contract termination, were appropriate means of dealing with failure to adhere to a contractual agreement. One commenter also requested that we clarify the procedure physicians should follow to obtain CAP drugs when an approved CAP vendor is terminated from the program.

Response: As mentioned earlier, entities seeking a contract to furnish CAP drugs will be required to submit detailed information that will be used during the bid evaluation. Ongoing quality assessment will be conducted in a variety of ways, including routine Medicare provider enrollment monitoring, carrier statistics, and complaint monitoring. Approved CAP vendors are also expected to maintain appropriate licensure to furnish CAP drugs in the States in which they are supplying drugs and to maintain status as a Medicare supplier through the contract's period of performance.

During the contract's period of performance, compliance with these standards, as well as such other terms and conditions as we may specify consistent with section 1847B of the Act, will be a contractual requirement. The contract between CMS and an approved CAP vendor shall provide for contract termination for patterns of poor performance, single serious breaches of contract, or failure to comply with applicable laws and regulations. Methods to improve vendor performance and to resolve disputes between parties are discussed in the dispute resolution section of this interim final rule in section II.B.3. We note that the process described in § 414.917 for reconsidering the termination of a CAP vendor's approved status applies not only in cases where the termination was the result of a drug

service or quality issue brought to our attention by a participating CAP physician, but also in cases where we suspend the CAP contract for noncompliance or terminate the CAP contract for cause under § 414.914(a). We believe that this process will provide approved CAP vendors with an adequate process to contest our decision to suspend or terminate the contract. As noted above, pending the final determination under § 414.917, the approved CAP vendor's contract is suspended. Finally, we note that we consider the termination of the approved CAP contract to be separate and distinct from any determination with respect to the approved CAP vendor's status as a Medicare supplier. Therefore, the provisions of 42 CFR part 498 would not apply in the case of the termination of a CAP contract.

Comment: One commenter stated that the statutory requirement to make payments to the vendor meant that vendors would not be permitted to subcontract with a local or State licensed pharmacy, because the pharmacy could not be reimbursed directly. The commenter believes that this would mean that an approved CAP vendor would be required to obtain a license in each State, and the overall cost of the program would be increased.

Response: We do not agree that the statutory requirement that states payments be made directly to the approved CAP vendor would preclude the vendor from subcontracting with another drug distributor or pharmacy. A vendor could subcontract with another entity as long as that entity met all of our approved CAP vendor requirements and the subcontracting arrangement was divulged in the vendor's CAP application. A subcontractor's qualifications, including its history, structure, ownership and measures used to ensure product integrity must be described on the application and will be reviewed during the bidding process. The applicant is also required to certify that other aspects of a subcontractor's operation are in compliance with licensing requirements, Federal and State requirements, including compliance with all applicable fraud and abuse requirements, and that key personnel have not been excluded from participation in various Federal and State health care programs, including Medicare. It is the approved CAP vendor's responsibility to determine that subcontractors remain compliant with these standards. We intend that subcontractors or other entities associated with furnishing CAP drugs under an approved CAP vendor's contract maintain the same standards as the approved CAP vendor for the role that they play in furnishing CAP drugs. Section 414.914(f)(9) of the regulation states subcontractors' requirements.

The approved CAP vendor and the subcontracted entity would need to make arrangements between themselves, so that even if the subcontractor handled the billing in a particular area, it would still be acting as an agent of the vendor and identify itself as acting on the vendor's behalf. Medicare will only make payment to the vendor, and the vendor is responsible for payment to the subcontractor. Payment from the vendor to the subcontractor shall be consistent with all applicable laws, including all fraud and abuse laws such as the physician self-referral (''Stark'') prohibition (section 1877 of the Act) and the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Several comments stated that proven capacity, including specific experience with Part B injectable drugs, was a desirable quality for a vendor. One commenter stated that evidence of Pharmacy licensing would be a sufficient measure as an alternative to the requirement for 3-years of experience furnishing Medicare Part B drugs. Among commenters who discussed a specific timeframe associated with furnishing Part B drug injectable drugs, 3 years was generally acceptable, but some commenters suggested that experience with the drugs in a category would be a better marker. One commenter asked if our 3-year requirement for ''furnishing'' Part B injectable drugs meant furnishing drugs that would be used by physicians for their Medicare beneficiaries under the ASP system, specialty pharmacy, and distribution experience. One commenter also stated that the ability to ship on an immediate basis was highly desirable. Other commenters stated that 3 years of experience furnishing Part B injectables did not measure services expected in a pharmacy dispensing model, and its restrictive nature could decrease competition. Another commenter specifically recommended that we ask for references that could describe the entity's customer service.

Response: Although pharmacy licensing may indicate some vendors' ability to meet certain standards and may be required in some States, we believe that 3 years' experience in furnishing Medicare Part B drugs serves to demonstrate the approved CAP vendors' commitment to maintaining an infrastructure required to acquire, store, and handle these drugs, to ship them in a timely manner, and also demonstrates familiarity with these products at the organizational level.

Information supplied during the provider enrollment process and from the Vendor Application Form addresses the comments above. Although this process does not specifically ask for references, the process collects and checks similar information, including licensure, financial stability, and business affiliations. In response to these comments, we plan to amend the Vendor Application form to include a request for references from businesses or organizations to which the bidding entity has supplied significant volumes of Medicare Part B injectables.

Comment: Several commenters raised issues regarding licensure and its relationship to quality. Although some comments supported the inclusion of pharmacists in the CAP order process, others pointed out that the involvement of additional professionals may not guarantee product integrity.

Response: The issue of licensing is discussed elsewhere in this IFC. We do not seek to pre-empt State law, but we also recognize that licensing requirements may not always guarantee quality. Approved CAP vendors will be required to have and maintain licensure that is required by the State(s) in which they furnish drugs under the CAP. This licensing requirement and additional quality requirements included in the vendor application process and ultimately in the approved CAP vendor's contract are intended to ensure that the CAP provides the highest quality services.

b. Product Integrity

Section 1847B(b)(3)(C) of the Act states that the Secretary must consider the ability of the applicant to ensure product integrity. We proposed that the evaluation include, but not be limited to, the applicants' ability to assure that products are not adulterated, misbranded, spoiled, contaminated, expired, or counterfeit. We stated that at a minimum, all drugs and biologics used in this program must be licensed under section 351 of the Public Health Service Act or approved under section 505 of the Federal Food, Drug, and Cosmetic Act. We also indicated approved CAP vendors would also be required to comply with sections 501 and 502 of the Federal Food, Drug, and Cosmetic Act concerning adulteration and misbranding. We note drug products furnished under CAP are expected to comply with FDA requirements including current good manufacturing practices (See 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act; 21 CFR Parts 210 and 211 for finished pharmaceuticals).

Additionally, we proposed that applicants would be required to employ trained personnel, have appropriate physical facilities, and use adequate security measures to assure that processing, handling, storage, and shipment of drugs and biologicals are adequate to maintain product integrity. Because Federal statutory and regulatory requirements are designed to meet the standards in the paragraph above, we also proposed to require that all applicants comply with State licensing requirements and be in full compliance with any State or Federal requirements for wholesale distributors of drugs or biologics in States where they furnish drugs for the CAP.

Although we did not propose to require applicants to employ measures beyond those required for licensure and regulatory compliance, we believe the measures set a minimum standard, and we requested that applicants discuss any additional measures they have taken to assure product integrity. We suggested that applicants review the report on counterfeit drugs issued by the Food and Drug Administration (FDA), ''Combating Counterfeit Drugs,'' available on the FDA Web site *http://www.fda.gov/counterfeit*. We proposed that applicants describe measures taken to ensure drug product integrity on the CAP vendor application. We provided examples of additional measures that posed minimal burden, but enhance the ability to detect adulterated, misbranded or counterfeit drugs that included the following:

- Complying with the ''Recommended Guidelines for Pharmaceutical Distribution System Integrity'' developed by the Healthcare Distribution Management Association, available at *http://www.healthcaredistribution.org*.
- Cooperating with Federal and State authorities in their investigations of suspected counterfeit drugs.
- Establishing mechanisms to obtain timely information about suspected counterfeits in the marketplace and to educate their employees on how to identify them.
- Notifying appropriate State and Federal authorities within 5 business days of any suspected counterfeit products discovered by the wholesaler.

Comment: A number of commenters agreed that vendors must demonstrate commitment to furnishing products that were not adulterated, misbranded, spoiled, contaminated, expired, or otherwise counterfeit. Commenters also supported CMS' overall approach to maintaining product integrity and vendor contract requirements that include the statutory requirement for acquiring CAP drugs directly from the manufacturer or from a distributor who has acquired the drug from a manufacturer. One commenter also suggested that we require approved CAP vendors to be in compliance with the Prescription Drug Marketing Act (PDMA) in addition to State and other Federal requirements.

Response: The CAP vendor application process, the maintenance of appropriate licensure and Medicare supplier status form the framework for protecting product integrity. We believe that these requirements address the qualifications of personnel who may be handling the drugs as well. The FDA, not CMS, is the agency that is charged with enforcing the PDMA, however approved CAP vendors are still subject to the PDMA's requirements, including the prohibition on the sale of drug samples. Vendors should consult with the FDA for further guidance on the PDMA.

Comment: Another commenter stated that distributors and vendors that participated in the CAP supply chain could verify a product's origin and avoid use of a paper pedigree (a document that tracks the product's origin) by including simple language with shipping materials. The language would verify that CAP drugs were obtained directly from the manufacturer or from a distributor that acquired them from the manufacturer. This commenter also noted that a ''paper pedigree'' system was burdensome and subject to forgery or other types of failure, and that practical electronic pedigrees are a future solution that is 2 to 4 years away.

Response: The statute does not exempt CAP vendors from PDMA requirements, therefore a CAP vendor who makes a wholesale distribution of prescription drugs for which it is not an authorized distributor is required to pass on a pedigree that complies with PDMA and current regulations (see U.S.C. 353(e)(1)(A). Since some CAP drug shipments may not be classified as drug distribution, we also require a distributor who ships to an approved CAP vendor or an approved CAP vendor who ships to a physician's office to include language with shipping material stating that the drug was acquired directly from the manufacturer or that the vendor possesses verification that the drug was acquired directly from the manufacturer and has been acquired in a manner that is consistent with statutory requirements. The approved CAP vendor or the distributor must also be able to immediately furnish evidence to support that information if requested by CMS, its contractors, law enforcement, the designated carrier, or a physician's office. We have modified the regulation text at § 414.906(a)(4) and § 414.914(c)(1) to reflect the comments above.

Comment: Some commenters expressed concern that physicians could not vouch for the quality of products that were opened by the vendor for repackaging, for mixing the drug with other drugs or injectable fluids (admixture), or for removing a part of the contents in order to supply the exact dose for a beneficiary. Therefore, these commenters recommended that vendors deliver their products in the same form in which they are received from the manufacturer, without opening packaging or containers, mixing or reconstituting vials, or repackaging. Specific points of concern included the capabilities of individuals who mix the drug, as well as shipping conditions, storage and stability.

Response: CAP is not intended to require approved CAP vendors to perform pharmacy admixture services, (for example, to furnish reconstituted or otherwise mixed drugs repackaged in IV bags, syringes, or other containers that are ready to be administered to a patient) when furnishing CAP drugs. Admixture services for injectable drugs require specialized staff, training, and equipment, and these services are subject to standards such as United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding—Sterile Preparations. These requirements have significant impact on drug shipping, storage, and stability requirements as well as system cost and complexity. Approved CAP vendors are to ship CAP drugs in unopened manufacturer's packaging. Packages containing multiple individual units of one drug (like vial trays) may be split into quantities that are appropriate for a beneficiary's shipment, but individual vials must be unopened and any packaging surrounding the individual vial must be left intact.

Comment: One commenter mentioned that because approved CAP vendors would obtain drugs directly from the manufacturer or from a distributor who had obtained the drugs directly from the manufacturer, the Healthcare Distribution Management Association (HDMA) Recommended Guidelines for Pharmaceutical Distribution System Integrity would not apply. The guidelines were not intended to be applied to relationships between distributors and manufacturers. Instead, they had been developed for situations when a distributor was planning to buy drug products from another distributor, or to establish trading partner agreements. Because the document was

a guideline, the commenter urged CMS to allow vendors to use the guidelines to fit the individual vendor's circumstances.

Response: The HDMA Guidelines were being used as an example of measures that could be used or adapted in order to decrease risk of product integrity. We did not propose to require applicants to employ further measures beyond those required for licensure and regulatory compliance. However, we would like bidders to be aware of specific additional measures, such as the HDMA Guidelines, that may be used to protect product integrity.

Comment: One commenter stated that a formal compliance program to ensure adherence to drug storage and handling requirements should be required of vendors and distributors, and that this information should be a part of the bid.

Response: We believe that the vendor application process we proposed will adequately assess a bidding entity's compliance plan. The vendor application form specifically requires the applicant to submit a compliance plan that describes written policies, procedures, and standards of conduct articulating the organization's commitment to abide by all applicable Federal and State standards; the designation of a compliance officer and compliance committee accountable to senior management. The compliance plan is also required to establish effective training and education of the compliance officer, organization employees, contractors, agents, and directors; effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee; disciplinary standards; procedures for internal monitoring and auditing; and procedures for ensuring prompt response to detected offenses and development of corrective action initiatives, relating to the applicant's contract as an approved CAP vendor.

In the application and under our regulation at § 414.914(c)(6)), we also recommend that applicants' compliance plans include provisions that require the reporting of fraud and abuse to the appropriate government authority. Approved CAP vendors that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines.

As we mentioned elsewhere, in order to monitor approved CAP vendor quality, we plan to include routine Medicare provider enrollment monitoring, carrier statistics, and complaint monitoring. Vendors are also expected to maintain appropriate licensure to furnish CAP drugs in the States in which they are supplying drugs.

Comment: For quality standards other than product integrity, two commenters suggested that we use the DMEPOS Supplier Manual as a guideline.

Response: The CAP does not encompass DME drugs and is intended to furnish medications to a physician's office. Therefore, we do not believe that the DMEPOS quality standards are an exact match for the CAP. However, we do note that our focus on product integrity, accurate delivery and other vendor qualifications, including enrollment as a Medicare supplier are similar to the DMEPOS standards.

Comment: Several comments questioned how the effects of shipping on product integrity would be addressed and were especially concerned with breakage, damage, and delays. One commenter asked who would bear the cost burden of shipping a damaged drug or a drug whose integrity was in question, and whether replacement would be offered. Another suggested that approved CAP vendors be responsible for maintaining records of product integrity from the time that the vendor received the product until it reached the physician's office, including situations where a third party shipper transported the drug to the physician's office.

Response: Approved CAP vendors are required to ship drugs in a manner that will protect product integrity and a manner that is consistent with the definitions of the CAP delivery time frames, contractual obligations under the CAP, and drug stability requirements. Approved CAP vendors are also responsible for keeping records of how and when a specific drug order was shipped to the physician's office. Finally, vendors are financially responsible for the shipping costs associated with the return of drugs, and the approved CAP vendor retains title to the drug until it is administered. However, as noted above, other issues regarding product liability laws and other laws applicable to financial liability associated with adverse drug events are beyond the scope of this rule.

Comment: Commenters suggested that we provide specific guidance on how to manage drug waste and returns.

Response: Although a variety of situations may create quantities of unused drugs at the place of administration, we believe the unused CAP drugs will come in 3 forms: an unopened vial (and/or vial package) as shipped by the approved CAP vendor, an opened vial (that may or may not be reconstituted or partly used), and a drug that has been removed from a vial or package and is in a syringe, IV bag, or other device or container used for drug administration. Unused quantities of a drug may increase the risk of waste, fraud and abuse, and attempts to use the excess drug may violate pharmacy law and may compromise product integrity. We expect that approved CAP vendors will furnish drugs in a manner that will minimize unused drug. We also expect that physicians and approved CAP vendors will both make an effort to label, ship, and store drugs in a manner that will allow the legal reuse of an unopened and intact container of a drug. Returns of unused products through a distribution system may be acceptable, however many States prohibit reusing drugs that have been dispensed by a pharmacy (For further information, see FDA CPG 460.300). We are aware of situations when an approved CAP vendor may label a vendor-supplied outer container for prescriptions to keep the actual manufacturer's packaging intact and unlabelled. We further expect approved CAP vendors to offer and ship units of a drug that match the beneficiary's dosing requirements and HCPCS billing amount as closely as practical. In this way, a degree of waste will be prevented. Specific details, including how waste, returns, and their cost burden are handled, will depend on State law and regulation as well as the individual situations. Approved CAP vendors should establish policies on these issues (making sure that they comply with applicable laws and regulations) and make the policies available for physicians to review during the election period and through the CAP contract's period of performance.

Approved CAP vendors will furnish drugs to physician's offices in unopened vials. However, in situations where a drug is dosed by body weight or body surface area, the amount of drug in vials may not match the patient's actual dose, and the vendor will be forced to ship excess drug. In certain States, pharmacy law may prevent the use of excess CAP drug for another beneficiary if the order must be labeled as a prescription.

The return process is guided by the following:

- Federal Law and guidelines (such as the FDA's CPG 460.300), State law, Medicare requirements (such as the Claims Processing Manual), drug stability, and appropriate standards (such as United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding—Sterile Preparations) will be used to determine how extra

drug product may be used for subsequent dosing on the same beneficiary or for use on another beneficiary.

• If excess drug product remaining in a vial shipped by an authorized CAP vendor must be returned, the approved CAP vendor is expected to accept excess drugs for disposal and is expected to pay for shipping. The physician is responsible for appropriately packing the drug. Consolidating shipping into larger and less frequent packages by the physician would be encouraged. We do not intend for this requirement to be used as a vehicle for routine disposal of empty or nearly empty vials, disposal of any drug product not shipped by an authorized CAP vendor, or disposal of drug mixed in IV bags, syringes, associated needles and tubing, or other devices used in the administration of the drug product to a beneficiary.

• The vendor bills Medicare only for the amount of drug administered to the beneficiary and the beneficiary's coinsurance amount will be calculated from the quantity of drug that is administered. Since the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment. We have modified the proposed regulation at § 414.906(a)(5).

The CAP dispute resolution process will be available to resolve any associated disputes. This process is described in the interim final rule at section II.B.3.

Comment: Commenters also cited ''brown-bagging'' (that is, having a beneficiary pick up a drug at a pharmacy and bring it to the physician's office for administration) as a potential threat to product integrity as well as an inconvenience for the beneficiary.

Response: We agree that the practice of brown bagging may jeopardize product integrity by potentially subjecting the drug to unknown storage conditions and exposing the drug to diversion. Brown bagging may also create a further burden on the beneficiary by requiring additional time and travel to obtain the drug product and then requiring appropriate storage of the drug. Section 1847B(b)(4)(E) of the Act indicates that drugs furnished under the CAP must usually be shipped directly to the physicians. The CAP is being implemented in a manner consistent with section 1847B(b)(4)(E) of the Act; therefore, we do not expect ''brown bagging'' to occur.

c. Financial Performance and Solvency Standards

Section 1847B(b)(2) of the Act discusses the financial performance and solvency standards we must develop for entities that seek to become approved CAP vendors. We proposed to fold integrity and internal control aspects of fiscal responsibility into this analysis.

In the March 4, 2005 proposed rule, we stated that while licensure by the State to distribute drugs may assess some degree of financial responsibility, we believe the focus and depth of financial capability evaluations associated with licensure might vary across States. To assess bidders' financial solvency in a consistent manner with appropriate scrutiny and minimal burden on the bidders, we proposed using criteria from the Federal Acquisition Regulation (FAR) Section 9.104 and following standards for ''responsible contractors'' as a baseline standard. The FAR standards also contain nonfinancial components that address areas such as integrity, performance, and ethics. In addition, we sought to add standards that would demonstrate the following:

Overall Capitalization and Financial Capability and Working Capital

We proposed that bidders furnish a copy of their most recent year's audited financial statements. Specific items, such as net worth, could be used in the evaluation process. We requested comments on the potential validity of specific financial indicators for this process and whether or not specific thresholds would be applicable. We also requested comment on this overall requirement from potential bidders, such as group purchasing organizations Group Purchasing Organizations (GPOs), who do not routinely take possession of drug products.

We proposed to review the audited financial statements to determine if the bidder has adequate working capital to meet contractual obligations. Ratios of current assets to current liabilities, total liabilities to net worth, and cash or cash equivalents to current liabilities are commonly used to assess financial capability (see the form at FAR 53.301–1407). Given the 3-year contract duration, we requested comments regarding the appropriateness of these tests, and thresholds to apply for the ratios.

Comment: Several commenters noted that financial standards in the proposed rule were not clearly defined. One commenter agreed that financial capability standards were important, but cautioned against setting standards that could unfairly or inadvertently exclude bidders due to insufficient capitalization, while another suggested that credit worthiness be evaluated in cases where a bidder was seeking to expand operations by participating as an approved CAP vendor. Other commenters suggested that vendors have significant financial stability to withstand the potential risk of participating in CAP and that debt to capital ratio be included in the evaluation because the commenter considered financial ratio to be particularly useful in assessing a prospective vendor's financial stability.

Response: In the proposed rule we stated that we sought to define a set of overall financial standards that would ensure that reputable and experienced vendors are chosen to participate in the CAP. As noted by several commenters, the proposed rule was intended to provide us with a framework to which we could add details based on public comment.

Financial data supplied by the bidders is intended to demonstrate that the entity is capitalized, generating sales volume, and is not operating at a loss. We also plan to use several simple financial ratios from Standard Form (SF) 1407, Preaward Survey of Prospective Contractor Financial Capability (see FAR 53.301–1407) to determine whether a contractor has financial resources to perform a contract. We expect bidders to have a current ratio (current assets : current liability) of >1. However, many bidders are expected to have significant inventory, particularly if they are engaged in drug distribution activities. We will also apply the quick ratio (also known as the acid test ratio, that is, current assets minus inventory : current liability). Comparison of the current and quick ratios also gives a sense of the relative amount of inventory that an entity may possess The debt to equity ratio (total liability : net worth) is intended to gain a sense of the role that creditors have in financing the entity's operations. These ratios will be used to help assess whether the vendor can meet obligations to deliver CAP drugs on receipt of a prescription order. More specific financial information, such as audited annual financial statements, will be used to confirm the general findings above.

Bidding entities could be a diverse group that could include single organizations or groups. The entities could have a variety of backgrounds including drug distribution, specialty pharmacy, or group purchasing. Therefore, in an effort to minimize the risk of having an absolute threshold disqualify a potentially capable bidder,

we are avoiding using absolute thresholds when possible. Instead, we plan to compare data, especially the financial ratios, and use the data to rank bidders relative to one another. We will rank the bidders on four basic financial categories: Financial ratios, profitability, capitalization, and total sales. These rankings would then be used along with quality information provided during the bidding process and bid prices to select vendors who will be offered a contract to furnish drugs under CAP. A lower financial ranking will not be an absolute reason for exclusion from the bidding process, but will be one of several factors being evaluated.

Comment: One commenter stated that requiring bidders to have Medicare sales account for less than half of their total predicted sales volume for the upcoming year would demonstrate an entity's scale and would limit the entity's dependence on Medicare as a means to ensure financial viability.

Response: Although we believe that experience with Medicare Part B injectable drugs is necessary for a vendor, we do not believe that it would be appropriate for us to set a limit in the manner the commenter suggests because it could interfere with the vendor's business planning and may have the effect of excluding qualified bidders.

Comment: Group Purchasing Organizations (GPOs) and similar entities who do not routinely take possession of drug products were invited to comment on the assessment of a bidder's financial capability. However, we received one comment from a GPO expressing concern about the significant financial risk of long-term receivables and low margins, but GPOs did not comment specifically on proposed financial indicators.

Response: We will use the financial evaluation process outlined earlier. By statute, payment for drugs furnished under CAP is conditioned upon the administration of a drug to the beneficiary. This limits how soon a vendor can be paid. We believe that establishment of operations and the opportunity for periodic price adjustments will create an opportunity for the vendors to achieve financial stability while participating in the CAP.

Comment: Several commenters agreed with deriving financial and solvency standards from the FAR. Commenters also suggested that FAR business integrity and conflict of interest standards be adopted. Finally, commenters requested details on how ongoing compliance would be monitored, which parameters would have to be reported, and penalties for failing to report standards or missing the standards.

Response: The proposed rule mentions using FAR Section 9.104 as a baseline for evaluating a prospective contractor. We also adapted a form (FAR 53.301–1407) used for the preaward financial evaluation of a contractor for use in the Vendor Application. However, the FAR does not contain specific financial solvency standards.

We did not propose a competition strictly based on FAR, nor do we plan on implementing CAP in this manner in this interim final rule. Business integrity, conflict of interest, compliance, and penalties are discussed in section 2.B.2 of this interim final rule.

Record of Integrity

We proposed that the bidders supply us with applicable information on whether any of the bidder's Board of Directors, employees, affiliated companies, or subcontractors—

- Know they are under investigation by any State, Federal, or Local Government agency related to a fraud issue; and
- Have escrowed money in anticipation of, or entered into a settlement agreement or corporate integrity agreement with any State or Federal Government agency related to a fraud issue.

We also proposed that bidders provide a conflict of interest mitigation plan to address financial relationships the bidder may have with manufacturers of drugs or biologicals in the CAP.

We received no comments on this topic. Therefore, we will finalize these requirements as proposed. The vendor application process, which includes enrollment as a Medicare Supplier and the completion of the Vendor Application and Bid Form will provide information related to a record of integrity. Bidders will also be required to submit a conflict of interest mitigation plan as described above during the vendor application process. Conflict of interest and mitigation strategies are described in section II.2.C.3. in this interim final rule.

Internal Control

We proposed to review information relating to the establishment and effectiveness of the bidder's internal control system designed to provide reasonable assurance of financial and compliance objectives. We provided examples of information that we might review as evidence of the design and effectiveness of a bidder's internal control system.

We proposed to set forth these requirements in regulations at proposed § 414.908.We received no comments about internal financial control. Therefore, we will finalize these requirements as proposed.

Deemed Compliance

In the proposed rule, we noted that some vendor applicants may already be subject to financial oversight by one or more State or Federal regulators. The vendor applicant's current financial reporting may satisfy one or more of the above requirements. We proposed to request documentation of this parallel oversight together with contact information for the regulator. We would contact the regulator to inquire as to the vendor applicant's status and we may deem certain portions of the above requirements ''met'' at our discretion. We received no comments on this topic.

Therefore, we will finalize these requirements as proposed.

2. Bidding Entity Qualifications

a. Quality and Financial Information—Vendor Application

In the March 4, 2005 proposed rule, we stated that the vendor would be responsible for completing and meeting all criteria on both the Vendor Application Form and the Provider/Supplier Enrollment Application (Form CMS 855B) (for the purpose of completing these applications, vendors will be considered suppliers) by the established deadlines in order to be considered as a potential vendor under the CAP. For example, if a vendor has been excluded from participation in a Federal health program, or has been convicted of a fraud-related crime, the vendor must record that on the form 855B. We would treat these admissions from vendors in the same manner as we do for other suppliers. Both a draft copy of the Vendor Application Form and the Provider/Supplier Enrollment Application (Form CMS 855B) are available on the CMS Web site at the following address: *http://www.cms.hhs.gov/providers/drugs/*). Both forms are needed to cover all required vendor qualifications.

In the proposed rule, we stated that we would require that the vendor be prepared to offer complete information in four major areas and complete a certification statement. The vendor's business experience would be required to be within the United States. In addition, we proposed to require that prospective vendor provide on the Vendor Application Form, a complete list of drugs that the vendor would

intend to bid by National Drug Code (NDC) number.

Management and Operations

We proposed to require that the vendor attest that adequate administrative arrangements are in place to ensure effective operations, such as but not limited to, policies that assure that business is conducted in the best interest of the customer, maintenance of fidelity bonds, and insurance policies to cover losses. General identifying information would also be required such as business name, address, taxpayer identification number, contacts representing the organization, and a description of the organization's structure. In addition, we proposed that each subcontractor, subsidiary, or business affiliate that is used by the vendor under the CAP would be required to provide the same information.

Experience and Capabilities

In the proposed rule we stated that the approved CAP vendor would be required to:

- Maintain the operation of a grievance process so that physician, beneficiary, and beneficiary caregiver complaints can be addressed;
- Provide a prompt response to any inquiry as outlined in the vendor application form;
- Maintain business hours on weekdays and weekends with staff available to provide customer assistance for the disabled, including the hearing impaired, and to Spanish speaking inquirers; and
- Provide toll free emergency assistance when the call center is closed.

We emphasized that customer service is a primary consideration, especially the ability to respond on an emergency basis to participating CAP physicians. In addition, we stated that a working telephone customer service number be submitted for verification during the bid evaluation process.

Section 1847B(b)(2)(A)(i)(II) of the Act gives some guidance regarding timeframes for routine and emergency shipment; however, the statute does not provide specific definitions of these timeframes. Therefore, we requested comment on how to define timely delivery for routine and emergency drug shipments. For the purposes of this discussion, we proposed that the delivery time period would begin when a drug order is received by the vendor and would end at the time of delivery to the participating CAP physician's office or other intended setting. We proposed that routine shipments of drugs furnished under the CAP would occur within a 1 to 2 business day time period. However, the duration of the delivery time period must not exceed the drug's stability in appropriate shipping containers and packaging. We requested comments on the feasibility of requiring a shorter duration for routine delivery of CAP drugs. This discussion is included in section II.B. of this interim final rule, ''Operational Aspects of the CAP.''

We proposed to require that approved CAP vendors maintain a formal mechanism for responding to complaints from participating CAP physicians, beneficiaries, and their caregivers (if applicable). In the proposed rule, we stated that evidence of this mechanism, in the form of any complaint resolution manuals, agendas, and minutes from complaint resolution committee meetings, or other evidence of complaints being resolved would be submitted as part of the bid application.

In addition to providing an audited financial statement as an attachment, we proposed that the vendor be required to present a standardized summary of financial information on the collection form. We also proposed that the vendor must have been in the business of furnishing Part B injectable drugs for at least 3 years, and specifically requested comment on whether the requirement of 3 tax reporting years of experience would prevent newer vendors with sufficient experience and resources from being included in the program. We also proposed that the vendor would be prepared to offer and substantiate the drug volume managed (in dollars and units) for the immediate previous calendar year and provide specific personnel statistics such as the number of staff assigned to various activities, and its policy-making organizational structure within the United States.

Finally, because selected approved CAP vendors would be considered a covered entity under the HIPAA Administrative Simplification Rules, to the extent that they conduct any of the standard HIPAA transactions electronically, these approved CAP vendors would be required to comply with the Administrative Simplification rules, including the Privacy Rule.

Comment: Some commenters were concerned with our proposed requirement for a vendor to have been in business for 3 years as one of the thresholds for participation in the CAP. These commenters argue that there is no correlation between business longevity and quality of care.

Response: The statute directs us to select among qualified bidders based on, among other things, past experience in the distribution of drugs and biologicals. We believe that it is reasonable to expect a vendor who seeks to participate in the CAP to have been in the business of furnishing Part B injectable drugs for at least 3 years because that will provide us with an appropriate amount of information to assess the applicant's past experience. We believe that requiring a potential vendor to prove 3 years of experience would allow us to evaluate their ability to use resources appropriately based on their past performance. Vendors with less than 3 years of experience would not be in a position to demonstrate any kind of a track record that could be reviewed so that we could be assured of their ability to perform effectively and in an acceptable manner under the CAP. Finally, a vendor who meets all the criteria except that it has not yet been in the business of furnishing Part B injectable drugs for the required 3-year threshold is free to participate in the CAP once it has met the 3-year requirement.

Comment: Commenters suggested that submitted bid information provided by the vendor should be kept confidential and protected from public disclosure.

Response: As we mentioned in the proposed rule, we will follow HIPAA standards to protect privacy. All cost information will be confidential and not made available for public display. In accordance with section 1927(b)(3) of the Act, bid prices will be kept confidential.

Comment: Commenters suggested that CMS collect additional information on the vendor's application forms.

Response: We believe that the vendor information submitted on the Form 855B (the Medicare fee-for-service physician/supplier enrollment form) and the vendor application forms is sufficient.

Licensure

We proposed that the vendor would be required to maintain an appropriate license in each State in which the drug vendor seeks to operate under the CAP. We also proposed to require that the vendor certify that any subcontractor or subsidiary also maintains a license that complies with State regulations in every applicable State.

Comment: Several commenters believed that we should require a vendor to be licensed to operate a pharmacy as well as to be a licensed wholesaler in the States in which the vendor seeks to do business under the CAP. These commenters stated that the drug dispensing duties of a vendor naturally require the experience and

expertise of a pharmacist, rather than a general wholesaler.

Response: We believe that vendors must operate as distributors in order to participate in the CAP, and we recognize that a natural outgrowth of participating in this program may be that those distributors also will need to be licensed as a pharmacy. Regardless, either the vendor, its sub-contractor under the CAP, or both, must be licensed appropriately by each State to conduct its operations under the CAP. Therefore, a vendor under the CAP would be required to be licensed as a pharmacy as well as a distributor if a State requires it. Because our initial competitive acquisition area is nationwide, appropriate licensure in all States would be required. We note that by its terms, nothing in section 1847B of the Act shall be construed as waiving applicable State requirements relating to the licensing of pharmacies.

Business Integrity

In the proposed rule, we stated that the vendor would be responsible for identifying and disclosing business relationships and conflicts of interest as well as potential conflicts of interest with other organizations. We also stated that the vendor would be required to answer questions and provide information about fraud investigations, settlement agreements, and Federal government exclusions.

Comment: We received several comments supporting our strong requirements related to vendor qualifications, including management and operations standards, operation of a grievance process, experience, HIPAA compliance, licensure, and business integrity. Commenters believe that the requirements were necessary to ensure that only qualified entities were selected as CAP vendors.

Response: In evaluating whether to award a CAP vendor contract or renew an approved CAP vendor contract, CMS will take into account a bidder's record of corporate integrity and performance and will review the bidder's internal integrity measures, which include at a minimum, a compliance plan to prevent fraud, waste and abuse. We appreciate comments in support of our approach to review these criteria as part of our selection and renewal process. As a result, we are retaining our requirements for potential vendors under the CAP. Additionally, in response to comments we are including language at § 414.908(c) that permits CMS to refuse to award or terminate a contract based on a potential CAP vendor's past violations or misconduct related to the marketing, distribution, or handling of drugs. This requirement will strengthen CMS' efforts to ensure that entities granted the ability to provide Medicare products or services have a record of corporate integrity and performance that reflects the provision of scrupulous products and services.

Certification

We proposed that the vendor be prepared to certify that all the information in the Vendor Application Form is true, accurate, and complete and to certify to any other requirements as specified by us. Failure to provide correct and updated information when it becomes available, if it affects the information provided on the Vendor Application Form, may be cause for termination of the vendor's contract under the CAP. We believe that it is vital to certify that the information provided is accurate. We received no comments on this issue, so, as a result, we are finalizing that requirement in this rule. In addition, we provide further direction for vendor and subcontractor conduct in the next two sections (Fraud and Abuse as well as Conflicts of Interest).

b. Specific Information Relating to Prevention of Fraud and Abuse

Section 1847B(b)(4)(D)(ii) of the Act requires that the approved CAP vendor comply with all applicable provisions relating to the prevention of fraud and abuse. This includes compliance with applicable guidelines of the Department of Justice (DOJ) and the Office of the Inspector General (OIG) of the DHHS.

In accordance with this statutory authority, we proposed that each approved CAP vendor develop and maintain a compliance plan to control program fraud, waste, and abuse, that includes at a minimum, the requirements proposed at § 414.914(c) of our regulations. These requirements already apply to many of the entities participating in the Medicare program, such as prescription drug plans administering the prescription drug benefit and Medicare Advantage organizations. In addition, the OIG has recommended these minimum elements in published guidance.

We stated in our proposed rule that a compliance plan should contain policies and procedures that control program fraud, waste and abuse. In developing written policies, procedures, and standards of conduct for detecting and preventing waste, fraud and abuse, we stated that approved CAP vendors should consult a variety of sources including applicable statutes and regulations and compliance guidance issued by CMS, our contractors, Program Safeguard Contractors (PSCs), and the OIG. We provided some recommended sources for relevant information. Approved CAP vendor compliance plans must be submitted with the CAP applications, and must be available to us and our contractors for periodic reviews.

We also proposed that approved CAP vendors and entities that they contract with establish effective training and education programs related to fraud, waste and abuse that address pertinent laws related to fraud and abuse including the physician self-referral (''Stark'') prohibition (section 1877 of the Act) and the Federal Anti-Kickback statute (section 1128B(b) of the Act), and the False Claims Act (31 U.S.C. 3729–3733). In addition, we proposed that approved CAP vendors and entities that they contract with be trained on detecting and preventing common fraudulent schemes in the pharmaceutical industry, as identified by CMS, the OIG, and/or the DOJ and provided examples of some common fraudulent or abusive problems within the pharmaceutical industry.

To ensure successful internal monitoring and auditing of fraud, waste, and abuse under Part B, we proposed that approved CAP vendors should regularly monitor and audit their processes and procedures to ensure that they are in fact taking the steps necessary to comply with all Federal and State regulations and to mitigate the potential for waste, fraud, and abuse within their organizations. Establishing procedures to ensure prompt responses to potential fraud violations is an important element in an effective fraud and abuse plan. Approved CAP vendors are responsible for monitoring and identifying potentially fraudulent or abusive activity. We further stated that after an approved CAP vendor has determined that any misconduct has violated or may violate criminal, civil or administrative law, the approved CAP vendor should report the existence of the misconduct to OIG or other appropriate government authority within a reasonable period, but no later than 60 days after the determination that a violation may have occurred. Self-reporting of fraud and abuse is a critical element to an effective compliance plan, and approved CAP vendors are strongly encouraged to alert CMS, the PSCs, the OIG, or law enforcement of any potential fraud or misconduct relating to the CAP. We investigate all cases referred as potentially fraudulent and then refer them to the appropriate law enforcement agency as warranted. Likewise, we expect that the approved CAP vendors would fully cooperate in

any investigations related to fraud identified in a particular approved CAP vendor's organization.

We are aware that there are many possible approaches to developing an effective compliance plan. Therefore, we requested comments on the scope and implementation of an effective compliance plan.

Comment: There were some operational comments regarding the opportunity for fraud, waste and abuse. One commenter pointed out that when a drug product sent to a physicians' office is unused and returned to the approved CAP vendor, this transaction could allow for the opportunity for fraud and drug spoilage. Because CAP drugs are kept in a separate inventory, a commenter asked if inventory errors would be subject to prosecution for fraud and abuse.

Response: We discuss the design of the inventory and return process in section II.B.2 of this interim final rule and the product integrity requirement in section II.C.1 of this interim final rule. We believe these processes, along with the fraud, waste and abuse provisions outlined above provide a framework for ensuring the integrity of the product delivery process. We note that the return of a product must be in accordance with applicable State and Federal laws. The approved CAP vendor is responsible for providing appropriate drug product delivery to the participating CAP physician's office that preserves that drug's integrity. The participating CAP physician is responsible for not accepting delivery of a drug product damaged during shipment or whose integrity the participating CAP physician believes was compromised. It is also the responsibility of the participating CAP physician to store appropriately an accepted product delivery to ensure its continued integrity.

Typically, there must be intent to commit fraud in order for the government to subject a physician or approved CAP vendor to prosecution for fraud and abuse. Minor inventory errors normally would not subject a participating CAP physician or approved CAP vendor to prosecution for fraud and abuse. Approved CAP vendors and participating CAP physicians each are responsible for complying with all laws and regulations applicable to them that govern the receipt, storage, and return of drug products. Participating CAP Physicians and approved CAP vendors may be held accountable for failing to adhere to any applicable requirements. We will investigate all cases brought to our attention as potentially fraudulent and then, if warranted, refer them to the appropriate law enforcement agency.

c. Conflicts of Interest

Section 1847B(b)(4)(D)(i)of the Act requires that approved CAP vendors participating in the CAP comply with a code of conduct, specified or recognized by the Secretary. The statute authorizes us to require approved CAP vendors to establish a code of conduct related to conflicts of interest in bidding and performance.

In the March 4, 2005 proposed rule, we stated that a code of conduct should function much like a constitution, that is, it should be a document that details the fundamental principles, values, and framework for action within an organization. We proposed that the code of conduct for approved CAP vendors articulate the approved CAP vendor's expectations of commitment to compliance by management, employees, and agents, and summarize the broad ethical and legal principles under which the company must operate.

Avoiding conflicts of interest and the appearance of these conflicts is critical to the operations of the CAP. In accordance with our statutory authority under the Act, we proposed to require that each approved CAP vendor establish and follow a code of conduct that addresses its policies and procedures for identifying and resolving any conflict of interest. We stated that a conflict of interest may occur where an approved CAP vendor, its representative, or contractor provides a product or service for a Medicare participating CAP physician or beneficiary and the approved CAP vendor, representative or contractor has a relationship with another person, entity, product or service that impairs or appears to impair the approved CAP vendor's or contractor's objectivity to provide the Medicare-covered product or service. Situations that compromise or appear to compromise an approved CAP vendor's ability to avoid self-dealing when providing a Medicare product or service create a conflict of interest and must be resolved. Approved CAP vendors should take steps to identify and mitigate any conflict of interest that may arise in the provision of a product or service for a Medicare participating CAP physician or beneficiary.

We indicated the code of conduct should communicate the need for all management, board of directors, employees, and agents to comply with the approved CAP vendor's code of conduct and policies and procedures for addressing and resolving conflicts of interest. It also should reflect the approved CAP vendor's commitment to detect and resolve any conflict of interest. The code of conduct should establish procedures for determining whether or not a conflict exists, and if so, how the conflict will be resolved. We proposed that the code of conduct address issues such as whether or not the offer or acceptance of some remuneration to or from an approved CAP vendor, physician, beneficiary, or manufacturer would diminish, or appear to diminish, the objectivity of professional judgment; or whether or not certain transactions raise patient safety or quality of care concerns.

In addition, throughout the solicitation of CAP contracts, we proposed that approved CAP vendors comply with the requirements of the FAR organizational conflict of interest guidance, found under 48 CFR Subpart 9.5, and the requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act. Consistent with FAR 9.507–2, in making awards to approved CAP vendors, we proposed that each contract contain a conflict of interest clause specific to the approved CAP vendor for inclusion in the contract.

We proposed fairly general conflict of interest requirements because we believe that individual contracts may be a better venue to address specific conflicts of interest. However, we solicited comments regarding what may or may not constitute a conflict of interest in the CAP program and how such conflicts might be identified and mitigated.

We proposed to set forth our conflict of interest policies and procedures in regulations at proposed § 414.912.

Comment: One commenter suggested that CMS require full disclosure of an approved CAP vendor's corporate relationships during the bidding process and take steps to prevent monopolization by any one company within the bidding or contract award stages of the CAP program. This includes adopting language that requires corporate-structure disclosure and specifically prohibits approved CAP vendor subsidiaries from bidding against their parent company or other subsidiaries with the same parent company. The commenter suggested that CMS revise the language of § 414.908(e), ''Multiple contracts for a category and area,'' § 414.910(a) on the bidding process, and elsewhere, to reflect this bidding and contract award restriction. Another commenter suggested that the final rule address situations in which a company affiliated with a potential approved CAP vendor

manages a physician or medical/nurse practice. In these cases the physician may have no effective choice of an approved CAP vendor and non-affiliate vendors may not have a meaningful opportunity to compete for the business of the practice. The commenter recommended that the final rule include explicit conflict of interest standards to guard against preferential selection and treatment of potential approved CAP vendors that are affiliated with physician and medical/nursing practice management companies.

Response: The proposed rule stated that the approved CAP vendor's code of conduct should communicate the need for all management, board of directors, employees, and agents to comply with the approved CAP vendor's code of conduct and policies and procedures for addressing and resolving conflicts of interest. Also, consistent with FAR 9.507–2, in making awards to approved CAP vendors, each contract will contain a conflict of interest clause specific to the approved CAP vendor for inclusion in the contract. We believe this will identify potential conflicts of interest pertaining to participation in the CAP. Approved CAP vendors that are affiliated with a medical practice management company do not create a per se conflict of interest. However, these relationships should be entered into carefully and monitored closely for the appearances of a conflict of interest. There are a minimum of two and a maximum of five approved CAP vendors in each category in a given CAP area. In the optimal situation, there will be five approved CAP vendors for a given drug category, and where a conflict of interest is obvious between one approved CAP vendor and a physician's practice, the physician's practice would have up to four other approved CAP vendors to choose from, and should choose one of those other approved CAP vendors accordingly. Based on the comments received and data analysis discussed elsewhere in this interim final rule with comment period, there will be one extensive CAP category of drugs covering one single national area including all States, the District of Columbia, and the U.S. Territories. If there are only two approved CAP vendors for a given drug category and there is a potential conflict of interest, the physician's practice has two options to consider. The physician's practice can choose to receive drug products under the CAP program from the approved CAP vendor with which it does not have a conflict, or the physician's practice can choose not to participate in the CAP program.

Medical and utilization review activities currently utilized by carriers and CMS Program Integrity contractors will be applied to the provision of drug products through the CAP program. These efforts will help to ensure the medical necessity of the drugs provided and to monitor for inappropriate utilization that may stem from improper preferential selection.

Comment: Some commenters were concerned that the creation of formularies could have the appearance of conflicts of interest if their purpose was to steer market share toward one drug in a category over another in response to contracting discounts and rebates. Commenters believed this could occur if physicians are required to acquire drugs within categories as defined by the approved CAP vendor, and the approved CAP vendor offers only a limited selection of the possible drugs.

Another commenter suggested that CMS prohibit approved CAP vendors from offering physicians financial incentives to stock preferred drugs specifically for ''re-supply'' under the CAP. This will help prevent approved CAPs from enforcing preferred status in the CAP by controlling which agents a physician keeps in-stock (for example, for their commercially insured patients).

Response: We believe that the code of conduct should address issues such as acceptance of remuneration to or from an approved CAP vendor, participating CAP physician, beneficiary, or manufacturer that would diminish, or appear to diminish, the objectivity of professional judgment; or whether or not certain transactions raise patient safety or quality of care concerns. Section II.A.2 of this interim final rule describes the development of the drug category. The drug category was intended to be a list of HCPCS codes for the Part B drugs and biologicals on which a potential CAP vendor may bid. It does not constitute a drug formulary. We do not expect there to be creation of a drug formulary. As discussed above, there will be one extensive CAP drug category. It will include many of the HCPCS for drugs commonly used by physicians' offices, but not all of them. Also, as discussed before, an NDC number represents a specific drug manufacturer's product formulation and package size for its drug product. Currently there may be more than one NDC number associated with a HCPCS code if the drug is multi-source, is available in multiple package sizes, or if the drug is available in different formulations. A participating CAP physician, who has elected a CAP vendor from whom he or she wishes to order drugs, may find it medically necessary to require a specific drug represented by a specific NDC within a given HCPCS code. If the CAP vendor has contracted to provide a drug within that HCPCS code but not the specific NDC that the participating CAP physician requires, then the participating CAP physician may obtain the drug through the ''Furnish As Written'' option discussed in section II.B.2 of this interim final rule. If the participating CAP physician needs to obtain a drug identified by a HCPCS code that is not available from the CAP vendor, the participating CAP physician may continue to obtain the drug through the normal ASP system.

In response to the re-supply comment, section II.B.1 of this interim final rule describes the conditions under which a drug administered from the participating CAP physician's supply may be replaced with a CAP drug. These occurrences are expected to be few and only in the event of an emergency. The utilization of this option will be monitored to detect patterns of abuse through carrier and CMS Program Integrity contractor oversight.

Comment: A commenter commended CMS on the thorough code of conduct language. The commenter stated that they currently have an objective third party that monitors and prevents conflicts, and assures some equity within the market.

Response: We believe the commenter is indicating that it has a process in place to monitor for and prevent conflicts in the healthcare market. The commenter seems to indicate that this function should now be the responsibility of the CAP. The CAP is only a small part of the healthcare market. Approved CAP vendors are ultimately responsible for monitoring and preventing conflicts of interest related to only their participation in the CAP. Our contracts with approved CAP vendors will require that approved CAP vendors adhere to a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest. We will also continue to apply the medical and utilization review activities currently used by carriers and CMS Program Integrity contractors to the provision of drugs through the CAP. These monitoring efforts will help to ensure the medical necessity of the drugs provided and to monitor for inappropriate utilization that may stem from conflicts of interest. If an undisclosed conflict is discovered through one of our various reviews, such as a Program Safeguard Contractor audit, we will raise the issue with our

Contracting department and inform law enforcement where appropriate.

Physicians, suppliers, and approved CAP vendors should be aware that we expect all entities with whom we do business to continue to comply with all applicable conflict of interest rules, including the Stark law and Anti-Kickback Statute. We also hope that all entities involved in the CAP will continue to take whatever measures they believe necessary to assure the prevention of conflicts of interest.

Comment: Commenters recommended that CMS prohibit approved CAP vendors from using, sharing or selling patient information for any purpose other than that which is strictly related to fulfilling CAP orders.

Response: An approved CAP vendor is a HIPAA covered entity and is subject to the HIPAA Privacy Rule that governs the use and disclosure of protected health information. As covered entities, approved CAP vendors also are subject to the HIPAA Security Rule.

Record Retention

As in other regulations that apply to entities that retain records of their dealings with the Medicare program, we believe approved CAP vendors should be held to reasonable record retention standards. We seek additional comment on whether these requirements should be further explicated in the final CAP regulation.

After reviewing the comments, we are finalizing § 414.912 with amendments to the content of the code of conduct which is submitted as part of the application process.

3. CAP Bidding Process—Evaluation and Selection

a. Evaluating Bid Prices by the Composite Bid Price

In the March 4, 2005 proposed rule we stated that in selecting vendors, the statute requires consideration of both price and non-price (for example, quality of service and financial qualifications) aspects of the bid. We also stated that technical and financial criteria for selecting CAP vendors would be used to determine which bidders will be awarded contracts to furnish drugs under the CAP. Our ultimate choice of an appropriate evaluation process will take into account the final policies concerning the drug categories, the geographic areas for the program, and comments on our proposed evaluation process. We proposed a basic approach to the evaluation and bidding selection process and encouraged comments on this proposal and recommendations for alternative approaches.

Comment: Several commenters suggested that CMS continue to provide interested parties with opportunities for learning more about the CAP. One commenter specifically suggested that a pre-bid conference be held for potential CAP vendors in order to provide potential bidders with detailed information that bidders could then use to calculate their bid prices.

Response: We agree that communicating information about the CAP bidding process (as well as other aspects of CAP) is necessary. Therefore, we plan to use several methods to communicate bidding requirements, update existing information, provide clarification, and answer questions. While we may not have time to host a formal pre-bid conference, these methods may include a public conference call with potential vendors. We also may hold an open door forum. We will also provide updates to the CAP Web site, and other channels.

Comment: One comment asked for clarification about whether the vendor could provide services to manufacturers for fees and whether this payment would influence ASP calculations.

Response: Bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for an actual service provided by the entity, and that are not passed on in whole or in part to a client or customer of an entity, are not included in the calculation of ASP because these fees would not ultimately affect the price realized by the manufacturer. ''Bona fide service fees'' means expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities.

In the discussion of our proposal for the bidding process as set forth in § 414.910, we assumed that we were conducting competitive bidding for some number of distinct drug categories. We also assumed that bidders with relatively large (including national) distribution networks might also want to submit bids for multiple acquisition areas (depending upon the area definitions that we adopted in the final rule). We stated that these bidders would be permitted either to submit the same bid price for all areas in which they wish to compete, or to submit separate bid prices for each acquisition area. The procedure for evaluating the price component of the bids (and setting payment rates) would be the same regardless of the method for defining the categories of drugs (HCPCS) adopted in the final rule. Section 1847B(c)(6) of the Act requires that the submitted bid price include all costs related to the delivery of the drug to the selecting physician, and the costs of dispensing (including shipping) the drug and management fees. Costs related to the administration of the drug or wastage, spillage, or spoilage may not be included in the submitted bid. We proposed to specify these requirements at § 414.910 of the regulations.

As discussed in the proposed rule, the purpose of requiring vendors to bid for all drugs in a category would be to identify a set of vendors that can supply the range of drugs in that category at an appropriate overall cost. Because a vendor may have different discounts that it can negotiate for a drug, a vendor may be able to bid a lower price for one drug, but not for another drug within a category. We sought to identify a selection process that, in the aggregate, could provide drugs at reasonable cost to the program while maintaining the required quality standards.

We therefore proposed to employ a ''composite bid,'' constructed from the bid prices for the individual drugs in the CAP category, in the process of selecting bidders for the CAP. The composite bid would be constructed by weighting each HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in a particular drug category during the prior year. Within each CAP category, the drug weights would sum to one. Based on data availability, the volume data used for bids in the first CAP bidding cycle (for supplying drugs starting January 1, 2006) would be from 2004 because bidding is anticipated to occur in mid-2005. (We noted that we had not developed a method to weight drugs introduced during and after 2004, but invited public comment on methods for consideration.) The calculated composite bid would equal the average price per HCPCS unit for drugs in that category. In this way, the composite bid would be proportional to the expected cost to the program of acquiring drugs from that vendor (based on the assumption that the 2004 volume in each HCPCS category is roughly proportional to volume in 2006). If one vendor has a lower composite bid than another, it will also have a lower expected cost of supplying all drugs in the particular CAP category.

The statute requires consideration of price and non-price (for example, quality of service and financial qualifications) aspects of the bid. In order to implement this requirement, we proposed a two-step bidder selection process:

• First, all bidders must meet certain quality and financial thresholds.

• Second, winning bidders would be selected from those that meet the quality and financial thresholds based on the composite bids.

We considered several basic methods for evaluating the composite bids. From these alternatives, we proposed a method that bases the selection of winning bidders on a predetermined threshold. Specifically, we proposed that we would select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bidders for a drug category within each area. However, we would not select any bid for the category that is higher than 106 percent of the weighted ASP for the drugs in that category. We believe that limiting the maximum bid price that we would accept is consistent with Congressional intent that the CAP promote savings.

We proposed this method for selecting bids because it is straightforward and relatively easy to implement. In addition, rejecting composite bids that exceed the payment level under the new ASP payment methodology is consistent with one major purpose of the new competitive acquisition system, since it creates the possibility of realizing savings to the Medicare program. We believe this method was preferable to other options and provided a discussion of an alternative method that could have been used. This would have been to accept any composite bid for a drug category that is less than 106 percent of the weighted ASP for the drugs in that category. Under this alternative method, it would be possible for every bidder to submit a bid price just below ASP plus 6 percent, in the confidence that the bid would be accepted. This alternative method would thus limit the potential for savings to the program, compared to the bidding process that we proposed. Under the process that we proposed, bidders retain an incentive to submit the best bid price that is possible for them. Restricting the number of bids that might be accepted provides for more competition in the bidding process than accepting all bidders under a designated threshold. Thus, we proposed to accept up to five composite bids, for a category of drugs, but we proposed not to accept any bid that exceeds a composite bid threshold of 106 percent of ASP. We would compute the composite bids, and the 106 percent composite bid threshold, in the manner described in the example we provided in the proposed rule (70 FR 10763).

We requested comments on this proposed process, as well as recommendations for alternative approaches.

Comment: Several commenters expressed general agreement with our proposal to employ a composite bid to compare bids. However, a number of commenters objected to our proposal not to accept any bid for a category that is higher than 106 percent of the weighted ASP of the drugs in a category. Some of these commenters expressed concern that such a limit would discourage vendors from bidding, and result in too few vendors participating in the program. Some commenters pointed out that the ASP system itself is new, and that it remains to be determined whether it provides adequate reimbursement. Some commenters pointed out that the statute itself does not require a ceiling. Some commenters also expressed concern that the methodology would result in a ''race to the bottom,'' as potential vendors elect to bid only on drugs that can be offered at a savings to the Medicare program. Other commenters recommended that we impose no ceiling on the level of acceptable composite bids; others advocated a higher ceiling (120 percent of ASP). One commenter suggested that the ceiling be waived if it was necessary to do so in order to approve at least 3 bidders in any competitive acquisition area. Still other commenters recommended the adoption of methods such as risk corridors to protect vendors against unexpected losses in the early stages of the program and simultaneously allow the program to share in any savings that may be realized from the CAP. One commenter asked for confirmation that the bidding threshold should be established on the basis of ASP prices in effect during the quarter in which the bids are generated. A few commenters suggested not announcing the composite bid threshold.

Response: Although the statute does not specifically require adopting a ceiling on acceptable bids, we believe that doing so is appropriate, as well as consistent with the statute. Indeed, one major purpose of the CAP is to create the possibility of realizing savings to the Medicare program. This is one reason why the statute gives the Secretary the authority (which we are not specifically exercising with respect to our determination of which competitively biddable drugs are included in the current drug category) to exclude from the CAP drugs that are not likely to result in significant savings (see section 1847B(a)(1)(D). The bid ceiling that we proposed ensures that the CAP will be no more costly to the Medicare program than the alternative method of paying for drugs at 106 percent of ASP. This ceiling is thus consistent with the possibility of realizing savings to the Medicare program. It would also serve to maintain a level of parity between the two systems, preventing a situation in which significant payment differentials might skew incentives and choices. We are therefore finalizing that provision in this interim final rule. We are not adopting some of the alternatives recommended by some commenters (for example, no ceiling, a higher ceiling, waiver of ceiling under certain circumstances) because the recommendations would not preserve the possibility of realizing some savings to the Medicare program. We are not adopting the recommendation for establishing risk corridors because we do not believe that such a provision would be consistent with the statute. Section 1847B(d)(1) of the Act specifically requires that the Secretary establish a ''single payment amount for each competitively biddable drug'' in an area. We do not believe that the composite bid methodology we are adopting will lead to a ''race to the bottom,'' in which vendors bid only on drugs that will yield savings to the Medicare program. In the first place, we are requiring potential vendors to bid on all the drugs in the broad category of Part B physician drugs that we are establishing for this initial stage of implementing the CAP. Vendors will not be able to choose among the HCPCS codes included in the drug category. In addition, the methodology that we are adopting does not require that the bid for each drug be at or below the level of 106 percent of ASP. Rather, it requires only that weighted average of the bids for all drugs in the category will be less than or equal to 106 percent of the weighted average of the ASPs for all the drugs in a category. Under this methodology, potential vendors can bid more than 106 percent of ASP for some drugs in the broad, single category that we are establishing. In order to meet the threshold requirement, bidders will only have to bid below 106 percent of ASP on enough drugs in our large single drug category to produce composite bids at or below 106 percent of the weighted average of the ASPs for all the drugs in a category. We believe that it is reasonable to expect that potential vendors will be able to realize sufficient efficiency in obtaining and delivering Part B drugs commonly administered incident to a physician's service to produce a composite bid at or below this threshold.

Finally, we are confirming that the composite bid ceiling will be

determined on the basis of ASP prices in effect during the quarter in which the bids are generated. Specifically, we will determine the threshold (106 percent of the weighted ASP for the drugs included in our single drug category) on the basis of the ASP prices in effect at the time of the bidding, which will be conducted during the second quarter of calendar year 2005. Potential vendors will be able to find the ASP pricing file on our Web site at *http://www.cms.hhs.gov/providers/drugs/asp.asp.* We will provide potential vendors with the ceiling in time for consideration in developing bids. Vendors will also be able to compute the ceiling from the weighting factors in Addendum A of this interim final rule with comment period and the ASP prices in effect for the second quarter of calendar year 2005.

We also note that we have revised § 414.910(b) of our proposed regulations to clarify that the amount of a bid for any CAP drug must be uniform for all portions of a specific competitive acquisition area.

Comment: Several commenters expressed concern about the lag in the utilization data that would be employed in weighting the bid prices under the composite bid methodology. Even the most recent available utilization data may not reflect utilization patterns in the payment year, creating a potential vulnerability for vendors if physicians increase their utilization of more costly drugs.

Response: We will always employ the most recent available utilization data to compute the weights that will be employed in computing composite bids. In this interim final rule, we are employing utilization data from FY 2003 and FY 2004 for this purpose. (We describe the utilization data used to construct the weights in section II.A.2 of this interim final rule. We display the weights that we computed on the basis of these data in our table of the drugs that we are including in our single drug category. See Addendum A of this interim final rule with comment period.) At the same time, we do not believe that the composite bid methodology creates the vulnerability described by the commenters. It is important to keep in mind that while it is necessary to employ a prior year's utilization data in the computation and evaluation of composite bids, the composite bids themselves do not determine the single payment price for each drug. Rather, as we describe below in section 3.b. of this interim final rule, the single price for a drug is a function of the bids submitted for that drug by the winning bidders: specifically, we are setting the single price for each drug at the median of the bids of the winning bidders for that drug. The utilization data will play a role in determining acceptable composite bids (those composite bids that are no greater than 106 percent of the weighted average of the ASPs for all the drugs in the category) and the winning bids (up to the five lowest composite bids below the threshold in our nationwide competitive acquisition area, from qualified applicants). However, once the winning bidders have been determined, only those bidders' specific bids for each HCPCS code are used to set the single price. Utilization data from a prior year has no effect on the single price for any drug under this methodology.

Comment: Several commenters recommended that, in order to provide greater choice among vendors, we should accept all bidders with composite bids at or below 106 percent of the weighted average of the ASPs for all the drugs in a category. These commenters therefore requested that we drop our proposal to accept up to the five lowest bids.

Response: As we discussed in the proposed rule (70 FR 10763), we had considered this alternative to our proposal that we accept the five lowest bids in any area with composite bids at or below 106 percent of the weighted average of the ASPs for all drugs in the category. We stated in that discussion that one alternative to the method we proposed is simply to accept any composite bid for a drug category that is less than 106 percent of the weighted ASP for the drugs in that category. Under this method, it would be possible for every bidder to submit a bid price just below ASP plus 6 percent, in the confidence that the bid would be accepted. This method would thus limit the potential for savings to the program, compared to the bidding process that we proposed. Under the process that we proposed, bidders retain an incentive to submit the best bid price that is possible for them. Thus, restricting the number of bidders that might be accepted provides for more competition in the bidding process than accepting all bidders under a designated threshold. We continue to find this rationale persuasive. Therefore, in order to promote competition among vendors and the possibility of realizing some savings for the Medicare program, we are finalizing our proposal to select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bids for a drug category in our nationwide competitive acquisition area. However, we would not select any bid that is higher than 106 percent of the weighted ASP for the drugs in our single drug category.

Comment: One comment suggested that the vendor be allowed to include costs of spoilage and breakage in the bid. Another commenter suggested that vendors be paid for patient and provider education, counseling and compliance checks.

Response: The costs that a bidding entity may include in their bid price are described in section 1847B(c)(6) of the Act. The statute requires that the submitted bid price include ''all costs related to the delivery of the drug or biological to the selecting physician'' and ''the costs of dispensing (including shipping) of such drug or biological and management fees.'' The statute specifically prohibits including ''any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.'' We therefore do not have the statutory authority to allow inclusion of costs for spoilage and breakage in the bid. We also do not have the authority to provide separate payment to vendors for patient and provider education, counseling, and compliance checks.

Comment: One comment stated that the method for determining the bid price for multiple source drugs was not clear and suggested that it should be the same method that is used for single source drugs. Another comment suggested that using a pre-MMA fee schedule as the threshold was more appropriate.

Response: We assume that the commenter is referring to the drug prices established under the AWP methodology in effect prior to the MMA. We do not believe that employing the prices determined under that methodology as a benchmark would be appropriate, because Congress has specifically replaced that methodology with the ASP system for most Part B drugs. Under the composite bidding methodology that we have adopted, bidders must submit bid prices for each HCPCS code included in our broad category of drugs. As we note in section A.2 of this rule, HCPCS codes can often describe products represented by multiple National Drug Codes (NDCs). We are requiring vendors to submit bids for each HCPCS code within a category, and to provide at least one drug within each code. Vendors will also be required to provide potential physician participants in the competitive acquisition program the specific NDCs within each HCPCS code that they will be able to provide to the physician. In constructing their bids for each code, vendors will need to take into account

which specific drug(s) they intend to provide within that code. In constructing their bids, it will also be important for potential vendors to consider whether the drug or drugs within a specific code are multiple source or single source, and the prices at which they may be able to obtain these drugs from the respective manufacturers. However, it is neither necessary nor advisable for us to prescribe the manner in which vendors should take these considerations into account in developing the bid price for each specific code. Rather, we believe that the CAP will function most efficiently in this respect if bidders have the flexibility to construct their bids in the light of their own business goals and cost analysis within the statutory and regulatory parameters (that bid prices may not include any costs related to wastage, spillage, or spoilage).

As discussed above, our method for computing composite bids requires us to weigh the bids for the specific drugs in our single drug category. We proposed to employ volume data, specifically each HCPCS code's share of volume (measured in HCPCS units) for the prior year. In the proposed rule, we invited public comment on methods for weighting drugs introduced during and after 2004 within the composite bidding methodology (70 FR 10762).

Comment: Many commenters urged us to provide for inclusion of newer drugs within the drug categories that we adopt. Commenters did not offer specific proposals for developing weights for these drugs in order to provide for considering them with the composite bidding methodology. Commenters generally suggested using the new ASP system as a basis of bidding and payment for these drugs within the CAP, or allowing for payment based on a vendor's actual costs for acquiring these drugs.

Response: We agree with the commenters that it is important to include newer drugs within the CAP as quickly as possible. In the case of drugs that have been introduced during and after 2003 (but in time for consideration in developing this interim final rule), we have decided upon the following methodology. We have developed a list of drugs that have been introduced during and after 2003 and that are appropriate for inclusion within the established category of Part B drugs that are commonly administered incident to a physician's services. We have included in this list only those drugs that meet a minimum threshold in allowed charges ($50,000) in our billing data from the first quarter of CY 2005. The drugs on this list include important new therapies such as risperidone. The complete list of these drugs is shown in Addendum B of this interim final rule with comment period. We will require that prospective vendors include bids for these drugs in their submissions and provide these drugs to physicians who elect to participate in the CAP. However, we will not incorporate the bids for these drugs into the composite bid methodology, because we lack sufficient utilization data to compute appropriate weights for these drugs. Instead, we will consider these bids separately from, but parallel to, evaluation of the composite bid for the other drugs for which we have adequate utilization data. Specifically, we will require bidders to submit a separate bid for each drug in the list. We will also impose a ceiling on acceptable bids. As in the case of the composite bids, that ceiling will be tied to the ASP payment methodology. Specifically, we will not accept any bid for a new drug that is higher than 106 percent of the ASP for that drug (as determined at the time when the bidding begins, which will be the second quarter of calendar year 2005). Vendors will be able to locate the appropriate prices for that quarter on our Web site at *http://www.cms.hhs.gov/providers/drugs/asp.asp.* In order to be selected as a CAP vendor, a bidder must submit acceptable bids on each of the new drugs listed in Addendum B of this interim final rule with comment period.

In order to be selected as a vendor, then, a bidder must meet three conditions. First, a bidder must submit a composite bid on the single drug category that is less than or equal to the 106 percent of the weighted ASP for the drugs in that category (based on the ASP prices in effect during the second quarter of CY 2005, during which the bidding will begin). Second, a bidder must submit one of the five lowest bids for the single drug category in our nationwide competitive acquisition area. Third, a bidder must also submit acceptable bids on each of the new drugs listed in Addendum B of this interim final rule with comment period. An acceptable bid on one of these new drugs is less than or equal to 106 percent of the ASP for that drug (as determined at the time of the bidding, which will begin during the second quarter of CY 2005).

In this interim final rule, we are therefore finalizing our proposal to employ a ''composite bid,'' constructed from the bid prices for the individual drugs in the CAP category, in the process of selected bidders for the CAP. The composite bid will be constructed by weighting each HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in our single drug category during the prior year. Within the single category, the drug weights will thus sum to one. Based on data availability, the volume data used for bids in the first CAP bidding cycle (for supplying drugs starting January 1, 2006) will from FY 2004. The calculated composite bid will be equal to the average price per HCPCS unit for drugs in that category. In this way, the composite bid will be proportional to the expected cost to the program of acquiring drugs from that vendor (based on the assumption that the 2004 volume is roughly proportional to volume in 2006). If one vendor has a lower composite bid than another, it will also have a lower expected cost of supplying all drugs in the CAP category. Also, as a point of clarification, although it will not impact the initial implementation of CAP since it is one area, we are revising § 414.910 to clarify in the case of multiple areas, entities can bid on one or more areas.

To illustrate how the composite bid will be calculated, we are providing the following example. Suppose that there are four drugs in a CAP drug category (Drug A, Drug B, Drug C, and Drug D). The first column of Table 3 below provides the total volume (HCPCS units) of these drugs administered in 2004 for this hypothetical drug category.

TABLE 3.—EXAMPLE DRUG VOLUMES AND RELATIVE VOLUMES, 2004

Drug	Total HCPCS units	Relative volume
Drug A	1,452,472	0.3520
Drug B	988,586	0.2395
Drug C	1,671,567	0.4050
Drug D	14,302	0.0035
Total	4,126,927	1.0000

Three drugs (Drugs A, B, and C) have volumes (total HCPCS units) much greater than that of the fourth (Drug D). The second column of Table 3 gives the relative volumes, computed by dividing the volumes of the individual components of this CAP category by the total volume of HCPCS units for drugs in this category. These relative volumes are the weights used to construct the composite bids.

The computation of the composite bids for these four bidders is shown in Table 4. The composite bid for Bidder 1 is computed as the weighted sum of the bids for the four drugs: ($520 × 0.3520) + ($400 × 0.2395) + ($135 × 0.4050) + ($4,780 × 0.0035), which is equal to $350.25. The composite bids for the other three bidders are computed similarly.

TABLE 4.—EXAMPLE COMPOSITE BID COMPUTATION

Drug	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Low bidder
Drug A	0.3520	$520	$530	$550	$530	1
Drug B	0.2395	400	410	380	390	3
Drug C	0.4050	135	105	135	120	2
Drug D	0.0035	4,780	4,830	4,430	4,800	3
Composite Bid		$350.25	$344.19	$354.79	$345.37	2

As Table 4 illustrates, it is possible for a bidder to submit the lowest bid on more individual drugs than other bidders (such as, Bidder 3 has submitted the lowest bids for Drug B and Drug D), but have the highest composite bid. This is because Bidder 3 submitted relatively high bids for Drug A and Drug C, which have the largest volumes (in HCPCS units). Also note that although Bidder 4 did not submit the lowest bid for any of the four drugs, its composite bid is the second lowest.

As we have discussed above, we have decided to adopt a method that bases the selection of winning bidders on applying a predetermined ceiling on the composite bid. Specifically, under the method we are adopting, we will select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bidders for the single drug category in our nationwide competitive acquisition area. However, we will not select any bid for the category that is higher than 106 percent of the weighted ASP for the drugs in that category. As we have also discussed, we believe that limiting the maximum bid price we would accept is consistent with Congressional intent that the CAP promote savings.

As an example of this computation, suppose that the ASPs for four drugs in the composite bid example above (see Table 4) are as follows: $516 for Drug A, $376 for Drug B, $111 for Drug C, and $4,831 for Drug D. Using the relative weights in Table 4, we would compute the composite bid threshold as $1.06 \times (\$516 \times 0.3520 + \$376 \times 0.2395 + \$111 \times 0.4050 + \$4{,}831 \times 0.0035)$, which is equal to $353.56. In this example, three bidders (Bidder 1, 2 and 4) would be selected as CAP vendors. (See Table 5.)

TABLE 5.—EXAMPLE: PROPOSED COMPOSITE BID SELECTION METHOD

Drug	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Bids selected
Drug A	0.3520	$520	$530	$550	$530	
Drug B	0.2395	400	410	380	390	
Drug C	0.4050	135	105	135	120	
Drug D	0.0035	4,780	4,830	4,430	4,800	
Composite Bid		$350.25	$344.19	$354.79	$345.37	
Maximum Bid		$353.56	$353.56	$353.56	$353.56	1, 2, 4

b. Determining the Single Price for a Category of Drugs

Once the winning bidders have been identified, section 1847B(d)(1) of the Act requires that a single price must be determined for each drug in a competitive acquisition area, ''based on bids submitted and accepted.'' We considered a number of options for determining this single price on the basis of the accepted bid prices. In the proposed rule at § 414.906(c)(1), (which describes the computation of the payment amount), we proposed to establish a single price for each drug in a competitive acquisition area, based on the median bid of the winning bidders if there is an odd number of vendors (3 or 5). If there are four vendors, we will employ the median through averaging of the bids of the second and third highest bidders on each drug to set the price for the drugs. If only two bidders are selected, we would use the median, in this case also the average, of the two bids for the drug to set the price for that drug. [Note the mean (or average) is the median of the two middle bids or the straight average if there are only two bids.] The qualified vendors would be made aware of the established price set for the CAP drugs before he or she signs the contract to be an approved vendor.

We proposed to employ the median bid for several reasons. First, this method is straightforward and relatively easy to implement. The median bid is an obvious statistical method to determine a single price based on using the information provided by bids, as required by the statute. In addition, this method could realize some savings to the Medicare program: Unless the bids for a given drug of all selected bidders are at or above the level of the maximum allowable bid (106 percent of ASP), this method for determining the single price would yield savings to the program.

In cases where there are four winning bidders for a drug category in an area, we proposed to employ the average of the bids of the second and third highest bidders on each drug to set the price for the drug. If there are only two bidders, we would use the average of the two bids for the drug to set the price for that drug. We noted that the qualified vendors would be made aware of the established price set for the CAP drugs before they sign the contract to be an approved vendor. As we stated in the proposed rule (70 FR 10763), qualified vendors will be made aware of the established price set for the CAP drugs before he or she signs the contract to be an approved vendor.

We requested comments on our proposed approach for determining the price of the drug under the CAP and any alternative approaches that might be utilized.

Comment: One commenter suggested that vendor-specific payment be considered, but also acknowledged that this would require a change to the statute. Some commenters also recommended that we pay each vendor the actual bid amount rather than pay a median of the bids of all the winning vendors.

Response: We agree with the commenter who acknowledged that statutory change would be necessary to adopt vendor-specific payment. The statute specifically requires establishment of a ''single payment amount for each competitively biddable

drug or biological'' in an area (section 1847B((d)(1) of the Act). It is not possible to establish a single price for each drug in the nationwide competitive acquisition area and simultaneously to provide for vendor-specific payment. Because paying each vendor the actual bid amount would essentially establish a vendor-specific payment, that method also is not permitted by the statute.

Comment: One commenter expressed concern that one expensive and heavily utilized HCPCS code in a category could have a significant impact on the entire category's price.

Response: We do not believe that our proposed method for using bids to determine single prices for drugs will lead to this result. In particular, we did not propose establishing a price for an entire category. Rather, we proposed using the bids, for each specific HCPCS code, of the successful bidders to set the price for the drug. In addition, we proposed that the single price for a drug would be the median of those bids (or in the cases of even numbers of accepted bidders, averages of the bids, as previously described). The weighting of heavily utilized drugs will thus have an effect on the calculation of composite bids and the determination of successful bids. However, our decision to establish one large category with a large number of HCPCS codes will minimize the effect of any one drug or one manufacturer on the composite bids as a whole. In addition, using the median to determine the single price limits the effects of any one highly expensive drug in a HCPCS code on the determination of the single price for that code.

Comment: Several comments asked us to confirm which ASP quarter would be used to evaluate bid prices. Some commenters also requested that we provide some allowance for price increases from that quarter until the contract period during which the single drug prices would be in effect. One commenter suggested using the Producer Price Index for this purpose. Other commenters suggested tying single price updates to changes in ASP prices.

Response: As we discussed in section 3.a above, the composite bid ceiling will be determined on the basis of ASP prices in effect during the quarter in which the bids are generated. Specifically, we will determine the threshold (106 percent of the weighted ASP for the drugs included in our single drug category) on the basis of the ASP prices in effect at the time when the bidding begins, which will be during the second quarter of calendar year 2005.

We agree with the commenters that adopting some mechanism for updating prices from the period in which bidding begins (the second quarter of calendar year 2005) to the period in which the single prices will actually be in effect (calendar year 2006) is appropriate. We also agree with the suggestion of some commenters that the most appropriate mechanism for doing so is to employ the changes in the Producer Price Index (PPI) for prescription preparations over the same period. Therefore, in this interim final rule, we are providing that the single price for each drug (HCPCS code) will be initially determined on the basis of the median of the bids submitted during the second quarter of calendar year 2005 for that drug. The price of each drug will then be updated to the mid-point of calendar year 2006 (five quarter increase) PPI for prescription preparations. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) reflects price changes at the retail stage. Because the CAP drugs are purchased direct from the manufacturer or wholesaler, this is an appropriate price index to use. In addition, the PPI for prescription drugs is the measure used in various market baskets that update Medicare payments to hospitals, physicians, skilled nursing facilities and home health agencies. We will be using the most up to date forecast data available from Global Insight Inc. at the time of contract award to determine the PPI. We feel that the use of an independent forecast, in this case from Global Insight, Inc. is superior to using the National Health Expenditure Projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases in Medicare prospective payment systems.

Currently, we do not believe there has been enough experience with the ASP payment methodology to update the bids based on growth in the ASP. We are only in the second quarter of using ASP as a payment, and we do not have enough data to make reliable projections in growth. However, we will continue to analyze the ASP data and will revisit this issue in the future. We welcome comments on this method of updating the single drugs prices to the payment year, and will consider those comments as we develop and refine the CAP.

Under our approach of updating to the mid-point of 2006, it is also important to note that the CAP prices may be somewhat higher than the ASP prices during the first half of calendar year 2006. We have chosen to update to the mid-point of the year to most accurately reflect the increase in prices that will occur over the course of the year. ASP prices are updated on a quarterly basis so there is no need to make projections under that payment system. On balance and over the entire year, CAP and ASP prices should be equivalent. We welcome comments on this method of updating the single drugs prices to the payment year, and will consider those comments as we develop and refine the CAP in subsequent regulations.

Section 1847B(d)(2) of the Act requires the Secretary to ''establish rules regarding the use * * * of the alternative payment amount provided under section 1847A of the Act'' for payment of a new drug or biological under the CAP. Section 1847A of the Act establishes the average sales price methodology for most drugs paid under Part B of the Medicare program. Section 1847A(c)(4) of the Act further provides alternatives for the Secretary to determine the amount payable for new drugs during an initial period. In accordance with the requirement at section 1847B(d)(2) of the Act, we proposed to apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) the drug or biological is properly assigned to a category established under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological. We also stated we would employ the payment amount determined in accordance with the methodology provided under section 1847A(c)(4) of the Act until the next annual update of the single price amounts.

Comment: Many commenters asked us to clarify whether and how we would pay for new drugs. Many of these commenters recommended that vendors be required to provide new drugs, so that beneficiaries will have access through the CAP to the most recent therapies available. These commenters variously recommended that vendors be reimbursed at the ASP price or at cost for providing these new drugs. Alternatively, some commenters asked us to clarify that physicians who elect to obtain their drugs through a CAP vendor may still obtain drugs that are not available through the vendor, such as new drugs or drugs not included in the drug category provided under the CAP contract, from other sources and receive payment under the ASP system. Another comment recommended that new drugs be added to CAP no later than 2 quarters after introduction.

Response: It is important to distinguish two categories of new drugs in relation to the CAP. The first category consists of drugs that have been released in the period just prior to the bidding in a given year, have been assigned codes, and have established prices under the ASP system. In these cases, we sometimes do not have sufficient data on volume to include these drugs in the composite bidding methodology. As we discuss in section 3.a above, we have decided to include a select list of drugs that have been introduced during and after 2004 within the single drug category that we are adopting. We will also require that prospective vendors include bids for these drugs in their submissions and provide these drugs to physicians who elect to participate in the CAP. However, we will not incorporate the bids for these drugs into the composite bid methodology, but rather consider these bids separately, imposing a ceiling tied to the ASP payment methodology on acceptable bids. That is, the bids for each drug on the list must not exceed the payment level determined under section 1847A of the Act.

The second category of new drugs consists of those that are introduced too late even to be incorporated under this special methodology. These drugs may have been introduced prior to the bidding period, but too late to obtain HCPCS codes and/or ASP prices. Other such new drugs may not be introduced until after the bidding period, even in the second or third years of the vendor contracts under the CAP. We agree with the commenters that it is important to provide beneficiaries with access to these drugs as quickly and effectively as possible. However, we do not agree that it is appropriate, especially during the initial stages of implementing the CAP, to impose a requirement on vendors to include all new drugs introduced too late to be taken into consideration during the bidding period. Such a requirement may impose unpredictable, and sometimes difficult or impossible, burdens on some vendors. Vendors may not be able to make the acquisition arrangements necessary to obtain some new drugs, or at least to obtain them at a reasonable price. It would also be difficult to develop the administrative mechanisms necessary to identify new drugs that should be included within the CAP, to advise vendors that they must begin providing specific new drugs, to monitor vendor compliance, and to enforce these requirements (where necessary) in a timely fashion. Therefore, we are not adopting such a requirement at this time. It is important to note that physicians who have elected to participate in CAP are expected to order all of the CAP drugs they use through the CAP vendor except when a CAP physician is utilizing the ''furnish as written'' exception. If a physician obtains a CAP drug elsewhere, the drug will not be covered. When a participating CAP physician is purchasing a drug under the ''furnish as written'' exception or is purchasing a drug that is not available under the CAP, he or she can receive payment for those drugs through the ASP system and would be expected to bill Medicare directly for the drugs. At the same time, we certainly encourage vendors to add such new drugs as they are introduced. We are therefore adopting the mechanism we proposed in order to make it possible for vendors to do so. In accordance with the requirement at section 1847B(d)(2) of the Act and § 414.906(c)(2), we will apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) The drug or biological would be properly assigned to the single drug category that we are establishing for this initial stage of implementation under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological and will revise the regulation at § 414.906(c)(2) to ensure that it is explicit. We will provide for payment to CAP vendors for these new drugs at the time of the next quarterly update after the drug receives a code. Vendors may contact CMS in order to propose adding a new drug to their approved list. If we determine that the new drug is appropriate for inclusion on the approved CAP vendor's approved list, we will approve the vendor's request to add the drug under the CAP contract and provide for payment at the next quarterly update. The new drug will be considered a CAP drug for purposes of the CAP program, and the coverage rules described above will apply (that is, the physician must obtain the drug from the approved CAP vendor in order for payment to be made for the drug, unless the ''furnish as written'' exception applies). We will not formally revise the CAP categories in order to accommodate vendor requests to add new drugs, since such additions will not be mandatory. If there are any further annual updates during the period of a vendor's contract after we initially provide for payment of a new drug that the vendor is providing, we will employ the mechanism for annual updates of single price amounts that we describe below.

Section 1847B(b)(4)(B) of the Act provides that contracts for the acquisition of competitively biddable drugs under the CAP must be for a period of 3 years. Therefore, it is necessary to determine some mechanism for setting the single price for each category of drugs in the second and third years of this 3-year contract. We proposed to employ the mechanisms provided under section 1847B(c)(7) of the Act for this purpose. Specifically, that section requires that each contract must provide for disclosure to the Secretary of the vendor's ''reasonable, net acquisition costs'' on a regular basis (not more often than quarterly). It further requires that contracts must provide for ''appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a vendor's reasonable, net acquisition costs, as so disclosed.'' Therefore we proposed at § 414.906(c)(1) to update the CAP prices for each drug in a category in year 2 and year 3 based on the vendor's ''reasonable, net acquisition costs'' for that category as determined by CMS based, in part, on information disclosed to the Secretary and limited by the weighted payment amount established under 1847A of the Act across all drugs in that category.

Section 1847B(c)(7) of the Act gives the Secretary the discretion to establish an appropriate schedule for the CAP vendor's disclosure of this cost information to us, provided that disclosure is not required more frequently than quarterly. We proposed to require that each vendor disclose to the Secretary its reasonable, net acquisition costs for the drugs covered under the contract annually during the period of its contract. Annual disclosure imposes the minimal burden on vendors consistent with employing this provision to determine the single price for drugs in the second and third years of a contract. More frequent disclosure (for example, quarterly) is, of course, also consistent with this purpose. We anticipate that the annual disclosure would be required in or around October of each year, to provide sufficient time to determine what, if any, update in drug prices would be appropriate for the following year. We invited comments regarding an appropriate disclosure schedule under section 1847B(c)(7) of the Act for this purpose.

Comment: Several commenters stated that yearly cost disclosure and price adjustments would be sufficient. One commenter favored yearly adjustment because more frequent adjustment may cause vendors to leave the program if rates are not adjusted in their favor.

Many other commenters recommended more frequent reporting and updates. Some of these commenters recommended a biannual process, but most preferred quarterly updates. Some comments acknowledged that more frequent acquisition cost reporting could be a burden for vendors, but many commenters noted that increasing the frequency of acquisition cost reporting and price adjustments would provide for greater consistency between CAP and ASP systems, minimize the payment difference between CAP and ASP, and would be less financially risky for vendors.

Response: We appreciate the concerns of the commenters who recommended more frequent (biannual or quarterly) updates. However, we continue to believe that annual reporting and payment updates provide the most appropriate balance between vendor and CMS administrative burden and paying for CAP drugs based upon the most timely data, at least during this initial stage of implementing the CAP. Specifically, we remain concerned that more frequent updates would also require more frequent reporting. We are reluctant to impose the burden of semiannual or quarterly reporting at this time. When the administrative mechanisms of the CAP are operational and vendors have more experience under the program, we will consider whether more frequent reporting would be appropriate.

We proposed the following methodology for developing an appropriate adjustment on the basis of the net reasonable cost information disclosed by vendors. We would employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced significant increases or decreases in the reasonable, net acquisition costs across a category of drugs. For this purpose, we stated that we were considering establishing a threshold percentage change in these costs, to determine whether the changes warrant computing an adjustment to the single prices for the drugs in that category. If the change in the costs reported by a particular vendor meet this threshold, we would use a two-step process to recompute the single price for each drug in that class. First, we would adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of these adjusted bid prices. We noted that this mechanism would apply in the case of any significant change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs. It is therefore possible that the single price for a drug could decrease in the second or third year of a contract where, for example, acquisition costs for the drug have decreased because of the introduction of a generic equivalent.

Comment: A number of commenters recommended that we apply no threshold test in determining whether price adjustments should occur. One commenter supported using a rolling 12 month ASP as the basis of price adjustments in order to smooth out the influence of price spikes. Another comment recommended that price changes from manufacturers should be automatically reflected in an update. Comments asked for more specific information about how the threshold would be calculated, specifically, which quarter's data would be used to calculate an adjustment, noting that the ''lag'' period between the time of adjustment and the time that financial information was collected should be minimal.

Response: We agree with the commenters who recommended that we not employ a threshold for determining whether a change in costs warranted an update in the single prices for drugs. Rather, we will adopt the mechanism that we described in the proposed rule without applying any threshold. Specifically, we will employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced changes in the reasonable, net acquisition costs for the drugs included in our single category of drugs. If there is a change in the costs reported by a particular vendor, we would use a two-step process to recompute the single price for each drug in the single drug category. First, we would adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of all of these adjusted bid prices. We would then notify all of the vendors of the single price that we would be paying for the particular drugs in the following year. As we noted in the notice of proposed rulemaking, this mechanism would apply in the case of any change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs. It is therefore possible that the single price for a drug could decrease in the second or third year of a contract where, for example, acquisition costs for the drug have decreased because of the introduction of a generic equivalent. It is also possible that one vendor would report large increases while the other vendors report price decreases or vice versa. In this situation, we would follow the same two step process for updating the single price. As noted in the proposed rule, we will limit the annual update by the weighted payment amount established under section 1847A of the Act across all drugs in the category. We will require submission of net reasonable cost information by each vendor at the beginning of the fourth quarter in each year of the contract, in order to provide sufficient time to determine any update in drug prices for the following calendar year. We believe that this reporting deadline reduces the inevitable lag between the reporting of financial information and the time of adjustment to an acceptable, minimal level.

We indicated in the proposed rule that we would consider ''reasonable, net acquisition costs'' to be those costs actually incurred by the vendor that are necessary and proper for acquiring the drugs that the vendor is obligated to provide under a CAP contract. Actual acquisition costs are net of all discounts and rebates provided by the vendor's own suppliers. We would require full disclosure of the vendor's acquisition costs for drugs included in the CAP contract. We proposed that this disclosure would reflect the vendor's purchases of these drugs from all manufacturers, and the total number of units purchased from each manufacturer. The vendor would be required to submit full documentation reflecting actual purchase prices. This documentation would include all records reflecting discounts that result in a reduction of actual cost to the vendor. (Such discounts would include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions regardless of when they are recognized.)

Comment: One commenter recommended that all costs related to drug delivery and dispensing be included in the report and that all factors be considered in determining the price adjustment. Other commenters stated that only CAP program prices be used in the price determination. Another commenter stated that prompt pay discounts should be excluded for the net acquisition cost, since the discount actually occurs as a term of financing.

Response: We do not agree with the recommendation to exclude prompt pay discounts from the determination of reasonable, net acquisition costs for purposes of Section 1847B(c)(7) of the Act. It is not obvious to us that this

discount occurs exclusively as a term of financing, nor that it should be excluded from consideration even if that is the case. We do not see how prompt pay discounts are any different from other types of price concessions and why they would need to be treated differently for purposes of the CAP. We are interested in learning more about how these discounts are arranged and whether they are indeed different from other price concessions and discount arrangements. We appreciate the comment that only CAP program prices be used in the determination of whether acquisition costs have increased. However, we are concerned that it may be administratively difficult for approved CAP vendors to distinguish their acquisition costs for provision of drugs under the CAP program from acquisition costs for drugs generally. We are therefore not adopting the recommendation at this time. Finally, we cannot adopt the recommendation that all costs related to drug delivery and dispensing be included in the report. Section 1847B(c)(7) of the Act provides only for the disclosure of contractor's ''reasonable, net acquisition costs'' to the Secretary, and for basing price adjustments under the CAP on ''significant increases or decreases'' in those costs. Therefore, only net acquisition costs that meet these criteria may be included. We would also note that we are not adopting any specific definition of ''significant'' at this time. In this initial stage of the program, we will treat all cost increases and decreases as significant.

Comment: Two commenters expressed concern about whether price information could be made exempt from Freedom of Information Act requests and suggested that vendors certify the accuracy of CAP drug price information in a manner similar to ASP pricing certification. Another commenter mentioned confidentiality provisions of the Trade Secrets Act. These commenters requested details about how confidentiality of manufacturer's pricing information would be handled. Two commenters stated that the pricing information is proprietary and should be treated as such. Several comments noted that price data provided to CMS should be afforded the same protection as ASP data and data submitted to Medicaid.

Response: Section 1847B(a)(1)(C) of the Act provides that, in implementing the CAP, the Secretary may waive provisions of the Federal Acquisition Regulation (FAR), ''other than provisions relating to the confidentiality of information.'' The confidentiality provisions of the FAR thus apply to the data submitted by bidders and vendors under the CAP. Generally, the FAR requires contractors and bidders to clearly mark all information they seek to protect, and generally, a bidder's confidential business strategies and unit prices are protected as confidential. However, what is confidential for FAR purposes may not necessarily be protected under the provisions of the Freedom of Information Act (FOIA). In the event that CMS receives a FOIA request for pricing information, the CMS FOIA officer will process the request in accordance with 5 U.S.C 552 and 5 CFR part 5, and determine whether any of the FOIA's exemptions to mandatory disclosure may apply to protect the information. In addition, under section 1847B(c)(5) of the Act, the Medicaid drug rebate confidentiality provisions of section 1927(b)(3)(D)of the Act apply to periods during which a bid is submitted with respect to a CAP drug in the same manner as it applies to information disclosed under the Medicaid drug rebate statute. We also require that vendors certify the accuracy of their CAP drug pricing information on the vendor application form.

We also proposed to make more frequent adjustments (but not more often than quarterly) in three cases: introduction of a new drug, expiration of a drug patent, or a material shortage that results in a significant price increase for a drug. We may restrict the circumstances in which we would make adjustments to account for shortages to those in which the Secretary has declared a public health emergency under section 319 of the Public Health Service Act. We invited comments on this approach.

Comment: We received no comments addressing our specific proposal for more frequent updates in these cases. However, several commenters asked for clarification about the obligations of vendors when a drug offered under the CAP becomes unavailable (such as in the case of a recall). Some of these commenters recommended that the vendor be allowed to add a new drug to its list to replace or complement the drug that is no longer available. One commenter recommended that vendors should be allowed to remove drugs from the list of CAP drugs only when it is necessary to address safety concerns or when the drug has been removed from the market.

Response: We agree with the recommendation that vendors should be allowed to remove drugs from their lists in cases of withdrawals from the market. We also agree that vendors should be allowed to replace such drugs where it is possible to do so. Therefore, we are providing in § 414.906(c)(1)(iv) of this interim final rule with comment period that, in cases where drugs are withdrawn from the market, vendors may substitute another drug if one is available (for example, another drug within a HCPCS code that contains multiple NDCs). In order to make such substitutions more feasible for vendors, we will also expand our proposal for more frequent updates (restricted in the proposed rule to introduction of a new drug, expiration of a drug patent, or a material shortage) to include this case. This mechanism will not, of course, be available if no replacement (another available NDC within the HCPCS) is available. Until we have the opportunity to update the drug price, we will pay for these substitutions at the price previously established for the drug code.

Comment: Many commenters also requested clarification about whether the prices determined under CAP will be taken into account in computing the average sales price (ASP) under section 1847A of the statute. Most of these commenters recommended exclusion of CAP prices from the ASP calculation. Some of these commenters pointed out that inclusion of CAP prices in the ASP computation may discourage manufacturers from offering price concessions to CAP vendors. A congressional commenter supported exclusion of CAP prices from the ASP computation, stating that it was the intent of Congress that these two programs should not interact, and that prices developed under the CAP should not be incorporated into ASP calculations. Another commenter noted, however, that section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. This commenter therefore contended that manufacturer prices offered under the CAP must be included in ASP calculations.

Response: We do not believe that we have the statutory authority to exclude prices determined under the CAP from the computation of ASP under section 1847A of the Act. Section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. Prices offered under the CAP must therefore be included in ASP calculations.

In this interim final rule, we are therefore establishing the following policies and procedures for establishing single prices for drugs under the CAP, and updating those prices as

appropriate. Once the winning bidders have been identified, section 1847B(d)(1) of the Act requires that a single price must be determined for each drug in a competitive acquisition area, ''based on bids submitted and accepted.'' Consistent with that requirement, we calculate a single price, for each drug in a competitive acquisition area, based on the median of the bids for that drug submitted by the winning bidders. (In case there are four winning bidders, we will employ the average of the bids of the second and third highest bidders on each drug to set the median price for the drug. If there are only two winning bidders, we would use the average of the two bids for the drug to set the median price for that drug.)

We will also update the single prices from the period in which bidding is conducted (the second quarter of calendar year 2005) to the period in which the single prices will actually be in effect (calendar year 2006). Specifically, the price of each drug will be updated to the mid-point of calendar year 2006 on the basis of projecting the overall change in PPI prices for prescription preparations.

Section 1847B(d)(2) of the Act requires the Secretary to ''establish rules regarding the use ''of the alternative payment amount provided under section 1847A of the Act'' for payment of a new drug or biological under the CAP. Section 1847A of the Act establishes the average sales price methodology for most drugs paid under Part B of the Medicare program. In accordance with this requirement and as established in § 414.906(c)(2), we will apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) the drug or biological is properly assigned to a category established under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological. We are encouraging vendors to add such drugs that are introduced too late to be incorporated into the bidding process to the lists of the drugs provided under CAP. However, due to systems limitations during this initial stage of the CAP, we will only be able to provide for payment to CAP vendors at the time of the next quarterly update of the CAP prices. If there are any further annual updates during the period of a vendor's contract after we initially provide for payment of a new drug that the vendor is providing, we would employ the mechanism for annual updates of single price amounts that we describe below. As noted above, participating CAP physicians are expected to order all of the CAP drugs they use through the CAP vendor except when the ''furnish as written'' exception applies. If a physician obtains a CAP drug elsewhere, the drug will not be covered. When a participating CAP physician is purchasing a drug under the ''furnish as written'' exception or is purchasing a drug that is not available under the CAP, he or she can bill for those drugs under the ASP system.

Section 1847B(b)(4)(B) of the Act provides that contracts for the acquisition of competitively biddable drugs under the CAP must be for a period of 3 years. Therefore, it is necessary to determine some mechanism for setting the single price for each category of drugs in the second and third years of this 3-year contract. We will employ the mechanisms provided under section 1847B(c)(7) of the Act for this purpose. Specifically, that section requires that each contract must provide for disclosure to the Secretary of the vendor's ''reasonable, net acquisition costs'' on a regular basis (not more often than quarterly). It further requires that contracts must provide for ''appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a vendor's reasonable, net acquisition costs, as so disclosed.''

In this interim final rule, we are providing in § 414.906(c)that we will employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced changes in the reasonable, net acquisition costs for the drugs included in our single category of drugs. Such disclosure will be required annually, at the beginning of the fourth quarter of each calendar year of the contract. If there is a change in the costs reported by a particular vendor, we will use a two-step process to recompute the single price for each drug in the single category for all vendors. First, we will adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of these adjusted bid prices. This mechanism would apply in the case of any change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs.

We will also make more frequent adjustments (but not more often than quarterly) in four cases: introduction of a new drug, expiration of a drug patent, substitution of a drug for a drug withdrawn from the market, or a material shortage that results in a significant price increase for a drug.

4. Contract Requirements

Section 1847B(b)(4) of the Act discusses items to be incorporated in the contract entered into with an approved CAP vendor. These include the following:

- The length of the contract.
- Assurance of the integrity of the drug distribution system.
- A pledge to comply with code of conduct and fraud and abuse rules.
- Assurance that drugs are only supplied directly to CAP physicians, with limited exceptions, upon receipt of a prescription and other necessary data.

We set forth the contract terms between CMS and the approved CAP vendor as well as approved CAP vendor responsibilities in proposed § 414.914.

Comment: A potential vendor commented that a vendor should be allowed to withdraw from the CAP at any time upon a showing of financial hardship or if the vendor can demonstrate it cannot acquire product directly from the manufacturer for less than the reimbursed amount.

Response: We appreciate the potential vendor's comment on the duration of the approved CAP vendor's contract. Given the statutory requirement that the term of the contracts are for 3 years, we are specifying at § 414.914(a)(2) that an approved CAP vendor may terminate the contract in the absence of a contract violation, if the approved CAP vendor provides notice to us by June 30 for an effective date of termination of December 31 of the same year. We believe that to allow for a mid-year termination, except where we terminate the contract as provided in § 414.914(a) or § 414.917, including in cases of quality problems, would be unnecessarily disruptive to services being provided and to the operation of the CAP.

Contract terms between CMS and the approved CAP vendor, as well as approved CAP vendor responsibilities, will be addressed at § 414.914 as proposed; however, modifications have been made to incorporate revisions based on issues discussed elsewhere in this preamble.

5. Judicial Review

Provisions of section 1847(B)(g) of the Act concerning administrative and judicial review are set forth in regulations at proposed § 414.920. This section of the Act specifies aspects of the CAP that are not subject to administrative or judicial review.

We received no specific comments on requirements proposed under § 414.920 concerning administrative and judicial reviews, so we are finalizing this section as proposed.

D. Implementation of the CAP

1. Participating CAP Physician Election Process

Section 1847B(a)(1)(A) of the Act specifies that each physician be given the opportunity annually to elect to participate in the CAP. Physicians who do not elect to participate in the CAP would continue to buy the drugs they provide to beneficiaries incident to a physician's service and bill the Medicare program for them under section 1847A of the Act, the ASP system.

Section 1847B(a)(5)(A) of the Act requires that we develop a process that physicians who wish to participate in the CAP may use on an annual basis to select the approved CAP vendor from whom they wish to obtain the categories of drugs they wish to obtain under the CAP program. The statute also requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. To inform physicians about the choices of drugs and approved CAP vendors available to them under the CAP, we are required to post a directory on our Web site or to make such a directory available to interested physicians on an ongoing basis.

In the proposed rule, we specified that physicians who elect to participate in the CAP would remain in the program for at least 1 calendar year. As described in more detail later in this section, physicians who elect to participate in the CAP would be required to complete a CAP election agreement. By completing this participating CAP physician election agreement, the participating CAP physician would select the approved CAP vendor that he or she would use under the CAP and would agree to the participating CAP physician requirements. As described in further detail in this section and the regulations, a participating CAP physician agrees to—

- Share information with the approved CAP vendor to facilitate the collection of applicable deductible and coinsurance.
- Promptly file drug administration claims.
- Timely and appropriately pursue claims that are denied because of medical necessity issues.
- Accept assignment for CAP drug administration claims.
- Notify the approved CAP vendor when a drug is not administered.
- Agree to comply with emergency drug replacement rules.
- Agree to requirements for using the ''furnish as written'' provision.
- Maintain an inventory for each CAP drug he or she obtains.
- Provide support to the approved CAP vendor on an administrative appeal of the drug administration claim denial. Such support may include medical records and written statements.

If we find it necessary, we could suspend the physician's election to participate in the CAP if the participating CAP physician fails to abide by the participating CAP physician election agreement.

We proposed to initiate an annual participating CAP physician election process and modeled this proposed process after the existing Medicare Participating Physician Process to the extent possible. In addition, we communicated information to physicians about the upcoming CAP through the fact sheet that accompanied the 2005 Participating Physician Mailing, and proposed to continue to use that vehicle to communicate information about CAP to physicians in future years. However, we noted that the annual physician participation election process for accepting assignment runs from November 14 to December 31 of each year. Waiting until December 31 to receive information about physicians' CAP election choices would not provide sufficient time for us and our claims processing contractors to record information about participating CAP physicians and their approved CAP vendor selections, update claims processing files, perform testing, and inform approved CAP vendors so that we are ready to pay CAP claims on January 1, 2006. For this 3-year contract cycle for the approved CAP vendors, there will be one drug category. In the future, as more CAP drug categories are developed, the collection of information on the selection of the approved CAP vendor and drug category will be more complicated. In addition, a deadline of December 31 would not allow sufficient time for approved CAP vendors to meet the operational timeframe of January 1. Therefore, we proposed that the participating CAP physician election process would run from October 1 to November 15 of each calendar year. We proposed that participating CAP physicians who intend to continue into subsequent years may signal that preference by executing an abbreviated participating CAP physician election agreement. The abbreviated agreement would be used to indicate a preference to change approved CAP vendors or, as applicable, drug categories from year to year. We proposed that a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process if the previously selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor or relocates to another competitive area once multiple CAP competitive areas are developed. We proposed to set forth the exceptions to the annual selection process at § 414.908(a)(2) of our regulations.

We requested comments on the potential options available to affected participating CAP physicians when an approved CAP vendor's contract is terminated during the middle of the CAP year. The proposed participating CAP physician options included leaving the CAP or selecting another approved CAP vendor as presented in the proposed participating CAP physician election agreement for the physician to participate in the CAP.

Comment: One commenter expressed concern that for this first year in 2005 participating CAP physician election agreements must be postmarked by November 15 but that the carrier is not expected to be ready to pay claims until January 1, 2006. This meant that the earlier a physician elects CAP and acquires drugs from CAP, the longer the physician will wait for reimbursement for drug administration. The commenter expressed concern that the time lag would be more than 3 months for those who elect early. The commenter suggested that we permit physicians to complete the participating CAP physician election process, with the agreement effective as of January 1, 2006, and allow them to use the ASP system until then.

Response: Although the participating CAP physician election period ends on November 15, 2005, the CAP does not begin until January 1, 2006. Physicians who elect to participate in the CAP are to continue to use the ASP system through December 31, 2005. On January 1, 2006, physicians who have elected to participate in the CAP should order drugs from the approved CAP vendor they have selected. The early selection process is necessary so that the local carrier and the designated carrier can begin system testing to be ready to pay claims. This is consistent with the statute, which requires that the CAP be phased in beginning in 2006.

Comment: Commenters opposed the election period of October 1 to November 15 for physicians to elect to participate in the CAP. They asserted that this deadline would confuse physicians because it is different from

the Medicare participation agreement timeline. They proposed that the deadline coincide with the participation agreement election period (November 14 through December 31) and that although notification of enrollment may occur after December 31, physicians could bill for drugs under the ASP system until the vendor had processed and acknowledged approval of the physician application. A commenter suggested that we should provide vendor notification of selection by a physician.

Response: We believe that an election period that is earlier than the participating physician enrollment process is necessary to allow both the approved CAP vendors and us to prepare for the CAP and to be ready to ship drugs and pay claims on January 1, 2006. Waiting until December 31 to receive information about physicians' CAP election choices will not provide sufficient time for the approved CAP vendors to acquire the necessary volume of drugs and make introductions with participating CAP physicians who have selected them in order to meet the operational timeframe of January 1, 2006. Further, waiting until December 31 will not allow for us and our claims processing contractors to record information about participating CAP physicians and their selected approved CAP vendor, update the Web site with CAP information, update the claims processing files, perform testing, and inform approved CAP vendors so that we are ready to pay CAP claims on January 1, 2006. For this 3-year contract for the approved CAP vendors, there will be one drug category. In the future, as more CAP drug categories are developed, the collection of information on the election of the approved CAP vendor and drug category will be more complicated.

Comment: Several commenters asserted that physicians should have the ability to elect into the system more than once per year. Commenters suggested election options that ranged from the ability to disenroll or switch vendors at any time, to the adoption of a transition period ranging anywhere from 3 to 24 months during which there would be greater flexibility to opt in or out of the CAP. Commenters were concerned that the 1-year enrollment period would commit them to a poor performing vendor with no recourse available to them. In particular, commenters were concerned with the quality of the products, timely delivery of drugs, overall performance of the vendor, and the physician's financial situation if he or she chooses the CAP versus the ASP system. Other commenters asserted that although the statute does provide for an annual election, nothing in the statute requires or supports the use of a ''lock-in'' period. Still other commenters requested that we provide more flexibility within the CAP enrollment period to be able to evaluate the impact on a practice's financial situation by being able to asses the most current ASP payment rates, published quarterly, and then determining whether to elect to participate in the CAP.

Response: Section 1847B(a)(1)(A)(ii) and section 1847B(a)(5)(A)(ii) of the Act require that each physician be given the opportunity annually to elect to obtain drugs and biologicals through the CAP and to select an approved CAP vendor. Furthermore, section 1847B(a)(5)(A)(i) of the Act allows for selection of another approved CAP vendor more frequently than annually in exigent circumstances as defined by CMS. As discussed above, we proposed that a participating CAP physician would select an approved CAP vendor outside the annual election process if the previously selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor, or the participating CAP physician relocates to another competitive area (once multiple CAP competitive areas are developed). Physicians will need to carefully consider their options because the CAP election agreement will be binding for 1 calendar year. We proposed to set forth the exceptions to the annual selection process at § 414.908(a)(2) of our regulations.

It is typical for Government and private sector programs to operate on a 1-year basis. However, we have built in safeguards in the CAP that participating CAP physicians may use in addressing operational issues that arise in addition to communicating their program issues to their local carrier. These include the dispute resolution option that participating CAP physicians may use to address operational and quality issues (see section II.B.3 of this interim final rule on dispute resolution). If approved CAP vendor quality issues cannot be resolved, we may terminate the approved CAP vendor's contract. The participating CAP physician would then have the option to elect a new approved CAP vendor mid-cycle. We also believe that by the time physicians are given the option to elect the CAP, they will have had almost 1 year of experience in the ASP system and will be able to choose which option is best for their practice. However, in response to comments, we have modified § 414.908(a)(2), to allow a participating CAP physician to either select an approved CAP vendor outside of the annual selection process or opt out of the CAP for the remainder of the annual selection period when one of the conditions specified in § 414.908(a)(2) is met.

Comment: Commenters urged us to assure physicians that vendors will be required to accept all physicians who elect to participate in the CAP. A few commenters also requested assurance that vendors not be allowed to terminate the ''contract'' with a physician because the beneficiaries are not making their coinsurance payments.

Response: As noted above in section II.B.2 of this preamble, this interim final rule does not prohibit CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services. However, we will not require contracts between participating CAP physicians and the approved CAP vendor they select. Instead, there will be 3-year contracts between CMS and the approved CAP vendors, and participating CAP physicians will sign annual participating CAP physician election agreements with CMS. Discussed elsewhere in this interim final rule are the criteria for the selection of the approved CAP vendor and the content of the approved CAP vendor contracts. We will include a provision in the approved CAP vendor contract that requires an approved CAP vendor to accept all physicians who elect to participate in the annual CAP election process. In addition, the contract will specify that approved CAP vendors may not unilaterally drop participating CAP physicians. Rather, the approved CAP vendor may ask the designated carrier to intervene under the dispute resolution process described elsewhere in this preamble.

As noted above, in addition to the 3-year approved CAP vendor contract there will be an initial participating CAP physician election agreement, and an abbreviated participating CAP physician agreement for subsequent years, that participating CAP physicians will sign to notify us of their intent to elect the CAP and agree to the terms and conditions of the CAP participation. We are clarifying the definition of the participating CAP physician election agreement at § 414.902 to codify that participating CAP physicians must sign this agreement to notify us of their participation in CAP and to agree to the terms and conditions of CAP participation as set forth in these regulations.

A physician may elect to participate in the CAP independently of his or her

choice to participate in Medicare. Participation in Medicare is not a requirement for participation in the CAP. However, as noted below, all participating CAP physicians must be enrolled in Medicare.

Participating CAP physicians will select the approved CAP vendor to provide them with drugs for their Medicare patients on an annual basis. We previously described the circumstances, listed in § 414.908(a)(2), under which a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process. In addition to those circumstances, for the specific circumstance that the beneficiary does not pay their coinsurance, we will allow a participating CAP physician the opportunity to opt out of that drug category; and while there is only one drug category for CAP, the participating CAP physician would be allowed to opt-out of the CAP altogether. The opt-out would be effective until the next election cycle begins at which time the physician can elect a new approved CAP vendor, that same approved CAP vendor or leave CAP. We are amending our regulations at § 414.908 to include this provision.

Comment: Commenters questioned whether information for the CAP election would be available timely. One commenter stated that targeting to complete the following steps by Fall 2005 appeared to be an unrealistic timeframe: Bidding and finalizing vendors, having materials sent to physicians, notifying beneficiaries, and allowing physicians time to evaluate the specific NDCs. Another commenter would like to see the list of approved CAP vendors within a sufficient amount of time to be able to make a decision on whether to select a CAP vendor or the ASP system.

Response: We stated in the proposed rule that we would prepare a posting on our Web site approximately on October 1, describing the approved CAP vendors we have selected for CAP, their categories of drugs, and the geographic areas within which they would operate. We stated that we would publicize the participating CAP physician election information on our Web site via our physicians' listservs, and through our Medicare fee-for-service contractors' Web sites and newsletters. We would also coordinate with physician specialty organizations to inform their members that the participating CAP physician election information is available.

We agree that this is an ambitious timeline and intend to provide timely communication about the CAP. The CAP fact sheet is scheduled for completion this summer so that the carriers can disseminate it to their physicians by September 1, 2005. Before October 1 2005, there will be an education campaign to inform physicians about the CAP Web site and the election process. By October 1, 2005, we will make available, on our Web site, information on the CAP, a directory of the approved CAP vendors and the specific NDC numbers the approved CAP vendors will be providing, and the participating CAP physician election agreement forms. We will continue to update the approved CAP vendor directory on our Web site or make the directory available to interested physicians on an ongoing basis, as required under the statute.

Physicians will be asked to access the participating CAP physician election agreement on our Web site and determine whether they would like to elect to participate in the program. They will have 6 weeks in which to evaluate the information, download and complete the election forms and mail them to their carrier. Physicians who elect to participate will be asked to download, complete, and sign the CAP election agreement. The participating CAP physician election agreement will require that they select the approved CAP vendor(s) in their area from which they would like to obtain drugs and the categories of drugs they wish to obtain through the program when multiple categories of drugs become available. For this 3-year contract-cycle with the approved CAP vendor, there will only be one category of drugs.

Physicians will be instructed to return the completed participating CAP physician election agreement to their local carrier. The participating CAP physician election agreement must be postmarked by November 15. The local carrier will note the physician's decision to participate in the CAP, and the approved CAP vendor and categories of drugs selected when multiple categories of drugs become available. The local carrier will forward information from the participating CAP physician election agreement to the CAP designated carrier. The designated carrier will compile a master list of all participating CAP physicians' approved CAP vendor and drug category selections. In addition, the designated carrier will notify each approved CAP vendor of the participating CAP physicians who have elected to enroll with that approved CAP vendor.

Comment: One commenter urged us to modify the proposed § 414.908(a)(2)(ii) to remove the example of ''physician relocates to another competitive area'' as an exigent circumstance that would permit a physician to choose another vendor. The commenter believes that it would not be necessary for a nationally based acquisition area program.

Response: For a nationally based approved CAP vendor, it would not be necessary for a relocating participating CAP physician to choose another approved CAP vendor. This would be the case for this first round of competitive acquisition. In the future, when we create other competitive acquisition areas, we believe participating CAP physicians who are relocating to another competitive acquisition area will need to be able to select a different approved CAP vendor. Therefore, we retain this provision in the regulation.

Comment: Commenters suggested that if a vendor leaves the program mid-year, the physician should have the option to either leave the program or choose another vendor. In particular, one commenter suggested that physicians might choose to be in the CAP based on the specific brand-name drugs a vendor would supply. In that case, the commenter believes, if that vendor leaves the program mid-cycle, the physician should be given the option to choose another vendor or return to the ASP system. However, another commenter indicated that because physicians are accustomed to changing suppliers on a frequent basis, it should not be problematic for them to select a different CAP vendor.

Response: We previously described the circumstances, listed in § 414.908(a)(2), under which a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process. These were if the selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor, or the participating CAP physician relocates to another competitive acquisition area, once multiple CAP competitive areas are developed, or other exigent circumstances defined by CMS. However, under these specific circumstances, the participating CAP physician may also opt out of CAP. We have revised the regulation accordingly.

Requirements for Group Practices

We specified in the proposed rule that, consistent with the Medicare Participating Physician Process, if members of a group practice elect to participate in the CAP, the entire practice would participate. Physician groups that elect to participate in the

CAP would be paid for drug administration based on the group PIN number that they place on their claim. We proposed that when a physician bills as a member of a group using the group PIN, he or she must follow the group's election to participate or not to participate in the CAP. However, we also proposed that if a group practice physician maintains a separate solo practice, he or she could make a different determination to participate or not to participate in the CAP with respect to the solo practice if using his or her individual PIN.

Comment: Commenters asserted that requiring a single CAP election for an entire physician group practice is contrary to the statute. Some of these commenters suggested that we allow physicians that practice in groups to elect to participate in CAP on an individual or on a specialty basis. This flexibility would allow a specialty having difficulty obtaining its drugs to elect CAP while not affecting another specialty within the same group that is satisfied with ''buy and bill.'' The commenters asserted that, without such flexibility multi-specialty groups may break up into separate practices. Alternatively, the commenters suggested that physicians might provide care at other sites operated by the group, thereby potentially decreasing patient access to care in order to comply with the group election provision.

In contrast, other commenters supported the recommendation that all physicians in a group practice who enroll in the CAP program under the group number must adhere to the participation decision of the group because it simplifies the need to enroll all group practice physicians in the CAP program. One commenter requested that the group CAP election apply across group and private practice affiliations. They recommended that we require group practices to submit both group and individual unique provider identification number (UPIN) numbers upon application to avoid the possibility of allowing physicians to ''cherry pick'' medications to administer in their private practice, thereby requiring approved CAP vendors to supply a disproportionate share of the unprofitable drugs. Another commenter asserted that there is a possibility that a group practice may channel different purchases through different physicians, allowing the group to choose on a per drug basis whether to use the CAP or the ASP system. The commenter suggested that to avoid such abuses, group practices (including any entities controlled by a group practice) should be required to choose, as a group, to participate in the CAP and that physicians who are part of the group practice should not be permitted to bill separately for drugs covered under the CAP.

A commenter requested that we clarify whether an individual physician in a group practice would be allowed to enroll in the CAP program under his or her own individual number; in particular, the commenter questioned whether the group would be held accountable to the individual's decision. Commenters asserted that it would be the individual physician's choice to participate in the CAP and it should not be attributed to the whole group, unless the business as a whole enrolls the entire group under its number in the program.

Response: We do not believe that CAP elections on a group basis violate the statutory provision requiring each physician to be given an opportunity to elect to obtain drugs under the CAP program. The statute requires us to coordinate the selection of the approved CAP vendor with agreements entered into under section 1842(h) of the Act (agreements to become a Medicare participating physician). The participating physician enrollment process coordinates the participation election of, and claims processing for, physicians, including those who work in one or more group practices. Consistent with the rules for Medicare participation agreements under section 1842(h) of the Act, CAP elections are linked to the billing number under which an individual physician bills. Accordingly, if a physician in a group practice chooses to bill for his or her professional services through a billing number assigned to a group, he or she has chosen to delegate the CAP election to the group. If a physician practices in a group that has elected to participate in CAP, but the physician wants to ''buy and bill,'' the physician may avoid participating in CAP by billing all of his or her professional services under his or her own billing number instead of under a billing number assigned to the group (this would require the physician to revoke his or her reassignment agreement with the group in accordance with applicable Medicare procedures). Thus, a physician in a group practice may not participate in the two payment systems (ASP and CAP) at the same time in the same practice. However, if a physician renders professional services in more than one group practice (or in a group practice and in a separate solo practice), the CAP elections of the different groups or practices need not be the same. We believe that our interpretation will preserve each physicians' choice while simplifying the election process, assuring that election into the CAP is correctly identified for billing purposes, and minimizing the potential for program abuse.

With respect to the comment that the group CAP election apply across group and private practice affiliations, we believe the commenter is recommending not allowing a physician in a group and a solo practice in another location separately to determine whether to participate in the CAP. In the proposed rule, we noted that if a physician has a solo practice in another location, he or she will be able to make a separate determination about whether to participate in the CAP. To assist the approved CAP vendor in identifying for which practice a physician has elected CAP, we will be requiring collecting on the participating CAP physician election form the participating CAP physician's UPIN and the PIN or Group PIN, or both, for each practice that has elected the CAP. We believe this information will avert the unethical practices that were of concern to the commenter.

Comment: Some commenters stated that groups whose physicians cannot agree on whether to elect CAP participation will dissolve or break up. The commenters asserted that the dissolution or breakup of group practices had implications under the physician self-referral prohibition (also known as the ''Stark law'') in section 1877 of the Act. Specifically, the commenter feared that groups suffering a partial breakaway of group members might be unable to satisfy the ''substantially all test'' under the Stark definition of a ''group practice'' (§ 411.352), which in turn would jeopardize the group's ability to rely on the Stark exception for in-office ancillary services.

Response: We think it is unlikely that CAP will cause a significant number of group practices to dissolve because a group physician may still ''buy and bill,'' even though the group has elected to participate in CAP, as long as the physician bills all of his or her professional services rendered to group patients under his or her own individual PIN. Moreover, we believe that physicians choose to practice in a group for many reasons having nothing to do with whether or not a vendor furnishes a particular item or service to patients served by the group (for example, the ability to share overhead costs, coverage duties, and expertise).

Under the ''substantially all test'' referenced by the commenter, substantially all of the patient care services of the physicians who are members of the group must be furnished

through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. We see no reason why the resignation of one or more physician members of a group would cause the remaining group members to be unable to satisfy the ''substantially all test.'' On the other hand, depending on the circumstances, it is possible that the decision of some group members to bill individually and not through a number assigned to the group could cause the group to fail the ''substantially all test.'' Accordingly, physicians and their group practices will have to consider the Stark law implications of their CAP elections and exercise their choice in a manner that will ensure compliance with Stark.

CAP Election Agreement

Consistent with the Medicare participating physician enrollment process, we will give physicians who are newly enrolled in Medicare 90 days in which to decide to elect to participate in the CAP. We will provide information about the CAP when they enroll in Medicare and will be instructed how to find the election information and forms on our Web site. If they elect to participate in the CAP, they will download the participating CAP physician election agreement and submit it to their Medicare carrier.

The final election process is summarized as follows:

(1) We will prepare a posting on our Web site approximately on October 1, describing the approved CAP vendors, the categories of drugs they will be providing, and the geographic areas within which each approved CAP vendor will operate.

(2) We will publicize the availability of the participating CAP physician election information on our Web site via our physicians' listservs, and our Medicare fee-for-service contractors' Web sites and newsletters. We will also coordinate with physician specialty organizations to enlist their assistance in informing their members that the physician election information is available.

(3) Physicians will be asked to access the participating CAP physician election agreement on our Web site and determine whether they would like to elect to participate in the program.

(4) Physicians who elect to participate will be asked to download, complete and sign the participating CAP physician election agreement. The participating CAP physician election agreement will require that they select the approved CAP vendor(s) in their area from which they would like to obtain drugs and the categories of drugs they wish to obtain through the program (when multiple categories of drugs become available). For this 3-year contract-cycle with the approved CAP vendors, there will only be one category of drugs.

(5) Physicians will be instructed to return the completed participating CAP physician election agreement to their local carrier. The participating CAP physician election agreement must be postmarked by November 15 for participation in the CAP beginning January 1 of the following year.

(6) The local carrier will note the physician's decision to participate in the CAP, and the approved CAP vendor and categories of drugs selected (when multiple categories of drugs become available). For this 3-year contract-cycle with the approved CAP vendor, there will only be one category of drugs.

(7) The local carrier will forward information from the CAP election agreement to the CAP designated carrier.

(8) The designated carrier will compile a master list of all participating CAP physicians' approved CAP vendor and drug category selections. In addition, the designated carrier will notify each approved CAP vendor of the participating CAP physicians who have selected that approved CAP vendor.

(9) After the necessary claims processing files are prepared, the local carrier and the designated carrier will begin system testing to be ready to pay claims by January 1, 2006.

The requirements concerning a physician's election to participate in the CAP are set forth in § 414.908(a).

Comment: Commenters requested clarification as to whether a physician must participate in Medicare in order to participate in the CAP.

Response: We believe that the commenter is asking if the physician must agree to accept assignment for all Medicare covered services, not if a physician must be enrolled in the Medicare program. A physician is required to be enrolled into the Medicare program as a supplier in order to receive a Medicare billing number. Physicians who participate in Medicare must accept assignment, but non-participating physicians are not required to accept assignment. A physician can be in the CAP and have a CAP election agreement if he or she is enrolled in the Medicare program, but is not required to be a Medicare participating physician who has elected to accept assignment of all Medicare covered services. However, as we have implemented the CAP, participating CAP physicians must appeal drug administration claim denials. Therefore, non-participating physicians who elect to join the CAP will need to accept assignment for CAP drug administration claims on a case-by-case basis in order to be in compliance with their CAP election agreements. We are revising the definition of participating CAP physician to address this issue at § 414.902.

Toward the end of each calendar year (generally in November), all Medicare carriers have an open enrollment period. Also toward the end of each calendar year (generally in October), we will be making available to physicians the option to participate in the CAP. As noted above, a physician who is newly enrolled in Medicare will have the opportunity to elect to join the CAP.

Comment: One commenter requested that we clarify whether physicians will be penalized if they do not elect to participate in the CAP in the first year. Another commenter requested that we clarify the definition of ''new physician'' for the purposes of the CAP program and the triggering event for the 90 days notification timeline.

Response: We will not penalize physicians if they choose not to participate in the CAP in the first year. If a physician chooses not to enroll the first year, there will be an annual process for physicians to participate in CAP, and the physician may enroll during the next available period. However, if the reason for not electing to participate in the first year of the CAP was that the physician was newly enrolled in Medicare, he or she may elect to participate within 90 days of his or her billing number activation, and his or her initial CAP election agreement will continue through December 31 of the calendar year. The date that the billing number is activated is the triggering event of the 90-day election time-period. This is consistent with the process for new physicians to choose to participate in Medicare and accept assignment.

We will finalize the requirements at § 414.908 with modification. At § 414.908(a)(2), we set forth the exceptions to the annual selection process. At § 414.908(a)(5), we amend the provision to include the option for a physician to opt out of that drug category; and while there is only one drug category for CAP, the physician would be allowed to opt-out of the CAP altogether for the remainder of the year. At § 414.902, we are clarifying the definition of the participating CAP physician election agreement.

2. Vendor or Physician Education

To ensure that vendors and physicians have timely access to accurate Medicare program information regarding the CAP, in the proposed rule, we indicated we would instruct the CAP designated carrier to use various communication channels at the local and national levels to disseminate information about the CAP and assist vendors and physicians in understanding the Medicare program's operations, policy, and billing and administration procedures regarding the CAP. The CAP designated carrier would be instructed to use data analyses in tailoring its outreach and educational efforts for vendors and physicians regarding identified areas of confusion about the CAP. Additionally, we specified that the CAP designated carrier would be instructed to use mass media, as well as educational and outreach products, services, forums, and partnerships in an effort to disseminate information about, and provide assistance regarding, the CAP to the vendor and healthcare practitioner communities. The fundamental goal of our outreach and education requirements of the CAP designated carrier would be to ensure that those who provide services to beneficiaries receive the information they need to understand the Medicare program so that it is administered appropriately and billed correctly. As such, we would be involved in oversight of, and partnership with, the CAP designated carrier's vendor and physician outreach and educational program regarding the CAP.

Comment: Commenters were supportive of our proposal to utilize numerous outreach and educational activities to disseminate information about the CAP and emphasized that education is paramount to successful implementation of the CAP program. Commenters also stressed that information provided by the CAP designated carrier must be correct and timely and that CMS stay actively involved in the process.

Response: We also believe that education will be vital to the success of the CAP and will be ensuring that the CAP designated contractor fulfills the responsibility of providing timely and accurate information on the CAP.

As proposed we will have the CAP designated carrier utilize a variety of communication channels at the local and national levels to disseminate information about the CAP and assist approved CAP vendors and physicians in understanding this new program.

3. Beneficiary Education

The CAP will have an impact on beneficiaries who receive physician-administered drugs. As discussed in the March 4, 2005 proposed rule, if a physician elects to participate in the CAP, beneficiaries receiving services from this physician would receive a separate medical summary notice (MSN) from the designated carrier that processes invoices for the approved CAP vendor as well as a bill from the approved CAP vendor for the coinsurance of the drug. This could cause confusion for the beneficiary because he or she would only know that the drugs were administered by a physician. In addition, because the activity of the approved CAP vendor would be transparent to the beneficiaries, they may question why they are receiving a bill from an unknown entity.

To educate beneficiaries in a proactive fashion, we proposed to develop a beneficiary-focused fact sheet and to update existing related educational materials to reflect these changes. The fact sheet would be available for physicians who elect to participate in the CAP to provide to beneficiaries at the time of service. It would explain the CAP and its impact on the beneficiary. We would also make this fact sheet available at 1–800–MEDICARE, as well as on the *http://www.medicare.gov* Web site. Although we did not propose to require participating CAP physicians to provide beneficiaries with the fact sheet, we requested comments on the administrative burden associated with this activity. In addition, although we did not propose to require any additional options for specific outreach, we requested comments on other mechanisms that might be used to inform the beneficiary of services provided as part of the CAP and the burden that would be associated with this mechanism.

We also proposed to provide information about the CAP in the 2006 versions of the Medicare & You handbook and Your Medicare Benefits. The handbook is mailed annually to each beneficiary household. Your Medicare Benefits is available upon request at 1–800–MEDICARE, as well as on the *http://www.medicare.gov* Web site. We also proposed to provide information to the 1–800–MEDICARE helpline so that operators can answer CAP-related questions. The *http://www.medicare.gov* Web site would also have consumer-friendly information available about the CAP.

Comment: Several commenters were pleased with the proposals to create and distribute material on CAP to educate stakeholders while one commenter believed that a fact sheet was not sufficient. Some commenters indicated that the physician should be required to provide information about the CAP to the beneficiary. However, one commenter stated that proactive communication for services that they may never receive will increase costs to CMS and physicians for a program not applicable to all beneficiaries, while another commenter recommended the fact sheet be developed as a template with sections that could be customized by each CAP physician so information relevant to a specific beneficiary could be added (for example, CAP drugs being procured, name of vendor).

Other commenters opposed a mandate to require physicians to distribute outreach materials to beneficiaries. One of these commenters stated it was not the physician's responsibility to make this information available to their patients, while another stated practice management systems cannot easily identify patients who are participating in a subprogram of an individual health insurance product. Other commenters, while agreeing this information is important, believed that this information should come from CMS and added that the physician and the CAP vendor should not be required to educate the beneficiary directly as this is outside their role.

One commenter also encouraged us to have the CAP vendors supply fact sheets or introductory letters to the CAP physicians who contract with them that the physician can provide to beneficiaries.

Response: We agree that the education of the stakeholders in the CAP is extremely important and we will be providing information on the CAP as discussed in the proposed rule. Because we are aware that the CAP may not impact all beneficiaries, we will not provide specific information on the CAP to all Medicare beneficiaries. However, we will provide some general information about the CAP in the Medicare & You booklet so that beneficiaries will be aware of this program. Although a few commenters recommended that the participating CAP physician should not be required to provide a fact sheet to beneficiaries, we believe that it is important that beneficiaries understand that their physician has elected to participate in the CAP and what this will mean to the beneficiary. Therefore, we will require the physician to provide the fact sheet developed by us during the beneficiary's

first visit to the office subsequent to the physician enrolling in the CAP.

This fact sheet detailing the CAP program in plain language will also be available to beneficiaries via 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov*. When distributing the fact sheet, physicians may include additional information specific to the beneficiary. We believe that this approach will allow the participating CAP physician to address the specific needs of the beneficiary and minimize the burden on the participating CAP physician. As commenters suggested, we will also encourage the approved CAP vendors to provide introductory information about themselves and the CAP program that could be shared with beneficiaries. As discussed in section II.B.3 of this interim final rule, we will also have the approved CAP vendor include information on the beneficiary grievance process with any bill that is sent to the beneficiary. As a final point, as part of the vendor application process, we have stated that customer service is of primary importance and approved CAP vendors must demonstrate the ability to respond to inquiries on both weekdays and weekends.

Because we recognize the impact the CAP will have on Medicare beneficiaries, we will use a multi-tiered educational approach to provide information that will increase beneficiary awareness of the issues related to the CAP. The outreach efforts will include the following:

- A plain language fact sheet to be distributed by participating CAP physicians and available upon request via 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov.*
- New language in the existing Medicare & You and Your Medicare Benefits booklets. The Medicare & You booklet is mailed each fall to every beneficiary household. Your Medicare Benefits is available through 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov*.
- CAP related scripts for the customer service representatives at 1–800–MEDICARE (1–800–633–4227).
- Frequently asked questions and answers in consumer friendly language regarding the CAP available at *http://www.medicare.gov* on the Web.

III. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption ''Provisions to the Interim Final Rule'' at the beginning of your comments.]

For the most part, this interim final rule incorporates the provisions of the March 4, 2005 proposed rule. Those provisions of this interim final rule that differ from the proposed rule follow.

Under § 414.902, we are revising our definitions section to revise current definitions set forth in the proposed rule and to add new definitions:

We are making a conforming change to revise ''approved vendor'' to read ''approved CAP vendor.'' In § 414.902, we are also making a technical clarifying revision to the definition of an ''approved CAP vendor'' to specify that this vendor is one that has been approved by CMS to participate in the CAP program under ''1847B of the Act'' to avoid confusion with the competitive acquisition program for DME provided for under section 1847 of the Act. We are also revising the definition of ''participating CAP physician'' to clarify that physicians who do not participate in Medicare but elect to participate in the CAP agree to accept assignment for CAP drug administration services.

We are adding a definition of ''CAP drug'' to mean a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

- Under § 414.902, we are adding the definition of emergency delivery to mean the delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. We are also adding that this timeframe may be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.
- We are adding the definition of an emergency situation to mean an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for the purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements for the CAP under § 414.906 are met.
- We are adding a definition ''Pacific territories'' to mean, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.
- We are making a conforming change to revise ''CAP election agreement'' to read ''Participating CAP physician election agreement.'' In addition, we are revising the definition to clarify that this is an agreement the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in our regulations.
- We are adding a definition for prescription order. We are defining a prescription order as a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of part 414, subpart K.
- Under § 414.902, we are adding the definition of routine delivery to mean the delivery of a drug within 2 business days in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. This timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.
- Under § 414.902, we are adding the definition of ''timely delivery'' to mean the delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.
- We are also making additional conforming changes to terms under our definitions section to include revising ''competitive area'' to read ''competitive acquisition area.''

We are revising § 414.906(a)(4) to specify that when the approved CAP vendor delivers the drugs directly to the participating CAP physician, the drugs must be in unopened vials or other original container as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer, and the shipping material must include language stating that the drug was acquired in a manner that is consistent with statutory requirements. In addition, we are providing the process that the approved CAP vendor must follow if the approved CAP vendor opts to split shipments. We are revising § 414.906(a)(5) to specify that the approved CAP vendor bills Medicare only for the amount of the drug that the participating CAP physician has administered to the patient, and the beneficiary's

coinsurance will be calculated from the quantity of the drugs that is administered.

We are making revisions under § 414.906(c)(1) to clarify the payment methodology for CAP drugs.

We are making revisions under § 414.906(c)(2) regarding those circumstances under which the alternative payment amount established under section 1847A of the Act may be used to establish payment for a competitively biddable drug. At § 414.906(c)(2)(i) and (ii), we are clarifying that this alternative payment amount may be allowed if the drug is properly assigned to a category established under the CAP and if a HCPCS code must be established for the drug.

We are adding § 414.906(f) to specify the process the approved CAP vendor must follow if the approved CAP vendor substitutes a CAP drug.

We are revising § 414.908(a)(2) to clarify that under certain circumstances, the participating CAP physician not only has the option to choose another approved CAP vendor outside of the annual selection process but also the option to ''opt out'' of the CAP for the remainder of the annual selection period. The circumstances may include when the approved CAP vendor ceases to participate in the CAP; the participating CAP physician leaves a group practice participating in CAP; the participating CAP physician relocates to another competitive acquisition area; or other exigent circumstances defined by CMS.

We are revising § 414.908(a)(3)(iii) to specify that the participating CAP physician will submit a ''prescription order'' to the approved CAP vendor with complete patient information for the initial orders or when the information changes. In addition, we are specifying how and when abbreviated information may be used and we are also adding that the participating CAP physician may initiate the prescription orders by telephone with a follow-up written order within a specified period of time.

We are revising § 414.908(a)(3)(v) to set forth the specific information that the participating CAP physician must provide to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance (except where applicable State pharmacy law prohibits it).

We are adding new § 414.908(a)(3)(vi) to specify that the participating CAP physician must also notify the approved CAP vendor when a drug is not administered, or when he or she administers a smaller amount of the drug than was originally ordered. The participating CAP physician and the approved CAP vendor will agree on how to handle the unused CAP drug. We outlined the procedures the participating CAP physician follows if an agreement is reached for this physician to maintain the CAP drug in his or her inventory to be administered later.

We are adding new § 414.908(a)(3)(x) to state that the physician participating in the CAP agrees not to transport CAP drugs from one practice location (place of service) to another location.

We are adding new § 414.908(a)(3)(xi) to specify that the physician participating in the CAP agrees to provide the CMS-developed CAP fact sheet to beneficiaries.

We are adding a new § 414.908(a)(3)(xii) to specify that the participating CAP physician may receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

We are adding a new § 414.908(a)(5) to set forth the opt out provision for participating CAP physicians that is in addition to the circumstances described under § 414.908(a)(2). We specify that if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914 have been met, the physician can withdraw from CAP for the remainder of the year immediately upon notice to us and the approved CAP vendor.

We are revising § 414.908(b)(1)(i) to specify that competing bidders and vendors will submit the bid prices ''using the OMB Approved Vendor Application and Bid Form'' for competitively biddable drugs within the category and competitive acquisition area.

Under § 414.908(b)(1), we specify the criteria we use to select an approved bidder. We are adding additional criteria. We are revising § 414.908(b)(1)(iii) to add that the potential vendor's ''grievance process'' is considered when we select a bidder. We are also adding a new § 414.908(b)(1)(ix) to include that the approved CAP vendor must maintain appropriate licensure to supply CAP drugs in States in which the approved CAP vendor supplies the drugs as well as new § 414.908(b)(1)(x) to indicate that the approved CAP vendor must provide cost-sharing assistance. We are redesignating proposed § 414.908(b)(1)(ix) as § 414.908(b)(1)(xi) with minor editorial revisions.

At § 414.908(c)(3), we are adding language indicating that CMS may refuse to award a contract or terminate an approved CAP vendor contract for past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

At § 414.914(a), we are making revisions to clarify that the term of the contract between the approved CAP vendor and us is 3 years, ''unless terminated or suspended earlier as provided in this section or § 414.917.'' At § 414.914(c)(1), we describe the elements of the approved CAP vendor's compliance plan. We indicated in the proposed rule that the approved CAP vendor must comply with all applicable Federal and State laws, regulations, and guidance and we have added that this also includes, but is not limited to, compliance with the Prescription Drug Marketing Act, the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute, and the False Claims Act.

Under 414.914(f)(2), we are clarifying that the approved CAP vendor must have arrangements for shipment at least 5 ''weekdays'' each week of CAP drugs under the contact.

Under § 414.914(f)(7), we are clarifying that the terms of the contract for the approved CAP vendor must also specify that the approved CAP vendor comply with all ''applicable Federal and State laws, regulations, and guidance'' related to the prevention of fraud and abuse.

- Under § 414.914, we are adding additional conditions under the terms of the contract between the approved CAP vendor and us under new § 414.914(f)(8), (f)(9), (f)(10), and (f)(11).

We are adding a new § 414.914(g) to include additional vendor requirements under the contract. These terms specify that the approved CAP vendor must provide appropriate assistance to patients experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

- Referral to a bona fide and independent charitable organization.
- Implementation of a reasonable payment plan.
- A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in § 1003.101 of this title. The availability

of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors may inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers.

We are adding a new § 414.914(h) to specify the procedures that the approved CAP vendor must comply with before it may refuse to make further shipment of CAP drugs to a participating CAP physician on behalf of a specific beneficiary.

We are revising the heading of § 414.916 to read ''Dispute resolution process for vendors and beneficiaries.''

Under § 414.916, regarding the responsibilities of the designated carrier, we are removing paragraph (b)(2)(i) under this section that stated that the designated carrier will investigate and make a recommendation to us on whether the participating CAP physician has been meeting the claims and appeals obligations in his or her CAP election agreement. We are also redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as paragraphs (b)(2)(i) and (b)(2)(ii), respectively.

Upon receiving the designated carrier's recommendation, we will make a determination regarding suspension of the participating CAP physician's election agreement. Specifically, we are revising § 414.916(b)(3) to clarify the suspension period for participating CAP physicians. We are adding that a suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year. We are removing the last sentence in § 414.916(b)(3), which indicated a participating CAP physician could select another approved CAP vendor while a reconsideration was pending.

Under § 414.916(c)(8) regarding the findings of the hearing officer, we are clarifying that if the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician ''within 10 days of receipt of the hearing request.''

Under § 414.916(c)(9), we are clarifying our language regarding the final reconsideration determination. Under § 414.916(c)(9)(i) we are clarifying that if the decision is favorable to the participating CAP physician, the participating CAP physician may resume participation in the CAP. We are also adding that the hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician. Under § 414.916(c)(9)(iv), we are clarifying that if our decision is unfavorable to the participating CAP physician, the participating CAP physician's CAP election agreement is terminated.

We are removing proposed § 414.916(d) that stated the following: ''The approved CAP vendor treats quality and service issues through its grievance process. If the approved CAP vendor does not resolve a quality issue to the participating CAP physician's satisfaction, the participating CAP physician may escalate the matter to the designated carrier. The designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved CAP vendor.'' This language has been incorporated into new § 414.917. We are also redesignating the proposed paragraph (e) as new (d) under this section.

We are adding a new § 414.917 to set forth the process and responsibilities for the dispute resolution for participating CAP physicians and for suspension or termination of an approved CAP vendor's CAP contract. We believe that moving this language to a separate section more clearly presents the process and the responsibilities of the particular parties.

Under the dispute resolution process set forth under § 414.916 and § 414.917, we are adding that the designated carrier will include in its recommendation to us, ''numbered findings of fact'' when it makes a recommendation whether the participating CAP physician has been filing his or her drug administration claims in accordance with the requirements of physician participation in the CAP.

In addition, we are making editorial and technical revisions as well as necessary conforming changes.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Delayed Effective Date

[If you choose to comment on issues in this section, please include the caption ''Waiver of Delayed Effective Date'' at the beginning of your comments.]

We also ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

The Secretary finds that good cause exists to implement the requirements related to the selection process for approved CAP vendors immediately upon publication in the **Federal Register**. Under section 1847B of the Act, we are required to phase in the CAP beginning in 2006. In addition, section 1847B(a)(5)(A)(ii) of the Act requires that the physicians' annual selection of approved CAP vendors be coordinated with the Medicare participating physician described in the (PARDOC) process under section 1842(h) of the Act, which occurs in November and December each year. To comply with that statutory mandate, it will be necessary for us to have contracts in place with approved CAP vendors in time to give physicians a meaningful opportunity to review and select an available approved CAP vendor in their competitive acquisition areas. If contracts with vendors are not in place by that time, the next available physician selection period would be at the end of 2006 for a CAP implementation date of January 1, 2007. Such a delay would not be consistent with the statutory mandate that the CAP be phased-in beginning in 2006. Therefore, the Secretary has determined that it would be impractical and contrary to the public interest to delay the effective date of the provisions that apply to the vendor application and bidding process would be impracticable and contrary to the public interest. An effective date of July 6, 2005, for the requirements related to the selection process for approved CAP vendors will ensure that the selection of approved CAP vendors can proceed and will afford the approved CAP vendors needed time to prepare for the enrollment of physicians and education

of beneficiaries concerning the CAP program.

We note that only the provisions associated with the selection process for approved CAP vendors will be implemented within 60 days of the date of publication of this rule. There will be at least 60 days between publication of this rule and the implementation of other provisions of this rule, including the provisions related to physician selection and operation of the CAP program.

For all these reasons, we believe that a 60-day delay in the effective date of the provisions that apply to the vendor application and bidding process would be impracticable and contrary to the public interest. We therefore find good cause for waiving the 60-day delay in the effective date for the requirements related to the selection process for approved CAP vendors.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Competitive acquisition program as the basis for payment (§ 414.906). A physician who elects to participate in the program and has selected an approved CAP vendor, must provide information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(2).

The burden associated with this requirement is the time and effort necessary for the participating CAP physician to provide the information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance.

We estimate the burden to be approximately 29167 hours. We believe there will be 500,000 claims and it will take five minutes for the initial claim per beneficiary and three minutes for subsequent beneficiary claims. The collection of information for the initial claim is estimated to take five minutes and subsequent claims will take approximately three minutes. We estimate 25 percent of claims to be initial and 75 percent to be subsequent.

Competitive acquisition program (§ 414.908). A physician is provided an application process for the selection of an approved CAP vendor on an annual basis. The CAP election agreement will facilitate physician enrollment and designation of their approved CAP vendor and agreement to abide by the CAP program requirements.

In addition, physicians participating in the CAP must elect to use an approved CAP vendor for the drug category area as discussed in § 414.904(a)(1); submit a written order or prescription to the approved CAP vendor; not receive payment for the competitively biddable drug except as described in § 414.906(c)(2)(ii); provide information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3); notify the approved CAP vendor when a drug is not administered; maintain a separate electronic or paper inventory for each CAP drug obtained; agree to file the Medicare claim when the drug is administered.

The revised burden associated with this requirement is the time and effort necessary for the participating CAP physician to provide and/or maintain the information required as discussed above. We revised our original estimate to reflect new estimates on how many physicians may participate in CAP and the time required to fill out the most current revision of the Physician election form. For these burden purposes, we estimate that there will be 10,000 physicians who fill out an application and it will take the physician 2 hours to complete the application. Therefore, the burden estimate is 20,000 hours.

Bidding process (§ 414.910). Vendors may bid to furnish competitively biddable drugs in all areas of the United States, or a specific region that meets the requirements of this section.

The burden associated with these requirements is the time and effort necessary to submit the bid application, supporting documentation, and maintain necessary documentation demonstrating that the requirements set forth in the contract have been or will be met.

We currently estimate that it will require 12 bid applicants 40 hours each to meet the bidding and contract requirements. This revised estimate is based on data from the CAP RFI that concluded in January and the policies outlined in this IFC. The estimate of hours required for one bidder to meet this burden is unchanged.

Terms of contract (§ 414.914). The terms of the contract between CMS and the approved CAP vendor will be for a term of 3 years. During the contract period the approved CAP vendor must disclosure to CMS or its agent, the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, on at least an annual basis.

The burden associated with these requirements is the time and effort necessary for the approved CAP vendor to submit to CMS or its agent, the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, at least on an annual basis.

We estimate that it will require each of the five vendors 8 hours on an annual basis to submit the necessary information, for total annual burden of 8 hours per vendor. The estimate was revised to reflect a maximum of five approved CAP vendors for one national area.

Dispute resolution for vendors and beneficiaries. Dispute resolution (§ 414.916). Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process.

The dispute resolution process may involve the gathering of information, however, since the requirements set forth in this section are in accordance with administrative action, audit, or investigation, the requirements of this section are exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Dispute resolution and process for suspension or termination of an approved CAP vendor (§ 414.917). If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug to be dissatisfactory, then the participating CAP physician may treat the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. In addition, if CMS suspends or terminates an approved CAP vendor's CAP contract for cause, the approved CAP vendor may request a reconsideration of this decision.

This process may involve the gathering of information, however, since the requirements set forth in this section are in accordance with administrative action, audit, or investigation, the requirements of this section are exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Jim Wickliffe, CMS–1325–IFC, Room C5–13–28, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS–1325–P, Christopher *Martin@omb.eop.gov.* Fax (202) 395–6974.

Comments Related to the Collection of Information Requirements

Comment: One commenter suggested that CMS revise its estimate for completing the physician application for CAP election to reflect the additional time it will take for physicians to evaluate the CAP.

Response: While we understand this concern, paperwork burden estimates generally do not include the time necessary to evaluate or consider taking a specific action. Paperwork burden estimates generally the time to complete the information collection, including the time to review instructions, search existing data resources, gather the needed data, and complete and review the information collection. Accordingly, CMS is not adopting this recommendation.

Comment: Several commenters recommended that CMS closely monitor physician clerical and inventory resources associated with the CAP during the initial years of the program, and if appropriate, consider making additional payment to physicians to cover the administrative costs associated with CAP.

Response: CMS will monitor the impact of the CAP program on physicians, patients, and on Part B drug prices closely. CMS will monitor its implementation approach and, if necessary, make adjustments to ensure patient access and reduce the administrative costs for providers.

VII. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of $100 million or more in any 1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities).

We indicated in the March 4, 2005 proposed rule that we were considering this to be a major rule, but at that time we had not yet defined geographic area(s) and category(ies) of CAP drugs. Based on the establishment of the CAP initially as a national program with one drug category, we continue to believe that this rule is a major rule, and we anticipate more than $100 million will pass through the CAP payment system in 2006. Therefore, we have prepared a regulatory impact analysis (RIA). However, as previously discussed in the preamble, certain sections of this rule will be effective immediately. Specifically, the provisions related to the vendor bidding process will not be subject to the 60-day delay in effective date applicable to major rules under the Congressional Review Act (5 U.S.C. 801 *et seq.*) because of the need to meet the statutory requirement to coordinate the physicians' election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. We can only meet this statutory requirement if the delay in effective date for these particular portions of the rule are waived. We note that although the vendor bidding process will begin immediately, vendors will not be required to sign contracts with Medicare until after the effective date of all of the provisions of this rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $6 million to $29 million in any 1 year. We prepare an initial or final regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason the action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. Individuals and States are not included in the definition of a small entity. For the reasons described in the section on ''Anticipated Effects,'' we certify that this rule will not have a significant economic impact on a substantial number of small entities.

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of $8.5 million or less. Approximately 96 percent of physicians in private practice are considered to be small entities. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are more concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent in urology.

The impact of this interim final rule on an individual physician is dependent on the drugs they provide to Medicare beneficiaries and whether these drugs are included in the category of ''incident to'' drugs identified in the preamble for competitive acquisition and whether the physician chooses to obtain drugs administered to Medicare beneficiaries through the CAP.

In addition, this interim final rule will have a potential impact on entities, either existing or formed specifically for this purpose, that are involved in the dispensing or distribution of drugs. This aspect was dependent on our determination of the particular category/categories of drugs to be included in the CAP and the geographic areas in which

it is to take place. It also depends on the ability of potential vendors to successfully compete and receive approval as a vendor under the CAP. As previously discussed, the CAP will be a national program, and an approved CAP vendor must be able to furnish all the drugs in the established CAP category of drugs.

Comment: At least one commenter believed that the initial regulatory flexibility analysis was not sufficient to allow small vendors sufficient notice that the CAP could have an impact on them.

Response: We believe that small businesses received ample notice that this rule could have an impact on them. We provided detailed explanations of the options for the areas and categories in the preamble to the proposed rule, and indicated that the impact on small entities would depend on how those choices played out. We received more than 500 comments from a variety of sources, including potential CAP vendors and individual physicians. We believe that all possibly affected entities, including small vendors, had an opportunity to comment.

Also, section 1102(b) of the Social Security Act requires us to prepare an initial and final regulatory flexibility analysis if a rule has a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this interim final rule will have no significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule that mandates expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined this interim final rule in accordance with Executive Order 13132 and UMRA and have determined that this regulation will have no consequential effect on the rights, roles, or responsibilities of State, local, or tribal governments, or impose direct costs on State, local, or tribal governments. Nor does the rule mandate direct costs on the private sector.

Comment: Several commenters believe that, should CMS include oncologists and oncology drugs in the CAP, more Medicare beneficiaries will require hospital treatment due to delayed access to necessary drugs for their treatment programs and this will potentially impact small hospitals.

Response: Based on the comments received and the results of our data analysis, we will be including certain oncology drugs in the CAP, and we anticipate that some oncologists may elect to participate in the CAP. However, participation under the CAP is voluntary, and we would not expect these physicians to participate if this would result in adverse consequences for their Medicare beneficiary patients. Moreover, we believe that we have built into the program various safeguards that will preserve beneficiary access and prevent treatment delays or unnecessary hospital referrals, as discussed elsewhere in the preamble: For example, the provisions related to ''furnish as written'' and the resupply of inventories for drugs administered in an emergency situation will help ensure that Medicare beneficiaries will receive their treatments timely within their physicians' offices. Finally, the likely effects on physicians and Medicare beneficiary patients are discussed at greater length in the discussion of ''Anticipated Effects'' below.

B. Anticipated Effects

We have prepared the following analysis related to the assessment requirements. It explains the rationale for, and purposes of, the rule, details the costs and benefits of the rule, analyzes alternatives, and presents the measures we are using to minimize the burden on small entities. As indicated elsewhere in this rule, this program provides an alternative to the method that physicians currently use to obtain and pay for certain Medicare drugs in response to the requirements of section 1847B of the Act. The provisions of this rule discuss how this option will be offered to physicians. The CAP process is an alternative payment system for Part B drugs and biologicals. This rule does not impose reporting, recordkeeping, and other compliance requirements except as described in sections II.B, II.C and II.D. of the preamble. We are not aware of any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Comment: Several commenters expressed concern that there would be a significant administrative as well as a financial impact on physicians. These commenters claimed that physicians who elect to participate in the CAP will not be appropriately compensated for additional costs such as maintaining separate drug storage for CAP medications, hiring additional personnel to order and keep track of CAP medications, and the additional time required to adequately track the actual drug administrations.

Response: Although we recognize that electing to participate in the CAP imposes certain new burdens on physicians who choose to participate, we believe these are offset by the decrease in burden associated with no longer having to buy most Part B drugs and bill the Medicare program for them. The administrative payment burdens that are relieved or reduced include collecting the applicable deductible and coinsurance from the beneficiary or other supplemental insurer and the time and cost of assuming legal ownership of the drugs covered under the CAP. As the physician does not assume legal ownership of the drug under the CAP (ownership remains with the approved CAP vendor), this removes the burden of negotiating with drug suppliers for the best price. Further, it is possible that the time and effort involved in generating the drug in a quantity other than that in which it was received also could be removed from the physician. Receiving drugs in the proper administration dosage, where possible, saves the physician time and effort. We note that the CAP is an option offered to physicians who believe that it is a viable alternative to the buy and bill system, especially when dealing with extremely expensive drugs. Physicians who believe the CAP burden would be too onerous for their practice always will have the option of electing not to participate in the CAP and continue to be paid under the ASP payment system for the medically necessary drugs that they obtain and administer under Medicare. We remain committed to working with members of the health care community to assist them in identifying the most appropriate payment scenarios for providers as well as the highest quality of care for beneficiaries.

Comment: Several commenters were concerned that if CMS selected a national geographic area, then approved CAP vendors who participate in the CAP would be asked to handle business on a national level. Small vendors who want to operate under the CAP in a specific area for a small number of local physicians believe that in such an event, they will have been excluded from the CAP out of hand.

Response: Initially, we believe that, in order to get the program started, the CAP needs to be administered on a national level. Most of the comments we received indicated that small vendors were not limited geographically but, instead, by drug specialty. The CAP requirements are in place to facilitate access to care for Medicare beneficiaries and to maintain quality of care in the treatment programs of these beneficiaries. However, that does not mean that larger vendors cannot contract with smaller vendors under the CAP to provide drugs to smaller geographic areas of the country or specific physicians, as long as all other criteria can be met by the sub-contracted vendor. Furthermore, there is nothing that precludes a relatively small firm from providing services on a national basis. In this way, every qualified vendor has the opportunity to participate, even though it may not be in a direct way. In the future, we will establish additional or alternative competitive acquisition areas and drug categories and solicit comments on those additions or alternatives, as necessary.

The effect of this interim final rule on an individual physician will be dependent on the drugs he or she provides to Medicare beneficiaries and whether the drugs he or she furnishes are included in the category of drugs considered for the CAP. For example, a physician may (1) determine the cost associated with acquiring drugs through the competitive acquisition program; (2) determine the cost associated with acquiring drugs through traditional means and billing Medicare under the ASP payment system methodology; and (3) determine whether there is a cost savings to them associated with either program. Different outcomes may result from these calculations depending on the drug mix, overhead cost, and Medicare beneficiary patient mix.

A physician who elects to participate in the program would obtain all of his or her Medicare-related drugs included in the category through an approved CAP vendor. The approved CAP vendor will collect applicable deductibles and coinsurance from the beneficiary. Under this option, the participating CAP physician will never take legal ownership of the drug and will eliminate the cost associated with collecting deductibles and coinsurance. Because the drug remains the property of the approved CAP vendor until the time of administration, the participating CAP physician also may be able to reduce the cost associated with storage and individual drug supplier negotiations. The CAP may also save participating CAP physicians money because they will not be in the drug purchasing and procurement business and will not have to collect coinsurance for those drugs from beneficiaries.

Comment: Several commenters were concerned about increased drug waste by physicians who participate in the CAP because, in their view, the physician will not be able to return the unused drug to the approved CAP vendor or to use the drug when a beneficiary's treatment plan changes on short notice. These commenters further cited problems with redirecting these unused medications to alternative beneficiaries due to State regulations in some instances.

Response: If it becomes apparent that there is a problem with excessive waste under the CAP, then we will examine ways to specifically address the issue. One question would concern whether some types of physician practices may be affected because drugs they use are more prone to wastage for particular reasons, or if waste is more of a random problem that would lead us to deal with the issue on an individual basis.

This rule also establishes rules whereby drugs administered by the participating CAP physician in emergency situations that were not originally acquired through a Medicare-approved CAP vendor may be resupplied through the Medicare-approved CAP vendor, as described elsewhere in the preamble.

C. Impact of Establishment of a Competitive Acquisition Program

The purpose of the CAP program is to potentially achieve budgetary savings to Medicare and beneficiaries through a competitive bidding approach to determining Medicare payment rates for selected drugs and to provide physicians with an alternative way to obtain these selected drugs that they use for treating their Medicare beneficiaries in their offices. We have estimated the impact of the costs of furnishing or administering drugs through the CAP on the Medicare program and expect it to be negligible, at least during the beginning until participating CAP physicians, approved CAP vendors and CMS gain more experience with the program. During the first year, we anticipate no significant additional cost savings or increases associated with the CAP, particularly relative to the ASP payment system. The CAP program will provide alternatives to physicians who do not wish to be in the drug purchasing and coinsurance collection business. We will further refine theses impacts as participating CAP physicians, approved CAP vendors, and CMS gain experience with this new program.

D. Alternatives Considered

As we developed the CAP, we considered whether to break the country into smaller geographic regional or State areas as opposed to one national competitive acquisitions area (the 50 United States, the District of Columbia and the U.S. territories). We also considered whether to include all drugs available under the CAP in one category as opposed to breaking the drugs out into different categories such as oncology drugs, non-oncology drugs, and crossover drugs. We also considered variations of these options such as breaking down the drug categories at the national level versus offering one drug category at the regional or State level. In reference to these options, we did not receive any comments about administering the CAP in specific regions of the country or specific States or any data to support such a conclusion. As we stated earlier in this section, vendors who wish to be approved CAP vendors and who also wish to operate in certain States, regions, or areas of the country, as opposed to nationally, are free to seek out vendors who plan to participate in the CAP at the national level to see whether their services can be used at the sub-contractor level. We do not intend to direct such an arrangement other than to reiterate that our criteria for participation in the CAP must be met by any and all potential approved CAP vendors; however, we encourage this communication between potential CAP vendors as we believe that it will enhance the opportunities for approved CAP vendors as well as participating CAP physicians under the CAP.

We also considered whether or not to split drugs into more than one category as well as several options for defining drug categories across a wide spectrum of physician Part B drugs, as described in the preamble. Commenters on the proposed rule were divided about whether to employ broadly defined or narrowly defined categories of drugs. We are persuaded that more broadly defined categories would better serve the purposes of the program, at least in the initial stage. This approach would make it more feasible for participating CAP physicians to obtain all, or almost all, of their Part B drugs from one approved CAP vendor. We expect that the approved CAP vendors participating on a nationwide scale will be able to provide the broad spectrum of drugs without appreciably more difficulty, if any, than narrower sets of drugs. In accordance with the statute, we will

develop more narrowly defined categories if it seems advisable at a later stage.

In this interim final rule, based on the comments and our data analysis, we are implementing the CAP with one extensive category as it provides the most expansive category of drugs and it is the most simple in terms of operationalization. We believe that this option will encourage the highest number of approved CAP vendors to participate under the CAP due to the potential for larger market share and the opportunity for smaller vendors to contract with the larger vendors. We also believe that this option will encourage the highest number of physicians to participate under the CAP due to the potential for acquiring a large portion of the drugs administered to their Medicare beneficiaries from a single approved CAP vendor.

However, we will monitor the program carefully, assessing all the issues discussed above, and make appropriate program adjustments if these seem warranted. We welcome input on any and all issues.

E. Impact on Beneficiaries

We have estimated the potential changes in beneficiary coinsurance for drugs and related changes in beneficiary Part B premium payments resulting from the implementation of the CAP for Part B drugs. We do not expect, during the first year of the program, that there will be an appreciable difference to the beneficiaries if their drugs were to be administered by a physician participating in the CAP or purchasing them and being reimbursed for them within the ASP payment system. At least initially, until approved CAP vendors, participating CAP physicians, and CMS gain more experience with this new program, we do not anticipate there would be any significant additional costs or savings to a beneficiary whose physician participates in the CAP. The CAP should be largely transparent to the beneficiary population. The only change should be the entity that bills the beneficiary for the coinsurance.

We do not believe that beneficiaries would experience drug access issues as a result of implementation of the CAP. However, we intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future, if necessary.

We intend to develop educational material to distribute to beneficiaries, such as pamphlets and a discussion in The *Medicare & You Handbook*, to help explain the CAP and the changes they will see on their Medicare summary notices. Specifically, under the CAP, beneficiaries will now pay their coinsurance and deductibles to their approved CAP vendor instead of the administering participating CAP physician.

Comment: Several commenters believed that beneficiary access to a drug or drugs associated with the beneficiary's specific treatment program will be compromised under the CAP, resulting in multiple trips to the physician's office by not only the beneficiary, but the beneficiary's family members, for a single treatment. Also, these commenters believe that the beneficiary's condition may be compromised and, in fact, may decline, resulting in a hospital admission, because treatment was delayed in these circumstances. The commenters stated that, often, a beneficiary's treatment program is altered on short notice. A participating CAP physician that stocked his or her own drugs would, presumably, be able to accommodate these treatment changes onsite, rather than having to plan a subsequent visit while an alternative drug prescription order is filled.

Response: We appreciate the concerns of these commenters, and we will monitor beneficiary access under the CAP. We believe that the construct of the CAP will enhance beneficiary access in several ways. The participating CAP physician will have access to a category of drugs that he or she can order to meet the beneficiary's needs. If the approved CAP vendor does not offer a particular drug that is medically necessary for a beneficiary's treatment plan, then the participating CAP physician may use the ''furnish as written'' option and access the specific drug through this channel. Further, if a beneficiary presents in a condition that requires the participating CAP physician to alter his or her treatment plan, and the participating CAP physician determines it is an emergency, and the other criteria under the resupply provision are met such as, that the need is unanticipated and the vendor cannot provide the drug in time, then the participating CAP physician could immediately administer a drug out of his or her own stock and then order a replacement from the approved CAP vendor. Although we cannot say that a situation would never occur wherein a beneficiary would need a drug that is not immediately available, this could also occur under the current ASP payment system.

Comment: Some commenters pointed out that beneficiaries may be disadvantaged if an approved CAP vendor cannot react expeditiously when new drugs are introduced or patents expire due to the restrictions of the CAP. An approved CAP vendor is limited to offering drugs within a certain category while the participating CAP physician can act outside the CAP for drugs that are different or new.

Response: We appreciate the fact that new drugs may become available through the FDA drug or biological approval process, or alternatively that previously approved drugs may be discontinued on an ongoing basis. New drugs may be included in the CAP once they are assigned a permanent HCPCS code, as described elsewhere in this preamble. If a new drug or biological is not offered by the participating CAP physician's approved CAP vendor, participating CAP physician can purchase it and bill for it through the ASP payment system.

A drug approved by the FDA as a generic for an existing drug with a HCPCS code may not be available within the CAP because for multiple source drugs, the approved CAP vendor is required to provide only one NDC within a HCPCS code (although the approved CAP vendor is free to bid to provide multiple NDCs within a HCPCS code). If a participating CAP physician finds it medically necessary to prescribe a new drug that is within an existing HCPCS code in the CAP drug category, but that his or her selected approved CAP vendor has not contracted to provide, he or she can obtain it and bill for it under the ASP payment system using the ''furnish as written'' provision.

Comment: A large number of commenters involved in the mental health arena stated that the inclusion of psychiatric drugs under the CAP would enable more patients in need of valuable mental health medications to have access to them, especially in rural areas, and, as a result, bring new psychiatric therapies into wider use. In the view of these commenters, the current ASP payment system presents them with barriers to care for their patients because of the administrative burden of locating new mental health therapies and then billing Medicare and tracking the claims, which often are only partly paid. If psychiatric drugs were included as an available category, then this burden would be removed.

Response: We appreciate the positive response from the mental health community for the CAP. We are working to ensure the availability of the most effective treatments to enable at-risk individuals to live productive lives in the least restrictive environments. As previously stated, several mental health

drugs are included in the drug category we have established for the CAP.

Comment: Several commenters believe that Medicare beneficiaries will have a difficult time understanding why they receive two statements (one from the participating CAP physician for the administration of the drug and one from the approved CAP vendor for the coinsurance and deductible payments) about each episode of treatment.

Response: We have built extensive educational tools into the CAP for beneficiaries, as described elsewhere in the preamble. Beneficiaries will receive information on the implementation of the CAP and how it will affect them and what they see as far as Medicare billing is concerned. They will also be provided with access to a help line for the questions about their bills as well as written information that they can reference. Of course, regardless of which option they select, we would expect most participating CAP physicians to explain to their Medicare beneficiaries the process by which they will be billed.

Comment: Some commenters were concerned that beneficiaries who were financially burdened would be adversely affected by the CAP because they would be removed from dealing directly with their physicians in working out payment options for their deductibles and copayments because the approved CAP vendor would be responsible for billing the beneficiaries for these items.

Response: Beneficiaries are legally responsible for paying their coinsurance, and providers, including participating CAP physicians and other suppliers such as the approved CAP vendors, are required to make an effort to collect it. We address above in this preamble measures that the approved CAP vendor may take to address this issue. We encourage beneficiaries to talk to the approved CAP vendor in these circumstances and encourage the approved CAP vendor to provide beneficiaries information about patient assistance programs. Again, we will be monitoring beneficiary access under the CAP. In addition, approximately 80 percent of Medicare beneficiaries have some type of supplemental coverage for Part B that will pay their deductible and coinsurance amounts either in whole or in part.

F. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart K—Payment for Drugs and Biologicals Under Part B

■ 2. Revise the heading of subpart K to read as set forth above.

■ 3. Amend § 414.900 by—

■ A. Revising the section heading.

■ B. Revising paragraph (a).

■ C. Revising paragraph (b)(3)(ii).

The revisions read as follows:

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) * * *

(3) * * *

(ii) Pneumococcal and Hepatitis B vaccines.

* * * * *

■ 4. Amend § 414.902 by republishing the introductory text to the section and adding the definitions of ''Approved CAP vendor,'' ''Bid,'' ''CAP drug,'' ''Competitive acquisition area,'' ''Competitive acquisition program,'' ''Designated carrier,'' ''Emergency delivery,'' ''Emergency situation,'' ''Local carrier,'' ''Pacific Territories,'' ''Participating CAP physician,'' ''Participating CAP physician election agreement,'' ''Prescription order,'' ''Routine delivery,'' and ''Timely delivery.''

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

* * * * *

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

* * * * *

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

* * * * *

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

* * * * *

■ 5. Amend § 414.904 by revising the section heading to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

■ 6. Add § 414.906 to read as follows:

§ 414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under § 414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in § 414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* (1) Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted, as a result of the bidding process as described in § 414.910. Based on these bids, a single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the payment year. This single payment amount is then updated on an annual basis based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS based, in part, on information disclosed to CMS and limited by the weighted payment amount established under section 1847A of the Act across all drugs in that category. Adjustment to the payment amounts may be made more often than annually, but no more often than quarterly, in any of the following cases:

(i) Introduction of new drugs.

(ii) Expiration of a drug patent or availability of a generic drug.

(iii) Material shortage that results in a significant price increase for the drug.

(iv) Withdrawal of a drug from the market.

(2) The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in § 414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in § 414.902.

(f) *Substitution of CAP drugs.* An approved CAP vendor may agree to furnish more than one CAP drug (defined at the NDC level) for a HCPCS code. Payment is based on a bid price defined by the HCPCS code and the unit of measure for the HCPCS code. Substitution of a different NDC within the HCPCS code for the NDC currently furnished by the approved CAP vendor can occur in the following situations:

(1) On an occasional basis, if the approved CAP vendor is willing to accept the payment amount that was established for the original NDC within a HCPCS code under the CAP, and the participating CAP physician approves the substitution; or

(2) For an extended period of time (more than 2 weeks), if the approved CAP vendor identifies the replacement product, the designated carrier's medical director approves the long-term substitution on behalf of CMS, and all participating CAP physicians who have selected the approved CAP vendor are notified of the change. In the case of such long-term substitution, payment is based on the price established in accordance with § 414.906(c).

■ 7. Add § 414.908 to read as follows:

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor.* (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2).

Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) For other exigent circumstances defined by CMS.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information: Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/ Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9.

(vi) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(vii) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(viii) Agrees to file the Medicare claim within 14 calendar days of the date of drug administration;

(ix) Agrees to submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment if the participating CAP physician's drug administration claim for a CAP drug is denied;

(x) Agrees not to transport CAP drugs from one practice location (place of service) to another location;

(xi) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xii) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(5) *Additional opt out provision.* In addition to the circumstances listed in § 414.908(a)(2), if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) have been met, the physician can withdraw from CAP for the remainder of the year immediately upon notice to CMS and the approved CAP vendor.

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

■ 8. Add § 414.910 to read as follows:

§ 414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

■ 9. Add § 414.912 to read as follows:

§ 414.912 Conflicts of interest.

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

■ 10. Add § 414.914 to read as follows:

§ 414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in § 414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at § 414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(6) Be enrolled in Medicare as a participating supplier;

(7) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(8) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of § 414.914(h) are met;

(9) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(10) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(11) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in § 1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors may inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers.

(h) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of final payment by Medicare, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) If after that action is taken, a balance remains, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary.

(3) At the time of billing, the approved CAP vendor may inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and § 414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) If after 45 days from the postmark date of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary; however, if the beneficiary has requested cost-sharing assistance within the 45-day period, the provisions of paragraph (6), (7), or (8), as applicable, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in § 414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and § 414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with § 414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

■ 11–12. § 414.916 to read as follows:

§ 414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in § 414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of § 414.908(a)(3).

(c) *Reconsideration.* (1) *Right to reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

■ 13. Add § 414.917 to read as follows:

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with § 414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract.

(c) *Reconsideration.* (1) *Right to reconsideration.* An approved CAP

vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

■ 14. Add § 414.918 to read as follows:

§ 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

■ 15. Add § 414.920 to read as follows:

§ 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 23, 2005.

Michael O. Leavitt,

Secretary.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST

HCPCS	Long description
J0150	INJECTION, ADENOSINE FOR THERAPEUTIC USE, 6 MG.
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG.
J0170	INJECTION, ADRENALIN, EPINEPHRINE, 1 ML AMPULE.
J0207	INJECTION, AMIFOSTINE, 500 MG.
J0215	INJECTION, ALEFACEPT, 0.5 MG.
J0280	INJECTION, AMINOPHYLLIN, 250 MG.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG.
J0475	INJECTION, BACLOFEN, 10 MG.
J0540	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 1,200,000 UNITS.
J0550	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 2,400,000 UNITS.
J0570	INJECTION, PENICILLIN G BENZATHINE, 1,200,000 UNITS.
J0585	BOTULINUM TOXIN TYPE A, PER UNIT.
J0587	BOTULINUM TOXIN TYPE B, PER 100 UNITS.
J0600	INJECTION, EDETATE CALCIUM DISODIUM, 1000 MG.
J0637	INJECTION, CASPOFUNGIN ACETATE, 5 MG.
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG.
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML.
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG.
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG.
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG.
J0698	INJECTION, CEFOTAXIME SODIUM, PER GM.
J0702	INJECTION, BETAMETHASONE ACETATE & BETAMETHASONE SODIUM PHOSPHATE, PER 3 MG.
J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG.
J0735	INJECTION, CLONIDINE HYDROCHLORIDE, 1 MG.
J0800	INJECTION, CORTICOTROPIN, 40 UNITS.
J0880	INJECTION, DARBEPOETIN ALFA, 5 MCG.
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG.
J1000	INJECTION, DEPO-ESTRADIOL CYPIONATE, 5 MG.
J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG.
J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG.
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG.
J1051	INJECTION, MEDROXYPROGESTERONE ACETATE, 50 MG.
J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG.
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG.
J1190	INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 MG.
J1200	INJECTION, DIPHENHYDRAMINE HCL, 50 MG.
J1212	INJECTION, DMSO, DIMETHYL SULFOXIDE, 50%, 50 ML.
J1245	INJECTION, DIPYRIDAMOLE, PER 10 MG.
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG.
J1260	INJECTION, DOLASETRON MESYLATE, 10 MG.
J1335	INJECTION, ERTAPENEM SODIUM, 500 MG.
J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG.
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG.
J1450	INJECTION, FLUCONAZOLE, 200 MG.
J1580	INJECTION, GARAMYCIN, GENTAMICIN, 80 MG.
J1600	INJECTION, GOLD SODIUM THIOMALATE, 50 MG.
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG.
J1631	INJECTION, HALOPERIDOL DECANOATE, PER 50 MG.
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS.
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS.
J1645	INJECTION, DALTEPARIN SODIUM, PER 2500 IU.
J1650	INJECTION, ENOXAPARIN SODIUM, 10 MG.
J1655	INJECTION, TINZAPARIN SODIUM, 1000 IU.
J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, 50 MG.
J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, 100 MG.
J1745	INJECTION, INFLIXIMAB, 10 MG.
J1750	INJECTION, IRON DEXTRAN, 50 MG.
J1756	INJECTION, IRON SUCROSE, 1 MG.
J1885	INJECTION, KETOROLAC TROMETHAMI.NE, PER 15 MG.
J1940	INJECTION, FUROSEMIDE, 20 MG.
J1956	INJECTION, LEVOFLOXACIN, 250 MG.
J2001	INJECTION, LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG.
J2010	INJECTION, LINCOMYCIN HCL, 300 MG.
J2150	INJECTION, MANNITOL, 25% IN 50 ML.
J2260	INJECTION, MILRINONE LACTATE, 5 MG.
J2300	INJECTION, NALBUPHINE HYDROCHLORIDE, PER 10 MG.
J2324	INJECTION, NESIRITIDE, 0.25 MG.
J2353	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG.
J2354	INJECTION, OCTREOTIDE, NON-DEPOT SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG.
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG.
J2430	INJECTION, PAMIDRONATE DISODIUM, PER 30 MG.
J2505	INJECTION, PEGFILGRASTIM, 6 MG.
J2550	INJECTION, PROMETHAZINE HCL, 50 MG.
J2680	INJECTION, FLUPHENAZINE DECANOATE, 25 MG.
J2765	INJECTION, METOCLOPRAMIDE HCL, 10 MG.
J2780	INJECTION, RANITIDINE HYDROCHLORIDE, 25 MG.
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG.
J2912	INJECTION, SODIUM CHLORIDE, 0.9%, PER 2 ML.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG.
J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 40 MG.
J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 125 MG.
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG.
J3260	INJECTION, TOBRAMYCIN SULFATE, 80 MG.
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10 MG.
J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5 MG.
J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5 MG.
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG.
J3370	INJECTION, VANCOMYCIN HCL, 500 MG.
J3396	INJECTION, VERTEPORFIN, 0.1 MG.
J3410	INJECTION, HYDROXYZINE HCL, 25 MG.
J3420	INJECTION, VITAMIN B–12 CYANOCOBALAMIN, UP TO 1000 MCG.
J3475	INJECTION, MAGNESIUM SULFATE, PER 500 MG.
J3480	INJECTION, POTASSIUM CHLORIDE, PER 2 MEQ.
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG.
J7030	INFUSION, NORMAL SALINE SOLUTION, 1000 CC.
J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML=1 UNIT).
J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT).
J7050	INFUSION, NORMAL SALINE SOLUTION , 250 CC.
J7051	STERILE SALINE OR WATER, 5 CC.
J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT).
J7070	INFUSION, D5W, 1000 CC.
J7120	RINGERS LACTATE INFUSION, 1000 CC.
J7317	SODIUM HYALURONATE, PER 20 TO 25 MG DOSE FOR INTRA-ARTICULAR INJECTION.
J7320	HYLAN G-F 20, 16 MG, FOR INTRA ARTICULAR INJECTION.
J9000	DOXORUBICIN HCL, 10 MG.
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG.
J9031	BCG (INTRAVESICAL) PER INSTILLATION.
J9040	BLEOMYCIN SULFATE, 15 UNITS.
J9045	CARBOPLATIN, 50 MG.
J9050	CARMUSTINE, 100 MG.
J9060	CISPLATIN, POWDER OR S0LUTION, PER 10 MG.
J9062	CISPLATIN, 50 MG.
J9065	INJECTION, CLADRIBINE, PER 1 MG.
J9070	CYCLOPHOSPHAMIDE, 100 MG.
J9080	CYCLOPHOSPHAMIDE, 200 MG.
J9090	CYCLOPHOSPHAMIDE, 500 MG.
J9091	CYCLOPHOSPHAMIDE, 1.0 GRAM.
J9092	CYCLOPHOSPHAMIDE, 2.0 GRAM.
J9093	CYCLOPHOSPHAMIDE, LYOPHILIZED, 100 MG.
J9094	CYCLOPHOSPHAMIDE, LYOPHILIZED, 200 MG.
J9095	CYCLOPHOSPHAMIDE, LYOPHILIZED, 500 MG.
J9096	CYCLOPHOSPHAMIDE, LYOPHILIZED, 1.0 GRAM.
J9097	CYCLOPHOSPHAMIDE, LYOPHILIZED, 2.0 GRAM.
J9098	CYTARABINE LIPOSOME, 10 MG.
J9100	CYTARABINE, 100 MG.
J9110	CYTARABINE, 500 MG.
J9130	DACARBAZINE, 100 MG.
J9140	DACARBAZINE, 200 MG.
J9150	DAUNORUBICIN, 10 MG.
J9170	DOCETAXEL, 20 MG.
J9178	INJECTION, EPIRUBICIN HCL, 2 MG.
J9181	ETOPOSIDE, 10 MG.
J9182	ETOPOSIDE, 100 MG.
J9185	FLUDARABINE PHOSPHATE, 50 MG.
J9190	FLUOROURACIL, 500 MG.
J9200	FLOXURIDINE, 500 MG.
J9201	GEMCITABINE HCL, 200 MG.
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG.
J9206	IRINOTECAN, 20 MG.
J9208	IFOSFAMIDE, 1 GM.
J9209	MESNA, 200 MG.
J9211	IDARUBICIN HYDROCHLORIDE, 5 MG.
J9213	INTERFERON, ALFA–2A, RECOMBINANT, 3 MILLION UNITS.
J9214	INTERFERON, ALFA–2B, RECOMBINANT, 1 MILLION UNITS.
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG.
J9245	INJECTION, MELPHALAN HYDROCHLORIDE, 50 MG.
J9250	METHOTREXATE SODIUM, 5 MG .
J9260	METHOTREXATE SODIUM, 50 MG.
J9263	INJECTION, OXALIPLATIN, 0.5 MG.
J9265	PACLITAXEL, 30 MG.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J9268	PENTOSTATIN, PER 10 MG.
J9280	MITOMYCIN, 5 MG.
J9290	MITOMYCIN, 20 MG.
J9291	MITOMYCIN, 40 MG.
J9293	INJECTION, MITOXANTRONE HYDROCHLORIDE, PER 5 MG.
J9310	RITUXIMAB, 100 MG.
J9320	STREPTOZOCIN, 1 GM.
J9340	THIOTEPA, 15 MG .
J9350	TOPOTECAN, 4 MG.
J9355	TRASTUZUMAB, 10 MG.
J9360	VINBLASTINE SULFATE, 1 MG.
J9370	VINCRISTINE SULFATE, 1 MG.
J9375	VINCRISTINE SULFATE, 2 MG.
J9390	VINORELBINE TARTRATE, PER 10 MG.
J9395	INJECTION, FULVESTRANT, 25 MG.
J9600	PORFIMER SODIUM, 75 MG.
Q0136	INJECTION, EPOETIN ALPHA, (FOR NON ESRD USE), PER 1000 UNITS.
Q0137	INJECTION, DARBEPOETIN ALFA, 1 MCG (NON-ESRD USE).
Q3025	INJECTION, INTERFERON BETA–1A, 11 MCG FOR INTRAMUSCULAR USE.

ADDENDUM B.—NEW DRUGS FOR CAP BIDDING FOR 2006

Code	2005 Description
J0128	Abarelix injection.
J0180	Agalsidase beta injection.
J0878	Daptomycin injection.
J1931	Laronidase injection.
J2357	Omalizumab injection.
J2469	Palonosetron HCl.
J2794	Risperidone, long acting.
J7518	Mycophenolic acid.
J9035	Bevacizumab injection.
J9041	Bortezomib injection.
J9055	Cetuximab injection.
J9305	Pemetrexed injection.

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Part III

Environmental Protection Agency

40 CFR Part 51

Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[FRL–7925–9]

RIN 2060–AJ31

Regional Haze Regulations and Guidelines for Best Available Retrofit Technology (BART) Determinations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On July 1, 1999, EPA promulgated regulations to address regional haze (64 FR 35714). These regulations were challenged, and on May 24, 2002, the U.S. Court of Appeals for the District of Columbia Circuit issued a ruling vacating the regional haze rule in part and sustaining it in part. *American Corn Growers Ass'n* v. *EPA,* 291 F.3d 1 (D.C. Cir. 2002). Today's rule addresses the court's ruling in that case.

In addition, prior to the court's decision, EPA had proposed guidelines for implementation of the Best Available Retrofit Technology (BART) requirements under the regional haze rule, (66 FR 38108, July 20, 2001). The proposed guidelines were intended to clarify the requirements of the regional haze rule's BART provisions. We proposed to add the guidelines and also proposed to add regulatory text requiring that these guidelines be used for addressing BART determinations under the regional haze rule. In addition, we proposed one revision to guidelines issued in 1980 for facilities contributing to ''reasonably attributable'' visibility impairment.

In the *American Corn Growers* case, the court vacated and remanded the BART provisions of the regional haze rule. In response to the court's ruling, on May 5, 2004 we proposed new BART provisions and reproposed the BART guidelines. The *American Corn Growers* court also remanded to the Agency its decision to extend the deadline for the submittal of regional haze plans. Subsequently, Congress amended the deadlines for regional haze plans (Consolidated Appropriations Act for Fiscal Year 2004, Public Law 108–199, January 23, 2004). The May 5, 2004 proposed rule also contained an amendment to the regional haze rule to conform to the new statutory deadlines.

We received numerous comments on both the July 20, 2001 proposal and the May 5, 2004 reproposal. Today's final rule reflects our review of the public comments.

DATES: The regulatory amendments announced herein take effect on September 6, 2005.

ADDRESSES: Docket. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the OAR Docket, EPA/DC, EPA West, Room B102, 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 OAR Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Kathy Kaufman at (919) 541–0102 or by e-mail at *Kaufman.Kathy@epa.gov* or Todd Hawes at 919–541–5591 or by e-mail *Hawes.Todd@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities. This final rule will affect the following: State and local permitting authorities and Indian Tribes containing major stationary sources of pollution affecting visibility in federally protected scenic areas.

This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This list gives examples of the types of entities EPA is now aware could potentially be regulated by this action. Other types of entities not listed could also be affected. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should examine the applicability criteria in Part II of this preamble. If you have any questions regarding the applicability of this action to a particular entity, consult the people listed in the preceding section.

Outline. The contents of today's preamble are listed in the following outline.

I. Overview of Today's Proposed Actions
II. Background
  A. Regional Haze Rule
  B. Partial Remand of the Regional Haze Rule in *American Corn Growers*
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  D. *Center for Energy and Economic Development* v. *EPA*
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  A. Introduction
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  I. National Technology Transfer Advancement Act
  J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. Overview of Today's Actions

Today's rulemaking provides the following changes to the regional haze regulations:

(1) Revised regulatory text in response to the *American Corn Growers* court's remand, to require that the BART determination include an analysis of the degree of visibility improvement resulting from the use of control technology at each source subject to BART,

(2) Revised regulatory text in 40 CFR 51.308(b) and deletion of 40 CFR 51.308(c) *Options for regional planning* in response to Congressional legislation amending the deadlines for submittal of regional haze implementation plans. This provision had provided for an alternative process for States to submit regional haze implementation plans in attainment areas,

(3) BART guidelines, contained in a new Appendix Y to 40 CFR part 51,

(4) New and revised regulatory text, to be added to 40 CFR 51.308(e), regarding the use of Appendix Y in establishing BART emission limits, and

(5) Revised regulatory language at 40 CFR 51.302 to clarify the relationship between New Source Performance Standards (NSPS) and BART for reasonably attributable visibility impairment.

How This Preamble Is Structured. Section II provides background on the

Clean Air Act (CAA) BART requirements as codified in the regional haze rule, on the D.C. Circuit Court decision which remanded parts of the rule, and on the April 2004 reproposal responding to the remand. Section III discusses specific issues in the BART guidelines in more detail, including background on each issue, major comments we received on the July 2001 proposal and May 2004 reproposal, and our responses to those comments. Section IV provides a discussion of how this rulemaking complies with the requirements of Statutory and Executive Order Reviews.

II. Background

A. The Regional Haze Rule

In 1999, we published a final rule to address a type of visibility impairment known as regional haze (64 FR 35714, July 1, 1999). The regional haze rule requires States to submit implementation plans (SIPs) to address regional haze visibility impairment in 156 Federally-protected parks and wilderness areas. These 156 scenic areas are called ''mandatory Class I Federal areas'' in the Clean Air Act (CAA)[1] but are referred to simply as ''Class I areas'' in today's rulemaking. The 1999 rule was issued to fulfill a long-standing EPA commitment to address regional haze under the authority and requirements of sections 169A and 169B of the CAA.

As required by the CAA, we included in the final regional haze rule a requirement for BART for certain large stationary sources that were put in place between 1962 and 1977. We discussed these requirements in detail in the preamble to the final rule (64 FR at 35737–35743). The regulatory requirements for BART were codified at 40 CFR 51.308(e) and in definitions that appear in 40 CFR 51.301.

The CAA, in sections 169A(b)(2)(A) and in 169A(g)(7), uses the term ''major stationary source'' to describe those sources that are the focus of the BART requirement. To avoid confusion with other CAA requirements which also use the term ''major stationary source'' to refer to a somewhat different population of sources, the regional haze rule uses the term ''BART-eligible source'' to describe these sources. The BART-eligible sources are those sources which have the potential to emit 250 tons or more of a visibility-impairing air pollutant, were put in place between August 7, 1962 and August 7, 1977, and whose operations fall within one or more of 26 specifically listed source categories. Under the CAA, BART is required for any BART-eligible source which a State determines ''emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any such area.'' Accordingly, for stationary sources meeting these criteria, States must address the BART requirement when they develop their regional haze SIPs.

Section 169A(g)(7) of the CAA requires that States must consider the following factors in making BART determinations:

(1) The costs of compliance,

(2) The energy and nonair quality environmental impacts of compliance,

(3) Any existing pollution control technology in use at the source,

(4) The remaining useful life of the source, and

(5) The degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

These statutory factors for BART were codified at 40 CFR 51.308(e)(1)(ii).

In the preamble to the regional haze rule, we committed to issuing further guidelines to clarify the requirements of the BART provision. The purpose of this rulemaking is to fulfill this commitment by providing guidelines to assist States as they identify which of their BART-eligible sources should undergo a BART analysis (*i.e.*, which are ''sources subject to BART'') and select controls in light of the statutory factors listed above (''the BART determination'').

B. Partial Remand of the Regional Haze Rule in American Corn Growers v. *EPA*

In response to challenges to the regional haze rule by various petitioners, the D.C. Circuit in American Corn Growers[2] issued a ruling striking down the regional haze rule in part and upholding it in part. This section discusses the court's opinion in that case as background for the discussion of specific changes to the regional haze rule and the BART guidelines presented in the next two sections, respectively.

We explained in the preamble to the 1999 regional haze rule that the BART requirements in section 169A(b)(2)(A) of the CAA demonstrate Congress' intent to focus attention directly on the problem of pollution from a specific set of existing sources (64 FR 35737). The CAA requires that any of these existing sources ''which, as determined by the State, emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility [in a Class I area],'' shall install the best available retrofit technology for controlling emissions.[3] In determining BART, the CAA requires the State to consider several factors that are set forth in section 169(g)(2) of the CAA, including the degree of improvement in visibility which may reasonably result from the use of such technology.

The regional haze rule addresses visibility impairment resulting from emissions from a multitude of sources located across a wide geographic area. Because the problem of regional haze is caused in large part by the long-range transport of emissions from multiple sources, and for certain technical and other reasons explained in that rulemaking, we had adopted an approach that required States to look at the contribution of all BART sources to the problem of regional haze in determining both applicability and the appropriate level of control. Specifically, we had concluded that if a source potentially subject to BART is located within an upwind area from which pollutants may be transported downwind to a Class I area, that source ''may reasonably be anticipated to cause or contribute'' to visibility impairment in the Class I area. Similarly, we had also concluded that in weighing the factors set forth in the statute for determining BART, the States should consider the collective impact of BART sources on visibility. In particular, in considering the degree of visibility improvement that could reasonably be anticipated to result from the use of such technology, we stated that the State should consider the degree of improvement in visibility that would result from the cumulative impact of applying controls to all sources subject to BART. We had concluded that the States should use this analysis to determine the appropriate BART emission limitations for specific sources.[4]

In *American Corn Growers* v. *EPA,* industry petitioners challenged EPA's interpretation of both these aspects of the BART determination process and raised other challenges to the rule. The court in *American Corn Growers* concluded that the BART provisions in the 1999 regional haze rule were inconsistent with the provisions in the CAA ''giving the states broad authority over BART determinations.'' 291 F.3d at 8. Specifically, with respect to the test for determining whether a source is subject to BART, the court held that the

[1] See, e.g. CAA Section 169A(a)(1).

[2] *American Corn Growers et al.* v. *EPA,* 291 F.3d 1 (2002).

[3] CAA sections 169A(b)(2) and (g)(7).

[4] *See* 66 FR at 35737–35743 for a discussion of the rationale for the BART requirements in the 1999 regional haze rule.

method that EPA had prescribed for determining which eligible sources are subject to BART illegally constrained the authority Congress had conferred on the States. *Id.* The court did not decide whether the general collective contribution approach to determining BART applicability was necessarily inconsistent with the CAA. *Id.* at 9. Rather, the court stated that ''[i]f the [regional haze rule] contained some kind of a mechanism by which a state could exempt a BART-eligible source on the basis of an individualized contribution determination, then perhaps the plain meaning of the Act would not be violated. But the [regional haze rule] contains no such mechanism.'' *Id.* at 12.

The court in *American Corn Growers* also found that our interpretation of the CAA requiring the States to consider the degree of improvement in visibility that would result from the cumulative impact of applying controls in determining BART was inconsistent with the language of the Act. 291 F.3d at 8. Based on its review of the statute, the court concluded that the five statutory factors in section 169A(g)(2) ''were meant to be considered together by the states.'' *Id.* at 6.

C. Changes in Response to American Corn Growers

Today's rule responds to the *American Corn Growers* court's decision on the BART provisions by including changes to the regional haze rule at 40 CFR 51.308, and by finalizing changes to the BART guidelines. This section outlines the changes to the regional haze rule due to the court's remand. It also explains the minor change we are making to the section of the regulation governing the use of the 1980 BART guidelines when conducting BART analyses for certain power plants for reasonably attributable (*i.e.,* localized) visibility impairment.

1. Determination of Which Sources Are Subject to BART

Today's action addresses the *American Corn Growers* court's vacature of the requirement in the regional haze rule requiring States to assess visibility impacts on a cumulative basis in determining which sources are subject to BART. Because this requirement was found only in the preamble to the 1999 regional haze rule (see 291 F.3d at 6, citing 64 FR 35741), no changes to the regulations are required. Instead, this issue is addressed in the BART guidelines, which provide States with appropriate techniques and methods for determining which BART-eligible sources ''may reasonably be anticipated to cause or contribute to any impairment of visibility in any mandatory Class I Federal area.'' These processes, to address the holding of *American Corn Growers* by eliminating the previous constraint on State discretion, are explained in further detail in sections II.D. and III below.

2. Consideration of Anticipated Visibility Improvements in BART Determinations

Pursuant to the remand in *American Corn Growers,* we are amending the regional haze rule to require the States to consider the degree of visibility improvement resulting from a source's installation and operation of retrofit technology, along with the other statutory factors set out in CAA section 169A(g)(2), when making a BART determination. This has been accomplished by listing the visibility improvement factor with the other statutory BART determination factors in 40 CFR 51.308(e)(1)(A), so that States will be required to consider all five factors, including visibility impacts, on an individual source basis when making each individual source BART determination.

D. Center for Energy and Economic Development v. EPA

After the May 2004 reproposal of the BART guidelines, the D.C. Circuit decided another case where BART provisions were at issue, *Center for Energy and Economic Development* v. *EPA,* 398 F.3d 653, 2005 (''CEED''). In this case, the court granted a petition challenging provisions of the regional haze rule governing the optional emissions trading program for certain western States and Tribes (the ''WRAP Annex Rule'').

The court in *CEED* affirmed our interpretation of CAA section 169A(b)(2) as allowing for non-BART alternatives where those alternatives are demonstrated to make greater progress than BART. (*CEED,* slip. op. at 13). The court, however, took issue with provisions of the regional haze rule governing the methodology of that demonstration. Specifically, 40 CFR 51.308(e)(2) requires that visibility improvements under source-specific BART—the benchmark for comparison to the alternative program—be estimated based on the application of BART controls to all sources subject to BART. (This section was incorporated into the WRAP Annex rule by reference at 40 CFR 51.309(f)). The court held that we could not require this type of group BART approach—vacated in *American Corn Growers* in a source-specific BART context—even in a program in which State participation was wholly optional.

The BART guidelines as proposed in May 2004 contained a section offering guidance to States choosing to address their BART-eligible sources under the alternative strategy provided for in 40 CFR 51.308(e)(2). This guidance included criteria for demonstrating that the alternative program achieves greater progress towards eliminating visibility impairment than would BART.

In light of the D.C. Circuit's decision in *CEED,* we have not included the portion of the proposed BART guidelines addressing alternative programs in today's rulemaking. We remain committed to providing States with the flexibility to address BART through alternative means, and we note again that our authority to do so was upheld in *CEED.* Therefore, we intend to revise the provisions of the regional haze rule governing such alternatives and provide any additional guidance needed in a subsequent rulemaking conducted as expeditiously as practicable.

E. Relationship Between BART and the Clean Air Interstate Rule (CAIR)

On March 10, 2005, EPA issued the Clean Air Interstate Rule (CAIR), requiring reductions in emissions of sulfur dioxide (SO_2) and nitrogen oxides (NO_X) in 28 eastern States and the District of Columbia. When fully implemented, CAIR will reduce SO_2 emissions in these states by over 70 percent and NO_X emissions by over 60 percent from 2003 levels. The CAIR imposes specified emissions reduction requirements on each affected State, and establishes an EPA-administered cap and trade program for EGUs in which States may participate as a means to meet these requirements. The relationship between BART and the Clean Air Interstate Rule (CAIR) is discussed in section IV. below.

F. Overview of the BART Process

The process of establishing BART emission limitations can be logically broken down into three steps: First, States identify those sources which meet the definition of ''BART-eligible source'' set forth in 40 CFR 51.301. Second, States determine whether such sources ''emit[] any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility [in a Class I area.]'' A source which fits this description is ''subject to BART.'' Third, for each source subject to BART, States then identify the appropriate type and the level of control for reducing emissions.

Identifying BART-eligible sources. The CAA defines BART-eligible sources as those sources which fall within one of 26 specific source categories, were built during the 15-year window of time from 1962 to 1977, and have potential emissions greater than 250 tons per year. The remand did not address the step of identifying BART-eligible sources, which is conceptually the simplest of the three steps.

Sources reasonably anticipated to cause or contribute to visibility impairment (sources subject to BART). As we noted in the preamble to the 1999 regional haze rule, defining the individual contributions of specific sources of the problem of regional haze can be time-consuming and expensive. Moreover, Congress established a very low threshold in the CAA for determining whether a source is subject to BART. We are accordingly finalizing several approaches for States for making the determination of whether a source ''emits any pollutants which may reasonably be anticipated to cause or contribute to any visibility impairment.'' Certain of these approaches would allow States to avoid undertaking unnecessary and costly studies of an individual source's contribution to haze by allowing States to adopt more streamlined processes for determining whether, or which, BART-eligible sources are subject to BART.

In 1999, we adopted an applicability test that looked to the collective contribution of emissions from an area. In particular, we stated that if ''a State should find that a BART-eligible source is 'reasonably anticipated to cause or contribute' to regional haze if it can be shown that the source emits pollutants within a geographic area from which pollutants can be emitted and transported downwind to a Class I area.'' [5] States certainly have the discretion to consider that all BART-eligible sources within the State are ''reasonably anticipated to cause or contribute'' to some degree of visibility impairment in a Class I area.

This is consistent with the *American Corn Growers* court's decision. As previously noted, the court's concern with our original approach governing BART applicability determinations was that it would have ''tie[d] the states' hands and force[d] them to require BART controls at sources without any empirical evidence of the particular source's contribution to visibility impairment.'' 291 F.3d at 8. By the same rationale, we believe it would be an impermissible constraint of State authority for the EPA to force States to conduct individualized analyses in order to determine that a BART-eligible source ''emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any [Class I] area.'' [6] *American Corn Growers* did not decide whether consideration of visibility impact on a cumulative basis would be invalid in all circumstances. 291 F.3d at 9. Given the court's emphasis on the importance of the role of the States in making BART determinations, we believe that a State's decision to use a cumulative analysis at the eligibility stage is consistent with the CAA and the findings of the D.C. Circuit.

We believe a State may conclude that all BART-eligible sources within the State are subject to BART.[7] Any potential for inequity towards sources could be addressed at the BART determination stage, which contains an individualized consideration of a source's contribution in establishing BART emission limits.

States also have the option of performing an analysis to show that the full group of BART-eligible sources in a State cumulatively may not be reasonably anticipated to cause or contribute to any visibility impairment in Class I areas. We anticipate that in most, if not all States, the BART-eligible sources are likely to cause or contribute to some visibility impairment in Class I areas. However, it is possible that using a cumulative approach, a State could show that its BART sources do not pose a problem.

Finally, States may consider the individualized contribution of a BART-eligible source to determine whether a specific source is subject to BART. Specifically, States may choose to undertake an analysis of each BART-eligible source in the State in considering whether each such source meets the test set forth in the CAA of ''emit[ting] any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any [Class I] area.'' Alternatively, States may choose to presume that all BART-eligible sources within the State meet this applicability test, but provide sources with the ability to demonstrate on a case by case basis that this is not the case. Either approach appears consistent with the D.C. Circuit's statement that a collective contribution approach may be appropriate so long as the States are allowed to exempt sources on the basis of an individualized contribution determination. 291 F.3d at 8.

Today's guidelines include different options States can use to assess whether source should be subject to BART. States need to determine whether to make BART determinations for all of their BART-eligible sources, or to consider exempting some of them from BART because they may not reasonably be anticipated to cause or contribute to any visibility impairment in a Class I area. For assessing the impact of BART-eligible sources on nearby Class I areas, we are including a process whereby the States would use an air quality model able to estimate a single source's contribution to visibility impairment and a different process whereby States could exempt groups of sources with common characteristics based on representative model plant analyses. Finally, States may use cumulative modeling to show that no sources in a State are subject to BART.

The BART determination. The State must determine the appropriate level of BART control for each source subject to BART. Section 169A(g)(7) of the CAA requires States to consider the following factors in making BART determinations: (1) The costs of compliance, (2) the energy and nonair quality environmental impacts of compliance, (3) any existing pollution control technology in use at the source, (4) the remaining useful life of the source, and (5) the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology. The remand did not address the first four steps of the BART determination. The remand did address the final step, mandating that we must permit States to take into account the degree of improvement in visibility that would result from imposition of BART on each individual source when deciding on particular controls.

The first four factors are somewhat similar to the engineering analysis in the original BART guidelines proposed in 2001 and reproposed in 2004. The BART guidelines also contains a detailed discussion of available and cost-effective controls for reducing SO_2 and NO_X emissions from large coal-fired electric generating units (EGUs).

For assessing the fifth factor, the degree of improvement in visibility from various BART control options, the States may run CALPUFF or another appropriate dispersion model to predict visibility impacts. Scenarios would be

[5] 64 FR 335740, July 1, 1999. The regional haze rule discusses at length why we believe that States should draw this conclusion. 64 FR at 35739–35740.

[6] CAA section 169A(b)(2)(A).

[7] See 64 FR at 35714, 35721; see also *Supporting Information for Proposed Applicability of Regional Haze Regulations,* Memorandum by Rich Damberg to Docket A–95–38, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, July 29, 1997.

run for the pre-controlled and post-controlled emission rates for each of the BART control options under review. The maximum 24-hour emission rates would be modeled for a period of three or five years of meteorological data. States have the flexibility to develop their own methods to evaluate model results.

III. Detailed Discussion of the Final BART Guidelines

A. Introduction

In this section of the preamble, we discuss changes or clarifications to the reproposed BART guidelines. Where relevant, we also respond to comments received during the comment period on the 2001 proposal. For each provision of the guidelines that we are changing or clarifying, we provide discussion of, as appropriate:

—Background information,
—How the provision was addressed in the May 2004 reproposal (and in the 2001 proposal, if different from the reproposal),
—A summary of comments received on the provision, either from the May 2004 reproposal, from the July 2001 proposal, or from both, and
—The changes or clarifications that we are finalizing and the reasons for these changes or clarifications.

B. Scope of the Rule—Whether To Require States To Follow the Guidelines for All BART Sources

Background. Section 169A(b)(1) of the CAA requires EPA to issue regulations to provide guidelines to States on the implementation of the visibility program. In addition, the last sentence of section 169A(b) states:

> In the case of a fossil-fuel fired generating powerplant having a capacity in excess of 750 megawatts, the emission limitations required under this paragraph shall be determined pursuant to guidelines, promulgated by the Administrator under paragraph (1).

This statutory requirement clearly requires us to promulgate BART guidelines that the States must follow in establishing BART emission limitations for power plants with a total capacity exceeding the 750 megawatt cutoff. The statute is less clear regarding the import of the guidelines for sources other than 750 megawatt power plants.

Proposed rules. Both the 2001 proposal and the 2004 reproposal included a requirement for States to follow the procedures set out in the guidelines in determining BART for sources in all of the 26 listed BART categories. The 2001 proposal requested comment on whether the regional haze rule should: (1) Require the use of the guidelines only for 750 megawatt utilities, with the guidelines applying as guidance for the remaining categories, or (2) require the use of the guidelines for all of the affected source categories.

Comments. We received comments on this issue in both 2001 and 2004. Comments varied widely on whether we can or should require the use of the guidelines for all of the affected source categories.

Comments from State, local and tribal air quality agencies generally supported our proposal to require the use of the guidelines for all of the source categories. These comments cited a need for national consistency in the application of the BART requirement across the source categories, and from State to State. One State agency commenter questioned our legal authority to require the use of the guidelines for all source categories; and several State agency commenters, while supporting the proposal, requested that we provide clarification of the legal authority for requiring the States to use the guidelines in establishing BART emission limitations for all categories.

Comments from the utility industry, from various manufacturing trade groups, and from individual companies were critical of the proposal to require States to follow the guidelines generally. Many commenters also argued that EPA lacked the authority to issue guidelines for any industrial category other than 750 megawatt powerplants, whether the use of such guidelines were mandatory or not. Other commenters stated that the language in the CAA clearly restricts the scope of mandatory guidelines to larger powerplants. The commenters cited the legislative history of the 1977 Clean Air Act amendments in support of this position, and frequently claimed that requiring the guidelines for all 26 categories of sources would deprive States of flexibility in implementing the program.

Comments from environmental organizations and the general public supported the approach in the proposed rule and stated that EPA is obligated to establish regional haze BART guidelines by rulemaking for all 26 categories of stationary sources. Environmental organization comments noted that while Congress expressed a particular concern for 750 MW powerplants, this added emphasis on one sector does not change requirements in the Act for all BART-eligible sources. Accordingly, these commenters believed that we should not construe a special emphasis on powerplants as a restriction on our authority to require use of the guidelines for all categories.

Final rule. The CAA and the relevant legislative history make clear that EPA has the authority and obligation to publish mandatory guidelines for powerplants exceeding 750 megawatts. As previously noted, Congress in section 169A(b) of the CAA expressly provided that emission limitations for powerplants larger than 750 megawatts ''*shall be determined* pursuant to guidelines promulgated by the Administrator.'' (Emphasis added). This unambiguous language leaves little room to dispute that the guidelines EPA is required to promulgate must be used by States when making BART determinations for this class of sources.

Having carefully considered the comments and further reviewed the CAA and the legislative history, we have concluded that it would not be appropriate for EPA to require States to use the guidelines in making BART determinations for other categories of sources. The better reading of the Act indicates that Congress intended the guidelines to be mandatory only with respect to 750 megawatt powerplants. Thus, while we acknowledge the State agency comments and the policy reasons support consistency across States, we are not requiring States to use the BART guideline for these other categories. In response to State concerns about equitable application of the BART requirement to source owners with similar sources in different States, we do encourage States to follow the guidelines for all source categories but are not requiring States to do so. States should view the guidelines as helpful guidance for these other categories.

We disagree with comments that the CAA and the legislative history prohibit us from issuing guidance for other source categories. As the guidelines make clear, States are not required to follow the approach in the guidelines for sources other than 750 megawatt powerplants. As such, although we believe that the guidelines provide useful advice in implementing the BART provisions of the regional haze rule, we do not believe that they hamper State discretion in making BART determinations.

C. How To Identify BART-Eligible Sources

Section II of the BART guidelines contains a step-by-step process for identifying stiationary sources that are ''BART-eligible'' under the definitions in the regional haze rule. The four basic steps are:

Step 1: Identify the emission units in the BART categories.

Step 2: Identify the start-up dates of those emission units.

Step 3: Compare the potential emissions from units identified in Steps 1 and 2 to the 250 ton/year cutoff.

Step 4: Identify the emission units and pollutants that constitute the BART-eligible source.

In this section of the preamble, we discuss some of the comments we received on the steps in this process, and any changes we are making in light of those comments.

Step 1: Identify the Emission Units in the BART Categories

The BART guidelines list the 26 source categories that the CAA uses to describe the types of stationary sources that are BART-eligible. Both proposals clarified the descriptions of particular source categories.

Comments. The final rule addresses comments on the following source categories. Some comments discussed below were submitted in response to the 2001 propoosal and were not addressed in the reproposal; other comments were submitted in response to the reproposal in 2004.

(1) ''Charcoal production facilities.'' We received comments in 2001 from two industry trade groups requesting that the final guidelines explicitly exclude ''low-emission'' charcoal production facilities from BART. These comments cited a 1975 study considered by Congress in development of the BART category list in the 1977 CAA amendments. This 1975 study noted that some charcoal production facilities have much higher emissions factors (i.e., 352 pounds of PM per ton of charcoal produced versus 20 to 25 pounds of PM per ton of charcoal produced). Accordingly, the comments asserted that the intent of Congress in the 1977 CAA amendments was to provide incentives for higher-emitting facilities to reduce their emissions, rather than to make the entire category BART-eligible.

(2) ''Chemical process plants.'' In 2001 a trade group representing the pharmaceutical industry requested that we determine in the guidelines that the term ''chemical process plants'' does not include pharmaceutical plants.

(3) ''Primary aluminum ore reduction.'' Comments from the aluminum industry in 2001 noted that not all emissions units at these facilities are necessarily involved in ''primary ore reduction.'' Thus, the comments recommended that we clarify that contiguous sources that are not related to primary aluminum ore reduction, such as fabricating facilities and ingot operations, are not BART-eligible. Further, the comments recommended that we use definitions in the NSPS for primary aluminum plants to describe the BART-eligible emissions units.

(4) ''Fossil-fuel fired steam electric plants of more than 250 million Btu/hour heat input.'' The 2004 reproposal contained the clarification, requested by commenters, that this source category refers only to those fossil-fuel fired steam electric plants that generate electricity for sale. One commenter objected to this clarification on the basis that emissions from co-generators would be excluded; many other commenters supported the clarification. Another commenter requested that we also clarify that this category includes only those steam electric plants that burn greater than 50 percent fossil fuel, in order to be consistent with the definition of fossil-fuel boilers proposed in the guidelines. Other commenters requested that we clarify whether the definition includes units which are located at a steam electric plant, but which themselves are not in any of the 26 BART source categories, such as simple cycle turbines, emergency diesel engines, and reciprocating internal combustion engines (RICE).

Several commenters opined that the category should exclude combined cycle units with heat recovery steam generators that lack auxiliary firing, arguing that these units should count as simple cycle turbines. These commenters pointed to other EPA regulatory programs that treat combined cycle units with supplemental firing differently from combined cycle units without supplemental firing. They argued that we should only consider a combined cycle unit to be a ''steam electric plant'' if it has supplemental firing.

(5) ''Fossil-fuel boilers of more than 250 million Btu/hour heat input.'' The 2004 reproposal clarified that this category should be read as including only those boilers individually greater than 250 million Btu/hour heat input. We received many comments on this interpretation, both in favor and opposed. Those favoring this interpretation (generally industry commenters) cited the implementation burden that including smaller boilers would pose, the high cost-effectiveness of controlling smaller boilers, and the relatively smaller impact on regional haze that smaller boilers would pose. They also noted that this interpretation is most consistent with definitions in the NO_X SIP call and new source performance standards (NSPS).

Commenters opposing this interpretation (environmental groups, one state, and one regional planning organization) noted that regarding all boilers, irrespective of size, as BART-eligible so long as the aggregate heat input exceeds 250 million Btu/hour is more consistent with the definition of stationary source under the Prevention of Significant Deterioration (PSD) program. These commenters noted that under the CAA, BART and PSD are complementary programs aimed at regulating the same source categories; either one or the other applies depending upon when the source was constructed.

The 2004 reproposal also clarified that if a boiler smaller than 250 million Btu/hour heat input is an integral part of an industrial process in a BART source category other than electric utilities, then the boiler should be considered part of the BART-eligible source in that category. Under these circumstances, the boiler, as part of the BART-eligible source, should be considered for emission control. Some commenters opposed this interpretation, asserting that it would result in an ''arbitrary and capricious'' inconsistency, in that some smaller boilers would be BART-eligible, and others would not. These commenters also noted that these boilers could be included in regional haze SIPs as necessary for making ''reasonable progress'' toward CAA visibility goals, even if they are not considered to be BART-eligible.

Final rule. After considering the comments, we have made the following determinations on the definitions of the following source categories:

(1) ''Charcoal production facilities.'' We believe that in using the term ''charcoal production facilities'' Congress intended to encompass all types of charcoal production facilities. We do not agree with comments that any inferences can necessarily be made regarding the presence of different PM emission factors for different types of charcoal production facilities in the 1975 report. For example, if Congress only intended to regulate a subset of the charcoal production industry, then we believe Congress could have easily indicated this in the source category title, as was done for ''kraft pulp mills'' and for ''coal cleaning plants (thermal dryers).'' We also note that it is more likely that plants in the charcoal production industry with lower emission factors have emissions that are less than the 250 tons per year cutoff for BART eligibility.

(2) ''Chemical process plants.'' We believe that there is a clear precedent to include pharmaceutical manufacturing operations as ''chemical process plants.'' In the standard industrial classification (SIC) system, pharmaceutical operations are generally

in SIC codes 2833 and 2834, which are a subset of 2-digit category 28 ''Chemical and Allied products.'' Similarly, in the new North American Industrial Classification Codes (NAICS), pharmaceutical manufacturing is codes 32541 and 32542, which is a subset of the ''chemical manufacturing subsector'' which is code 325. Accordingly, in the PSD program, pharmaceutical plants have been treated as ''chemical process plants.'' The commenter is correct in noting that EPA has consistently distinguished between chemical manufacturing and pharmaceutical manufacturing. Examples where different standards or guidelines are established included control technique guideline (CTG) documents, NSPS standards under section 111 of the CAA, and, most recently, maximum achievable control technology (MACT) standards under section 112 of the CAA. We do not agree that these differentiations for emissions standards necessarily require differentiation for purposes of determining BART eligibility. Therefore we believe pharmaceuticals should not be excluded from BART. However, we expect that because of the MACT standards, there is a very low probability that BART determinations will lead to further control requirements from chemical production processes at pharmaceutical plants.

(3) ''Primary aluminum ore reduction.'' We agree with commenters that BART-eligible units in this source category should be defined consistently with the NSPS definition for primary aluminum ore reduction. Therefore we have added a clarification to that effect in the final BART guidelines. We note that this definition is also consistent with the definition at 40 CFR 63.840, which establishes applicability for this source category for the MACT program.

(4) ''Fossil-fuel fired steam electric plants of more than 250 million Btu/hour heat input.'' We have retained the clarification that this source category refers only to those fossil-fuel fired steam electric plants that generate electricity for sale. We believe that this clarification helps to distinguish those plants that are electric utilities from plants in other industrial categories. We also believe that while large co-generators would be excluded from the fossil-fuel fired steam electric plant source category, most large co-generators will be BART-eligible under the fossil-fuel fired boilers source category.

We do not believe it makes sense for this category to include only those steam electric plants that burn greater than 50 percent fossil fuel. We do not believe that a boiler should be excluded from BART review simply because it is located at a plant which burns less than 50 percent fossil fuel. Emissions from any such boiler could be a significant contributor to regional haze, and as such, we believe that each fossil-fuel fired boiler merits a BART review.

We do wish to clarify that units which are located at a steam electric plant, but which themselves are not in any of the 26 BART source categories, should not be considered to be BART-eligible units. We believe that Congress intended that BART review be focused on units in the source categories it delineated. This interepretation is most consistent with the definition of BART-eligible source as we have explained it elsewhere in this preamble in reference to whether entire plants are included if only some units at the plant meet the statutory criteria.

Finally, we believe that all combined cycle units are included in the definition of fossil fuel fired steam electric plant, regardless of whether the combined cycle unit's heat recovery steam generator lacks auxilliary firing. Commenters are correct that some EPA programs have treated combined cycle units with supplemental firing differently from combined cycle units without supplemental firing. However, while some EPA programs do not consider a unit to be a combined cycle unit unless it contains supplemental firing, the definition at issue here is the definition of fossil-fuel fired steam electric plant, not fossil-fuel fired unit. The CAA defines both ''stationary source'' (for visibility purposes) and ''major emitting facility'' (for PSD purposes) to include ''fossil fuel fired steam electric plants.'' In previous guidance for PSD, we have explained that combined cycle gas turbines do fall within the category of ''fossil-fuel fired steam electric plants.'' [8]

(5) ''Fossil-fuel boilers of more than 250 million Btu/hour heat input.'' We have decided to retain the interpretation that this category should be read as including only those boilers individually greater than 250 million Btu/hour heat input. We agree with commenters who noted that including smaller boilers would pose considerable implementation burden. As noted in the 2004 reproposal notice, we do not believe that this interpretation is likely to have a substantial impact. Because smaller boilers are generally less cost-effective to control, we believe that BART review would be unlikely to result in a significant amount of control on these boilers.

We are also retaining the clarification that if a boiler smaller than 250 million Btu/hour heat input is an integral part of an industrial process in a BART source category other than electric utilities, then the boiler should be considered part of the BART-eligible source in that category. (By ''integral to the process'', we mean that the process uses any by-product of the boiler, or vice-versa. We have added this clarification to the definition in the BART guidelines.) We believe that if a State is already considering a BART-eligible industrial process for control, and a boiler is integrated into that process, it makes common sense not to prematurely rule out control options any of the emissions from that process as a whole. (Note that a boiler which is not integral, but is simply attached to a plant, should not be included.) For example, Kraft pulp mills may have boilers that are not serving the energy infrastructure of the plant but typically are serving a process directly by using the waste liquor from the process. Including such a boiler in consideration of control options for the process adds minimal additional burden while leaving maximum discretion to the State in determining BART for the process as a whole.

We are also clarifying today that we have determined that this category should include all individual boilers of greater than 250 million Btu/hour heat input burning any amount of fossil fuel, as opposed to only those boilers that burn greater than 50 percent fossil fuel. We believe that it is quite possible that boilers of this size could contribute to regional haze in a Class I area even if they burn less than 50 percent fossil fuel. Therefore we believe that each fossil fuel-fired boiler merits a BART review.

Step 2: Identify the Start-up Dates of Those Emission Units

Background. BART applies only to a major stationary source which ''was in existence on August 7, 1977 but which has not been in operation for more than fifteen years as of such date.'' The visibility regulations define ''in existence'' and ''in operation'' in 40 CFR 51.301. Under these regulations, promulgated in 1980, ''in existence'' means

> that the owner or operator has obtained all necessary preconstruction approvals or permits * * * and either has (1) begun, or caused to begin, a continuous program of physical on-site construction of the facility or (2) entered into binding agreements or contractual obligations.

[8] See *http://www.epa.gov/Region7/programs/artrd/air/nsr/nsrmemos/turbines.pdf.*

The term ''in operation'' means engaged in activity related to the primary design function of the source.

Step 2 also addresses the treatment of ''reconstructions'' and ''modifications.'' Under the definition of BART-eligible facility, sources which were in operation before 1962 but reconstructed during the 1962 to 1977 time period are treated as new sources as of the time of reconstruction.[9] The same policies and procedures for identifying reconstructed ''affected facilities'' under the NSPS are used to determine whether a source has been reconstructed for purposes of the BART requirements. ''Modifications'' under the CAA refers to physical change or change in the method of operation at a source which has led to an increase in emissions. In the proposed BART guidelines, we stated that the best interpretation of the visibility provisions is that a modification to a source does not change an emission's unit construction date for purposes of BART applicability. We requested comment on an alternative interpretation that we believed would be more difficult to implement. Under this approach, sources built before 1962 but modified during the 1962 to 1977 time frame would be considered ''new'' at the time of modification.

Comments. We received comments in 2001 and 2004 on the discussion in the guideline of the term ''in existence.'' These comments were critical of our statement in the guidelines that sources which had ''commenced construction,'' that is, those which had entered into binding contracts, would be considered to be in existence, even if actual operations did not begin until after the August 7, 1977 cutoff date. These commenters asserted that Congress did not intend to treat a source as ''existing'' in 1977 if it was not yet built.

Other commenters interpreted the proposed guidelines as expanding the definition of BART-eligible sources by requiring States to find that all emission units at a facility are BART-eligible if one part of the facility was built within the 1962–1977 time period. Other comments did not suggest that we had already expanded the definition in the proposed guidelines, but did suggest that we should expand the definition in that way in the final guidelines. Some commenters noted that there was a degree of confusion in the regulated community on whether the proposed guidelines were requiring BART for all units at a power plant, including those that were in operation before August 7, 1962, if these units are co-located with one or more units that were put in place within the 1962–1977 time period. These commenters requested that we clarify that such pre-1962 units would not be BART-eligible.

Some commenters asserted that our proposed approach is unworkable, because the approach requires States to identify all emissions units put in place between the 1962 and 1977. Some of these commenters asserted that Congress intended that BART would apply only if entire plants satisfy the statutory criteria. These comments suggested that BART should apply only if an entire plant that is one of the 26 listed source category types had been placed in operation at a discrete point within the 15 year time period for BART eligibility. These commenters asserted that our proposed guidelines, which involved the identification and aggregation of individual emission units within the 1962–1977 time period, were inconsistent with Congress' intent. Other comments suggested that EPA could improve implementation of the program by covering discrete projects rather than individual emissions units. A few commenters suggested that for purposes of identifying such discrete projects, we consider using the term ''process or production unit'' that we used in hazardous air pollutant regulations under CAA section 112(g).

One commenter requested that the guidelines clarify that emissions from ''linked'' emission units should not be considered in determining BART eligibility. That is, even if changes in emissions from one unit could affect the emissions from a ''linked'' unit that was not put in place within the 1962–1977 time period, that would not affect whether the ''linked'' unit was BART-eligible. Another commenter suggested that the approach set forth in the guidelines for identifying BART-eligible sources is inappropriate because the particular set of units identified as BART-eligible will not necessarily ''provide a reasonable and logical platform for the installation of controls.''

Other commenters stated that facilities that had been modified after 1977 should not be included in the pool of sources subject to BART. Such facilities, it was argued, already meet the BART requirements because of the controls installed to meet the requirements of PSD, NSR, or the NSPS.

Final rule. We disagree with the comments recommending that we interpret the term ''in existence'' to refer to sources that are in actual operation. The discussion of this term in Step 2 is based on the regulatory definition which has been in place since 1980. The guidelines reiterate this definition and provide examples of its application. Interpreting the term ''in existence'' as suggested by commenters would not be consistent with the plain language of the regulations.

In the 2001 and 2004 proposed guidelines, we noted that ''the term 'in existence' means the same thing as the term 'commence construction' as that term is used in the PSD regulations.'' Commenters were critical of this statement, claiming that EPA was unlawfully reinterpreting section 169A in the guidelines. The statement in Step 2 of guidelines, however, is not a reinterpretation of the term ''in existence,'' but merely a statement noting that the definitions used in the visibility regulations and the PSD regulations are essentially identical.

To the extent that commenters are claiming that the existing regulatory definition of ''in existence'' is unlawful, EPA's interpretation of this term in promulgating the 1980 regulations was a reasonable one. First, it is worth noting that the regulations adopting this interpretation of the term ''in existence'' were in effect in 1990 and implicitly endorsed by Congress in its 1990 amendments to the CAA.[10] Moreover, the definition at issue accurately reflects Congress' intent that the BART provision apply to sources which had been ''grandfathered'' from the new source review permit requirements in parts C and D of title I of the CAA. For all the above reasons, we are neither revising the regional haze regulations to change the definition of ''in existence,'' nor adopting a strained interpretation of the regulation in the guidelines.

We agree with commenters that the definition of ''BART-eligible source'' does not require States to find that all emission units at a facility are subject to the requirement of the BART provisions if only one part of the facility was built within the 1962–1977 time period. We received comments on this issue in 2001 and clarified in 2004 that the BART guidelines do not direct States to find that all boilers at a facility are BART-eligible if one or more boilers at the facility were put in place during the relevant time period. Under Step 2 of the process for identifying BART-eligible sources set out in the guidelines, States are required to identify only those boilers that were put in place between 1962 and 1977. As explained in the preamble to the 2004 reproposed guidelines, only these boilers are potentially subject to BART.

[9] However, sources reconstructed after 1977, which reconstruction had gone through NSR/PSD permitting, are not BART-eligible.

[10] See CAA section 193.

We do not agree with those commenters claiming that Congress clearly intended to apply BART only if an ''entire plant'' was put into place between 1962 and 1977. Most of the BART source categories are broad descriptions types of industrial facilities such as ''kraft pulp mills,'' ''petroleum refineries'' or ''primary copper smelters.'' For such source categories, the implication of commenters' argument would that if any portion of the plant was in operation before August 7, 1962, then Congress intended to exempt the entire plant from BART. Such an interpretation is problematic and inequitable. For example, under this approach BART would not apply if a company chose to expand its production by building a second production line at an existing line in 1965, but would apply if the same company chose to build the same equipment at a greenfield site. Under the approach set forth in the guidelines, such a production line would be treated similarly under either set of facts. We do not believe that either the plain language of the statute or the relevant legislative history indicate that Congress intended for major-emitting sources of visibility-impairing pollutants to be exempted from the BART requirements because a plant contains some emission units that began operation before 1962.

Also, we disagree with the comment that modifications after 1977 should change an emissions' unit date of construction for purposes of BART applicability. The commenter's suggestion that such sources already meet BART requirements may be accurate, but does not provide a basis for exempting the source from review. As we note in the guideline, the review process will take into account the controls already in place and the State may find that these controls are consistent with BART.

We agree with the comments related to ''linked'' emission units. The comment appears to address whether emissions from the ''linked'' units are considered in determining BART eligibility. In the guidelines, we are focusing on only the emissions units that were put in place during the 1962 to 1977 dates and the emissions from those units. We agree that even if changes in emissions from one unit could affect the emissions from a ''linked'' unit that was not put in place within the 1962–1977 time period, this would not affect whether the ''linked'' unit was BART-eligible.

We disagree with commenters that the approach set forth in the guidelines for identifying BART-eligible sources is inappropriate because the particular set of units identified as BART-eligible will not necessarily ''provide a reasonable and logical platform for the installation of controls.'' We do not agree that this factor is relevant to the identification of those emissions units which meet the definition of BART-eligible source. Such factors are important in the States' consideration of control strategies and options but do not clearly relate to the first step of identifying those sources which fall within one of 26 source categories, were built during the 15 year window of time from 1962 to 1977, and have potential emissions of greater than 250 tons per year. We do thus agree generally with the commenter's recommendation of allowing States to consider the particular history and control potential of units in determining BART, but do not agree that it is relevant to the predicate question of identifying the BART-eligible source.

Finally, the approach to identifying a ''BART-eligible source'' in the guidelines is based on the definitions in the regional haze rule of the relevant terms. For 750 MW power plants, States are required to apply the definitions as set forth in the guidelines; for other sources, States may adopt a different approach to the task of identifying BART-eligible sources, so long as that approach is consistent with the Act and the implementing regulations. In other words, while the guidelines adopt an approach for large power plants which involves the aggregation of all emissions units put into place between 1962 and 1977, States have the flexibility to consider other reasonable approaches to the question of identifying BART-eligible sources for other source categories.

For 750 MW power plants, many of the issues identified by commenters with the approach of looking at a facility on an emission unit by emission unit basis do not exist. Unlike many types of industrial processes, power plants consist generally of a discrete number of very large emission units. For other types of facilities such as kraft pulp mills or chemical process plants which may have many small emission units that have undergone numerous changes, the guidelines do not limit the ability of the States to approach the question of identifying BART-eligible sources in ways which make sense for the particular sources given their design and history.

Step 3: Compare the Potential Emissions to the 250 Ton/Yr Cutoff.

Background. Step 3 of the guidelines addresses the question of whether the units identified in Steps 1 and 2 have emissions in excess of the threshold for major sources set forth in section 169A(g)(7) of the CAA. The guidelines pose the following questions to help the States in determining whether the relevant emissions units have the potential to emit in excess of the 250 tons per year threshold of any single visibility-impairing pollutant:

(1) What pollutants should I address?

The 2001 proposed guidelines included the following list of visibility-impairing pollutants: SO_2, NO_X, particulate matter, volatile organic compounds (VOCs), and ammonia. We proposed in 2001 and again in 2004 that States use PM_{10} as the indicator for particulate matter. As explained in the guidelines, there is no need to have separate 250 ton thresholds for PM_{10} and $PM_{2.5}$ because emissions of PM_{10} include the components of $PM_{2.5}$ as a subset. In addition, because of various uncertainties associated with regulating VOCs and ammonia, we requested comment in 2004 on the level of discretion States should exercise in making BART determinations for VOCs and took ammonia off the list of visibility-impairing pollutants.

In both proposals, we clarified that the 250 tons per year cutoff applies to emissions on a pollutant by pollutant basis. In other words, a source is subject to BART only if it emits at least 250 tons per year of an individual visibility-impairing pollutant.

(2) What does the term ''potential'' emissions mean?

The proposed guidelines in 2001 and the reproposed guidelines in 2004 excerpt the definition of ''potential to emit'' from the regulations at 40 CFR 51.301. As the definition makes clear, the potential to emit of a source is calculated based on its capacity to emit a pollutant taking into account its physical and operational design. Under this definition, federally enforceable emission limits may be taken into account in calculating a source's potential emissions; however, emission limitations which are enforceable only by State and local agencies, but not by EPA and citizens in Federal court, cannot be used to limit a source's potential to emit for purposes of the regional haze program.

(3) What is a ''stationary source?'

As explained above, States are required to make a BART determination only for ''stationary sources'' of a certain size that fall within one of 26 types of industrial categories listed in the statute and that were built within a certain time frame. The regional haze rule contains definitions that are relevant to the determination of the emissions units that comprise a ''stationary source.'' First, the regulations at 40 CFR 51.301

define ''stationary source'' as ''any building, structure, facility, or installation which emits or may emit any air pollutant.'' Second, the terms ''building, structure, or facility'' are defined in part based on grouping pollutant-emitting activities by industrial category:

Building, structure, or facility means all of the pollutant-emitting activities which belong to the same industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same person (or persons under common control). Pollutant-emitting activities must be considered as part of the same industrial grouping if they belong to the same Major Group (*i.e.*, which have the same two-digit code) as described in the Standard Industrial Classification Manual, 1972 as amended by the 1977 Supplement (U.S. Government Printing Office stock numbers 4101–0066 and 003–005–00176–0 respectively).

In the 2001 proposed guideline, we noted that support facilities, *i.e.* facilities used to convey, store, or otherwise assist in the production of the principal product, are considered to fall within the same industrial grouping as the primary facility. To clarify this, in 2004 we proposed to add language to the guideline noting that emission units at a plant, even if they are a ''support facility'' for purposes of other programs, would not be subject to BART unless they were within one of the 26 listed source categories and were built within the 1962 to 1977 time frame.

Discussion of ''What Pollutants Should I Address?''

Comments. PM_{10} as an indicator. Some comments questioned the use of PM_{10} (which includes both coarse and fine particulate matter) as the indicator for particulate matter. Commenters noted that the coarse fraction, that is particulate matter between 10 and 2.5 micrograms in diameter, fundamentally differs compared to the fine mass in how it interacts with light. Commenters suggested that only the fine mass ($PM_{2.5}$) component of particulate matter is likely to contribute to visibility impairment. Accordingly, these commenters recommended that the 250 ton cutoff for particulate matter should be based upon emissions of $PM_{2.5}$.

Ammonia. Many commenters addressed the exclusion of ammonia from the list of visibility-impairing pollutants. A number of commenters, primarily from industry but also from one state and one regional planning organization, supported the exclusion of ammonia. These commenters generally cited the complexity and variability of ammonia's role in the formation of $PM_{2.5}$ in the atmosphere, the relative greater benefits of controlling NO_X and SO_2, the uncertainties in the inventory of ammonia emissions, and the inherent complexities of gauging the contribution of potential ammonia reductions to improving visibility in Class I areas. In addition, commenters noted that few, if any, point sources emit ammonia in amounts that exceed the 250 ton per year threshold.

Other commenters, including a number of environmental groups and several states, regional planning organizations, and industry commenters, argued that ammonia should be included in the list of visibility-impairing pollutants in the guidelines. In support of this view, commenters cited evidence that ammonia is a known precursor to $PM_{2.5}$. One commenter noted that improvements are being made to ammonia inventories and to the understanding of ammonia's role in the formation of haze. Other commenters pointed to a National Park Service (NPS) analysis of monitoring data that indicates that visibility-impairment due to nitrate aerosol formation (to which ammonia contributes) is of significant concern [11] and to a 2003 direction to policy-makers from the North American Research Strategy for Tropospheric Ozone (NARSTO) [12] indicating that consideration of control strategies needs to include ammonia in combination with other precursors to particle formation. Many commenters also argued that EPA should encourage or allow the States to consider ammonia in their visibility protection plans, and noted that ammonia reductions could be a cost-effective way to improve visibility under certain conditions.

Volatile Organic Compounds (VOCs). Several commenters responded to our request for comments on whether States should treat VOCs in urban areas differently from VOCs in rural areas. Environmental groups and a few States argued that the current state of scientific knowledge does not support a differentiation between urban and rural sources of VOCs. One environmental commenter cited evidence that organic aerosols are a major constituent of visibility-reducing aerosols and that VOCs are important precursors to the formation of secondary organic aerosols. One commenter also stated that VOCs may play a particularly significant role in particle formation in those rural areas with significant nearby sources of NO_X. Commenters also cited evidence that the contribution of VOC to particle formation likely varies widely in different areas of the country, and argued that States should retain flexibility to address local VOC sources if they determine that those sources are contributors of concern.

Several industry commenters stated that more focus should be placed on controlling VOCs in urban rather than rural areas. A few commenters from industry argued that VOCs in rural areas have not been shown to be a significant contributor to particle formation, and should be excluded from the list of pollutants to be addressed in the BART process. One argued that VOCs should be excluded from BART entirely based upon uncertainties in the current state of knowledge, and a few argued that VOCs from both power plants and rural sources should be excluded from BART, based on low emissions and the cost of controls. One regional planning organization requested that EPA clarify the definitions of ''urban'' and ''rural'' areas.

Final rule. PM_{10} as an indicator. While it is always necessary to assess $PM_{2.5}$ impacts, we agree with commenters who stated that the coarse fraction is less efficient at light scattering than fine particles, there is ample evidence that the coarse fraction does contribute to visibility impairment.[13] For example, standard methods for calculating reconstructed light extinction routinely include a calculation for the contribution to light extinction from the coarse fraction, an implicit recognition that these particles contribute measurably to visibility impairment.[14] We do recognize that coarse PM is likely to contribute more to regional haze in arid areas than humid areas. We believe that, as the Grand Canyon Visibility Transport Commission (GCTVC) recognized,[15] States in the arid West in particular should take the coarse fraction of particulate matter into account in determining whether a source meets the threshold for BART applicability.

Because long-range transport of fine particles is of particular concern in the formation of regional haze, we also

[11] See *http://wrapair.org/forums/ioc/meetings/030728/index.html* (specifically presentation by John Vimont, National Park Service).

[12] *NARSTO, Particulate Matter Assessment for Policy Makers: A NARSTO Assessment.* P. McMurry, M. Shepherd, and J. Vickery, eds. Cambridge University Press, Cambridge, England (2004).

[13] See *Fine particles: Overview of Atmospheric Chemistry, Sources of Emissions, and Ambient Monitoring Data,* Memorandum to Docket OAR 2002–0076, April 1, 2005.

[14] These methods are described at the following Web site: *http://vista.cira.colostate.edu/improve/Tools/ReconBext/reconBext.htm.*

[15] Grand Canyon Visibility Transport Commission, Recommendations for Improving Western Vistas, Report to the U.S. EPA, June 10, 1996.

believe that it is very important to estimate the $PM_{2.5}$ fraction of direct particulate emissions as correctly as possible. In addition, we believe that air quality modeling results will be more meaningful provide a more accurate prediction of a source's impact on visibility if the inputs account for the relative particle size of directly emitted particulate matter (e.g. PM_{10} vs. $PM_{2.5}$).

States should consider whether their current test methods for measuring particulate matter emissions from stationary sources account for the condensible fraction of particulate matter and consider revising any such stationary source test methods to account for the condensible fraction of particulate emissions. See the source testing technical support document (TSD) in the docket for this rule, which discusses test methods for particulate matter in more detail.[16]

Ammonia. In regard to ammonia, we believe there is sufficient uncertainty about emission inventories and about the potential efficacy of control measures from location to location such that the most appropriate approach for States to take is a case-by-case approach. There are scientific data illustrating that ammonia in the atmosphere can be a precursor to the formation of particles such as ammonium sulfate and ammonium nitrate;[17] however, it is less clear whether a reduction in ammonia emissions in a given location would result in a reduction in particles in the atmosphere and a concomitant improvement in visibility. In other words, the question of whether ammonia contribute to visibility impairment in a specific instance can be a difficult one.

It may be that States will not be faced often with the question of addressing ammonia in making BART determinations. As noted above, States are required to make BART determinations only for stationary sources that fall within certain industrial categories. The types of sources subject to the BART provisions are not typically significant emitters of ammonia. Because of this, it is unlikely that including ammonia on the list of visibility-impairing pollutants in the BART guidelines would have much impact on the States' determinations of whether a source is BART-eligible. Thus, while ammonia can contribute to visibility impairment, we believe the decision whether to consider ammonia as a visibility-impairing pollutant in a specific case where a potential BART source actually emits more than 250 tons per year of ammonia is best left to the State.

VOCs. Organic compounds can be categorized according to their varying degrees of volatility: highly reactive, volatile compounds with six or fewer carbon atoms which indirectly contribute to PM formation through the formation of oxidizing compounds such as the hydroxyl radical and ozone; semivolatile compounds with between seven and 24 carbon atoms which can exist in particle form and can readily be oxidized to form other low volatility compounds; and high molecular weight organic compounds—those with 25 carbon atoms or more and low vapor pressure—which are emitted directly as primary organic particles and exist primarily in the condensed phase at ambient temperatures. The latter organic compounds are considered to be primary $PM_{2.5}$ emissions and not VOCs for BART purposes.

Current scientific and technical information shows that carbonaceous material is a significant fraction of total $PM_{2.5}$ mass in most areas and that certain aromatic VOC emissions such as toluene, xylene, and trimethyl-benzene are precursors to the formation of secondary organic aerosol.[18] However, while progress has been made in understanding the role of VOCs in the formation of organic PM, this relationship remains complex, and issues such as the relative importance of biogenic versus anthropogenic emissions remain unresolved.

Therefore we believe that the best approach for States to follow in considering whether VOC emissions are precursors to $PM_{2.5}$ formation is a case-by-case approach. States should consider, in particular, whether a source's VOC emissions are those higher-carbon VOCs that are more likely to form secondary organic aerosols. In addition, given the variable contribution of a given amount of VOC emissions to $PM_{2.5}$ formation, States may also wish to exercise discretion in considering only relatively larger VOC sources to be BART-eligible.

After careful consideration of the comments, we agree with commenters who assert that EPA should not suggest a general distinction between the relative contributions of urban and rural VOC emissions to particle formation. The state of knowledge in this area is complex and rapidly evolving. Monitoring data in the East[19] suggest that there may be a greater contribution to particle formation in urban areas from VOCs as compared to rural areas, but we recognize that further research is needed to better determine the extent of the contribution of specific VOC compounds to organic PM mass. We do not agree, however, with commenters who make the blanket assertion that rural VOCs are not a significant contributor to particle formation, as it is possible that in specific areas, such as where NO_X emissions are high, rural anthropogenic VOCs could potentially play a significant role.

Discussion of the Term ''Potential'' Emissions

Comments. A number of commenters were critical of the restriction in the regional haze rule that allows States to credit federally enforceable limitations on emissions but not limitations that are enforceable only by States and local agencies. These commenters believed that this restriction had been rejected by the D.C. Circuit for a number of other EPA regulations and noted that EPA has developed policies that currently credit state-enforceable limits. The comments recommended that EPA issue guidance consistent with what commenters claimed were current policies for other regulations. In addition, we received comments arguing that in determining whether a source is a major stationary source, the States should consider a source's actual—rather than potential—emissions. These commenters stated that using a source's potential emissions overstates a source's actual emissions and impacts on visibility.

Final rule. CAA section 169A(g)(7) defines a ''major stationary source'' as a source with the potential to emit 250 tons or more any pollutant. Based *inter alia* on that statutory definition, EPA's implementing regulations define BART-eligible sources as those with the potential to emit 250 tons or more of any air pollutant. As these definitions clearly require consideration of a source's potential emissions, the guidelines state that a State should determine whether a source's potential emissions exceed the 250 ton threshold in determining whether the source is BART-eligible.

As explained in the 2001 and 2004 proposed guidelines, the regional haze regulations define ''potential to emit.'' The guidelines repeat that regulatory definition and provide an example illustrating its application. EPA did not propose to change the definition in 2001 or 2004, but merely highlighted the

[16] *Fine particles: Overview of Source Testing Approaches,* Memorandum to Docket OAR 2002–0076, April 1, 2005.

[17] See *Fine particles: Overview of Atmospheric Chemistry, Sources of Emissions, and Ambient Monitoring Data,* Memorandum to Docket OAR 2002–0076, April 1, 2005.

[18] Ibid.

[19] Ibid.

current definition in 40 CFR 51.301. Although we noted in the 2001 proposed guidelines that we expected to undertake a rulemaking to determine whether only federally enforceable limitations should be taken into account in the regional haze program definition, we have not yet begun the process for such a rulemaking. However, we consider the comments criticizing EPA's definition of ''potential to emit'' as a request for reconsideration of the visibility regulations and will take these requests into account in determining any future rulemaking efforts to address the general definition of ''potential to emit.'' For the time being, we believe that States may consider federally enforceable limits or emissions limitations in State permits, which are enforceable under State law, in determining a source's ''potential to emit.''

Discussion of What Emissions Units Should Be Considered Part of a ''Stationary Source''

Comments. A number of comments in 2001 expressed concern with our statement that a ''support facility'' should be grouped with a primary facility in determining which emissions units belong to the same industrial grouping. These comments generally coincided with comments discussed above that EPA should determine BART on a plantwide basis, rather than by aggregating emissions units. Commenters on the 2004 reproposal noted with approval the clarification that ''support facilities'' should only be considered BART-eligible if these units themselves were both constructed within the 1962–1977 time frame and fell within one of the listed source categories.

Two commenters felt that we should more clearly define the BART-eligible source, either by identifying emission units within source categories, or by somehow accounting for the specific set of emission units, within the fenceline, to which controls would logically apply.

Final rule. The guidelines continue to note that the definition of ''building, structure or facility'' in the regional haze rule is based upon aggregating emissions units within the same industrial grouping. This discussion in the guidelines is consistent with the language in the definition of ''building, structure or facility'' in the regional haze rule which contains a specific reference to the 2-digit SIC classifications. The BART guidelines refer to this definition and explain how 2-digit SIC codes are used in determining the scope of BART for a given plantsite. (In the rare situation where industrial groupings in separate 2-digit SIC codes exist at a single plant site, then there would be more than one separate ''stationary source'' present. In that situation, each ''stationary source'' should be looked at individually for purposes of determining BART-eligibility.)

We agree that more clarity is needed to account for situations where a specific set of units constitute the logical set to which BART controls would apply. The CAA requires BART at certain major stationary sources. Accordingly we believe it could be appropriate, at the BART determination step, for States to allow sources to ''average'' emissions across a set of BART-eligible emission units within a fenceline, so long as the amount of emission reductions from each pollutant being controlled for BART would be at least equal to those reductions that would be obtained by simply controlling each unit. We have added language to the guidelines to this effect.

Step 4: Identify the Emission Units and Pollutants That Constitute the BART-Eligible Source

Background. The final step in identifying a ''BART-eligible source'' is to use the information from the previous three steps to identify the universe of equipment that makes up the BART-eligible source. The 2001 and 2004 proposed BART guidelines stated that if the emissions from the list of emissions units at a stationary source exceed a potential to emit of 250 tons per year for any individual visibility-impairing pollutant, then that collection of emissions units is a BART-eligible source. The guidelines also stated that a BART analysis would be required for each visibility-impairing pollutant emitted from this collection of emissions units.

In the 2004 reproposed BART guidelines, we noted that we believed that section 169A(b)(2)(A) of the CAA requires a State to undertake a BART analysis for ''any'' visibility-impairing pollutant emitted by a BART-eligible source, regardless of the amount emitted. We proposed, however, to provide the States with the flexibility to identify *de minimis* levels for pollutants at BART-eligible sources, but limited that flexibility so that any such *de minimis* levels could not be higher than those used in the PSD program: 40 tons per year for SO_2, NO_X, and VOC, and 15 tons per year from PM_{10}. We requested comment on this provision and on the use of *de minimis* values.

Discussion of Whether To Include All Emitted Visibility-Impairing Pollutants in the BART Analysis

Comments. A number of commenters supported the concept of including all pollutants in the BART analysis once an individual pollutant triggers the BART review. Other commenters, although supportive of the concept generally, recommended that we should add the pollutants together before the comparison with the threshold.

A number of commenters disagreed with EPA's conclusion that the CAA requires States to make a BART determination for any visibility-impairing air pollutant emitted by a BART eligible source. These commenters stated that undertaking a BART analysis for all pollutants emitted by a major stationary source is an unnecessary administrative burden with minimal environmental benefit. Commenters argued that Congress intended for BART to apply only to those pollutants for which a source is major. Commenters accordingly recommended that the 250 ton per year threshold apply to each pollutant emitted by a source and that BART apply only to those pollutants which meet this threshold. A number of these commenters argued alternatively that only those pollutants from a source demonstrated, individually, to cause or contribute to visibility impairment are required to go through a BART determination.

Final rule. We disagree with the comment that emissions of different visibility-impairing pollutants must be added together to determine whether a source exceeds the 250 ton per year threshold. The CAA, in section 169A(g)(7), defines a ''major stationary source'' as one with the potential to emit 250 tons or more of ''any pollutant.''

We disagree with comments that the BART analysis is required only for those pollutants that individually exceed the 250 ton per year threshold. Section 169A(b)(2)(A) specifically requires States to submit SIPs that include a requirement that a major stationary source

> which, as determined by the State * * * emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any [Class I area], shall procure, install, and operate * * * the best available retrofit technology, as determined by the State * * * for controlling emissions from such source for the purpose of eliminating or reducing any such impairment.

The regional haze regulations similarly require that the States submit a SIP that contains

A determination of BART for each BART-eligible source in the State that emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any mandatory Class I Federal area.

40 CFR 51.308(e)(1)(ii). Nothing in these statutory or regulatory requirement suggests that the BART analysis is limited to those pollutants for which a source is considered major. At best, these provisions can be read as requiring a BART determination only for those emissions from a specific source which do, in fact, cause or contribute to visibility impairment in a particular Class I area, or which could reasonably be anticipated to do so. Commenters, however, have not presented any evidence that as a general matter emissions of less than 250 tons per year of $PM_{2.5}$, SO_2, or other visibility-impairing pollutants from potential BART sources do not ''cause or contribute to any impairment of visibility'' in any of the Class I areas covered by the regional haze rule. As there is no such evidence currently before us, there is no basis to conclude that the States are required to make BART determinations only for those pollutants emitted in excess of 250 tons per year.

At the same time, we agree with certain commenters that the CAA does not require a BART determination for any visibility impairing pollutant emitted by a source, regardless of the amount. After reviewing the language of the Act and the comments received, we have concluded that our interpretation of the relevant language in section 169A(b)(2)(A) of the Act in the 2004 proposed guidelines is not necessarily the best reading of the BART provisions. Section 169A(b)(2)(A) of the Act can be read to require the States to make a determination as to the appropriate level of BART controls, if any, for emissions of any visibility impairing pollutant from a source. Given the overall context of this provision, however, and that the purpose of the BART provision is to eliminate or reduce visibility impairment, it is reasonable to read the statute as requiring a BART determination only for those emissions from a source which are first determined to contribute to visibility impairment in a Class I area.

The interpretation of the requirements of the regional haze program reflected in the discussion above does not necessitate costly and time-consuming analyses. Consistent with the CAA and the implementing regulations, States can adopt a more streamlined approach to making BART determinations where appropriate. Although BART determinations are based on the totality of circumstances in a given situation, such as the distance of the source from a Class I area, the type and amount of pollutant at issue, and the availability and cost of controls, it is clear that in some situations, one or more factors will clearly suggest an outcome. Thus, for example, a State need not undertake an exhaustive analysis of a source's impact on visibility resulting from relatively minor emissions of a pollutant where it is clear that controls would be costly and any improvements in visibility resulting from reductions in emissions of that pollutant would be negligible. In a scenario, for example, where a source emits thousands of tons of SO_2 but less than one hundred tons of NO_X, the State could easily conclude that requiring expensive controls to reduce NO_X would not be appropriate. In another situation, however, inexpensive NO_X controls might be available and a State might reasonably conclude that NO_X controls were justified as a means to improve visibility despite the fact that the source emits less than one hundred tons of the pollutant. Moreover, as discussed below, we are revising the regional haze regulations to allow the States to exempt *de minimis* emissions of SO_2, NO_X, and $PM_{2.5}$ from the BART determination process which should help to address the concerns of certain commenters associated with the burden of a broad BART analysis.

De minimis levels

Comments. Many commenters agreed that we should establish *de minimis* levels for individual pollutants in order to allow States and sources to avoid BART determinations for pollutants emitted in relatively trivial amounts. Many commenters suggested that States would be unlikely to impose emission limits for pollutants emitted at the proposed *de minimis* levels because it would not be cost-effective to do so and such emission reductions could not be expected to produce any perceptible improvements in visibility. Several commenters agreed that the pollutant coverage requirements for BART eligibility should be consistent with those for the PSD program, but others argued that BART should be required only for pollutants emitted in amounts greater than 250 tons per year. Commenters also noted that the guidelines were not clear as to whether the *de minimis* provision would apply on a plant-wide or unit by unit basis. A few commenters also noted that the final guidelines should clarify where in the BART determination process *de minimis* levels may be used.

Other commenters opposed the use of *de minimis* exemptions. These commenters argued that it would be unreasonable to rule categorically that a certain level of emissions had a trivial impact on visibility without assessing the impacts of these emissions in particular circumstances. These commenters argued that States should consider the emissions of all visibility-impairing pollutants in a BART determination regardless and that, consequently, there should be no *de minimis* levels.

Final rule. As proposed in 2004, we believe that it is reasonable to give States the flexibility to establish *de minimis* levels so as to allow them to exempt from the BART determination process pollutants emitted at very low levels from BART-eligible sources. As explained by the D.C. Circuit, ''categorical exemptions from the requirements of a statute may be permissible 'as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis*.' '' [20] The ability to create *de minimis* exemptions from a statute is a tool to be used in implementing the legislative design.[21]

The intent of Congress in requiring controls on emissions from certain major stationary sources was to eliminate or reduce any anticipated contribution to visibility impairment from these sources. This, as section 169A(b)(2)(A) states, is the ''purpose'' of BART. In making a determination as to the appropriate level of controls, however, the States are required to take into account not only the visibility benefits resulting from imposing controls on these sources but also the costs of complying with the BART provision. The BART provision is accordingly designed to ensure that the States take into consideration all emissions of certain stationary sources in making a BART determination, but also to provide States with the flexibility to include the costs and benefits of controlling these sources in the calculus of determining the appropriate level of BART.

We believe it would be permissible for States to create *de minimis* levels at a low level. If a State were to undertake a BART analysis for emissions of less than 40 tons of SO_2 or NO_X or 15 tons of PM_{10} from a source, it is unlikely to result in anything but a trivial improvement in visibility. This is

[20] *EDF et al.* v. *EPA,* 82 F.3d 451, 466 (D.C. Cir. 1996) citing *Alabama Power* v. *Costle,* 636 F.2d 323 (D.C. Cir. 1979).

[21] Id.

because reducing emissions at these levels would have little effect on regional emissions loadings or visibility impairment. We believe most States would be unlikely to find that the costs of controlling a few tons of emissions were justified. Because the overall benefits to visibility of requiring BART determinations for emissions of less than the *de minimis* levels would be trivial, we are amending the regional haze rule to make clear that the States have this flexibility.

The *de minimis* levels discussed today apply on a plant-wide basis. Applying *de minimis* levels on a unit by unit basis as suggested by certain commenters could exempt hundreds of tons of emissions of a visibility-impairing pollutant from BART analysis. In at least some of the twenty-six source categories covered by the BART provisions, a single control device can be used to control emissions from multiple units. Thus, it is possible that while emissions from each unit are relatively trivial, the costs of controlling emissions from multiple units might be cost-effective in light of the BART-eligible source's total emissions of the pollutant at issue. States should consider the control options in such situations and determine the appropriate approach for the specific source.

We are revising the regional haze rule to provide States with the ability to establish *de minimis* levels up to the levels proposed in 2004. We believe States may, if they choose, exclude from the BART determination process potential emissions from a source of less than forty tons per year of SO_2 or NO_X, or 15 tons per year for PM_{10}. (Note also that for sources that are BART-eligible for one pollutant, we also believe that States could allow those sources to model the visibility impacts of pollutants at levels between *de minimis* and 250 tons in order to show that the impact is negligible and should be disregarded. See section D below). In the guidelines, we include this as part of the BART determination in section IV of the guidelines. (We note that these emission levels represent the maximum allowable *de minimis* thresholds—States retain their discretion to set the thresholds at lesser amounts of each pollutant, or to not provide any pre-determined *de mininis levels.*) We believe that this approach is the clearest method for exempting trivial emissions from the BART determination process. Alternatively, States may find it useful to exclude *de minimis* emissions in identifying whether a source is subject to BART in section III of the guidelines. Either approach is consistent with the regulation issued in this rule.

D. How To Determine Which BART-eligible Sources Are ''Subject to BART''

Cause or Contribute

Background. Under section 169A(b)(2)(A) of the Act, each State must review its BART eligible sources and determine whether they emit ''any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in [a Class I] area.'' If a source meets this threshold, the State must then determine what is BART for that source.

Proposed rule. In the reproposed guidelines, we identified three options for States to use in determining which BART-eligible sources meet the test set forth in section 169A(b)(2)(A) of the CAA. To determine whether a BART-eligible source is ''reasonably anticipated to cause or contribute to visibility impairment,'' the first proposed option was that a State could choose to consider the collective contribution of emissions from all BART-eligible sources and conclude that all BART-eligible sources within the State are ''reasonably anticipated to cause or contribute'' to some degree of visibility impairment in a Class I area. The preamble to the 1999 regional haze rule explains at length why we believe that looking to the collective contribution of many sources over a broad area is a reasonable approach, and we explained in the 2004 reproposed guideline that we believed that a State's decision to use a cumulative analysis at this stage of the BART determination process would be consistent with the CAA and the findings of the D.C. Circuit in *American Corn Growers.*

The second proposed option was to allow a State to demonstrate, using a cumulative approach, that none of its BART-eligible sources contribute to visibility impairment. Specifically, we proposed to provide States with the option of performing an analysis to show that the full group of BART-eligible sources in a State cumulatively do not cause or contribute to visibility impairment in any Class I areas.

As a third option, we proposed that a State may choose to determine which sources are subject to BART based on an analysis of each BART-eligible source's individual contribution. We labeled this option as an ''Individualized Source Exemption Process,'' and proposed that States use an air quality model to determine an individual source's contribution to visibility impairment, calculated on a 24 hour basis, using allowable emissions, and compared to an established threshold.

Comments. Several commenters expressed the view that EPA was misinterpreting the *American Corn Growers* case to allow the States to apply a collective contribution test in determining whether BART-eligible sources are subject to BART. These commenters took the position that, because this approach does not allow for a source to show that it does not individually cause or contribute to visibility impairment, it is incompatible with the language of section 169A(b)(2)(A)of the Act. They argued that EPA should modify the provisions in the proposed rule to ensure that an individual source is afforded the opportunity to conduct an analysis to demonstrate that its emissions do not impair visibility in any Class I area. Conversely, several commenters indicated that the option to determine that all potential BART sources contribute to regional haze should be the starting point of determining BART eligibility.

Many industry commenters and some States supported the second proposed option which would allow a State to demonstrate through an analysis of the collective contribution of all its BART-eligible sources that none of these sources contribute to visibility impairment. Several of these commenters added, however, that if this cumulative analysis were to show a contribution, then, consistent with the decision in *American Corn Growers,* the State must allow each individual source to demonstrate that its own emissions do not, by themselves, contribute to the problem of visibility impairment. One commenter requested clarification on what visibility threshold a State should use in determining that no sources are reasonably anticipated to cause or contribute to any impairment in a Class I area.

A number of commenters supported the third option for determining BART applicability based on an analysis of source-specific effects on visibility. However, many of the commenters stated that the CAA requires that the States either conduct such an analysis in determining those sources subject to BART, or allow an individual source to make a showing that it does not cause or contribute to visibility impairment. In addition, although supportive of the general notion of allowing for an exemption process for BART-eligible sources, several commenters stated that the third option contained burdensome modeling requirements, and that States need a more flexible, straightforward,

and less costly method to make the ''cause or contribute'' determination.

Several environmental groups commented that the proposed options potentially go too far in allowing sources to be exempted from the BART requirements. These commenters asserted that EPA should clarify that States may not allow a BART-eligible source to avoid the BART requirements without an affirmative demonstration by the State, or by the source, showing that the source does not emit any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in a Class I area. Absent such a demonstration, they argue, a State may not choose to waive the requirement to conduct a BART review of the source.

Final rule. The final BART guidelines adopt the general approach contained in the reproposal, providing the States with several options for identifying the sources subject to BART. The final BART guidelines describe the options contained in the reproposal as well as one new option. The discussion of options in the final guidelines are structured somewhat differently from the reproposal, and the options are explained in greater detail. The guidelines reaffirm that a State may choose to consider all BART-eligible sources to be subject to BART, and to make BART determinations for all its BART-eligible sources.[22] For States that choose to consider exempting some or all of their BART-eligible sources from review, the guidelines then discuss three options that States may use to determine whether its sources are ''reasonably anticipated to cause or contribute'' to visibility impairment at a Class I area. Options 1 and 3 are similar to options in the 2004 reproposal; under option 1, States may use an individual source attribution approach, while option 3 provides the States with an approach for demonstrating that no sources in a State should be subject to BART. Option 2 is new; it is an approach for using model plants to exempt individual sources with common characteristics.

Threshold for visibility impact. One of the first steps in determining whether sources cause or contribute to visibility impairment for purposes of BART is to establish a threshold (quantified in units called ''deciviews'') against which to measure the visibility impact of one or more sources. We believe that a single source that is responsible for a 1.0 deciview change or more should be considered to ''cause'' visibility impairment; a source that causes less than a 1.0 deciview change may still contribute to visibility impairment and thus be subject to BART.

The guidelines note that because of varying circumstances affecting different Class I areas, the appropriate threshold for determining whether a source ''contributes to any visibility impairment'' for the purposes of BART may reasonably differ across States. Although the appropriate threshold may vary, the Guidelines state that the contribution threshold used for BART applicability should not be higher than 0.5 deciviews. We discuss threshold issues in greater detail in the subsection immediately following this one, entitled *Metric for Visibility Degradation.*

Pollutants

The guidelines direct that States should look at SO_2, NO_X, and direct particulate matter (PM) emissions in determining whether sources cause or contribute to visibility impairment, including both PM_{10} and $PM_{2.5}$. Consistent with the approach for identifying BART-eligible sources, States do not need to consider less than *de minimis* emissions of these pollutants from a source.

States may use their best judgement to determine whether VOC or ammonia emissions are likely to have an impact on visibility in an area. In addition, they may use PM_{10} or $PM_{2.5}$ as an indicator for $PM_{2.5}$ in determining whether a source is subject to BART. In determining whether a source contributes to visibility impairment, however, States should distinguish between the fine and coarse particle components of direct particulate emissions. Although both fine and coarse particulate matter contribute to visibility impairment, the long-range transport of fine particles is of particular concern in the formation of regional haze. Air quality modeling results used in the BART determination will provide a more accurate prediction of a source's impact on visibility if the inputs into the model account for the relative particle size of any directly emitted particulate matter (*i.e.* PM_{10} vs. $PM_{2.5}$).

We believe that PM_{10} is likely to contribute more to regional haze in arid areas than humid areas. As the Grand Canyon Visibility Transport Commission (GCTVC) recognized,[23] States in the arid West, in particular, will need to take the coarse fraction of particulate matter into account in determining whether a source meets the threshold for BART applicability.

Option 1. We agree with commenters supporting the use of an individual source analysis in determining if a BART-eligible source causes or contributes to visibility impairment. Consistent with *American Corn Growers,* this option provides a method for a State to evaluate the visibility impact from an individual source and show that the source is not reasonably anticipated to cause or contribute to visibility degradation in a Class I area and thus may be exempt from BART. (Note also that an individual source analysis is used to inform the BART determination). In general, a dispersion model is used to assess the visibility impact from a single source, and that impact is compared to a threshold which is determined by the State. The threshold (quantified in deciviews) is the numerical metric that is used to define ''cause or contribute''; if a source's impact is below the threshold, a State may exempt the source from BART; otherwise the source would be subject to BART.

We discuss specific issues on the individualized source attribution process, including changes since proposal and issues raised by commenters, in the subsections immediately following this one: Metric for visibility degradation; Use of CALPUFF for visibility modeling; The use of natural conditions in determining visibility impacts for reasonable progress and comparison to threshold values; Modeling protocol; and Alternatives for determining visibility impacts from individual sources.

Option 2. In the final guideline, we describe a modified approach, using model plants based on representative sources sharing certain characteristics, that the States may use to simplify the BART determination process, either to exempt (individually or as a group) those small sources that are not reasonably anticipated to cause or contribute to visibility impairment, or to identify those large sources that clearly should be subject to BART review. States could use the CALPUFF model, for example, to estimate levels of visibility impairment associated with different combinations of emissions and distances to the nearest Class I area. In carrying out this approach, the State could then reflect groupings of specific types of sources with important common characteristics, such as emissions, stack heights and plume characteristics, and develop ''composite model plants.'' Based on CALPUFF

[22] States choosing this approach should use the data being developed by the regional planning organizations, or on their own, as part of the regional haze SIP development process to make the showing that the State contributes to visibility impairment in one or more Class I areas.

[23] Grand Canyon Visibility Transport Commission, Recommendations for Improving Western Vistas, Report to the U.S. EPA, June 10, 1996.

analyses of these model plants, a State may find that certain types of sources are clearly reasonably anticipated to cause or contribute to visibility impairment. Conversely, representative plant analyses may show that certain types of sources are not reasonably anticipated to cause or contribute to visibility impairment. Based on the modeling results, a State could exempt from BART all sources that emit less than a certain amount per year and that are located a certain distance from the nearest Class I area.

Our analyses of visibility impacts from model plants provide a useful example of the type of analyses that might be used to exempt categories of sources from BART.[24] Based on our model plant analysis, EPA believes that a State could reasonably choose to exempt sources that emit less than 500 tons per year of NO_X or SO_2 (or combined NO_X and SO_2), as long as they are located more than 50 kilometers from any Class I area; and sources that emit less than 1000 tons per year of NO_X or SO_2 (or combined NO_X and SO_2) that are located more than 100 kilometers from any Class I area.

In our analysis, we developed two model plants (a EGU and a non-EGU), with representative plume and stack characteristics, for use in considering the visibility impact from emission sources of different sizes and compositions at distances of 50, 100 and 200 kilometers from two hypothetical Class I areas (one in the East and one in the West). Because the plume and stack characteristics of these model plants were developed considering the broad range of sources within the EGU and non-EGU categories, they do not necessarily represent any specific plant. However, the results of these analyses may be instructive in the development of an exemption process for groups of BART-eligible sources, without modeling each of these sources individually.

States may want to conduct their own model plant analysis that take into account local, regional, and other relevant factors (such as meteorology, sulfur dioxide, nitrogen dioxide, and ammonia). If so, you may want to consult your EPA Regional Office to ensure that any relevant technical issues are resolved before you conduct your modeling.

In preparing our hypothetical examples, we have made a number of assumptions and exercised certain modeling choices; some of these have a tendency to lend conservatism to the results, overstating the likely impacts, while others may understate the modeling results. On balance, when all of these factors are considered, we believe that our examples reflect realistic treatments of the situations being modeled.[25] A summary of the more significant elements and their implications is provided below.

Features of the modeling examples which may understate visibility impacts

- An annual emission rate was used for the example modeling (*e.g.* 10,000 TPY divided by 365 days divided by 24 hours). ''Real world'' sources have variable emission rates, and in any 24 hour period may be operating well above the annual rate.
- The monthly average relative humidity was used, rather than the daily average humidity, and would contribute to lowering the peak values in daily model averages.
- A 24-hour average was calculated from modeled hourly visibility impacts, reducing the impact of any one particular hour that could be higher due to a number of meteorological effects.

Features of the modeling examples which may overstate visibility impacts

- We located receptors using a grid of concentric circles for distances of 50, 100 and 200 km. A receptor was placed every 10 degrees around each circle, and highest impacts were reported regardless of direction from the source. In actuality, receptors would be located only in the Class I area, or in only one direction from the source.
- We used simplified chemistry (*i.e.* for conversion of SO_2 and NO_X to fine particles) and disperson techniques which tend to overstate model impacts.

Special care should be used to ensure that the criteria used in the modeling are appropriate for a given State. Our modeling may not be appropriate for every region of the country, due to the unique characteristics of different Class I areas and varying meteorological and geographical conditions in different regions. In addition, States may want to design their own model plants taking into account the types of sources at issue in their region.

Option 3. Under the BART guidelines, a State may consider exempting all its BART-eligible sources from BART by conducting analyses that show that all of the emissions from BART-eligible sources in their State, taken together, are not reasonably anticipated to cause or contribute visibility impairment. To make such a showing, a State could use CALPUFF or another appropriate dispersion model to evaluate the impacts of individual sources on downwind Class I areas, aggregating those impacts to determine the collective contribution from all-BART eligible sources in the State. A State with a sufficiently large number of BART-eligible sources could also make such a showing using a photochemical grid model.[26]

We agree with commenters who pointed out that the option of allowing a State to demonstrate that the full group of BART-eligible sources in the State do not contribute to visibility impairment would, by default, satisfy an individual source contribution assessment. Commenters have not shown any reason to believe that if the sum total of emissions from the BART-eligible sources in a State do not ''cause or contribute'' to visibility impairment in any Class I area, that emissions from one such source will meet the threshold for BART applicability. A State following this approach accordingly need not undertake an affirmative demonstration based on a source by source analysis of visibility impacts to find that its sources are not subject to BART.

Metric for Visibility Degradation

Background. The 2004 reproposed guidelines contained a proposed threshold for the States to use in determining whether an individual source could be considered to cause visibility impairment in a Class I area. We proposed a 0.5 deciview change relative to natural background conditions,[27] as a numerical threshold for making this determination.[28]

[24] Supplement to CALPUFF Analysis in Support of the June 2005 Changes to the Regional Haze Rule, U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

[25] CALPUFF Analysis in Support of the June 2005 Changes to the Regional Haze Rule, U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

[26] For regional haze applications, regional scale modeling typically involves use of a photochemical grid model that is capable of simulating aerosol chemistry, transport, and deposition of airborne pollutants, including particulate matter and ozone. Regional scale air quality models are generally applied for geographic scales ranging from a multi-state to the continental scale. Because of the design and intended applications of grid models, they may not be appropriate for BART assessments, so States should consult with the appropriate EPA Regional Office prior to carrying out any such modeling.

[27] *Guidance for Estimating Natural Visibility Conditions Under the Regional Haze Rule*, (U.S. Environmental Protection Agency, September 2003. *http://www.epa.gov/ttncaaa1/t1/memoranda/rh_envcurhr_gd.pdf.* Natural background conditions, expressed in deciviews, are defined for each Class I area. EPA has issued guidance for estimating natural background conditions which has estimates of default conditions as well as measures to develop refined estimates of natural conditions.

[28] In the proposal we noted that a 0.5 deciview change in visibility is linked to ''perceptibility,'' or

Continued

We proposed the CALPUFF model as the preferred approach for predicting whether a single source caused visibility impairment if the modeled results showed impacts from the source that exceeded the threshold on any given day during a five-year period. We also proposed that if a source had an estimated impact on visibility of less than 0.5 deciviews, a State could choose to exempt the source from further BART analysis.

Comments. We received numerous comments supporting the proposed threshold. A number of commenters stated that the 0.5 deciview threshold is appropriate given the low triggering threshold for applicability established by Congress, and that the literature supports it as the minimum level of perceptibility. Some commenters cited published documentation supporting their assertions that a minimum change in deciviews necessary for perceptibility is 0.5 deciviews.[29]

Other commenters criticized the threshold as too low. They stated that a change of 0.5 deciviews is inconsistent with language in the regional haze rule pointing to 1.0 deciview as the appropriate perceptibility threshold, and they cited more recent literature justifying perceptibility as greater than a change of 1 deciview.[30]

One commenter said that we should allow States and regional planning organizations (RPOs) the flexibility to determine appropriate visibility-impact thresholds in light of current knowledge about a range of perceptibility thresholds. Another commenter said that we should explain our basis for establishing a threshold of a one-time impact of greater than 0.5 deciviews, in light of the overall goal of the regional haze program. Yet another commenter said that the proposal would ''change the regulatory role of the deciview metric by converting it into a regulatory 0.5 deciview standard (versus a 'goal') for defining how States must exercise their authority and discretion in determining whether an individual source 'causes or contributes' to visibility impairment in a Class I area.''

Several commenters said that the 0.5 deciview threshold is too high. A recurring comment was that the statutory BART applicability test from CAA Section 169A(b)(2)(A) contains two separate elements: ''causation'' of any visibility impairment and ''contribution'' to any such impairment. Commenters pointed out that by setting a threshold of 0.5 deciviews, we had combined ''cause or contribute'' into a single test of causality, thus effectively eliminating the ''contribution'' element of the BART applicability test. The commenters asserted that a single BART-eligible source can ''contribute'' to visibility impairment with impacts much lower than 0.5 deciviews. They argued that we must set the minimum threshold for individual source contribution to visibility impairment at the lowest level detectable by modeling or other appropriate analysis, and that this minimum individual contribution level must in any event be set at no greater than a 0.1 deciview change relative to natural conditions, which is a clearly measurable level. One commenter suggested that a cause or contribute threshold be set at some percentage of the ''just noticeable'' change of 0.5 deciviews.

Another commenter said that in a case where multiple sources each have a visibility impact of less than a 0.5 deciview change, but together result in a change of more than 0.5 deciview, each of these sources contributes to the resulting visibility impairment. This commenter asserted that BART guidelines that result in exemptions for these ''contributing'' sources would subvert the goals of the regional haze program.

Similarly, several commenters suggested that if any combination of BART eligible sources causes visibility impairment in a Class I area of more than 0.5 deciviews (by CALPUFF modeling for any 24-hour period, for example), that State should determine that each individual source is subject to BART. Thus, the commenter added, the court's concern about the lack of ''empirical evidence of a source's contribution to visibility impairment'' would be addressed.

Two commenters said that our requirement to use the maximum 24-hour value over the 5-year period of meteorological data in the modeling, as proposed, is too stringent, unreasonable, inappropriate, and departs from the previous methodologies for the regional haze program. Additionally they said that the threshold is restrictive because the single highest 24-hour modeled impact over a three- or five-year period may be influenced by short-term weather conditions, like high humidity, and the BART applicability determination should not be made based on a one-time occurrence.

One commenter said that whatever the final threshold for a single-source impact for BART sources, EPA should clarify that the purpose of this modeling assessment is to evaluate a source's anticipated contribution to uniform regional haze over the Class I area. EPA should state that the assumption of a uniform haze contribution based on CALPUFF modeling eliminates the need to assess issues related to the size of the Class I area, views within a Class I area, and weather impact interactions. Finally, one commenter said that thresholds should be established separately for the eastern and western regions of the United States, as natural visibility conditions are established separately for eastern and western regions in the guidance.

Final Rule. Today's guidelines advise States to use a deciview metric in defining ''cause or contribute,'' as explained further below. The fact that the deciview is also used to track progress toward the goal of natural visibility does not in any way indicate that we are ''converting'' a ''goal'' into a requirement.[31] Use of the same metric in the ''cause or contribute'' context as used for establishing reasonable progress goals, tracking changes in visibility conditions, and defining baseline, current, and natural conditions simply provides for a consistent approach to quantifying visibility impairment.

In response to commenters who said we conflated the ''cause or contribute'' test, we are clarifying that for purposes of determining which sources are subject to BART, States should consider a 1.0 deciview change or more from an individual source to ''cause'' visibility impairment, and a change of 0.5 deciviews to ''contribute'' to impairment.[32]

In a regulatory context, we believe that a State's decision as to an

a just noticeable change in most landscapes. National Acid Precipitation Assessment Program (NAPAP), Acid Deposition: State of Science and Technology Report 24, Visibility: Existing and Historical Conditions—Causes and Effects (Washington, DC, 1991) Appendix D at 24–D2 (''changes in light extinction of 5 percent will evoke a just noticeable change in most landscapes''). Converting a 5 percent change in light extinction to a change in deciviews yields a change of approximately 0.5 deciviews.

[29] Ibid.

[30] Henry, R.C., Just-Noticeable Differences in Atmospheric Haze, Journal of the Air & Waste Management Association, 52:1238–1243, October 2002.

[31] Moreover, the fact that the ultimate purpose of the visibility provisions is expressed as a ''goal'' does not mean that all aspects of the program are merely aspirational. CAA section 169A(a)(4) requires EPA to establish regulations to ensure that reasonable progress is made toward the national visibility goal, and 169A(b)(2) provides that EPA must require SIPs to contain emission limits, schedules of compliance, and other measures as may be necessary to make reasonable progress towards meeting the goal.

[32] If ''causing'' visibility impairment means causing a humanly perceptible change in visibility in virtually all situations (*i.e.* a 1.0 deciview change), then ''contributing'' to visibility impairment must mean having some lesser impact on the conditions affecting visibility that need not rise to the level of human perception.

appropriate threshold for contribution could depend upon the number of sources affecting a class I area. To illustrate, if there were only one emissions source affecting visibility in a class I area, that source could have a deciview impact only slightly below the perceptibility threshold without contributing to noticeable impairment. However, if there were 100 sources each changing visibility by 0.1 deciviews, the total impact would be a 10-deciview change in visibility. In this hypothetical example, all 100 sources would be contributing, in equal amounts, to substantial visibility impairment.

Because circumstances will vary in different locations, we believe that States should have discretion to set an appropriate threshold depending on the facts of the situation. We believe, however, that it would be difficult for a State to justify a threshold higher than 0.5 deciviews. In particular, 0.5 deciviews represents one half of the 1.0 deciview level that we are equating with a single source ''causing'' visibility degradation. Typically, there are multiple sources that affect visibility in class I areas, so a source causing a 0.5 deciview change can be expected to be contributing to noticeable visibility impairment.

In determining whether the maximum threshold of 0.5 deciviews or a lower threshold is appropriate for purposes of BART, we believe that States should consider the number of emissions sources affecting the class I area and the magnitude of the individual sources' impacts.[33] In general, a larger number of sources causing impacts in a class I area may warrant a lower contribution threshold. In selecting a threshold, States may want to take into account the fact that individual sources have varying amounts of impact on visibility in class I areas. Depending on the facts regarding the number of sources affecting a class I area and their modeled impacts, the State could set a threshold that captures those sources responsible for most of the total visibility impacts, while still excluding other sources with very small impacts.[34]

We also note that under this guidance, States would have discretion in setting the threshold for ''contributes to'' based on modeled impacts of sources. Consistent with *American Corn Growers,* we are not requiring States to find sources subject to BART regardless of their impact on Class I areas. We are suggesting that, in establishing a threshold for assessing contribution for BART, it may be logical to draw a line between ''contribution'' and ''non-contribution'' based on the number and magnitude of the various sources affecting the Class I areas at issue. Such an approach gives States the ability to assess the empirical evidence showing contribution and to design an appropriate regulatory regime in light of the nature of the problem. We note that for 750 MW power plants, such a line drawing exercise is likely to be unnecessary, as such sources will in most or all cases have impacts far exceeding 1.0 deciviews.

Finally, we disagree that separate threshold levels should be established based on geography because a unit change in visibility expressed in deciviews, perceived or measured, is the same regardless of geography. As explained in the 1999 regional haze rule, the deciview can be used to express changes in visibility impairment in a way that corresponds to human perception in a linear manner. As a result, using the deciview as the metric for measuring visibility means, for example, that a one deciview change in a highly impaired environment would be perceived as roughly the same degree of change as one deciview in a relatively clear environment, and geography is not a factor.

Interpretation of CALPUFF Results

The standard CALPUFF modeling run provides day-by-day estimates of a source's visibility effects over a five-year period. In the proposed BART guideline, we indicated that if the maximum daily visibility value at any receptor over the five years modeled is greater than the ''cause or contribute'' threshold, then the State should conclude that the source is subject to BART. A number of commenters took issue with our proposal to use the 24-hour maximum modeled visibility impact over five years of meteorological data. Several of them pointed out, for example, that the maximum modeled 24-hour impact may be an outlier unduly influenced by weather. We agree that the maximum modeled effect in a five-year period could be the result of unusual meteorology. We also recognize that, although CALPUFF is the best currently available tool for analyzing the visibility effects of individual sources, it is a model that includes certain assumptions and uncertainties. Thus, we agree with commenters that a State should not necessarily rely on the maximum modeled impact in determining whether a source may reasonably be anticipated to contribute to visibility impairment in a Class I area.

The final guideline states that it would be reasonable for States to compare the 98th percentile of CALPUFF modeling results against the ''contribution'' threshold established by the State for purposes of determining BART applicability. Some stakeholders have argued for the 90th percentile value, or even lower, contending that EPA should not use extreme cases to make BART applicability decisions. EPA agrees that, in most cases, important public policy decisions should not be based on the extreme tails of a distribution. We have concluded, however, that the 98th percentile is appropriate in this case.

The use of 90th percentile value would effectively allow visibility effects that are predicted to occur at the level of the threshold (or higher) on 36 or 37 days a year. We do not believe that such an approach would be consistent with the language of the statute. Second, we note that the 98th percentile value would only be used to determine whether a particular BART-eligible source would be subject to further review by the State. In determining what, if any, emission controls should be required, the State will have the opportunity to consider the frequency, duration, and intensity of a source's predicted effect on visibility.

On the other hand, there are other features of our recommended modeling approach that are likely to overstate the actual visibility effects of an individual source. Most important, the simplified chemistry in the model tends to magnify the actual visibility effects of that source. Because of these features and the uncertainties associated with the model, we believe it is appropriate to use the 98th percentile—a more robust approach that does not give undue weight to the extreme tail of the distribution. The use of the 98th percentile of modeled visibility values would appear to exclude roughly 7 days per year from consideration. In our judgment, this approach will effectively capture the sources that contribute to visibility impairment in a Class I area, while minimizing the likelihood that the highest modeled visibility impacts might be caused by unusual meteorology or conservative assumptions in the model.

[33] All states are working together in regional planning organizations, and we expect that states will have modeling information that identifies sources affecting visibility in individual class I areas, and the magnitude of their impacts.

[34] Under our guidelines, the contribution threshold should be used to determine whether an individual source is reasonably anticipated to contribute to visibility impairment. You should not aggregate the visibility effects of multiple sources and compare their collective effects against your contribution threshold because this would inappropriately create a ''contribution to contribution'' test.

Use of CALPUFF for Visibility Modeling

Background. In providing the States with the option of making a determination as to which sources are subject to BART based on a consideration of each source's individual contribution to visibility impairment, we proposed that States use an air quality model such as CALPUFF. We also proposed that States use a CALPUFF or other EPA approved model in the BART analysis itself. The CALPUFF system, as explained in the 2004 reproposed guideline, consists of a diagnostic meteorological model, a gaussian puff dispersion model with algorithms for chemical transformation and complex terrain, and a post processor for calculating concentration fields and visibility impacts.

The regional haze rule addresses visibility impairment caused by emissions of fine particles and their precursors. As fine particle precursors, such as SO_2 or NO_X, are dispersed, they react in the atmosphere with other pollutants to form visibility-impairing pollutants. In fact, Congress implicitly recognized in 1977 the role of chemical transformation in creating visibility impairment, when it stated that the ''visibility problem is caused primarily by emissions of SO_2, [NO_X], and particulate matter.'' [35] In most cases, to predict the impacts of a source's specific contribution to visibility impairment, a State will need a tool that takes into account not only the transport and diffusion of directly emitted $PM_{2.5}$ but also one that can address chemical transformation.

Because the air quality model CALPUFF is currently the best application available to predict the impacts of a single source on visibility in a Class I area, we proposed that a CALPUFF assessment be used as the preferred approach first, for determining whether an individual source is subject to BART, and second, in the BART determination process. The CALPUFF assessment is specific to each source, taking into account the individual source's emission characteristics, location, and the particular meteorological, topographical, and climatological conditions of the area in which the source is located, any of which may have an impact on the transport of $PM_{2.5}$ and its precursors. CALPUFF can be used to estimate not only the effects of directly emitted $PM_{2.5}$ emissions from a source, but also to predict the visibility impacts from the transport and chemical transformation of fine particle precursors.

The CALPUFF model is generally intended for use on scales from 50 km to several hundred kilometers from a source. As a general matter, States will typically need to assess the impacts of potential BART sources on Class I areas located more than 50 km from the source.[36] However, in situations where the State is assessing visibility impacts for source-receptor distances less than 50 km, we proposed that States use their discretion in determining visibility impacts, giving consideration to both CALPUFF and other EPA-approved methods. As an example, we suggested that States could use an appropriate local-scale plume impact model, such as PLUVUEII,[37] to determine whether a source's emissions are below a level that would be reasonably anticipated to cause or contribute to visibility impairment in any Class I area.

Comments. A number of States, environmental groups, and some industry commenters strongly supported the use of CALPUFF as proposed. Many commenters supported the use of CALPUFF but indicated that States must have the flexibility to use additional tools for their individual source analyses. Some suggested options for the ''cause or contribute'' determination were the use of photochemical grid models, or more simplified, non-modeling approaches. Commenters claimed that States must have the option to incorporate advances in science and technologies into models or other applications that may produce more accurate simulations of meteorology, chemistry, and visibility impairment. Other industry groups and States argued that CALPUFF has significant limitations, especially simulating complex atmospheric chemistry, and that EPA's recommendation of CALPUFF as the preferred approach is therefore inappropriate.

Another issue raised by commenters was the use of CALPUFF for estimating secondary particulate matter formation. Commenters recognized that CALPUFF was incorporated into the ''Guideline on Air Quality Models'' at 40 CFR part 51, appendix W in April 2003 as the preferred model for Prevention of Significant Deterioration (PSD) increment and National Ambient Air Quality Standards (NAAQS) compliance assessments of long range transport of primary emissions of SO_2 and $PM_{2.5}$. However, commenters stated that CALPUFF has not been incorporated into the Guideline on Air Quality Models for predicting the secondary formation of PM. The commenters remarked that EPA guidance indicates that photochemical grid models be used to simulate secondary PM formation and concluded on this basis that the application of CALPUFF as we proposed is in conflict with our guidance.

Final rule. We believe that CALPUFF is an appropriate application for States to use for the particular purposes of this rule, to determine if an individual source is reasonably anticipated to cause or contribute to impairment of visibility in Class I areas, and to predict the degree of visibility improvement which could reasonably be anticipated to result from the use of retrofit technology at an individual source. We encourage States to use it for these purposes.[38]

CALPUFF is the best modeling application available for predicting a single source's contribution to visibility impairment. It is the only EPA-approved model for use in estimating single source pollutant concentrations resulting from the long range transport of primary pollutants. In addition, it can also be used for some purposes, such as the visibility assessments addressed in today's rule, to account for the chemical transformation of SO_2 and NO_X. As explained above, simulating the effect of precursor pollutant emissions on $PM_{2.5}$ concentrations requires air quality modeling that not only addresses transport and diffusion, but also chemical transformations. CALPUFF incorporates algorithms for predicting both. At a minimum, CALPUFF can be used to estimate the relative impacts of BART-eligible sources. We are confident that CALPUFF distinguishes, comparatively, the relative contributions from sources such that the differences in source configurations, sizes, emission rates, and visibility impacts are well-reflected in the model results. States can make judgements

[35] H.R. Rep. No. 95–294 at 204 (1077).

[36] To determine whether a BART-eligible source ''may reasonably be anticipated to cause or contribute to any visibility impairment in any Class I area,'' it may not always be sufficient for the State to predict the impacts of a BART-eligible source only on the nearest Class I area (or on the nearest receptor in the nearest Class I area). The particular meteorological and topographical conditions, for example, could mean that a source's greatest impacts occurred at a Class I area other than the nearest one.

[37] PLUVUEII is a model used for estimating visual range reduction and atmospheric discoloration caused by plumes resulting from the emissions of particles, nitrogen oxides, and sulfur oxides from a single source. The model predicts the transport, dispersion, chemical reactions, optical effects and surface deposition of point or area source emissions. It is available at *http://www.epa.gov/scram001/tt22.htm#pluvue.*

[38] The model code and its documentation are available at no cost for download from *http://www.epa.gov/scram001/tt22.htm#calpuff.*

concerning the conservativeness or overestimation, if any, of the results. In fact, although we focused on the use of CALPUFF for primary pollutants in revising the Guideline of Air Quality Modeling, section 7.2.1.e. of the Guideline states:

> e. CALPUFF (Section A.3) may be applied when assessment is needed of reasonably attributable haze impairment or atmospheric deposition due to one or a small group of sources. This situation may involve more sources and larger modeling domains than that to which VISCREEN ideally may be applied. The procedures and analyses should be determined in consultation with the appropriate reviewing authority (paragraph 3.0(b) and the affected FLM(s).

We believe that our proposed use of CALPUFF is thus fully in keeping with the *Guideline on Air Quality Models,* especially in light of the low triggering threshold for determining whether a source is reasonably anticipated to cause or contribute to visibility impairment in a Class I area, and the fact that the modeling results are used as only one of five statutory criteria evaluated to determine BART emission limits.

Even so, as commenters point out, CALPUFF has not yet been fully evaluated for secondary pollutant formation. For the specific purposes of the regional haze rule's BART provisions, however, we have concluded that CALPUFF is sufficiently reliable to inform the decision making process.

EPA revised the *Guideline on Air Quality Models* in 2003, in part, to add CALPUFF to the list of approved models for particular uses. At that time, we considered comments that CALPUFF should be approved for use in predicting the impact of secondary emissions on particulate matter concentrations. As we stated in the revision, CALPUFF represents a substantial improvement in methods for assessing long-range transport of air pollutants. However, as explained in the response to comments for that rulemaking, the modeling results in the context of a PSD review may be used as the sole determining factor in denying a source a permit to construct.[39] Although its use in simulating long-range transport is beneficial, given the significance of the modeling results in assessing increment consumption due to a single source's impacts, we made a determination that it would not be appropriate in the rulemaking revising Appendix W to approve CALPUFF for use in modeling secondary emissions.

In contrast to the significance of the modeling results in the PSD context, the use of CALPUFF in the context of the regional haze rule is not determinative of a source's ability to construct or operate. A State may use CALPUFF to determine whether a source can reasonably be anticipated to cause or contribute to visibility impairment and so should be subject to additional review to determine if the source should be subject to control.

Based on our analysis of the power plants covered by the guidelines, we believe that all but a handful of these plants have impacts of greater than 1.0 deciview on one or more Class I areas.[40] In fact, we anticipate that most of these plants are predicted to have much higher maximum impacts.[41] Because of the scale of the predicted impacts from these sources, CALPUFF is an appropriate or a reasonable application to determine whether such a facility can reasonably be anticipated to cause or contribute to any impairment of visibility. In other words, to find that a source with a predicted maximum impact greater than 2 or 3 deciviews meets the contribution threshold adopted by the States does not require the degree of certainty in the results of the model that might be required for other regulatory purposes.

In the unlikely case that a State were to find that a 750 MW power plant's predicted contribution to visibility impairment is within a very narrow range between exemption from or being subject to BART, the State can work with EPA and the FLM to evaluate the CALPUFF results in combination with information derived from other appropriate techniques for estimating visibility impacts to inform the BART applicability determination. Similarly for other types of BART eligible sources, States can work with the EPA and FLM to determine appropriate methods for assessing a single source's impacts on visibility.

As discussed in section E. below we also recommend that the States use CALPUFF as a screening application in estimating the degree of visibility improvement that may reasonably be expected from controlling a single source in order to inform the BART determination. As we noted in 2004, this estimate of visibility improvement does not by itself dictate the level of control a State would impose on a source; ''the degree of improvement in visibility which may reasonably be anticipated to result from the use of [BART]'' is only one of five criteria that the State must consider together in making a BART determination. The State makes a BART determination based on the estimates available for each criterion, and as the CAA does not specify how the State should take these factors into account, the States are free to determine the weight and significance to be assigned to each factor. CALPUFF accordingly is an appropriate application for use in combination with an analysis of the other statutory factors, to inform decisions related to BART.

We understand the concerns of commenters that the chemistry modules of the CALPUFF model are less advanced than some of the more recent atmospheric chemistry simulations. To date, no other modeling applications with updated chemistry have been approved by EPA to estimate single source pollutant concentrations from long range transport. In its next review of the Guideline on Air Quality Models, EPA will evaluate these and other newer approaches and determine whether they are sufficiently documented, technically valid, and reliable to approve for general use. In the meantime, as the Guideline makes clear, States are free to make their own judgements about which of these or other alternative approaches are valid and appropriate for their intended applications.

Theoretically, the CALPUFF chemistry simulations, in total, may lead to model predictions that are generally overestimated at distances downwind of 200 km. Again, States can make judgements concerning the conservativeness or overestimation, if any, of the results.

The use of other models and techniques to estimate if a source causes or contributes to visibility impairment may be considered by the State, and the BART guidelines preserve a State's ability to use other models. Regional scale photochemical grid models may have merit, but such models have been designed to assess cumulative impacts, not impacts from individual sources. Such models are very resource intensive and time consuming relative to CALPUFF, but States may consider their use for SIP development in the future as they are adapted and demonstrated to be appropriate for single source applications. However, to date, regional models have not been evaluated for single source applications. Their use may be more appropriate in the cumulative modeling options discussed

[39] Under CAA section 165(a), a major emitting facility may not be constructed unless the owner or operator of the facility demonstrates that the emissions from the facility will not cause or contribute air pollution in excess of an increment or NAAQS.

[40] CALPUFF Analysis in Support of the Regional Haze Rule, U.S. Environmental Protection Agency, April 15, 2005, Docket No. OAR–2002–0076.

[41] Ibid.

above.[42] In evaluating visibility improvement as one of the five factors to consider in setting BART controls, other models, used in combination with CALPUFF may be helpful in providing a relative sense of the source's visibility impact and can aid in informing the BART decision. A discussion of the use of alternative models is given in the *Guideline on Air Quality* in appendix W, section 3.2.

The Use of Natural Conditions in Determining Visibility Impacts for Reasonable Progress and Comparison to Threshold Values

Background. As set out in section 169A(a) of the CAA and stated in the 1999 regional haze rule, a return to natural visibility conditions, or the visibility conditions that would be experienced in the absence of human-caused impairment, is the ultimate goal of the regional haze program. To measure progress toward this goal, the regional haze rule requires that a comparison with natural conditions for the 20 percent best and worst days to calculate ''reasonable progress'' determinations. Default values for natural visibility conditions are provided in EPA guidance.[43] In the 2004 reproposal of the BART guidelines, we proposed that changes in visibility, expressed in deciviews, should be determined by comparing the impact from a single source to natural visibility conditions. That impact should then be compared to a threshold impact, also expressed in deciviews, to assess if a BART-eligible source should be subject to a BART review.

Comments. Opposing commenters said that a return to natural conditions is unattainable as it would require the elimination of every manmade source, and that changes should be compared against currently existing conditions. They added that true ''natural conditions'' cannot be verified, do not account for manmade emissions from other countries, and are not a realistic target for improvement. Further, they argued that natural conditions are a ''goal'' representing a benchmark that is relevant to the States' determination, under the regional haze program, of the level of ''reasonable progress'' to achieve; however they stated that there is no legal requirement (and there could not be a legal requirement) that the natural conditions goal ultimately must be achieved. Several commenters added that current visibility conditions make more sense as a baseline because sources that are subject to BART today will likely not be in operation in the 2064 time frame. A commenter added that using current visibility conditions for the analysis will give a more realistic, real-world prediction of whether controlling the source pursuant to BART will actually improve visibility. The commenter said that Congress did not intend for sources to have to consider retrofitting controls under the BART provision if those sources currently are not impacting real-world visibility. Other utility groups stated that in addition to international emissions, the estimated natural visibility conditions failed to account for natural phenomena such as sea salt, wildfires, and natural organics. One commenter noted that natural visibility estimates will be revised and refined over time and it would be unwise to compare impacts and improvements to a moving baseline.

On the other hand, numerous commenters supported the use of natural visibility conditions as a baseline for measuring visibility improvements. Several environmental groups said that any increase in the baseline beyond natural visibility conditions will unlawfully distort and weaken the BART requirement by effectively raising the applicability threshold in less protected, highly polluted areas, which would be illogical. Further, they pointed out that these BART-eligible sources clearly are contributing to the very manmade visibility impairment that the Act is explicitly designed to remedy by a return to natural conditions. They added that measuring natural conditions as opposed to some other baseline condition is a more appropriate approach, given that the planning goal is to achieve natural visibility by the end of the program. They also added that a baseline other than natural conditions would never assure ''reasonable progress''.

Finally, two commenters asked for clarification on the values for natural conditions to be used for estimating changes in visibility. The commenters appeared to assume that we intended for the comparison to be done for natural visibility conditions on the 20 percent best days.

Final Rule. We disagree with commenters saying that the use of natural conditions as the baseline for making visibility impact determinations is inappropriate. The visibility goal of the CAA is both the remedying of existing impairment, and prevention of future impairment. The court, in American Corn Growers, upheld our interpretation of that goal as the return to natural visibility conditions.[44] Long-term regional haze strategies are developed to make ''reasonable progress'' towards the CAA goal, and States must demonstrate reasonable progress in their regional haze State implementation plans (SIPs). Since the BART program is one component of that demonstration, visibility changes due to BART are appropriately measured against the target of natural conditions.

In establishing the goal of natural conditions, Congress made BART applicable to sources which ''may be reasonably anticipated to cause or contribute to any impairment of visibility at any Class I area''. Using existing conditions as the baseline for single source visibility impact determinations would create the following paradox: the dirtier the existing air, the less likely it would be that any control is required. This is true because of the nonlinear nature of visibility impairment. In other words, as a Class I area becomes more polluted, any individual source's contribution to changes in impairment becomes geometrically less. Therefore the more polluted the Class I area would become, the less control would seem to be needed from an individual source. We agree that this kind of calculation would essentially raise the ''cause or contribute'' applicability threshold to a level that would never allow enough emission control to significantly improve visibility. Such a reading would render the visibility provisions meaningless, as EPA and the States would be prevented from assuring ''reasonable progress'' and fulfilling the statutorily-defined goals of the visibility program. Conversely, measuring improvement against clean conditions would ensure reasonable progress toward those clean conditions.

[42] For regional haze applications, regional scale modeling typically involves use of a photochemical grid model that is capable of simulating aerosol chemistry, transport, and deposition of airborne pollutants, including particulate matter and ozone. Regional scale air quality models are generally applied for geographic scales ranging from a multi-state to the continental scale. Because of the design and intended applications of grid models, they may not be appropriate for BART assessments, so States should consult with the appropriate EPA Regional Office prior to carrying out any such modeling.

[43] Guidance for Estimating Natural Visibility Conditions Under the Regional Haze Rule, U.S. Environmental Protection Agency, September 2003. *http://www.epa.gov/ttncaaa1/t1/memoranda/rh_envcurhr_gd.pdf.* Natural background conditions, expressed in deciviews, are defined for each Class I area. EPA has issued guidance for estimating natural background conditions which has estimates of default conditions as well as measures to develop refined estimates of natural conditions.

[44] See also our explanation of the CAA goal provided in the regional haze rule at 64 FR at 35720–35722. We note that the court in *American Corn Growers* also observed, ''the natural visibility goal is not a mandate, it is a goal.'' 291 F.3d at 27.

With regard to BART-eligible sources not being in operation for the duration of the program, a State, in making BART determinations, is explicitly directed by the CAA to account for the remaining useful life of a source. Thus, States may factor into their reasonable progress estimates those shut-downs that are required and effected in permit or SIP provisions. In addition, as provided for under our guidance,[45] proper accounting for international emissions and natural phenomena is in the 5 year SIP progress report, not in the setting of natural visibility estimates. Finally, these final BART guidelines use the natural visibility baseline for the 20 percent best visibility days for comparison to the ''cause or contribute'' applicability thresholds. We believe this estimated baseline is likely to be reasonably conservative and consistent with the goal of natural conditions.

Modeling Protocol

Background. The 2004 guidelines proposed that a written modeling protocol be submitted for assessing visibility impacts from sources at distances greater than 200 km from a Class I area. The proposal indicated that the protocol should include a description of the methods and procedures to follow, for approval by the appropriate reviewing authority; critical items to include in the protocol are meteorological and terrain data, source-specific information (stack height, temperature, exit velocity, elevation, and allowable emission rate of applicable pollutants), and receptor data from appropriate Class I areas.

Comments. All of the comments supported the development of a written modeling protocol. Industry, Federal, and State commenters said a modeling protocol should be required of all States and stakeholders who are performing the BART modeling analysis. Commenters said the protocol should allow all interested parties an opportunity to understand the modeling approach and how the results will be used, and that the State should provide opportunity for comments on the procedures prior to the publication of the final results.

Many utility groups commented that the protocol should provide States with flexibility and that the choice of models should be at the States' (or RPOs') discretion. Some commenters stressed that it is important that states and sources retain the flexibility to decide how to set up and run the selected model, while others asked for specific guidance on the setup of CALPUFF or other approved models, including on specific parameters (*e.g.* how to adjust for cases where sources are greater than 200 km from a Class I area).

Regarding the approval of a modeling protocol, some commenters said that the protocol should be approved by EPA. Others stated, however, that we should have only an advisory role in development of the protocol. They said that States are in a better position to determine which modeling input values best reflect conditions in their States.

Several commenters representing environmental groups said we should develop a CALPUFF protocol that must be followed and should include, among other items, meteorological data (*i.e.*, where available 5 years of data should be used), emissions reported for the same meteorological years, documented source parameters, model physical parameters, and assumed background concentrations for ozone and ammonia (based on nearby reliable observations and/or regional modeling results). They added that a protocol developed by EPA would help to produce consistent BART determinations across various sources and geographic areas for both shorter and longer distances. FLMs stated that this is also an appropriate time to create regional modeling platforms for CALPUFF, which would allow States and sources to run the model more expeditiously and more consistently. They recommended that we consider a multi-agency process to reach agreement on an appropriate modeling protocol prior to allowing BART applicability and control determinations to be based on model results. FLMs added that it would be helpful to establish a national procedure for this process, including a methodology for establishing natural background conditions, background ammonia concentrations, and determining sulfuric acid emission rates. Such a process, they said, could reasonably be engaged in prior to deadlines for state implementation plans, and would not delay implementation of the BART guidelines. The FLMs noted that consistent, nationally applicable guidance is essential, and that once it is developed, virtually no deviations should be allowed. Finally, they added that the CALPUFF modeling exercises should follow the *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts*,[46] but that we, in consultation with the FLMs and States, should also publish additional guidance to address more recent issues such as particle speciation, emission rate averaging times, and ''natural obscuration.'' Another State commenter said that The Guideline on Air Quality Models (CFR Part 51, Appendix W) should be included along with the IWAQM Report as a reference for CALPUFF setup. One RPO commented that we should provide data, perhaps using example facilities, to demonstrate the effect of the process so that States can get a better feeling for which sources are likely to fall below the 0.5 deciview threshold. This would help States understand the net effect of all of the parameters chosen in the exemption process.

Commenters also said that we should continuously revise modeling protocols by providing a modeling clearinghouse to States, and further, that we should consider new models for use, such as the Community Multiscale Air Quality (CMAQ) model.

There were specific comments requesting guidance for calculating visibility impacts and other general modeling concerns. One technical comment was that the guidelines should specify that the IMPROVE monitor is the receptor by which modeled visibility impacts should be evaluated with the CALPUFF model. Another commenter suggested using recent scientific evidence to update the light extinction coefficients used by CALPUFF to calculate visibility changes. These commenters also stated that CALPUFF might be improved by capping the relative humidity to lower values than are currently used.

Additional commenters representing utility organizations discussed how to identify Class I areas that should be modeled. They said that the guidelines should require sources to model only the nearest Class I area (or possibly the two closest), and one commenter said that we should provide a reasonable methodology to minimize the effort needed to address impacts from BART-eligible sources on multiple Class I areas.

Final Rule. We agree that States should adopt modeling protocols for all modeling demonstrations, regardless of the distance from the BART-eligible source and the Class I area impacted. We are therefore dropping the 200 km and greater distance requirement from the guidelines. As noted in the 2004 re-

[45] Guidance for *Estimating Natural Visibility Conditions Under the Regional Haze Rule,* U.S. Environmental Protection Agency, September 2003. *http://www.epa.gov/ttncaaa1/t1/memoranda/rh_envcurhr_gd.pdf.*

[46] *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts,* U.S. Environmental Protection Agency, EPA–454/R–98–019, December 1998.

proposal, we believe that potential uncertainties in model performance may be greater at distances greater than 200 km for a source. A modeling protocol may reduce the need for additional analyses. We favor coordination among States, EPA regions, RPOs, and other federal agencies to agree on a modeling protocol(s) which would provide consistent application.

In developing a modeling protocol, we also encourage States to use the framework provided for model setup in EPA's IWAQM. CALPUFF model users may find default settings in that document which may be appropriate for their modeling situations and add an element of consistency to model applications. *The Guideline on Air Quality Models* (CFR Part 51, Appendix W) also provides useful guidance.

We do, however, understand and agree that States have flexibility developing a modeling protocol. Moreover, the diversity of the nation's topography and climate, and variations in source configurations and operating characteristics, dictate against a strict modeling ''cookbook''. A State may need to address site-specific circumstances at individual sources potentially affecting a specific Class I area. For example, in a particular area a State may have available emissions data, that is more representative of the modeling domain, which may supplement the model defaults. States may want to consult with the appropriate EPA regional office and Federal Land Managers in adjusting the model input parameters. The modeling input recommendations in the IWAQM report are designed for visibility impact applications, and those defaults allow for tailoring for a given application (*e.g.* puff splitting). The model developers Web site [47] also has a series of frequently asked questions with answers to assist users in tailoring model applications.

We agree that we have only an advisory role in development of the protocol as the States better understand the BART-eligible source configurations and the geophysical and meteorological data affecting their particular Class I area(s).

In the protocol development process, we support the idea of designing example runs, as we have done in our example analysis for EGUs,[48] so that States may get a better understanding of what visibility impacts might be expected from a particular type of source or sources. Once a protocol has been finalized, a State may be able to use example runs as a proxy in making BART determinations which could potentially eliminate the need for case-by-case review for every BART-eligible source. A common sense approach should be taken, particularly where an analysis may add a significant resource burden to a State. For example, if there are multiple Class I areas in relatively close proximity to a BART-eligible source, a State may model a full field of receptors at the closest Class I area. Then a few strategic receptors may be added at the other Class I areas (perhaps at the closest point to the source, a receptor at the highest and lowest elevation in the Class I area, a receptor at the IMPROVE monitor, and a few receptors that are expected to be at the approximate plume release height). If the highest modeled impacts are observed at the nearest Class I area, a State may choose not to analyze the other Class I areas any further and additional analyses might be unwarranted.

As models are revised and advances in science are incorporated into the models, we can make certain that revisions to protocols are made accordingly. We will work closely with States and FLMs, as should States; we expect that States will also work closely with FLMs throughout the protocol development process. We expect a similar protocol development process for other models that may be used, once those models are developed to predict and track single source impacts and demonstrate acceptable model performance. States should contact the appropriate FLM and EPA regional office for the latest guidance and modeling updates.

Alternatives for Determining Visibility Impacts From Individual Sources

Background. In the 2004 reproposal, we requested comment on the following alternatives to CALPUFF modeling for determining whether individual sources cause or contribute to visibility impairment: look-up tables developed from screening-level air quality modeling; running CALPUFF in a simpler screening mode than the preferred approach; a source ranking methodology; and an emissions divided by distance (Q/D) method. Except for the simplified CALPUFF approach, all alternatives were based on developing a relationship between source emissions and the source's distance to a Class I area. Each of these approaches was intended to reduce the resource burden on States.

Comments. Some commenters supported the use of alternative approaches, while others suggested that the alternatives could be used either in conjunction, or in hierarchical fashion, with modeling approaches. Many commenters were opposed to their use. The opposing comments were consistent in stating that the alternatives were inappropriate because they did not account for important factors such as terrain, local meteorological data, prevailing wind directions (which influence pollutant transport), and differences in stack release parameters. Commenters added that there is no direct connection between emissions, distance, and visibility impairment, and that the methods treat SO_2 and NO_X equally for impairment estimates.

Final Rule. We disagree that the alternatives are necessarily inappropriate, but we share most of the concerns articulated by the opposing commenters. We believe that alternatives should not be used to exempt a source from BART review without more rigorous evaluations and sensitivity tests showing that the results are at least as conservative as the CALPUFF model. We know of at least one study showing that, for one location and for one year, there is no guarantee that the simplified CALPUFF technique is as conservative as the preferred approach [49]. While we are not adopting in the guideline any specific alternative to modeling for power plants greater than 750MW, a State may develop its own alternative approach for the other source categories to determine if a source would be subject to BART, provided that the alternative demonstrates a sufficient basis to determine clearly that the source causes or contributes to visibility impairment, or that more refined analysis is warranted. Use of an alternative approach could be a conservative non-modeling method for easing a State's resource burden. We believe conservatism is needed because of the purpose of the test: *i.e.* solely to determine if a closer look at the source is warranted.

E. The BART Determination Process

Background. CAA section 169A(g)(7) directs States to consider five factors in making BART determinations. The regional haze rule codified these factors in 40 CFR 51.308(e)(1)(ii)(B), which directs States to identify the ''best system of continuous emissions control

[47] *http://www.src.com/calpuff/calpuff1.htm.*

[48] CALPUFF Analysis in Support of the June 2005 Changes to the Regional Haze Rule,U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

[49] Analysis of the CALMET/CALPUFF Modeling System in a Screening Mode, U.S. Environmental Protection Agency, November 1998, Docket No. OAR–2002–0076.

technology'' taking into account ''the technology available, the costs of compliance, the energy and nonair quality environmental impacts of compliance, any pollution control equipment in use at the source, and the remaining useful life of the source.'' Section IV. of the BART guidelines provides a step-by-step guide to conducting a BART determination which takes these factors into account.

This section of the preamble addresses a number of issues relative to the process for conducting a BART determination contained in Section IV of the BART guidelines.

1. What Is Meant by ''Technical Feasibility of the Control Options'' in Step 2 of the BART Determination?

Comments. We received several comments on this discussion, both on the 2001 proposal and on the 2004 reproposal. One commenter recommended that the concept of available technology for regional haze should be expanded to include those in the pilot scale testing phase, because these guidelines will precede the installation of controls by about 10 years. Other commenters believed that the discussion of technical feasibility introduced terms and concepts that were not clear, for example, what is meant by ''commercial demonstration.'' One commenter raised issues with deeming technologies used in foreign countries ''available'' unless their performance has been demonstrated in the United States. A few commenters expressed concern with the provision in the guidelines that new technologies should be considered up to the time of a State's public comment period on the BART determination. The commenter believed that this could create an endless review loop for States if new technologies continually became available.

Final rule. In the final guidelines, we have largely retained the language that was in the proposed guidelines. Because the guidelines call for consideration of technologies that become available by the time of the State's public comment process on the BART determination, technologies should be considered that become available well after we finalize the BART guidelines. We also note, for clarity, that the Guidelines state that technologies need to be *both* licensed *and* commercially available (*i.e.* commercially demonstrated and sold).

2. How Should the Costs of Control Be Estimated in Step 4 of the BART Determination?

Comments. This section of the guidelines remained unchanged between the 2001 proposal and the 2004 reproposal. Comments varied, ranging from questioning the reliance on EPA's OAQPS Control Cost Manual Fifth Edition, February 1996, EPA 453/B–96–001 (hereafter called the ''Control Cost Manual'') to requesting that we not include the concept of incremental cost effectiveness in the guidelines. A commenter expressed concerns that incremental cost effectiveness calculations, the cost of implementing each succeeding control option, is too dependent on the number of interim options included in the analysis. Moreover, the commenter believed that incremental cost calculations increase the complexity of the analysis, and they also increase the possibility for inconsistent cost results.

Final rule. We have finalized this section of the guidelines with some changes to how it was proposed. States have flexibility in how they caculate costs. We believe that the Control Cost Manual provides a good reference tool for cost calculations, but if there are elements or sources that are not addressed by the Control Cost Manual or there are additional cost methods that could be used, we believe that these could serve as useful supplemental information.

In addition, the guidelines continue to include both average and incremental costs. We continue to believe that both average and incremental costs provide information useful for making control determinations. However, we believe that these techniques should not be misused. For example, a source may be faced with a choice between two available control devices, control A and control B, where control B achieves slightly greater emission reductions. The average cost (total annual cost/total annual emission reductions) for each may be deemed to be reasonable. However, the incremental cost (total annual $cost_{A-B}$/total annual emission $reductions_{A-B}$) of the additional emission reductions to be achieved by control B may be very great. In such an instance, it may be inappropriate to choose control B, based on its high incremental costs, even though its average cost may be considered reasonable.

Finally, it is important to note that, while BART determinations are focused at individual sources, it is likely that in response to SIP requirements, States will be making BART determinations for many units in a subject source category all at the same time. In doing so, States are likely to compare costs across each source category as well as looking at costs for individual units in order to respond to SIP requirements in an efficient manner (from the State's perspective).

3. How Should ''Remaining Useful Life'' Be Considered in Step 4 of the BART Determination?

Comments. We received a number of comments on the issue of remaining useful life, both on the 2001 proposal and on the 2004 reproposal. One commenter asserted that remaining useful life should not be considered in the cost analysis and that if a source is in operation at the time of a State's SIP submittal, it must have plans to install controls. Other commenters believed that, to the extent that assertions regarding a plant's remaining useful life influences the BART decision, there must be an enforceable requirement for the plant to shut down by that date. Other comments questioned whether Congress intended enforceable restrictions in order to take into account the remaining useful life and whether EPA had the authority under the CAA to require plant shutdowns.

A number of comments were received regarding our request for comments on how to provide flexibility for situations where market conditions change. Some comments interpreted this provision as a loophole that would allow sources to continue operation for a number of years without BART. Another comment supported the concept of allowing a source to later change its mind, so long as BART is installed.

Final rule. We have retained the approach in the proposed guidelines, including the provision for flexibility for sources to continue operating, with BART in place, should conditions change. We believe that the CAA mandates consideration of the remaining useful life as a separate factor, and that it is appropriate to consider in the analysis the effects of remaining useful life on costs. We believe that, because the source would not be allowed to operate after the 5-year point without such controls, the option for providing flexibility would not create a loophole for sources. Moreover, any source operating after this point without BART controls in place would be subject to enforcement actions for violating the BART limit. For any source that does not agree to shut down before the 5-year point, the State should identify a specific BART emission limit that would apply after this point in time.

4. How Should ''Visibility Impacts'' Be Considered in Step 5 of the BART Determination?

Background. The fifth statutory factor addresses the degree of improvement in

visibility which may reasonably be anticipated to result from the use of the ''best control technology'' for sources subject to BART. The 2004 reproposal focuses on the use of single source emissions modeling to evaluate the BART control options. As part of the BART determination, we proposed that a State or individual source would run CALPUFF, or another EPA-approved model, to estimate, in deciviews, a BART source's visibility impact at a Class I area. The source would run the model once using its allowable emission rates, and then again at the various post-control emissions rates being evaluated for the BART determination. The 24-hour model results would then be tabulated for the pre- and post-control scenarios, for the average of the 20 percent worst modeled days at each receptor, over the time period of meteorology modeled. The difference in the averages for each receptor is the expected degree of improvement in visibility. Alternatively, the proposal requested comment on the option of using the hourly modeled impacts from CALPUFF at each receptor and determining the improvement in visibility based on the number of hours above the 0.5 deciview threshold for both the pre- and post-control model runs. We also requested comment on combinations of the proposed and alternative options and on the use of the simpler screening version of CALPUFF to do the analysis.

Comments. Several environmental groups said that issues relating to the determination of visibility improvement for evaluating BART controls are in many ways the same as for determining which BART-eligible sources are subject to BART. Thus, the commenter pointed out, the issues concerning the BART applicability test, discussed in section D., are all equally applicable here, including comments on: using the 0.5 deciview threshold on an aggregate basis for determining visibility impairment and potential exemption for BART-eligible sources, use of a natural visibility baseline versus current visibility, using a substantially lower deciview threshold than 0.5 deciviews to determine the contribution to visibility impairment by an individual source, and demonstration of those thresholds by means of appropriate modeling rather than other less reliable and more subjective techniques.

An industry commenter claimed that the American Corn Growers case emphasized the fact that the CAA clearly provides that BART determinations should balance the visibility benefits of controls comprehensively against their burdens; the commenter noted that this is not mentioned in our proposal; the commenter said that although the proposal would allow States to run the CALPUFF model, it fails to specify how they might consider the results.

One State commenter opposed the use of visibility modeling for the purpose of informing the choice of control option, stating that it is unnecessary, confusing and without adequate standards or guidance for implementation. The State added that the analysis of control options in the BART process should yield the greatest, most cost-effective control efficiency for NO_X and SO_2 at or above our presumptive levels of control. Moreover, it said that analysis of the degree of visibility improvement may result in very small increments of visibility improvements within Class I areas from an individual source, thus tilting the selection to the lower control efficiency option. The State added that we should remove this criterion from the analysis to ensure that the best cost effective controls will result. Another State agency said that modeling impacts should not be considered in BART determinations because they are not considered when determining BACT for the PSD program.

A variety of commenters pointed out several areas where the guidelines should be improved or clarified in regard to the degree of visibility improvement determination:

- We should clarify that the analysis is pollutant-specific (e.g., the modeling evaluation of a BART control option for SO_2 reduction should not be combined with the modeling evaluation of a BART control option for NO_X.)
- We should clarify that only the closest Class I area must be modeled.
- We should describe CALPUFF as one possible model to use, rather than as the only model that may be used.
- States and sources should have the flexibility to perform multiple modeling runs based on different levels of available control.
- Predicted visibility improvements that are imperceptible should be given no weight in determining the level of control that constitutes BART.
- States should be allowed to establish a factor for the required degree of visibility improvement.

Several industry and utility commenters expressed concern about using allowable emission rates to predict visibility impacts for BART control options; they argued that actual emission rates should be considered instead. Three commenters stated that we must make clear that States should use emission rates that will be permissible at the time BART controls take effect, not current emissions rates.

Additional comments from utilities, industry, and one State opposed the approach wherein the results from the 20 percent worst modeled days (pre- and post-control) were used to evaluate the visibility improvements expected from the various control options. Some believed this was too stringent, while others said it was not stringent enough. Two utilities added that the criteria should use the 20 percent worst days based on monitored data, not modeled data. An environmental group stated that sources should not be limited to just the worst days, but the improvements should be based upon controls reducing visibility impairment on any day. The commenter added that this rationale ignores the middle 60 percent of days in which visibility may worsen, because sources may increase emissions on these days as a trade-off for cutting emissions on the worst days. The commenter further argued that there are no data to support our assertion that improvement on the worst days means improvement on other days. They noted that default ''natural condition'' deciview values for Class I areas in our natural conditions guidance exist only for the average of the 20 percent best and worst days. The commenter added that we used the average default natural conditions (for the 20 percent best days) for the visibility impairment analysis, but there are no default ''maximum 24-hour'' values in the guidance.

Nine commenters supported implementation of visibility improvement thresholds, which were not proposed in 2004. A State commenter said it is unclear how the modeled net visibility improvement would be specifically utilized in the BART analysis, and requested a target level of improvement or a de minimis level by which to measure improvement. Two industry commenters suggested alternatives to the 24-hour value. One said that setting a threshold for comparison, as in the BART-applicability test, is more appropriate than the overall comparison of the 20 percent worst case days, and that the threshold for comparison should be on at least a daily average (or longer), not an hourly average, due to the possibility of short-term spikes based on certain meteorological conditions.

These commenters also said that a comparison of the number of days above or below a certain threshold is preferable since below a certain threshold, the impacts of visibility are not perceptible; unlike concentration

levels of certain pollutants (*i.e.*, ozone) which do not have a threshold below which there are no effects, there are concentration levels of particulate below which there is no visibility impact. They also asserted that comparing the number of days would allow for a more complete picture of how controls would potentially improve visibility. As noted previously, a small number of unusual meteorological conditions can produce significant spikes on a single day or days. Since the overall goal of the regional haze rule is long-term visibility improvement, they said that a comparison of the total number of days exceeding a threshold over multiple years will provide a better overall indicator of visibility improvement. One commenter suggested that if we retain the maximum 24-hour value for the visibility impairment analysis, we should at least allow the use of only 1 year, rather than 5 years, of meteorological data. That would simplify the modeling and would lessen the chance that one day with atypical, extreme conditions would dictate the result.

One FLM supported our proposed method to determine visibility improvement associated with installation of BART. However, with regard to the use of hourly data instead of 24 hour data for the degree of visibility improvement assessment, another FLM said that while hourly model data are, by their nature, less reliable in predicting actual conditions, a measure that reports the total number of hours above a given threshold would still be a useful measure of the long-term effect of BART control. They said we should require States to report a combination of measures of the visibility improvement expected from BART. Such measures would be the change in the 20 percent worst days as well as a metric that examines the amount of time during a year that the source's visibility impact would exceed a threshold with and without BART.

Another utility commenter added that, if a BART control option would result in no perceptible improvement in visibility at a Class I area, then it is not a cost-effective option. This commenter said that based on Pitchford and Malm (1994) [50] and Henry (2002) [51] a 2 deciview threshold of perception would be appropriate, with a 1 deciview threshold providing a margin of safety. Another commenter said that we should clarify that visibility improvement differences among BART control options should be considered insignificant if the differences are less than the perceptibility threshold level, which should be set in excess of 1 deciview. Other commenters said the minimum threshold should be 1 deciview.

Final Rule. We disagree with the comment that modeling should not be part of a BART review because it is not considered for BACT. CAA section 169A(g)(2) clearly requires an evaluation of the expected degree of improvement in visibility from BART controls. All five statutory factors, including cost-effectiveness and expected visibility improvement, should be reflected in the level of BART control that the State implements. We believe that modeling, which provides model concentration estimates that are readily converted to deciviews, is the most efficient way to determine expected visibility improvement.

For the purposes of determining visibility improvement, States may evaluate visibility changes on a pollutant-specific basis. If expected improvement is shown from the various control choices, the State can weigh the results with the other four BART determination factors when establishing BART for a particular source. For example, a State can use the CALPUFF model to predict visibility impacts from an EGU in examining the option to control NO_X and SO_2 with SCR technology and a scrubber, respectively. A comparison of visibility impacts might then be made with a modeling scenario whereby NO_X is controlled by combustion controls. If expected visibility improvements are significantly different under one control scenario than under another, then a State may use that information, along with information on the other BART factors, to inform its BART determination.

Even though the visibility improvement from an individual source may not be perceptible, it should still be considered in setting BART because the contribution to haze may be significant relative to other source contributions in the Class I area. Thus, we disagree that the degree of improvement should be contingent upon perceptibility. Failing to consider less-than-perceptible contributions to visibility impairment would ignore the CAA's intent to have BART requirements apply to sources that contribute to, as well as cause, such impairment.

Although we are not requiring States to use allowable emission rates to predict the anticipated future visibility impacts of BART controls, we disagree that daily average actual emission rates should be used to make this assessment. Emissions from a source can vary widely on a day to day basis; during peak operating days, the 24-hour actual emission rate could be more than double the daily average. On the other hand, in the long term, estimating visibility impacts based on allowable emission rates for every hour of the year may unduly inflate the maximum 24 hour modeled impairment estimate from a BART-eligible source. The emissions estimates used in the models are intended to reflect steady-state operating conditions during periods of high capacity utilization. We do not generally recommend that emissions reflecting periods of start-up, shutdown, and malfunction be used, as such emission rates could produce higher than normal effects than would be typical of most facilities. Where States have information on a source's daily emissions, an emission rate based on the maximum actual emissions over a 24 hour period for the most recent five years may be a more appropriate gauge of a source's potential impact as it would ensure that peak emission conditions are reflected, but would likely not overestimate a source's potential impact on any given day. We have accordingly included this change to the final guidelines. We recommend that the State use the highest 24-hour average actual emission rate, for the most recent three or five year period of meteorological data, to characterize the maximum potential benefit.

Because each Class I area is unique, we believe States should have flexibility to assess visibility improvements due to BART controls by one or more methods, or by a combination of methods, and we agree with the commenters suggestions to do so. We believe the maximum 24-hour modeled impact can be an appropriate measure in determining the degree of visibility improvement expected from BART reductions (or for BART applicability). We have pointed out, however, that States should have flexibility when evaluating the fifth statutory factor. A State is encouraged to account for the magnitude, frequency, and duration of the contributions to visibility impairment caused by the source based on the natural variability of meteorology. These are important elements to consider as they would provide useful information on both the short term peak impact and long term average assessments which are critical in making the visibility assessment.

We agree with the suggestion that the use of a comparison threshold, as is

[50] Pitchford, M. and Malm, W., ''Development and Applications of a Standard Visual Index,'' Atmospheric Environment, V. 28, no. 5, March 1994.

[51] Henry, R.C. ''Just-Noticeable Differences in Atmospheric Haze'', Journal of the Air & Waste Management Association, 52:1238–1243, October 2002.

done for determining if BART-eligible sources should be subject to a BART determination, is an appropriate way to evaluate visibility improvement. However, we believe the States have flexibility in setting absolute thresholds, target levels of improvement, or de minimis levels since the deciview improvement must be weighed among the five factors, and States are free to determine the weight and significance to be assigned to each factor. For example, a 0.3, 0.5, or even 1.0 deciview improvement may merit stronger weighting in one case versus another, so one ''bright line'' may not be appropriate.

In addition, comparison thresholds can be used in a number of ways in evaluating visibility improvement (e.g. the number of days or hours that the threshold was exceeded, a single threshold for determining whether a change in impacts is significant, a threshold representing an x percent change in improvement, etc.). In our example modeling analysis of a hypothetical source,[52] we used three different 24-hour thresholds (1.0, 0.5, and 0.1 deciviews) and examined the number of days that those thresholds were exceeded for a source with a 90 percent change, for example, in SO_2 emissions (i.e. 10,000 TPY and 1,000 TPY). The number of days that the thresholds were exceeded in the 10,000 TPY case was substantial, and the visibility improvement due to the reduction in emissions was dramatic (i.e. the number of days exceeding the thresholds dropped considerably).[53]

Other ways that visibility improvement may be assessed to inform the control decisions would be to examine distributions of the daily impacts, determine if the time of year is important (e.g. high impacts are occurring during tourist season), consideration of the cost-effectiveness of visibility improvements (i.e. the cost per change in deciview), using the measures of deciview improvement identified by the State, or simply compare the worst case days for the pre- and post-control runs. States may develop other methods as well.

5. In What Sequence Should Alternatives Be Assessed in Step 5 of the BART Determination?

Background. Both the 2001 proposal and the 2004 reproposal requested comments on two options for evaluating the ranked options. Under the first option, States would use a sequential process for conducting the impacts analysis, beginning with a complete evaluation of the most stringent control option. If a State determines that the most stringent alternative in the ranking does not impose unreasonable costs of compliance, taking into account both average and incremental costs, the analysis begins with a presumption that this level is selected. Under this option, States would then proceed to consider whether energy and non-air quality environmental impacts would justify selection of an alternative control option. If there are no outstanding issues regarding energy and non-air quality environmental impacts, the analysis is ended and the most stringent alternative is identified as the ''best system of continuous emission reduction.'' If a State determines that the most stringent alternative is unacceptable due to such impacts, this approach would require them to document the rationale for this finding for the public record. Then, the next most-effective alternative in the listing becomes the new control candidate and is similarly evaluated. This process would continue until the State identifies a technology which does not pose unacceptable costs of compliance, energy and/or non-air quality environmental impacts.

We also requested comment on an alternative decision-making approach that would not begin with an evaluation of the most stringent control option. For example, States could choose to begin the BART determination process by evaluating the least stringent technically feasible control option or by evaluating an intermediate control option drawn from the range of technically feasible control alternatives. Under this approach, States would then consider the additional emissions reductions, costs, and other effects (if any) of successively more stringent control options. Under such an approach, States would still be required to (1) display all of the options and identify the average and incremental costs of each option; (2) consider the energy and non-air quality environmental impacts of each option; and (3) provide a justification for adopting the technology selected as the ''best'' level of control, including an explanation of its decision to reject the other control technologies identified in the BART determination.

In selecting a ''best'' alternative, the proposed guidelines included a discussion on whether the affordability of controls should be considered. As a general matter, for plants that are essentially uncontrolled at present and emit at much greater levels per unit of production than other plants in the category, we believe it is likely that additional control will be cost-effective. The proposed guidelines noted, however, that we recognize there may be unusual circumstances that justify taking into consideration the conditions of the plant and the economic effects of requiring the use of a given control technology. These effects would include effects on product prices, the market share, and profitability of the source. We did not intend, for example, that the most stringent alternative must always be selected if that level would cause a plant to shut down, while a slightly lesser degree of control would not have this effect.

Comments. We received comments supporting both of the approaches for evaluating ranked control alternatives. Many commenters, including commenters from State agencies, were supportive of the first approach. Comments from State air quality agencies were strongly supportive of this approach. These commenters believed that this approach is consistent with past approaches by States for considering control options for case-by-case determinations, is well understood by all parties, and thus easier to implement. The first approach also was strongly supported in comments from environmental organizations and private citizens. Some comments noted that the plain terminology ''best'' suggests that there must be a sound reason for not using the most stringent control level.

Many comments from industrial trade organizations were critical of the first approach and believed that any requirement to use this approach would reduce State discretion because this approach, in the judgment of the commenters, would amount to use of the most stringent alternative as a default. Some of these comments asserted that the approach in option 1 would shift the BART analysis away from a cost-benefit approach mandated by the CAA towards a BACT-like technology analysis. Other commenters believed that EPA should recognize that BART, as a control requirement for retrofitting existing sources, should differ from BACT or other controls for new equipment. A number of comments, in supporting the second approach, believed that this approach provides greater consideration of the incremental cost of each succeeding option.

Final rule. In the final guidelines, we have decided that States should retain the discretion to evaluate control options in whatever order they choose, so long as the State explains its analysis of the CAA factors. We agree with

[52] CALPUFF Analysis in Support of the June 2005 Changes to the Regional Haze Rule, U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

[53] Ibid.

commenters who asserted that the method for assessing BART controls for existing sources should consider all of the statutory factors.

6. What Should Be the Presumptive Limits for SO_2 and NO_X for Utility Boilers?

Background. In the 2004 reproposal, we proposed that States, as a general matter, should require EGUs greater than 250 MW in size at power plants larger than 750 MW to control 95 percent of their SO_2 emissions, or control to within an SO_2 emission range of 0.1 to 0.15 lb/mmBtu. We also proposed to establish a rebuttable presumption that States should impose these BART SO_2 limits on all EGUs greater than 250 MW, regardless of the size of the power plant at which they are located.

For NO_X, we proposed that sources currently using controls such as SCRs to reduce NO_X emissions during part of the year should be required to operate those controls year-round. For power plants without post-combustion controls, we proposed to establish a presumptive emissions limit of 0.20 lbs/mmbtu for EGUs greater than 250 MW in size. We requested comment on the rate of NO_X emissions that can be achieved with combustion modifications on specific types of boilers. Many commenters responded both in favor and in opposition to these proposed BART presumptive limits.

Comments. A number of utility groups said the presumptive SO_2 emissions control approach inappropriately ignores the need for a visibility impact evaluation which is required in step 5 of the proposed case-by-case BART engineering analysis. They said that setting presumptive limits infringes on a state's authority to establish BART on a case-by-case basis considering not only visibility improvement, but the other statutory factors as well. The commenters said that visibility is both Class I area and source specific, which is the reason Congress gave the States the lead role and discretion in the BART program to determine which sources need to install or upgrade controls. Through the use of presumptions and default values, however, our prescriptive process, as proposed, would make the installation of maximum controls more likely without regard to visibility benefits. Instead, they argued, we should give the states maximum flexibility to use the five statutory factors in their BART determinations. Commenters said sources must be allowed to assess the visibility improvements of a variety of control options.

Several utilities raised concern that sources with existing controls should not be required to meet the presumptive limits without the chance to evaluate the degree of visibility improvement expected from the additional emission reduction requirements. They said that if a source can demonstrate a reduction in visibility impairment below the specified threshold (whether that threshold is our currently proposed 0.5 deciview or an alternative level) with less stringent controls, then neither we nor States should impose, by default, more stringent reduction requirements.

Commenters from industry, utilities, and States said that we had not indicated what previously-controlled sources must do to comply with BART, while we had determined what controls are necessary for uncontrolled sources. They were concerned that the guidelines would lead States to require previously-controlled sources to remove the controls and replace them with even newer controls at great cost and very little, if any, improvement in emission levels and visibility in Class I areas. Commenters added that States should be able to use their discretion to determine whether additional controls are needed.

Some commenters were concerned that the proposed rule would require some plants to install SCR to meet the NO_X control level proposed, as the potential retrofit of SCR technology for the BART determination may be supported by the degree of visibility improvement expected. They said that the guidelines indicate that if a State finds that a source's visibility contribution warrants the installation of SCR, then SCR may be imposed. The commenter added, however, that the guidelines also need to provide for instances where the visibility condition warrants a lesser control level than what would be achieved by advanced combustion control; the commenter claimed there was reference to this concept in the preamble but not the guidelines.

Final rule. In these guidelines, we are finalizing specific presumptive limits for SO_2 and NO_X for certain EGUs based on fuel type, unit size, cost effectiveness, and the presence or absence of pre-existing controls. The presumptive limits finalized in today's rulemaking reflect highly cost-effective technologies as well as provide enough flexibility for States to take particular circumstances into account.

The presumptive limits apply to EGUs at power plants with a total generating capacity in excess of 750 MW. As explained in greater detail below, for these sources we are establishing a BART presumptive emission limit for coal-fired EGUs greater than 200 MW in size without existing SO_2 control. These EGUs should achieve either 95 percent SO_2 removal, or an emission rate of 0.15 lb SO_2/mmBtu, unless a State determines that an alternative control level is justified based on a careful consideration of the statutory factors. For NO_X, we are establishing a set of BART presumptive emission limits for coal-fired EGUs greater than 200 MW in size based upon boiler size and coal type, and based upon whether selective catalytic reduction (SCR) or selective noncatalytic reduction (SNCR) are already employed at the source. See section d. below for a table listing those specific limits. Based on our analysis of emissions from power plants, we believe that applying these highly cost-effective controls at the large power plants covered by the guidelines would result in significant improvements in visibility and help to ensure reasonable progress toward the national visibility goal.

States, as a general matter, must require owners and operators of greater than 750 MW power plants to meet these BART emission limits. We are establishing these requirements based on the consideration of certain factors discussed below. Although we believe that these requirements are extremely likely to be appropriate for all greater than 750 MW power plants subject to BART, a State may establish different requirements if the State can demonstrate that an alternative determination is justified based on a consideration of the five statutory factors.

In addition, while States are not required to follow these guidelines for EGUs located at power plants with a generating capacity of less than 750 MW, based on our analysis detailed below, we believe that States will find these same presumptive controls to be highly-cost effective, and to result in a significant degree of visibility improvement, for most EGUs greater than 200 MW, regardless of the size of the plant at which they are located. A State is free to reach a different conclusion if the State believes that an alternative determination is justified based on a consideration of the five statutory factors. Nevertheless, our analysis indicates that these controls are likely to be among the most cost-effective controls available for any source subject to BART, and that they are likely to result in a significant degree of visibility improvement.

The rest of this section discusses these presumptive limits for SO_2 and NO_X for EGUs and the additional

visibility impact and cost-effectiveness analyses we have performed since proposal of the guidelines in 2004.

a. Visibility Analysis for SO_2 and NO_X Emissions From EGUs. In the 2004 reproposal, our preliminary CALPUFF modeling [54] suggested that controlling a single 250 MW EGU at a 90 percent level would improve visibility substantially from that source. Based on the expected degree of improvement in visibility and the use of highly effective control technologies that are available for sources of this capacity and greater, we concluded that the specific control levels in the proposal were appropriate. Even at that level of control however, our analysis indicated that emissions from the source might still cause a perceptible impact on visibility.

Following comments that we had ignored the need to consider the degree of improvement in visibility which could reasonably be anticipated from the use of the presumptive control technologies, we undertook a more comprehensive modeling analysis of the anticipated visibility impacts of controlling large EGUs. Based on this modeling analysis, we anticipate that a majority of the currently uncontrolled EGUs at power plants covered by the guideline are predicted to have 24-hour maximum impacts of greater than a change of 2 or 3 deciviews.[55] Our modeling examples included scenarios that were representative of typical EGUs, but, in our first hypothetical run #1, we conservatively assumed SO_2 emissions of 10,000 tons per year (TPY) and NO_X emissions of approximately 3,500 TPY.[56] Such levels of emissions are well below those that may be expected of an uncontrolled 200 MW EGU. The number of days during any year that such sources are predicted to have visibility impacts of greater than 0.5 deciviews or even 1.0 deciview were 29 days and 12 days on average, respectively, at 50 km from a hypothetical Class I area in the East; if the 98th percentile were considered, there would be five days above a 1.0 deciview change.

The modeled emission rates in the example were conservative; for much larger EGUs with capacities of 750 MW or more, and emission rates much higher than those which were modeled, visibility degradation is expected to be far worse. Clearly there is a substantial degree of visibility improvement which is likely from emission reductions at these sources.

Although we are confident that the EGUs for which we are establishing presumptive limits each have a significant impact on visibility at one or more Class I areas, a State retains the option and flexibility to conduct its own analysis or allow a source to demonstrate that it should not be subject to BART (based on its visibility effects).

b. BART Presumptive Limits for SO_2 From Coal-Fired Units. For currently uncontrolled coal-fired EGUs greater than 200 MW in size located at power plants greater than 750 MW, we are establishing a presumptive BART limits of 95 percent SO_2 removal, or an emission rate of 0.15 lb SO_2/mmBtu. We are not establishing a presumptive limit for EGUs with existing post-combustion SO_2 controls or for EGUs that burn oil.

In 2004, we proposed presumptive limits for SO_2 of 95 percent control or a comparable performance level of 0.1 to 0.15 lbs per million BTU as controls that would be achievable and cost-effective. We requested comment on the removal effectiveness of flue gas desulfurization (''FGD'' or ''scrubber'' controls) for various coal types and sulfur content combinations. Having considered the comments received, we have determined that there is ample data to support the determination that the BART presumptive limits outlined in today's action are readily achievable by new wet or semi-dry FGD systems across a wide range of coal types and sulfur contents based on proven scrubber technologies currently operational in the electric industry.[57]

We agree with the commenters who stated that our dual recommendation provided equity across sources burning coals of varying sulfur content. We believe the presumptive limits provide enough flexibility that absent unique circumstances, any BART-eligible coal-fired EGU will be able to achieve one of the limits with a new FGD system. We expect that BART-eligible EGUs burning medium to high sulfur coal will be able to achieve a removal efficiency of 95 percent in a cost effective manner by utilizing various wet FGD technologies, and that those EGUs burning lower sulfur coals could meet the emission limit of 0.15lb/mmBtu in a cost effective manner by utilizing dry FGD technologies. As described below, EPA's unit specific economic modeling showed that the majority of BART eligible units greater than 200 MW can meet the presumptive BART limit at a cost of $400 to $2000 per ton of SO_2 removed.

Some commenters expressed concerns that the proposed limits were too stringent in particular for: (1) EGUs less than 750 MW in size, (2) EGUs burning low sulfur coals, and (3) EGUs burning lignite coals. However, numerous examples exist of smaller EGUs and EGUs burning low sulfur or lignite coals achieving these SO_2 limits at reasonable cost.[58] We recognize that semi-dry FGD systems are most commonly utilized on units burning lower sulfur coals and are not typically designed for removal efficiencies of 95 percent or greater. However, we believe that most of these EGUs can readily achieve the presumptive emission rate limit of 0.15 lb SO_2/mmBtu. An analysis of EPA's RACT/BACT/LEAR Clearinghouse Dry FGD cost effectiveness data ranged from $393 to $2132 per ton SO_2 removed, with an average cost effectiveness of $792 per ton.[59]

We received a few comments expressing the belief that the presumptive limits should be more stringent, given that BART emission limits will not be fully implemented until 2013 or 2014. We recognize that while some scrubber units currently achieve reductions greater than 95 percent, not all units can do so. The individual units that currently achieve greater than 95 percent control efficiencies do not necessarily represent the wide range of unit types across the universe of BART-eligible sources. An analysis of the Department of Energy's U.S. FGD Installation Database supports our belief that 95 percent removal efficiencies would be obtainable by all types of EGUs burning medium and high sulfur coal by 2014, including BART-eligible EGUs. In addition, we note that the presumption does not limit the States' ability to consider whether a different level of control is appropriate in a particular case. If, upon examination of an individual EGU, a State determines that a different emission limit is appropriate based upon its analysis of the five factors, then the State may apply a more or less stringent limit.

Our analysis of presumptive BART limits accounted for variations in existing SO_2 controls. We accordingly considered (1) coal-fired EGUs without

[54] *Summary of Technical Analyses for the Proposed Rule,* Mark Evangelista, U.S. Environmental Protection Agency, April 12, 2004, Docket No. OAR–2002–0076.

[55] CALPUFF Analysis in Support of the the June 2005 Changes to the Regional Haze Rule, U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

[56] Ibid.

[57] *Technical Support Document for BART SO_2 Limits for Electric Generating Units,* Memorandum to Docket OAR 2002–0076, April 1, 2005.

[58] Ibid.

[59] *Summary of BART Source Analyses,* Memorandum from Bill Balcke and Doran Stegura, Perrin Quarles Associates, Inc., to Chad Whiteman, EPA March 24, 2003. See 2001 emissions data in BART AR file, attached.

existing SO_2 controls, and (2) coal-fired EGUs with existing SO_2 controls. This analysis consisted of the following key elements: (1) Identification of all potentially BART-eligible EGUs, and (2) technical analyses and industry research to determine applicable and appropriate SO_2 control options, (3) economic analysis to determine cost effectiveness for each potentially BART-eligible EGU, and (4) evaluation of historical emissions and forecast emission reductions for each potentially BART-eligible EGU.[60]

We identified 491 potentially BART-eligible coal-fired units based on the following criteria: (1) The unit was put in place between August 7, 1962 and August 7, 1977, and (2) the unit had the potential to emit more than 250 tons annually of SO_2. Our assessment of potential controls included various industry case studies, technical papers, public comments, BACT analyses, and historical Acid Rain emissions data. Our analysis is described in detail in the TSD.[61]

We calculated cost effectiveness and projected SO_2 emission reductions on a per unit basis based on removal efficiencies of 90 percent for dry FGD systems, in particular spray dry lime systems, and 95 percent for wet FGD systems, in particular limestone forced oxidation systems. Based on our analysis, the average cost effectiveness for controlling all BART-eligible EGUs greater than 200 MW without existing SO_2 controls was estimated to $919 per ton of SO_2 removed. Moreover, the range of costs effectiveness numbers demonstrates that the majority of these units can meet the presumptive limits at a cost of $400 to $2000 per ton of SO_2 removed.

FIGURE 1

Unit capacity (MW)	Tons (K) of SO_2 emitted in 2001	Percent of BART eligible coal-fired unit's 2001 emissions	Calculated average cost effectiveness for MW grouping ($/ton SO_2 removed)	Percent of estimated removable BART SO_2 emissions from coal-fired units*
<50 MW	26	0.4	1962	0.9
50–100 MW	93	1.4	2399	1.6
100–150 MW	171	2.5	1796	2.2
150–200 MW	235	3.5	1324	3.4
200–250 MW	253	3.8	1282	3.1
250–300 MW	281	3.2	1128	4.0
>300 MW	5712	85.2		84.8
All Units	6707	100	984	100
BART Units (>200MW)	6246	92.2	919	91.9

In establishing presumptive BART limits, we were cognizant of the fact that upgrading an existing scrubber system is typically considered more cost effective than constructing a new scrubber system. However, due to the diverse and complex nature of upgrading existing FGD systems (scrubber type, reagents, online year, absorber characteristics, current operating procedures, etc.), there is no single solution or standard appropriate for all EGUs. As a result, we are not including specific numerical presumptive limits for EGUs with pre-existing scrubbers. However, for scrubbers currently achieving removal efficiencies of at least 50 percent, we recommend States evaluate a range of scrubber upgrade options available for improving the SO_2 removal performance of existing units. There are numerous scrubber enhancements available to upgrade the average removal efficiencies of all types of existing scrubber systems, and the guidelines contains a discussion of the options that States should evaluate in making BART determinations for EGUs with existing scrubbers.

The guidelines do not require EGUs with existing FGD systems to remove these controls and replace them with new controls, but the guidelines do state that coal fired EGUs with existing SO_2 controls achieving removal efficiencies of less than 50 percent should consider constructing a new FGD system to meet the presumptive limits of 95 percent removal or 0.15 lb/mmBtu in addition to evaluating the suite of upgrade options. For these EGUs, the suite of available ''upgrades'' may not be sufficient to remove significant SO_2 emissions in a cost effective manner, and States may determine that these EGUs should be retrofitted with new FGD systems.

c. BART Limits for SO_2 From Oil-Fired Units. We are not establishing a presumptive BART limit for SO_2 from oil-fired EGUs. The guidelines state that the most appropriate control option for oil-fired EGUs, regardless of capacity, is to set limits on the sulfur content of the fuel oil burned in the unit.

Commenters suggested EPA evaluate two primary control options for BART oil-burning units: (1) Sulfur content fuel oil limitations, and (2) flue gas desulfurization systems. We have been unable to find any FGD application in the U.S. electric industry on an oil-fired unit. As a result, our analysis for oil-fired units focused on benchmarking previously imposed fuel oil restrictions on the electric industry and (2) a regional economic analysis of switching from high sulfur to low sulfur fuel oil.

Our study of currently imposed fuel oil restrictions on the electric industry suggested that all BART-eligible EGUs currently have some sort of imposed sulfur content or emission rate limitation. Of the 74 BART-eligible oil-burning EGUs, 32 currently have sulfur fuel oil restrictions of less than 1 percent, and 67 have some sort of sulfur content limitation. In addition, our economic analysis suggests that switching to low sulfur fuel oil is a cost effective method in reducing SO_2 emission from oil fired units.

As approximately 43 percent of the BART eligible oil units currently have a sulfur content limitation that is either equivalent to, or more stringent than, one percent sulfur by weight, the guidelines require States to consider a one percent or lower sulfur by weight fuel oil restriction on all BART eligible EGUs as part of their BART analysis, and recommends that States establish appropriate and sustainable sulfur content fuel oil restrictions, taking into

[60] Ibid.

[61] Ibid.

account fuel oil availability. States should accordingly evaluate a one percent sulfur content limitation as a starting point of their BART determination for oil-fired EGUs subject to BART.

d. BART Presumptive Limits for NO_X From Coal-fired Units. In the 2004 reproposal, in discussing NO_X controls on EGUs, we explained that there are two somewhat distinct approaches to reducing emissions of NO_X at existing sources. One is to use combustion controls (including careful control of combustion air and low-NO_X burners). The other approach is removal technology applied to the flue gas stream (such as SCRs and SNCRs).

For EGUs currently using controls such as SCRs or SNCRs to reduce NO_X during part of the year, we are establishing a presumption that use of these same controls year-round is BART. (Some commenters supported year-round operation of these controls. One commenter suggested the cost of year-round operation of SCRs would be significant. However, our analysis showed year-round operation of existing SCRs compared to operation during the 5-month ozone season only to be highly cost effective (average cost-effectiveness of $170 per ton).) Although only a few BART-eligible sources currently have SNCRs installed, we note that States may wish to consider SCR as an alternative to annual operation of SNCR in light of the relatively high operating costs associated with SNCR.

For sources without post-combustion controls (*i.e.*, SCRs and SNCRs), we are establishing a presumption as to the appropriate BART limits for coal-fired units based on boiler design and coal type. These presumptions apply to EGUs greater than 200 MW at power plants with a generating capacity greater than 750 MW and are based on control strategies that are generally cost-effective for all such units.

In 2004 we noted that, unlike the methods for controlling SO_2 (which fall within a fairly narrow range of cost effectiveness and control efficiencies), the removal efficiencies and costs associated with the control techniques for NO_X vary considerably, depending on the design of the boiler and the type of coal used. In response to comments on the proposal, we have performed additional analyses of all individual BART-eligible coal-fired units [62] and our analyses indicated that both cost effectiveness and post-control rates for NO_X do depend largely on boiler design and type of coal burned. Based on these analyses, we believe that States should carefully consider the specific NO_X rate limits for different categories of coal-fired utility units, differentiated by boiler design and type of coal burned, set forth below as likely BART limits.

In today's action, EPA is setting presumptive NO_X limits for EGUs larger than 750 MW. EPA's analysis indicates that the large majority of the units can meet these presumptive limits at relatively low costs. Because of differences in individual boilers, however, there may be situations where the use of such controls would not be technically feasible and/or cost-effective. For example, certain boilers may lack adequate space between the burners and before the furnace exit to allow for the installation of over-fire air controls. Our presumption accordingly may not be appropriate for all sources. As noted, the NO_X limits set forth here today are presumptions only; in making a BART determination, States have the ability to consider the specific characteristics of the source at issue and to find that the presumptive limits would not be appropriate for that source.

The table below indicates the types of boilers installed at the 491 BART-eligible coal-fired EGUs. Dry-bottom wall-fired boiler units and tangentially-fired boiler units make up a large majority of the total BART-eligible EGUs.

TABLE 1.—POPULATION OF BART-ELIGIBLE COAL-FIRED EGUS

Boiler type	Number	Number	Number
	All units	Units > 200 MW	Units > 200 MW at 750 MW plants
Cyclone	56	35	19
Cell Burner	35	35	29
Dry Bottom—Wall fired	188	121	77
Dry Bottom Turbo-fired	14	10	4
Stoker	5	0	0
Tangentially-fired	186	164	112
Wet Bottom	6	5	5
Other	1	0	0
Total BART-eligible coal-fired EGUs	491	370	246

For all types of boilers other than cyclone units, the limits in Table 2 are based on the use of current combustion control technology. Current combustion control technology is generally, but not always, more cost-effective than post-combustion controls such as SCRs. For cyclone boilers, SCRs were found to be more cost-effective than current combustion control technology;[63] thus the NO_X limits for cyclone units are set based on using SCRs. SNCRs are generally not cost-effective except in very limited applications and therefore were not included in EPA's analysis. The types of current combustion control technology options assumed include low NO_X burners, over-fire air, and coal reburning.

We are establishing presumptive NO_X limits in the guidelines that we have determined are cost-effective for most units for the different categories of units below, based on our analysis of the expected costs and performance of controls on BART-eligible units greater than 200 MW. We assumed that coal-fired EGUs would have space available to install separated over-fire air. Based on the large number of units of various boiler designs that have installed separated over-fire air, we believe this assumption to be reasonable. It is

[62] See *Technical Support Document for BART* NO_X Limits for Electric Generating Units and Technical Support Document for BART NO_X Limits for Electric Generating Units Excel Spreadsheet, Memorandum to Docket OAR 2002–0076, April 15, 2005.

[63] The current combustion control technology EPA analyzed for cyclone units is coal reburning.

possible, however, that some EGUs may not have adequate space available. In such cases, other NO_X combustion control technologies could be considered such as Rotating Opposed Fire Air (''ROFA''). The limits provided were chosen at levels that approximately 75 percent of the units could achieve with current combustion control technology. The costs of such controls in most cases range from just over $100 to $1000 per ton. Based on our analysis, however, we concluded that approximately 25 percent of the units could not meet these limits with current combustion control technology. However, our analysis indicates that all but a very few of these units could meet the presumptive limits using advanced combustion controls such as rotating opposed fire air (''ROFA''), which has already been demonstrated on a variety of coal-fired units. Based on the data before us, the costs of such controls in most cases are less than $1500 per ton.

TABLE 2.—PRESUMPTIVE NO_X EMISSION LIMITS FOR BART-ELIGIBLE COAL-FIRED UNITS [64]

Unit type	Coal type	NO_X presumptive limit (lb/mmbtu) [65]
Dry-bottom wall-fired	Bituminous	0.39
	Sub-bituminous	0.23
	Lignite	0.29
Tangential-fired	Bituminous	0.28
	Sub-bituminous	0.15
	Lignite	0.17
Cell Burners	Bituminous	0.40
	Sub-bituminous	0.45
Dry-turbo-fired	Bituminous	0.32
	Sub-bituminous	0.23
Wet-bottom tangential-fired	Bituminous	0.62

TABLE 3.—AVERAGE COST-EFFECTIVENESS OF NO_X CONTROLS FOR BART-ELIGIBLE COAL-FIRED UNITS

Unit type	Coal type	Number units nation-wide	National average ($/ton)
Dry-bottom wall-fired	Bituminous	114	1229
	Sub-bituminous	66	576
	Lignite	3	1296
Tangential-fired	Bituminous	105	567
	Sub-bituminous	72	281
	Lignite	9	614
Cell Burners	Bituminous	32	1287
	Sub-bituminous	3	1021
Dry-turbo-fired	Bituminous	7	775
	Sub-bituminous	7	599
Wet-bottom	Bituminous	6	378
Cyclones (with SCR)	All	56	900

The advanced combustion control technology we used in our analysis, ROFA, is recently available and has been demonstrated on a variety of unit types. It can achieve significantly lower NO_X emission rates than conventional over-fire air and has been installed on a variety of coal-fired units including T-fired and wall-fired units. We expect that not only will sources have gained experience with and improved the performance of the ROFA technology by the time units are required to comply with any BART requirements, but that more refinements in combustion control technologies will likely have been developed by that time. As a result, we believe our analysis and conclusions regarding NO_X limits are conservative.[66] For those units that cannot meet the presumptive limits using current combustion control technology, States should carefully consider the use of advanced combustion controls such as ROFA in their BART determination.

A detailed discussion of our analysis is in the docket.[67] For data on emissions and existing control technology in use at the BART-eligible EGUs, we used EPA's Clean Air Markets Division database.[68]

C. Selective Catalytic Reduction (''SCR'') and Cyclone Units

We also analyzed the installation of SCRs at BART-eligible EGUs, applying SCR to each unit and fuel type. The cost-effectiveness was generally higher than for current combustion control technology except for one unit type, cyclone units. Because of the relatively high NO_X emission rates of cyclone units, SCR is more cost-effective. Our analysis indicated that the cost-effectiveness of applying SCR on coal-fired cyclone units is typically less than $1500 a ton, and that the average cost-

[64] No Cell burners, dry-turbo-fired units, nor wet-bottom units burning lignite were identified as BART-eligible, thus no presumptive limit was determined. Similarly, no wet-bottom units burning sub-bituminous were identified as BART-eligible.

[65] These limits reflect the design and technological assumptions discussed in the technical support document for NO_X limits for these guidelines, *e.g.*, EPA assumed space would be available for over-fire air. See *Technical Support Document for BART NO_X Limits for Electric Generating Units* and *Technical Support Document for BART NO_X Limits for Electric Generating Units Excel Spreadsheet,* Memorandum to Docket OAR 2002–0076, April 15, 2005.

[66] See *Technical Support Document for BART NO_X Limits for Electric Generating Units and Technical Support Document for BART NO_X Limits for Electric Generating Units Excel Spreadsheet,* Memorandum to Docket OAR 2002–0076, April 15, 2005.

[67] Id.

[68] Reporting requirements for the Acid Rain Program and NO_X SIP Call affected sources, see 40 CFR 75 subpart G (parts 7562–64), and EPA Clean Air Markets Division Web site, data and maps page *(http://www.epa.gov/airmarkets).*

effectiveness is $900 per ton.[69] As a result, we are establishing a presumptive NO_X limit for cyclone units based on the use of SCR. For other units, we are not establishing presumptive limits based on the installation of SCR. Although States may in specific cases find that the use of SCR is appropriate, we have not determined that SCR is generally cost-effective for BART across unit types.

Oil and Gas-Fired Units

For oil-fired and gas-fired units, we believe that installation of current combustion control technology is highly cost-effective and should be considered in determining BART for these sources. We performed an analysis of BART-eligible oil and gas-fired units similar to the analysis done for coal-fired units. Our analysis indicated that a number of units can make significant reductions in NO_X emissions which are cost-effective through the application of current combustion control technology.[70] However, for a number of units, the use of combustion controls does not appear to be cost-effective. As a result, we determined that it would be inappropriate to establish a general presumption regarding likely BART limits. As a result, the guidelines only indicate that States should consider the installation of current combustion control technology on oil and gas-fired units.

IV. How Does Today's Rule Affect States Options for Using Alternative Strategies in Lieu of Source-by-Source BART?

Background

Over the past several years, there have been a number of rule makings and court decisions on the subject of BART and BART-alternative programs. In order to understand today's actions, it is useful to again review the regulatory and litigation history, with a specific focus on BART-alternative issues.

As noted in part I of this preamble, the 1999 regional haze rule included provisions for BART, codified at 40 CFR 51.308(e), and in definitions that appear in 40 CFR 51.301. Among these provisions was section 308(e)(2), allowing States to implement cap and trade programs, or other alternative programs, in lieu of BART. Section 308(e)(2) provided that trading program alternatives must be demonstrated to achieve greater reasonable progress than BART, and provided the general parameters for making this demonstration. Of particular relevance, section 308(e)(2) directed States, in the course of estimating emissions reductions anticipated from source-by-source BART, to determine what comprises BART based on the four non-visibility factors, and then estimate visibility improvements based on the application of BART to all sources subject to BART. In other words, section 308(e)(2) indicated that states should use what has since been termed a ''group BART'' approach to estimating the source-by-source BART benchmark, for comparison to the alternative program. Section (e)(2) did not prescribe the specific criteria to be used to compare the progress estimated from source-by-source BART to that anticipated from the trading program. The preamble discussion indicated that the comparison should be based on both emission reductions and visibility improvement, but did not provide further specificity. See 64 FR at 35741–35743.

Specific criteria for making the comparison to programs was proposed in the BART Guidelines (40 CFR 51 App. Y) in 2001. These criteria—sometimes referred to as the ''better-than-BART test'' consist of the following. First, if the geographic distribution of emissions reductions from the two programs is expected to be similar, the comparison can be made based on emissions alone. Second, if the distribution of emissions reductions is anticipated to be significantly different, then a two-pronged visibility improvement test is employed. The first prong is that the alternative program must not result in a degradation of visibility at any Class I area. The second prong is that the alternative program must result in greater visibility improvement overall, based on an average across all affected Class I areas. See 66 FR 38133.

In 2002, the D.C. Circuit decided American Corn Growers. The court in that decision invalidated ''the BART provisions'' on the basis that EPA had improperly constrained State authority by requiring them to bifurcate visibility from the other statutory factors when making BART determinations, and by specifying that visibility impairment should be considered on a group basis when determining whether a BART eligible source is subject to BART. 291 F.3d 1, 8.

Because EPA's policy of allowing alternative programs to BART was not at issue in American Corn Growers, the decision contained no discussion of how such alternative programs would be compared to BART—neither the step of estimating emissions from source-by-source BART, nor the criteria for the actual comparison (*i.e.*, the test). Therefore, EPA interpreted the court's vacature of the BART provisions to apply to the source-by-source BART regulations under 40 CFR 51.308(e)(1). Accordingly, in our May 2004 reproposal of the BART guidelines, we did not propose any changes in section 308(e)(2), and we retained the section on trading programs in the guidelines (Appendix Y) as that section was proposed in 2001.

In June 2004, in the Supplemental Notice of Proposed Rulemaking (SNPR) for the Clean Air Interstate Rule (CAIR), we proposed to conclude that the CAIR will achieve greater reasonable progress than would BART for SO_2 and NO_X at BART-eligible EGUs in CAIR affected States and therefore may be treated as a program in lieu of BART for those sources. In doing so, we discussed regional haze rule section 308(e)(2) as precedent for the policy of allowing trading programs to substitute for BART.[71] However, noting that the CAIR trading program affected only one category of BART-eligible sources (EGUs), rather than all BART-eligible categories as envisioned for State-developed BART-alternative programs under section 308(e)(2), we proposed adding a 308(e)(3) applicable only to CAIR. This section would provide that states that comply with the CAIR by subjecting EGUs to the EPA administered cap and trade program may consider BART satisfied for NO_X and SO_2 from BART-eligible EGUs. In the CAIR SNPR and supporting documentation,[72] we provided analyses demonstrating that CAIR would achieve greater emission reductions than BART, and would make greater reasonable progress according to the two-pronged visibility test previously proposed in the BART guidelines.

In February 2005, in *CEED* v. *EPA,* the D.C. Circuit invalidated a BART-alternative program developed by the Western Regional Air Partnership (WRAP), which was also based on a requirement of group-BART analysis in setting source-by-source benchmark. It is important to note that the two-pronged better-than-BART test was not

[69] See *Technical Support Document for BART NO_X Limits for Electric Generating Units and Technical Support Document for BART NO_X Limits for Electric Generating Units Excel Spreadsheet,* Memorandum to Docket OAR 2002–0076, April 15, 2005.

[70] *Id.*

[71] Section 308(e)(2) was based, in turn, on the precedent set by our interpretation of CAA 169A(b)(2) in a single BART-source context—see 64 FR 35739, citing *Central Arizona Water Conservation District,* 990 F.2d 1531 (1993).

[72] ''Supplemental Air Quality Modeling Technical Support Document (TSD) for the Clean Air Interstate Rule (CAIR), May, 2004.'' *http://www.epa.gov/cair/pdfs/saqmtsd.pdf.*

at issue in CEED, as neither the States nor EPA had employed that test in determining that the WRAP's program achieved greater progress than BART. The issue on which the court based its decision was not how the two programs were compared, but how States were required to estimate reductions from source-by-source BART in order to make the comparison. The implications of this case to today's action are discussed in more detail below.

Finally, on March 10, 2005 we promulgated the final CAIR. In the final CAIR, we presented refined and updated analyses continuing to show that CAIR makes greater progress than BART. We concluded at that time that we should defer a final ''better than BART'' determinations until (1) the source-by-source BART guidelines for EGU were promulgated, and (2) the criteria for comparing alternatives to BART were also finalized. We are taking both of those actions today, and, as explained below, are therefore also making our final determination that CAIR achieves greater progress than BART and may be used by States as a BART substitute.

Final Criteria for Comparing Visibility Progress of an Alternative Program to BART

Proposed Rule. As noted, the criteria for determining if an alternative measure achieves greater reasonable progress than BART (also known as the ''better than BART'' test or the two-pronged visibility test) were first proposed in the 2001 BART guideline proposal and reproposed in the identical form in the 2004 BART guidelines reproposal. The test appeared as an element of the guideline's overview of the steps involved in developing a trading program consistent with regional haze rule section 308(e)(2).

Specifically, the guidelines provided that States could first look at the geographic distribution of emissions under the trading program. ''If [the] distribution of emissions is not substantially different than under BART, and greater emissions reductions are achieved, then the trading program would presumptively achieve ''greater reasonable progress.'' (69 FR at 25231). If the distribution of emissions is expected to be different, then States are directed to conduct an air quality modeling study. The guidelines then provide that

''[t]he modeling study would demonstrate ''greater reasonable progress'' if both of the following two criteria are met:

—Visibility does not decline in any Class I area, and

—Overall improvement in visibility, determined by comparing the average differences over all affected Class I areas

Comments Received

Several commenters stated that the trading criteria contained in the proposed BART guidelines were, along with other parts of the guidelines, beyond EPA's authority to impose under the CAA.

Several State commenters asked for clarification of what should be considered a significantly different geographic distribution of emission reductions, for purposes of proceeding to the two-pronged visibility test.

One comment, submitted by environmental groups in response to our preliminary application of the two-pronged test to the CAIR in the CAIR rulemaking, goes to the permissibility of that test in general and is therefore relevant to the finalization of the test. Specifically, these commenters stated that because section 169A(b)(2)(A) requires BART for an eligible source which may reasonably be anticipated to cause or contribute to any impairment of visibility in any Class I area, EPA is without basis in law or regulation to base a better-than-BART determination on an analysis that uses averaging of visibility improvement across different Class I areas.

Final Action. We are amending the regional haze rule to incorporate the two- prong visibility test as it was previously proposed in the BART guideline proposals. Specifically, we are adding the test to the rule provisions at section 51.308(e)(3).

The EPA has the authority to prescribe this methodology under its general rulemaking authority provided by CAA section 301(a), and under CAA sections 169A(4) and 169(e). The latter provisions require EPA to promulgate regulations to assure reasonable progress towards the national visibility goal and to assure compliance with the requirements of section 169A, which include the requirements for BART under section 169A(b)(2)(A), and to promulgate such measures as may be necessary to carry out these regulations. The EPA has determined that source-by-source BART need not be required when it is not necessary to meet reasonable progress because greater progress can be achieved by an alternative means. The D.C. Circuit in CEED upheld this interpretation of the BART provisions' relationship to the broader reasonable progress requirements of the Act. 398 F.3d at 660. In order to assure that such alternative programs meet the reasonable progress goals of the CAA, EPA has the authority, and perhaps a duty, to promulgate regulations governing how that determination is made.

Moreover, these requirements for making the ultimate comparison between an alternative program and BART do not affect in any way how states make BART determinations or how they determine which sources are subject to BART. It is in those areas where the Act and legislative history indicate that Congress evinced a special concern with insuring that States would be the decision makers. Nothing in American Corn Growers or CEED suggests that those cases rendered EPA's rulemaking authority under section 169A(a)(4) completely inoperable in any BART context.

With respect to the use of average overall improvement, we explained in the CAIR NFR preamble that we disagree with comments that CAA section 169A(b)(2)'s requirement of BART for sources reasonably anticipated to contribute to impairment at any Class I area means that an alternative to the BART program must be shown to create improvement at each and every Class I Area. Even if a BART alternative is deemed to satisfy BART for regional haze purposes, based on average overall improvement as opposed to improvement at each and every Class I Area, CAA section 169A(b)(2)'s trigger for BART based on impairment at any Class I area remains in effect, because a source may become subject to BART based on ''reasonably attributable visibility impairment'' at any area. See 40 CFR 51.302. In addition, within a regional haze context, not every measure taken is required to achieve a visibility improvement at every class I area. BART is one component of long term strategies to make reasonable progress, but it is not the only component. The requirement that the alternative achieves greater progress based on the average improvement at all Class I areas assures that, by definition, the alternative will achieve greater progress overall. Though there may be cases where BART could produce greater improvement at one or more class I areas, the no-degradation prong assures that the alternative will not result in worsened conditions anywhere than would otherwise exist, and the possibility of BART for reasonably attributable visibility protects against any potential ''hot spots.'' Taken together, the EPA believes these factors make a compelling case that the proposed test properly defines ''greater reasonable progress.'' The EPA anticipates that regional haze implementation plans will also contain measures addressing other sources as

necessary to make progress at every mandatory Federal Class I area.

We are therefore finalizing the test criteria in the same form in which they were proposed as part of the BART guidelines. We also recognize that the test criteria leave some terms and conditions undefined, and we believe States and Tribes should retain the discretion to reasonably interpret and apply these terms as appropriate to the context of the particular program at issue.

First, in the proposed test we did not specify the time period which should serve as the starting point for comparison under the first prong. That is, we did not specify whether potential degradation should be determined in relation to visibility conditions existing at the time of the proposed program, or in relation to base case visibility projections for the time of program implementation. While either option is, we believe, reasonable, in this rulemaking we have used the future projected base case, for the following reasons.

The underlying purpose of both prongs of the test is to assess whether visibility conditions at Class I areas would be better with the alternative program in place than they would without it. The first prong ensures that the program does not cause a decline in visibility at any particular Class I area. It addresses the possibility that the alternative program might allow local increases in emissions which could result in localized degradation. The second prong assesses whether the alternative program produces greater visibility improvement in the aggregate than would source specific BART.

In both cases, the logical reference point is visibility conditions as they are expected to be at the time of program implementation but in the absence of the program. This insures that the visibility improvements or degradations determined are due to the programs being compared—source-specific BART and the cap-and-trade alternative—and not to other extrinsic factors. For example, if large increases in wild land fires are expected, due to accumulation of fuel from past forest management practices, a degradation of visibility from current conditions may be expected. It would be irrational to disapprove an alternative program because of a modeled degradation from current conditions, where that degradation is actually anticipated because of smoke from such fires—sources which are not subject to the CAA BART provisions. By comparing the alternative to future projected baseline conditions, such extrinsic variables are accounted for. We are thus able to ascertain (to the extent possible where future projections are concerned) whether visibility under the alternative would decline at any Class I area, all other things being equal.

Therefore, in applying the test to the CAIR, we used the future (2015) projected baseline. We believe, however, that States should have discretion in determining the most appropriate baseline for this prong of the test, as long as the State's method is reasonable.

Second, although the proposed test indicated that dispersion modeling should be used to determine visibility differences for the worst and best 20 percent of days, the guideline did not specify the relationship between the worst and best days and the two prongs of the test. We believe that each prong of the test should ideally be based on an examination of both the worst and best 20 percent of days. Thus, under the first prong, visibility must not decline at any one Class I area on either the best 20 percent or the worst 20 percent days [73] as a result of implementing the alternative program; and, under the second prong both the best and worst days should be considered in determining whether the alternative program produces greater average improvement.

Third, the proposed guidelines did not define ''affected'' Class I areas for purposes of the comparison. In applying the test to the CAIR, we considered all federal mandatory Class I areas in the contiguous 48 States for which data was available. The principal Class I areas affected by the CAIR are those in the eastern U.S., therefore we calculated average improvement separately for the eastern areas, but also considered affects at all Class I areas nationally. We believe this was appropriate for a federally mandated program of the scope and magnitude of the CAIR. However, this may not be necessary for every BART-alternative program developed by States in the future, especially if proposed programs are limited to smaller geographic areas or are limited to source categories having significantly less widespread impacts than EGUs. In such circumstances, it may be reasonable for the States and Tribes involved to develop criteria for ''affected'' Class I areas. For example, the affected region could be considered to be the States and Tribes involved in the trading program as well as immediately adjacent States, or Class I areas within adjacent States that are within some defined distance of participating States.

With respect to comments on the degree of difference in the geographic distribution of emissions necessary to trigger application of the two prong test, we believe it is not necessary for EPA to define that in the rule. For our CAIR analysis, we explained in the SNPR that the fact that CAIR would produce greater emissions reductions than BART in most States, but less reductions than BART in a few States, was sufficient reason to employ the two pronged visibility test, 69 FR 32704. For other programs developed by States, a State would have the ability to make a reasonable decision as to whether there was a sufficient basis to make the demonstration that an alternative program would be better than BART based on modeling of the emissions distributions alone, or whether the State should proceed with the two-pronged visibility test. The State's discretion is subject as always to the condition that it must be reasonably exercised, and must be supported by adequate documentation of the analyses.

Finally, on a related issue, we note that in a separate rule making to follow soon after today's action, we will be soliciting comments on whether there might be other means of demonstrating that an alternative program makes greater reasonable progress than BART, in addition to the two-pronged visibility test we are finalizing in today's action. Such other means might take into account additional policy considerations, as well as the relative degree of visibility improvement of the two programs.

C. Final Determination That CAIR Makes Greater Reasonable Progress Than BART

Proposal. As noted in the background section above, in both the CAIR SNPR, and NFR, we discussed the proposed approach of allowing States to treat CAIR as an in-lieu-of BART program for EGUs in CAIR-affected States. In both actions, we presented analyses based on emission projections and air quality modeling showing that CAIR will achieve greater reasonable progress

[73] The regional haze rule requires States to establish reasonable progress goals for each Class I area that provide for improvement in visibility for the most impaired days and ensure no degradation in visibility for the most impaired days. The reasonable progress test in the regional haze rule remains as a separate test from better than BART. The SIPs must contain measures to achieve the reasonable progress goal; such measures could include not only stationary source programs such as BART but also programs to address emissions from other types of sources. The no degradation (on the 20 percent best days) component of the reasonable progress test must still be applied to the final future year emissions control strategy. This does not directly impact the conclusions of the better than BART test.

towards the national visibility goal than would BART for affected EGUs. These analyses were conducted according to the criteria for making such ''better than BART'' determinations which had been proposed in the BART guidelines, and which have now been finalized in the regional haze rule at 40 CFR 51.308(e)(3), as discussed above in section IV.B. Below, we briefly recap these prior analyses. See 69 FR 32684, 32702–32707 and 70 FR 25162, 25299–25304 and associated Technical Support Documents [74] for full details.

Scenarios Examined

The CAIR is applicable to 28 States and the District of Columbia and requires levels of SO_2 and NO_X emissions reductions based on those achievable on a highly cost effective basis from EGUs. BART, on the other hand, is applicable nationwide and covers 25 additional industrial categories, as well as EGUs, of a certain vintage. In our comparison, we sought to determine whether the CAIR cap and trade program for EGUs will achieve greater reasonable progress than would BART for EGUs only. Therefore, the relevant scenarios to examine were (1) SO_2 and NO_X emissions from all EGUs nationwide after the application of BART controls to all BART-eligible EGUs (''nationwide BART''), and (2) SO_2 and NO_X emissions from all EGUs nationwide after the emissions reductions attributable to CAIR in the CAIR region and application of BART controls to all BART-eligible EGUS outside the CAIR region (''CAIR + BART''). The latter scenario reflects the fact that source-by-source BART would remain a federal requirement outside the CAIR region, unless and until it is replaced by some other state or federally required program. Thus, in order to more accurately project CAIR emissions, it is necessary to impose BART controls outside the CAIR region, to account for potential load and emission shifting among EGUs.

In addition to these two scenarios, a third was used—the future base case in the absence of either program. This third scenario was used to ensure that CAIR would not cause degradation from otherwise existing conditions. See section IV.B above for a discussion of why the future baseline is an appropriate comparison point for the first prong of the ''better than BART'' test.

At the SNPR stage, a ''CAIR + BART'' scenario was not available, as the only projections available at that time had been developed for other purposes. Thus, the ''CAIR'' scenario used then, which was based on the Clear Skies proposal, was imperfect for purposes of this analysis in that it assumed SO_2 reductions on a nationwide basis (rather than in the CAIR region only) and assumed NO_X reductions requirements in a slightly different geographic region than covered by the proposed CAIR.

For the CAIR NFR, we redid the emissions projections for both the Nationwide BART and CAIR + BART in the West scenarios. For the former, we increased the number of BART-eligible units included by lowering the assumed threshold for BART applicability from 250 MW capacity for both NO_X and SO_2 to 100 MW for SO_2 and 25 MW for NO_X, and by reviewing the list of potentially BART-eligible EGUs. For the latter scenario, we produced emissions projections based on application of CAIR-level emission reductions in the States proposed for inclusion in the CAIR in the SNPR.

Emission Projections. For the analyses in both the SNPR and NFR, we used the Integrated Planning Model (IPM) to estimate emissions expected from the scenarios described above. Tables 1 and 2 present the results from the SNPR and NFR, respectively.

TABLE 1.—EGU SO_2 AND NO_X EMISSIONS—AS PROJECTED IN CAIR SNPR

[In thousands of tons per year]

	2015 Base case EGU emissions	2015 ''CAIR''	2015 Modeled nationwide e Bart	Additional reduction from ''CAIR'' (nationwide BART minus ''CAIR'')
Nationwide SO_2	9,081	5,260	7,012	1,752
Nationwide NO_X	3,950	2,248	2,781	533

TABLE 2.—EGU SO_2 AND NO_X EMISSIONS—AS PROJECTED IN CAIR NFR

[In thousands of tons per year]

	2015 Base case EGU emissions	2015 CAIR + BART	2015 Nationwide BART	Additional reduction from CAIR + BART (nationwide BART minus CAIR+BART)
Nationwide SO_2	9,084	4,735	7,162	2,427
Nationwide NO_X	3,721	1,816	2,454	638

As can be seen in the numbers in the right-most column, CAIR produced far superior emission reductions to nationwide BART, and the superiority of CAIR over BART increased between the SNPR and NFR projections, when the scenarios were corrected to more accurately reflect the anticipated reality in 2015.

Air Quality Modeling Results. The proposed ''better-than-BART'' test provided that if the distribution of emission reductions is substantially the same under the alternative program as under BART, then the demonstration can be made simply by comparing emission reductions. If, however, the distribution is significantly different,

[74] *Supplemental Air Quality Modeling Technical Support Document (TSD) for the Clean Air Interstate Rule (CAIR),* May, 2004. *http://www.epa.gov/cair/pdfs/saqmtsd.pdf;* Demonstration that CAIR Satisfies the 'Better-than-BART' Test as proposed in the Guidelines for Making BART Determinations, EPA Docket Number OAR–2003–0054–YYYY, March 2005. *http://www.epa.gov/cair/pdfs/finaltech04.pdf.*

then visibility modeling is required in order to apply the two pronged test previously described. As noted above, CAIR emission reductions were vastly greater than those under BART. However, because there were some differences in the geographic distribution of reductions on a state-by-state basis, in order to be conservative we conducted air quality modeling and evaluated CAIR under the two pronged test.

Specifically, using the above emissions projections, we completed numerous air quality modeling runs and postprocessing calculations to determine the impacts of emissions and emissions control strategies on visibility in Class I areas. We quantified the impacts of the CAIR and BART controls on visibility impairment by comparing the results of the future-year (2015) base case model runs with the results of the CAIR + BART and nationwide BART control strategy model runs. We quantified visibility impacts on the 20 percent best and 20 percent worst visibility days.

For the SNPR modeling, we used the Regional Modeling System for Aerosols and Deposition (REMSAD) model to calculate these visibility impacts. This modeling used base year meteorology from 1996. Complete year ambient monitoring data, which is necessary to model future improvements in visibility, was available for 1996 from Inter-agency Monitoring of Protected Visual Environments (IMPROVE) monitors located at 44 Class I areas—13 within the CAIR region and 31 outside of it.

For the NFR modeling, we used the Community Multiscale Air Quality (CMAQ) model. The base year meteorology used in the CMAQ modeling was 2001. This later base year enabled us to look at more Class I areas, because there were more IMPROVE monitors which had complete year data for 2001 than there had been in 1996. Specifically, 81 of the 110 IMPROVE sites have complete ambient air quality data for 2001. Moreover, because in some cases a given IMPROVE monitor is designated as representing more than one Class I area, these 81 sites are representative of 116 Class I areas. Twenty nine of the 116 are in the East (east of 100 degrees longitude) and 87 are in the West.

Using the modeling results, we then applied the two prong better than BART test which had been defined in the proposed BART rule. As explained above, under the first prong, visibility must not decline at any Class I area, as determined by comparing the predicted visibility impacts at each affected Class I area under the (CAIR) trading program with future base case visibility conditions. Under the second prong, overall visibility, as measured by the average improvement at all affected Class I areas, must be better under the trading program than under source-specific BART. The future year air quality modeling results were used to make this demonstration.

The visibility impacts of the CAIR + BART scenario were compared to base case 2015 visibility conditions (without CAIR or BART) to determine whether the CAIR resulted in a degradation of visibility at any Class I area. We also compared these visibility impacts with the visibility impacts of nationwide BART implementation, to assess whether the proposed CAIR would result in greater average visibility improvement than nationwide BART.

The CAIR passed the first prong by not causing a degradation of visibility at any Class I area, either in the West or nationally. This was true in both the SNPR and NFR modeling. The visibility projections for each Class I area are presented in the respective TSD's.[75]

The overall results are presented in tables 3 and 4 below, representing the SNPR and NFR modeling respectively.

TABLE 3.—AVERAGE VISIBILITY IMPROVEMENT IN 2015 VS. 2015 BASE CASE (DECIVIEWS) AS MODELED USING REMSAD IN CAIR SNPR

Class I areas	"CAIR" Scenario		Nationwide BART	
	East [76]	National	East	National
20 percent Worst Days	2.0	0.7	1.0	0.4
20 percent Best Days	0.7	0.2	0.4	0.1

TABLE 4.—AVERAGE VISIBILITY IMPROVEMENT IN 2015 VS. 2015 BASE CASE (DECIVIEWS) AS MODELED USING CMAQ IN CAIR NFR

Class I Areas	CAIR + BART in West		Nationwide BART	
	East [76]	National	East	National
20 percent Worst Days	1.6	0.5	0.7	0.2
20 percent Best Days	0.4	0.1	0.2	0.1

As can be see from the tables, although the models produced different absolute values, in both cases CAIR produced significantly greater visibility improvement than nationwide BART. For example, looking at the 20 percent worst days at Eastern Class I areas (the areas most influenced by the CAIR, since it is an eastern program), in both cases the visibility improvements from CAIR were at least twice as great as under nationwide BART (*i.e.*, in the SNPR, 2.0 deciviews compared to 1.0 deciviews improvement, and in the NFR, 1.6 deciviews compared to 0.7 deciviews improvement).

This historical overview is given in the interest of providing a more complete understanding of the analyses presented at various stages in the CAIR rule making progress. In the end, however, it is the analyses presented in the CAIR NFR on which we are basing our determination that CAIR makes greater reasonable progress towards the national visibility goals than does nationwide BART. Therefore, these NFR results are examined more closely in the ''Final Action'' section below, in light of additional emissions projections we

[75] See Footnote [74], Supra.

[76] Eastern Class I areas are those in the CAIR affected states, except areas in west Texas which are considered western and therefore included in the national average, plus those in New England

have conducted to insure that changes to the CAIR and BART rules made subsequent to the CAIR NFR do not affect that determination.

Comments Received and EPA's Responses

Although many comments were received regarding our proposal to determine that CAIR makes greater reasonable progress than BART, nearly all of them related either to the terms of the test itself, or to policy and legal implications of allowing CAIR required reductions to substitute for source-by-source BART. These are addressed in sections B (above) and D (below) respectively. One commenter asserted, with respect to modeling presented in the SNPR, that the improvement of CAIR compared to source-specific BART is so slight it may be potentially within the margin of error, and therefore insufficient for the better than BART demonstration, or for assuring that no hot spots will occur.

The EPA disagrees that the difference between CAIR and BART in the SNPR visibility projections was not significant. The visibility results presented in the NFR continue to show that the CAIR cap and trade program with BART in the non-CAIR region provides considerably more visibility improvement compared to nationwide BART (for EGUs only). The NFR modeling results show that the average visibility improvement from CAIR on the 20 percent worst days at 29 Eastern Class I areas is 1.6 deciviews (dv) compared to only a 0.7 dv improvement from nationwide BART controls. In the ''better than BART'' TSD we have provided modeling results for 116 individual Class I areas. The modeling shows that CAIR will not create any ''hot spots.'' On the 20 percent worst days, all of the Eastern Class I areas show more visibility improvement under CAIR+BART than under BART alone. In many of the Western Class I areas, nationwide BART and CAIR + BART in the West provide about the same visibility benefits. (This is to be expected, since the CAIR is only applicable in the East.) While the visibility benefits are similar in the West (outside of the CAIR region), they are clearly not similar in the East, where the CAIR is predicted to achieve twice as much visibility improvement compared to BART.

Final action. The CAIR vs. BART comparison presented in the CAIR NFR was developed while both rules were under development and therefore subject to change. Since the emissions projections and air quality modeling presented in the CAIR NFR was completed, several changes were, in fact, made to the CAIR region. In addition, since that time our assumptions regarding the likely maximum BART emission reductions from EGUs also changed. Therefore, we recalculated the emission projections to see if the rule changes could possibly affect the determination that CAIR will achieve greater reasonable progress than BART.

Most significantly, the final CAIR included Arkansas, Delaware, and New Jersey only for purposes of significant contribution to ozone non-attainment by summertime NO_X emissions, whereas our modeling had been based on the assumption that these States would be included for contribution to $PM_{2.5}$ non-attainment by SO_2 and NO_X emissions. The new emission projections are based on the application of CAIR only for ozone in these States.

With respect to the nationwide BART, for SO_2 the NFR projections assumed the application of a 90 percent control or 0.10 lbs/mmBtu at uncontrolled EGUs greater than 100 MW. In the new projections, the control assumptions were changed to 95 percent or 0.15 lbs/mmbtu, to reflect the presumptive control levels in the final BART guidelines. For NO_X, the NFR projections were based on an assumed emission rate of 0.2 lbs/mmBTU at all BART eligible EGUs nationwide. The new projections are based on the assumption of combustion controls on all BART eligible units except cyclones which have SCR, and the operation of all existing SCR and SNCRs annually, instead of just in the ozone season. Finally for both pollutants, the threshold for application of controls was increased to 200 MW, to better reflect the presumptions included in the final BART guidelines.

We used IPM to project 2015 emissions given these new parameters. The results are presented in Table 5 below, which also includes the CAIR NFR projections (as reported in Table 2) for the reader's convenience.

TABLE 5.—EGU SO_2 AND NO_X EMISSIONS—AS PROJECTED IN CAIR NFR AND AS PROJECTED IN SUBSEQUENT UPDATE

(In thousands of tons per year)

	2015 CAIR + BART	2015 Nationwide BART	Additional reduction from CAIR + BART (nationwide BART minus CAIR+BART)
CAIR NFR:			
Nationwide SO_2	4,735	7,162	2,427
Nationwide NO_X	1,816	2,454	638
Updated Projections:			
Nationwide SO_2	5,042	7,953	2,911
Nationwide NO_X	2,000	2,738	738

The updated emissions estimates for both the BART and CAIR with BART in the West scenarios are slightly higher than the NFR emissions estimates, but the difference between the CAIR + BART and nationwide BART scenarios are even larger compared to the NFR determination. For SO_2, the updated CAIR + BART achieves about 2.9 million tons more reductions than updated nationwide BART in 2015. For NO_X, the updated CAIR + BART policy is projected to result in about 738,000 tons more emissions reductions than the updated BART nationwide policy in 2015. The difference between the updated CAIR + BART and nationwide BART scenarios is now larger by 484,000 tons of SO_2 reduction (*i.e.*, 2,911,000 − 2,427,000) and 100,000 tons of NO_X reduction (*i.e.* 738,000 − 638,000).

Implications of New Emission Projections for the Two-Pronged Test

The first prong of the better than BART test specifies that no degradation of visibility can occur at any Class I area. In order to be sure that Class I areas do not experience a degradation in

visibility, we examined the updated State by State emissions estimates. Compared to the 2015 base case, in the updated CAIR + BART case, there are no individual Statewide increases in either SO_2 or NO_X (except for a very small ~1,000 ton increase in NO_X in Connecticut and 2,000 ton increase in SO_2 in New Jersey).[77] That is consistent with the NFR CAIR + BART case in which no degradation was found. Consequently we have determined that no degradation would occur under the updated CAIR + BART emissions scenario.

The second prong of the better than BART test specifies a greater average visibility improvement from the CAIR trading program (CAIR + BART). The average visibility improvement from the NFR CAIR + BART case was much greater (on the 20 percent worst visibility days) than the nationwide BART case. In the scenario we modeled for the NFR, the larger visibility improvement from CAIR + BART was achieved by reducing SO_2 emissions by an additional ~2.4 million tons per year compared to nationwide BART and NO_X emissions by an additional 638,000 tons per year compared to natiowide BART.

In the updated scenario, the emissions difference between the CAIR + BART and nationwide BART cases are even larger (2.9 million tons of SO_2 and 738,000 tons of NO_X).[78] The distribution of emission reductions changed somewhat in the new projections—that is, some States saw a larger difference between CAIR and BART, while in other States the difference was smaller. The largest change was in Kentucky, where the new projections showed that emission reductions from CAIR were even greater than those from BART by an additional 200,000 tons per year. Among States where the change between projections went the other direction—that is, showing that BART reductions were closer to CAIR reductions than previously projected—the greatest changes were in Alabama and Pennsylvania, where the difference between the programs decreased by 46,000 and 45,000 tons, respectively.

Perhaps more importantly, in the new projections, there are fewer States in which BART reductions are greater than CAIR reductions. In the NFR projections, there were 12 States[79] where nationwide BART SO_2 reductions were greater than CAIR + BART reductions.[80] In those 12 States, BART emissions achieved approx. 686,000 more tons of SO_2 reduction compared to CAIR + BART. In the rest of the States, CAIR + BART achieved an additional 3.1 million tons per year of SO_2 reduction compared to BART. All told, the modeling showed that visibility improvement was greater under the CAIR than under BART on an overall average basis, both at eastern Class I areas and at all Class I areas nationally. In the new projections, CAIR + BART achieved an additional 3.4 million tons per year of SO_2 reduction compared to BART in 39 of the 48 States. In the remaining 9 States[81] BART achieved approx. 472,000 more tons of SO_2 reduction compared to CAIR + BART in the west.[82]

Due to the fact that the new projections show that the difference between CAIR and BART reductions is even greater than previously estimated, and the visibility improvements due to CAIR + BART were previously modeled to be much larger than BART, we can state with a high degree of confidence that the updated CAIR + BART scenario passes the second prong of the better than BART test.

D. Revision to Regional Haze Rule To Allow CAIR States To Treat CAIR as a BART-Substitute for EGUs

In the SNPR, we proposed that States which adopt the CAIR cap and trade program for SO_2 and NO_X would be allowed to treat the participation of EGUs in this program as a substitute for the application of BART controls for these pollutants at affected EGUs. To implement this, we proposed an amendment to the Regional Haze Rule which would add a subpart 40 CFR 51.308(e)to read as follows:

> A State that opts to participate in the Clean Air Interstate Rule cap-and-trade program under part 96 AAA–EEE need not require affected BART-eligible EGUs to install, operate, and maintain BART. A State that chooses this option may also include provisions for a geographic enhancement to the program to address the requirement under § 51.302(c) related to BART for reasonably attributable impairment from the pollutants covered by the CAIR cap and trade program.[83]

We proposed that this would be codified at 40 CFR 51.308(e)(3); however, that section now incorporates the ''better than BART'' test as discussed above. In today's action, as described below we are finalizing this provision of the rule, where it will be codified as section 308(e)(4).

The EPA's authority to treat emissions reductions required by the CAIR as satisfying BART was not affected by *CEED.* As noted, the D.C. Circuit in *CEED* upheld the proposition that EPA can approve implementation plans which rely on alternative strategies to BART, as long as greater reasonable progress is achieved. *CEED,* 398 F.3d at 660. Moreover, the CAIR program is not infected in any way with the ''group BART'' methodology held invalid by the court. That is because CAIR emission reductions levels were not based on the invalid ''group-BART'' approach or any other assumptions regarding BART, but were developed for other reasons. Specifically, the CAIR was developed to assist with attainment of the NAAQS for $PM_{2.5}$ and ozone. Had EPA not performed the comparison of CAIR to BART for visibility progress purposes, the CAIR emission reduction requirements would remain unchanged. Therefore, EPA is not imposing an invalid BART requirement on States, but rather allowing States, at their option, to utilize the CAIR cap and trade program as a means to satisfy BART for affected EGUs.

We received numerous comments on this proposal, which are summarized along with our responses in the CAIR NFR preamble at 70 FR 25300–25302 and in the Response to Comment document. To summarize our responses to some of the most important comments:

[77] The 1,000 ton per year increase in NO_X in Connecticut represents approx. 0.003 percent of the total EGU NO_X in the 2015 base case and the 2,000 ton per year increase in SO_2 in New Jersey represents approx. 0.0005 percent of the total EGU SO_2 . Since the impacts on visibility from EGU SO_2 and NO_X are generally regional in nature, we would expect this small increase to have little or no impact on visibility in any Class I area.

[78] The difference between the updated CAIR + BART and nationwide BART scenarios is larger than the difference between the modeled CAIR + BART and nationwide BART scenarios. The ''difference of the differences'' is 485,000 tons of SO_2 and 100,000 tons of NO_X.

[79] California, Delaware, Florida, Georgia, Iowa, Louisiana, Michigan, Mississippi, Missouri, North Carolina, Texas, and Wisconsin.

[80] There were also four States where BART NO_X emissions reductions were slightly higher than CAIR + BART (a total of 4,000 tons per year). Those States are Connecticut, Delaware, New Jersey, and Oklahoma.

[81] Alabama, Louisiana, Michigan, Mississippi, Missouri, New Jersey, North Carolina, Texas, Wisconsin.

[82] We performed a similar analysis using projections including the Clean Air Mercury Rule, CAMR, which was promulgated after the CAIR NFR. The CAMR emission projections show slight additional emission reductions of SO_2 and NO_X as compared to the projections CAIR + BART without CAMR, and are nearly identical in terms of geographic distribution. Therefore CAIR + BART + CAMR, like CAIR + BART, passes the two-pronged test for demonstrating greater reasonable progress than BART. This is discussed in more detail in the TSD accompanying today's action.

[83] A geographic enhancement is a method, procedure, or process to allow a broad regional strategy, such as the CAIR cap & trade program, to accommodate BART for reasonably attributable impairment. For example, it could consist of a methodology for adjusting allowance allocations at a source which is required to install BART controls.

(1) We note that we are not constraining the discretion of States to determine which sources are subject to BART and to make BART determinations. CAIR-affected States are not required to accept our determination that CAIR may substitute for BART. Under the amended rule, States simply have the option of accepting this determination.

(2) The EPA does not believe that anything in the CAA or relevant case law prohibits a State from considering emissions reductions required to meet other CAA requirements when determining whether source by source BART controls are necessary to make reasonable progress. Whatever the origin of the emission reduction requirement, the relevant question for BART purposes is whether the alternative program makes greater reasonable progress. As discussed above, EPA has determined that CAIR does so with respect to SO_2 and NO_X from EGUs in the CAIR region.

Moreover, the fact that BART and CAIR originate from different provisions of the CAA does not mean that CAIR and BART emissions reductions would be additive if BART-eligible EGUs in the CAIR program were required to install and operate BART. Such source specific control requirements would simply result in a redistribution of emission reductions, as other EGUs could buy the excess allowances generated by the installation of controls at BART units. The net result would be the same level of emission reductions, but at a higher total cost, because the ability of the market to find the most cost effective emission reductions would be constrained.

(3) Although regional haze rule section 308(e)(2) is not directly applicable, as the CAIR is covered by the special provision newly codified at section 308(e)(4), this determination is consistent with the policy contained in section 308(e)(2) requiring in-lieu of BART programs be based on emissions reductions ''surplus to reductions resulting from measures adopted to meet requirements as of the baseline date of the SIP.'' The baseline date for regional haze SIPs is 2002;[84] therefore CAIR reductions are surplus to requirements as of that year.

(4) We agree with commenters that it was premature to make a final determination whether CAIR makes greater reasonable progress than BART in the final CAIR because at that time the BART guidelines and the criteria for making such determinations had not been finalized. In today's action, both those rule makings are complete and therefore such a determination is ripe.

(5) We disagree with commenters who thought that CAIR should be considered ''better than BART'' regardless of whether a State participates in the cap and trade program. Our demonstration that CAIR makes greater reasonable progress than BART is based only on an examination of emissions reductions from EGUs under both programs. The CAIR emissions projections and modeling assumes that EGU emissions will be capped at the levels specified in the CAIR. Therefore, States that choose to meet their CAIR emission reduction requirements in a manner other than through the participation of EGUs in the CAIR cap and trade program would have to develop an appropriate demonstration that the measures they employ make greater reasonable progress than would BART for any affected source categories, if the State wanted its CAIR-required reductions to substitute for source-by-source BART.

(6) We disagree with commenters who asserted that CAIR should satisfy BART for States that are subject to CAIR only for ozone season NO_X. We explained in the final CAIR preamble that a State subject to CAIR for NO_X purposes only would have to make a supplementary demonstration that BART has been satisfied for SO_2, as well as for NO_X on an annual basis. We wish to clarify here that a State which is only subject to CAIR for NO_X, but which also chooses to participate in the CAIR trading program for both SO_2 and NO_X, may consider BART to be satisfied for both SO_2 and NO_X from EGUs. Because we modeled these States as controlling for both SO_2 and NO_X in the CAIR NFR, our better than BART demonstration presented in that action would be valid in that scenario. Conversely, if such States choose to participate only in the ozone season NO_X trading program, the updated projections presented in today's action demonstrate that BART would be satisfied for NO_X, but such states would still need to address BART for SO_2 emissions from EGUs.

(7) We noted in the final CAIR preamble that although we believe it is unlikely that a State or FLM will find it necessary to certify reasonably attributable visibility impairment at any Class I area, as a legal matter that possibility exists. That is, the determination that CAIR makes greater reasonable progress than BART is made in the context of BART for regional haze under CAA 169B, and does not preclude a finding of reasonably attributable impairment under CAA 169A. The CAIR cap and trade program does not include geographic enhancements to accommodate the situation where BART is required based on reasonable attribution at a source which participates in the trading program, but States retain the discretion to include such enhancements in their SIPs.

(8) Our determination that CAIR makes greater reasonable progress than BART for EGUs is not a determination that CAIR satisfies all reasonable progress requirements in CAIR affected States. Each State, whether in the CAIR region or not, is required to set reasonable progress goals for each Class I area within the State as required in regional haze rule section 308(d)(1), and to develop long term strategies, considering all anthropogenic sources of visibility impairing pollutants, as required by section 308(d)(3).

In setting the reasonable progress goals, the State is to consider the amount of visibility improvement needed to achieve a uniform rate of progress towards natural background conditions in the year 2064. (This uniform rate of progress is sometimes referred to as the default glide-path). The State is also to consider the statutory reasonable progress factors contained in CAA section 169A(g)(1).[85]

In doing so, we anticipate that States will take into account the degree to which CAIR emissions reductions are projected to bring visibility conditions at its Class I areas in line with the default glide path. In some States, the improvements expected from CAIR, combined with the application of the reasonable progress factors to other source sectors, may result in a determination that few additional emissions reductions are reasonable for the first long term strategy period. Nonetheless, each State is required to set its reasonable progress goals as provided by the regional haze rule and cannot assume that CAIR will satisfy all of its visibility-related obligations.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget

[84] See Memorandum from Lydia Wegman and Peter Tsirigotis, *2002 Base Year Emission Inventory SIP Planning: 8-hr Ozone, $PM_{2.5}$, and Regional Haze Programs*, November 8, 2002. *http://www.epa.gov/ttn/oarpg/t1/ memoranda/2002bye_gm.pdf.*

[85] Similar to the BART factors, the reasonable progress factors are: the cost of compliance, the time necessary for compliance, the energy and nonair quality environmental impacts of compliance, and the remaining useful life of any existing sources subject to such requirements.

(OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action,'' thus EPA has submitted this rule to OMB for review. The drafts of the rules submitted to OMB, the documents accompanying such drafts, written comments thereon, written responses by EPA, and identification of the changes made in response to OMB suggestions or recommendations are available for public inspection at EPA's Air and Radiation Docket and Information Center (Docket Number OAR–2002–0076). The EPA has prepared the document entitled ''Regulatory Impact Analysis of the Final Clean Visibility Interstate Rule or Guidelines for Best Available Retrofit Technology Determinations Under the Regional Haze Regulations'' (RIA) to address the requirements of this executive order.

1. What Economic Analyses Were Conducted for the Rulemaking?

The analyses conducted for this final rule provide several important analyses of impacts on public welfare. These include an analysis of the social benefits, social costs, and net benefits of three possible regulatory scenarios that States may follow to implement the BART rule and guidelines. The economic analyses also address issues involving requirements of the Paperwork Reduction Act (PRA), potential small business impacts, unfunded mandates (including impacts for Tribal governments), environmental justice, children's health, energy impacts, and other statutory and executive order requirements.

2. What Are the Benefits and Costs of This Rule?

The benefit-cost analysis shows that substantial net economic benefits to society are likely to be achieved due to reductions in emissions resulting from this rule. The results detailed below show that this rule would be beneficial to society, with annual net benefits (benefits less costs) ranging from approximately $1.9 to $12.0 billion in 2015. These alternative net benefits estimates reflect differing assumptions about State actions taken to implement BART and about the social discount rate used to estimate the annual value of the benefits and costs of the rule. All amounts are reflected in 1999 dollars. The range of benefits and costs reported for the BART represent estimates of EPA's assessment of State actions that will likely be taken to comply with the BART rule and guidelines.

a. Control Scenarios

Today's rule sets forth presumptive requirements for States to require EGUs to reduce SO_2 and NO_X emissions for units greater than 200 megawatts (MW) in capacity at plants greater than 750 MW in capacity that significantly contribute to visibility impairment in Federal Class I areas (national parks). The analysis conducted in the RIA presents alternative control scenarios of possible additional controls for EGUs located at plants less than 750 MW in capacity. The EPA also calculated the amount of SO_2 and NO_X emissions reductions for several illustrative scenarios that reflect alternative State actions regulating industries with non-EGU sources. The analyses conducted include three regulatory alternative scenarios that States may choose to follow to comply with BART. The alternatives include three scenarios of increasing stringency—Scenario 1, Scenario 2, and Scenario 3. A brief discussion of the these alternatives for the EGUs and all other sources follows. More details of the alternative control scenarios and associated control costs are discussed in the RIA.

i. Electric Generating Units

In the revised BART guidelines, we have included presumptive control levels for SO_2 and NO_X emissions from coal-fired electric generating units greater than 200 megawatts (MW) in capacity at plants greater than 750 MW in capacity. Given the similarities of these units to other BART-eligible coal-fired units greater than 200 MW at plants 750 MW or less, EPA's guidance suggests that States control such units at similar levels for BART. The guidelines would require 750 MW power plants to meet specific control levels of either 95 percent control or controls of 0.15 lbs/MMBtu, for each EGU greater than 200 MW, unless the State determines that an alternative control level is justified based on a careful consideration of the statutory factors.[86] Thus, for example, if the source convincingly demonstrates unique circumstances affecting its ability to cost-effectively reduce its emissions, the State may take that into account in determining whether the presumptive levels of control are appropriate for the facility. For an EGU greater than 200 MW in size, but located at a power plant smaller than 750 MW in size, States may also find that such controls are cost-effective when taking into consideration the costs of compliance in the BART analysis in applying the five factor test for the BART determination. In our analysis we have assumed that no additional controls will occur where units have existing scrubbers and that no controls will occur for oil-fired units. While these levels may represent current control capabilities, we expect that scrubber technology will continue to improve and control costs will continue to decline.

For NO_X, for those large EGUs that have already installed selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) during the ozone season, States should require the same controls for BART. However, those controls should be required to operate year-round for BART. For sources currently using SCR or SNCR for part of the year, states should presume that the use of those same controls year-round is highly cost-effective. For other sources, the guidelines establish presumptive emission levels that vary depending largely upon boiler type and fuel burned. For coal-fired cyclone units with a size greater than 200 MW, our analysis assumes these units will install SCR. For all other coal-fired units, our analysis assumed these units will install current combustion control technology. In addition, we assume no additional controls for oil and/or gas-fired steam units.

We present alternative regulatory scenarios. Scenario 2 represents our application of the presumptive limits described above to all BART eligibility EGUs greater than 200 MW. For Scenario 1, we assume that only 200 MW BART-eligible EGUs located at facilities above 750 MW capacity will comply with the SO_2 requirements and NO_X controls. In this scenario, no

[86] These levels are commonly achievable by flue gas desulfurization controls (''scrubbers'').

facilities less than 750 MW capacity are assumed to install BART controls. For Scenario 1, we assume that units with existing SCRs will operate those SCR units year round annually. In contrast in Scenario 3, we analyzed SO_2 controls equivalent to 95 percent reductions or 0.1 lbs per MMBtu on all previously uncontrolled units. NO_X controls for this most stringent scenario presume SCRs will be installed on all units greater than 100 MW capacity and combustion controls will be installed on units greater than 25 MW but less than 100 MW capacity. The EPA analyzed the costs of each BART scenario using the Integrated Planning Model (IPM). The EPA has used this model extensively in past rulemakings to analyze the impacts of regulations on the power sector.

The analysis presented assumes that BART-eligible EGUs affected by the Clean Air Interstate Rule (70 FR 25162) have met the requirements of this rule. Thus, no additional controls for EGUs beyond CAIR are anticipated or modeled for the 28 State plus District of Columbia CAIR region. In addition, we are assuming no additional SO_2 controls for sources located in States of Arizona, Utah, Oregon, Wyoming, and New Mexico or Tribal lands located in these States due to agreements made with the Western Regional Air Partnership (WRAP).

ii. Sources Other Than Electric Generating Units

As previously discussed there are 25 source categories potentially subject to BART in addition to EGUs (referred to as non-EGU source categories) as defined by the CAA. The EPA evaluated a set of SO_2 and NO_X emission control technologies available for these source categories and estimated the associated costs of control using AirControlNET. The control scenarios evaluated reflect control measure cost caps of up to $1,000 per ton (Scenario 1), $4,000 per ton (Scenario 2), and $10,000 per ton (Scenario 3). The EPA also conducted a cost analysis for control costs of up to $2,000 per ton and $3,000 per ton, and the results of this analysis are presented in the RIA. The analysis consists of applying SO_2 and NO_X controls to each non-EGU source category up to the specified cost per ton ''cap'' in each scenario. These cost per ton caps are specified in average cost terms. As control stringency is increased, the marginal costs are also estimated for each non-EGU source category. The scenarios examined are based on the costs of technologies such as scrubbers for SO_2 control, and varying types of technologies for NO_X control. Scrubbers are the most common type of SO_2 control for most non-EGU sources for each scenario, while combustion controls such as low NO_X burners (LNB) and post-combustion controls such as selective noncatalytic reduction (SNCR) and selective catalytic reduction (SCR) are commonly applicable to most of the non-EGU source categories. Combustion controls are commonly applied as part of Scenario 1, while SNCR and SCR are more commonly applied either by themselves or in combination with combustion controls as part of Scenarios 2 and 3. Analyses are not available for 8 of the 25 non-EGU source categories, because there are no available control measures for these sources or there are no sources in these categories included in the non-EGU emissions data utilized in these analyses. All of these results are estimated using a nationwide database of BART-eligible non-EGU sources that is based on information collected from Regional Planning Organizations (RPOs) in the fall of 2004.

b. Baseline and Year of Analysis

The final rule sets forth the guidelines for States and Tribes for meeting the BART requirements under the CAA and the Regional Haze Rule. The Agency considered all promulgated CAA requirements and known State actions in the baseline used to develop the estimates of benefits and costs for this rule including the recently promulgated Clean Air Interstate Rule (70 FR 25162) and the proposal to include New Jersey and Delaware in the final CAIR region for fine particulate matter (70 FR 25408). However, EPA did not include within the baseline the actions States may take to implement the ozone and $PM_{2.5}$ NAAQS standards nor the recently promulgated Clean Air Mercury Rule. No additional SO_2 controls were assumed for any EGUs within the five WRAP States of Utah, Arizona, Wyoming, Oregon or New Mexico that have existing agreements to achieve reduction goals.

In the analysis, the controls and reductions are assumed to be required in 2015, a date that is generally consistent with the expected timing of the rule. States must submit SIPs relevant to the BART requirements in January 2008. After approval of the SIP, there is a 5 year compliance date. Thus, controls are likely to be installed and in operation by the end of 2013 or the beginning of 2014 to comply with the rule. In addition, EPA had existing inventories, modeling, and base case runs for 2015 to use for the analysis. The year 2015 is used in this analysis. All estimates presented in this report represent annualized estimates of the benefits and costs of BART in 2015 rather than the net present value of a stream of benefits and costs in these particular years of analysis.

c. Cost Analysis and Economic Impacts

For the affected region, the projected annual private incremental costs of BART to the power industry (EGU source category) range from $253 to $896 million in 2015 depending upon the scenario evaluated. These costs represent the private compliance cost to the electric generating industry of reducing NO_X and SO_2 emissions that EPA believes States may require to comply with BART.

In estimating the net benefits of regulation, the appropriate cost measure is ''social costs.'' Social costs represent the welfare costs of the rule to society. These costs do not consider transfer payments (such as taxes) that are simply redistributions of wealth. The social costs of this rule for the EGU sector only are estimated to range from approximately $119 to $567 million in 2015 assuming a 3 percent discount rate. These EGU sector costs become $141 to $688 million in 2015 assuming a 7 percent discount rate.

Overall, the impacts of the BART are modest, particularly in light of the large benefits we expect. Retail electricity prices are projected to increase roughly 0.1 percent with BART in the 2015 timeframe under Scenario 2. Coal-fired generation, as well as coal production and natural gas-fired generation are projected to remain essentially unchanged as a result of this rule. It is also not expected that BART will change the composition of new generation built to meet growth in electricity demand. BART is also not expected to impact coal or natural gas prices.

For today's rule, EPA analyzed the costs for the EGU source category using the Integrated Planning Model (IPM). The IPM is a dynamic linear programming model that can be used to examine the economic impacts of air pollution control policies for SO_2 and NO_X throughout the contiguous U.S. for the entire power system. Documentation for IPM can be found in the docket for this rulemaking or at *http://www.epa.gov/airmarkets/epa-ipm.*

The EPA also conducted an analysis of State actions in requiring emission controls for BART eligible sources in the non-EGU source categories. For the nation, the projected annual private incremental costs range from $150 million to $2.24 billion for industries with affected non-EGU sources. This cost range results from different assumptions about possible actions

States may take to comply with BART and alternative discount rates of 3 and 7 percent. The non-EGU private incremental control cost estimates are assumed to approximate the social costs of the rule for the non-EGU sector. The EPA analyzed the costs to non-EGUs sources using AirControlNET. The AirControlNET is a software tool that can be used to estimate the private costs and emission reductions of air pollution control policies for SO_2, NO_X, and other criteria pollutants throughout the contiguous U.S. for all manufacturing industries and many other industries. Documentation for AirControlNET can be found in the docket for this rulemaking or at *http://www.epa.gov/ttn/ecas/AirControlNET.htm.*

In summary, the EPA estimates that the annual social costs of this rule for the EGU and non-EGU source categories range from approximately $0.3 to $2.9 billion annually, based on alternative scenarios of State actions in response to the BART rule and guidelines assuming 3 or 7 percent discount rates. Estimates are reflected in 1999 dollars.

d. Human Health Benefit Analysis

Our analysis of the health and welfare benefits associated with this rule are presented in this section. Briefly, the analysis projects major benefits from implementation of the rule in 2015. As described below, thousands of deaths and other serious health effects would be prevented. We are able to monetize annual benefits ranging from approximately $2.2 to $14.3 billion in 2015. This range reflects different assumptions about States actions in response to the BART rule and the applicable discount rate (3 percent or 7 percent).

Table IV–1 presents the primary estimates of reduced incidence of PM- and visibility-related health effects for 2015 for the regulatory control strategy the EPA expects States may follow to comply with BART. In 2015 for Scenario 2, we estimate that PM-related annual benefits include approximately 1,600 fewer premature fatalities, 890 fewer cases of chronic bronchitis, 2,200 fewer non-fatal heart attacks, 2300 fewer hospitalizations (for respiratory and cardiovascular disease combined—admissions and emergency room visits) and result in significant reductions in days of restricted activity due to respiratory illness (with an estimate of one million fewer cases) and approximately 170,000 fewer work-loss days. We also estimate substantial health improvements for children from reduced upper and lower respiratory illness, acute bronchitis, and asthma attacks.

Ozone health-related benefits are expected to occur during the summer ozone season (usually ranging from May to September in the Eastern U.S.). Since we did not conduct ozone modeling for this rulemaking, we are unable to quantify or monetize the ozone related benefits that will likely result from BART.

Table IV–2 presents the estimated monetary value of reductions in the incidence of health and welfare effects. Annual PM-related health benefits and visibility benefits are estimated to range from approximately $2.2 to $14.3 billion annually. This range of estimates reflects different scenarios about States actions in response to the BART rule and the applicable discount rate (3 percent or 7 percent). Estimated annual visibility benefits in southeastern and southwestern Class I areas range from approximately $80 million to $420 million annually in 2015. All monetized estimates are stated in 1999$. These estimates account for growth in real gross domestic product (GDP) per capita between the present and 2015. As the table indicates, total benefits are driven primarily by the reduction in premature fatalities each year. Reductions in premature mortality account for over 90 percent of total benefits.

Table IV–3 presents the total monetized net benefits for 2015. This table also indicates with a ''B'' those additional health and environmental benefits of the rule that we were unable to quantify or monetize. These effects are additive to the estimate of total benefits. A listing of the benefit categories that could not be quantified or monetized in our benefit estimates are provided in Table IV–4. We are not able to estimate the magnitude of these unquantified and unmonetized benefits. While EPA believes there is considerable value to the public for the PM-related benefit categories that could not be monetized, we believe these benefits may be small relative to those categories we were able to quantify and monetize. In contrast, EPA believes the monetary value of the ozone-related premature mortality benefits could be substantial, but we were unable to estimate the benefits for this rulemaking.

e. Quantified and Monetized Welfare Benefits

Only a subset of the expected visibility benefits—those for Class I areas in the southeastern and southwestern U.S. are included in the monetary benefits estimates we project for this rule. We believe the benefits associated with these non-health benefit categories are likely significant. For example, we are able to quantify significant visibility improvements in Class I areas in the Northeast and Midwest, but are unable at present to place a monetary value on these improvements. Similarly, we anticipate improvement in visibility in residential areas where people live, work and recreate in the nation for which we are currently unable to monetize benefits. For the Class I areas in the southeastern and southwestern U.S., we estimate annual benefits ranging from $80 to $420 million beginning in 2015 for visibility improvements. The value of visibility benefits in areas where we were unable to monetize benefits could also be substantial.

TABLE IV–1.—CLEAN AIR VISIBILITY RULE: ESTIMATED REDUCTION IN INCIDENCE OF ADVERSE HEALTH EFFECTS IN 2015 [a,b]

Health Effect	Incidence reduction		
	Scenario 1	Scenario 2	Scenario 3
PM-Related Endpoints:			
Premature mortality [c]			
Adult, age 30 and over	400	1,600	2,300
Infant, age <1 year	1	4	5
Chronic bronchitis (adult, age 26 and over)	230	890	1,300
Non-fatal myocardial infarction (adults, age 18 and older)	570	2,200	3,000
Hospital admissions—respiratory (all ages) [d]	140	510	720
Hospital admissions—cardiovascular (adults, age >18) [e]	120	450	640
Emergency room visits for asthma (age 18 years and younger)	370	1,300	1,800
Acute bronchitis (children, age 8–12)	550	2,100	3,000

TABLE IV–1.—CLEAN AIR VISIBILITY RULE: ESTIMATED REDUCTION IN INCIDENCE OF ADVERSE HEALTH EFFECTS IN 2015 [a,b]—Continued

Health Effect	Incidence reduction		
	Scenario 1	Scenario 2	Scenario 3
Lower respiratory symptoms (children, age 7–14)	6,600	25,000	36,000
Upper respiratory symptoms (asthmatic children, age 9–18)	5,000	19,000	27,000
Asthma exacerbation (asthmatic children, age 6–18)	8,100	31,000	44,000
Work loss days (adults, age 18–65)	44,000	170,000	240,000
Minor restricted-activity days (MRADs) (adult age, 18–65)	260,000	1,000,000	1,400,000

[a] Incidences are rounded to two significant digits. These estimates represent benefits from BART nationwide. The modeling used to derive these incidence estimates assumes the final CAIR program in the baseline including the CAIR promulgated rule and the proposal to include SO_2 and annual NO_X controls for New Jersey and Delaware. Modeling used to develop these estimates assumes annual SO_2 and NO_X controls for Arkansas for CAIR resulting in a slight understatement of the reported benefits and costs for BART. The recently promulgated CAMR has not been considered in the baseline for BART.
[b] Ozone benefits are expected for BART, but are not estimated for this analysis.
[c] Adult premature mortality based upon studies by Pope et al., 2002. Infant premature mortality is based upon studies by Woodruff, Grillo, and Schoendorf, 1997.
[d] Respiratory hospital admissions for PM include admissions for chronic obstructive pulmonary disease (COPD), pneumonia, and asthma.
[e] Cardiovascular hospital admissions for PM include total cardiovascular and subcategories for ischemic heart disease, dysrhythmias, and heart failure.

TABLE IV–2. ESTIMATED MONETARY VALUE OF REDUCTIONS IN INCIDENCE OF HEALTH AND WELFARE EFFECTS FOR THE CLEAN AIR VISIBILITY RULE IN 2015

[In millions of 1999$] [a,b]

	Scenario 1	Scenario 2	Scenario 3
Health Effects:			
Premature mortality [c,d]			
Adult >30 years			
3 percent discount rate	$2,330	$9,180	$13,000
7 percent discount rate	1,960	7,730	10,900
Infant <1 year	6.12	23.8	34.2
Chronic bronchitis (adults, 26 and over)	90.5	353	498
Nonfatal acute myocardial infarctions			
3 percent discount rate	49.3	189	264
7 percent discount rate	45.8	175	245
Hospital admissions for respiratory causes	1.07	4.03	5.65
Hospital admissions for cardiovascular causes	2.6	10.0	14.1
Acute bronchitis (children, age 8–12)	0.207	0.79	1.12
Lower respiratory symptoms (children, 7–14)	0.109	0.415	0.587
Upper respiratory symptoms (asthma, 9–11)	0.137	0.523	0.74
Emergency Room Visits for Asthma (age 18 years and younger)	0.106	0.362	0.51
Asthma exacerbations	0.367	1.4	1.98
Work loss days	5.56	22.4	31.5
Minor restricted-activity days (MRADs)	13.8	54.1	76.3
Welfare Effects:			
Recreational visibility, 81 Class I areas	84	239	416
Monetized Total [e]			
Base Estimate:			
3 percent discount rate	2,600+B	10,100+B	14,300+B
7 percent discount rate	2,200+B	8,600+B	12,200+B

[a] Monetary benefits are rounded to three significant digits. These estimates are nationwide with the exception of visibility benefits. Visibility benefits relate to Class I areas in the southeastern and southwestern United States. Ozone benefits are expected for BART, but have not been estimated for this analysis. The benefit estimates assume the final CAIR program in the baseline that includes the CAIR promulgated rule and the proposal to include SO_2 and annual NO_X controls for New Jersey and Delaware. Modeling used to develop the CAIR baseline estimates assumes annual SO_2 and NO_X controls for Arkansas resulting in a slight understatement of the reported benefits and costs for BART. The recently promulgated CAMR is not considered in the baseline for BART.
[b] Monetary benefits adjusted to account for growth in real GDP per capita between 1990 and the analysis year of 2015.
[c] Valuation assumes discounting over the SAB-recommended 20-year segmented lag structure described in Chapter 4. Results show 3 percent and 7 percent discount rates consistent with EPA and OMB guidelines for preparing economic analyses (U.S. EPA, 2000; OMB, 2003).
[d] Adult premature mortality based upon studies by Pope et al., 2002. Infant premature mortality based upon studies by Woodruff, Grillo, and Schoendorf, 1997.
[e] B represents the monetary value of health and welfare benefits not monetized. A detailed listing is provided in Table IV–4. Totals rounded to nearest $100 million, and totals may not sum due to rounding.

TABLE IV–3.—SUMMARY OF ANNUAL BENEFITS, COSTS, AND NET BENEFITS OF THE CLEAN AIR VISIBILITY RULE IN 2015 [a]

[Billions of 1999$]

Description	Scenario 1	Scenario 2	Scenario 3
Social costs [b]			

TABLE IV–3.—SUMMARY OF ANNUAL BENEFITS, COSTS, AND NET BENEFITS OF THE CLEAN AIR VISIBILITY RULE IN 2015 [a]—Continued

[Billions of 1999$]

Description	Scenario 1	Scenario 2	Scenario 3
3 percent discount rate	$0.4	$1.4	$2.3
7 percent discount rate	0.3	1.5	2.9
Social benefits [c, d, e]			
3 percent discount rate	2.6 + B	10.1 + B	14.3 + B
7 percent discount rate	2.2 + B	8.6 + B	12.2 + B
Health-related benefits:			
3 percent discount rate	2.5	9.8	13.9
7 percent discount rate	2.1	8.4	11.8
Visibility benefits	0.08	0.24	0.42
Net benefits (benefits-costs) [e, f]			
3 percent discount rate	2.2 + B	8.7 + B	12.0 + B
7 percent discount rate	1.9 + B	7.1 + B	9.3 + B

[a] All estimates are rounded to three significant digits and represent annualized benefits and costs anticipated for the year 2015. Estimates assume a complete CAIR program in the baseline including the CAIR promulgated rule and the proposal to include SO_2 and annual NO_X controls for New Jersey and Delaware. Modeling used to develop the CAIR baseline estimates assumes annual SO_2 and NO_X controls for Arkansas resulting in a slight understatement of the reported benefits and costs for BART. The recently promulgated CAMR is not considered in the baseline for BART.

[b] Note that costs are the annualized total costs of reducing pollutants including NO_X and SO_2 for the EGU source category in areas outside the CAIR region and excluding additional SO_2 controls for the WRAP 309 States of UT, AZ, WY, OR or NM and include costs for non-EGU sources nationwide. The discount rate used to conduct the analysis impacts the control strategies chosen for the non-EGU source category resulting in greater level of controls under the 3 percent discount rate for Scenario 1.

[c] As this table indicates, total benefits are driven primarily by PM-related health benefits. The reduction in premature fatalities each year accounts for over 90 percent of total monetized benefits in 2015. Benefit estimates in this table are nationwide (with the exception of visibility) and reflect NO_X and SO_2 reductions. Ozone benefits are expected to occur for this rule, but are not estimated in this analysis. Visibility benefits represent benefits in Class I areas in the southeastern and southwestern United States.

[d] Not all possible benefits or disbenefits are quantified and monetized in this analysis. B is the sum of all unquantified benefits and disbenefits. Potential benefit categories that have not been quantified and monetized are listed in Table IV–4.

[e] Valuation assumes discounting over the SAB-recommended 20-year segmented lag structure described in Chapter 4. Results reflect 3 percent and 7 percent discount rates consistent with EPA and OMB guidelines for preparing economic analyses (U.S. EPA, 2000; OMB, 2003).

[f] Net benefits are rounded to the nearest $100 million. Columnar totals may not sum due to rounding.

TABLE IV–4.—UNQUANTIFIED AND NONMONETIZED EFFECTS OF THE CLEAN AIR VISIBILITY RULE

Pollutant/effect	Effects not included in primary estimates—changes in:
Ozone—Health [a]	• Premature mortality [b]. • Chronic respiratory damage. • Premature aging of the lungs. • Nonasthma respiratory emergency room visits. • Increased exposure to Uvb. • Hospital Admissions : respiratory. • Emergency room visits for asthma. • Minor restricted activity days. • School loss days. • Asthma attacks. • Cardiovascular emergency room visits. • Acute respiratory symptoms.
Ozone—Welfare	• Yields for: —Commercial forests, —Fruits and vegetables, and —Commercial and noncommercial crops. • Damage to urban ornamental plants. • Recreational demand from damaged forest aesthetics. • Ecosystem functions. • Increased exposure to UVb.
PM—Health [c].	• Premature mortality: short-term exposures [d]. • Low birth weight. • Pulmonary function. • Chronic respiratory diseases other than chronic bronchitis. • Nonasthma respiratory emergency room visits. • Exposure to UVb (+/−) [e].
PM—Welfare	• Visibility in many Class I areas. • Residential and recreational visibility in non-Class I areas. • Soiling and materials damage. • Ecosystem functions. • Exposure to UVb (+/−) [e].
Nitrogen and Sulfate Deposition—Welfare	• Commercial forests due to acidic sulfate and nitrate deposition. • Commercial freshwater fishing due to acidic deposition. • Recreation in terrestrial ecosystems due to acidic deposition. • Existence values for currently healthy ecosystems.

TABLE IV–4.—UNQUANTIFIED AND NONMONETIZED EFFECTS OF THE CLEAN AIR VISIBILITY RULE—Continued

Pollutant/effect	Effects not included in primary estimates—changes in:
	• Commercial fishing, agriculture, and forests due to nitrogen deposition. • Recreation in estuarine ecosystems due to nitrogen deposition. • Ecosystem functions. • Passive fertilization due to nitrogen deposition.
Mercury Health [g]	• Incidence of neurological disorders. • Incidence of learning disabilities. • Incidence of developmental delays. • Potential reproductive effects[f]. • Potential cardiovascular effects[f], including: —Altered blood pressure regulation [f] —Increased heart rate variability [f] —Incidence of myocardial infarction [f]
Mercury Deposition Welfare [g]	• Impacts on birds and mammals (e.g., reproductive effects). • Impacts to commercial, subsistence, and recreational fishing.

[a] In addition to primary economic endpoints, there are a number of biological responses that have been associated with ozone health effects including increased airway responsiveness to stimuli, inflammation in the lung, acute inflammation and respiratory cell damage, and increased susceptibility to respiratory infection. The public health impact of these biological responses may be partly represented by our quantified endpoints.

[b] Premature mortality associated with ozone is not currently included in the primary analysis. Recent evidence suggests that short-term exposures to ozone may have a significant effect on daily mortality rates, independent of exposure to PM. EPA is currently conducting a series of meta-analyses of the ozone mortality epidemiology literature. EPA will consider including ozone mortality in primary benefits analyses once a peer-reviewed methodology is available.

[c] In addition to primary economic endpoints, there are a number of biological responses that have been associated with PM health effects including morphological changes and altered host defense mechanisms. The public health impact of these biological responses may be partly represented by our quantified endpoints.

[d] While some of the effects of short term exposures are likely to be captured in the estimates, there may be premature mortality due to short term exposure to PM not captured in the cohort study upon which the primary analysis is based.

[e] May result in benefits or disbenefits. See discussion in Section 5.3.4 for more details.

[f] These are potential effects as the literature is insufficient.

[g] Mercury emission reductions are not anticipated for BART for the EGU source category due to the cap-and-trade program promulgated for the Clean Air Mercury Rule (March 2005); however, the geographic location of mercury reductions may change as a result of this rule. EPA believes any such effects for these sources would be minimal. Mercury reductions are expected for the non-EGU source categories. The mercury reduction for BART from the non-EGU source categories is expected to be small in comparison to reductions resulting from the recently promulgated Clean Air Interstate Rule and the Clean Air Mercury Rule (March 2005).

3. How Do the Benefits Compare to the Costs of This Final Rule?

In estimating the net benefits of regulation, the appropriate cost measure is ''social costs.'' Social costs represent the welfare costs of the rule to society. The social costs of this rule for the EGU and non-EGU sector sources are estimated to range from approximately $0.3 to $2.9 billion in 2015. This range depends upon the control scenario assumed and applicable discount rates of 3 percent and 7 percent. The net benefits (social benefits minus social costs) of the rule range from approximately $1.9 + B billion or $12.0 + B billion depending upon the scenario evaluated and the applicable discount rate (3 and 7 percent) annually in 2015. Implementation of the rule is expected to provide society with a substantial net gain in social welfare based on economic efficiency criteria.

There is uncertainty surrounding the actions States are likely to take to comply with the BART guidelines. States will determine BART-eligible sources based upon CAA criteria, determine those BART-eligible sources reasonably anticipated to cause or contribute to visibility impairment in Class I areas and then apply a 5 factor test for BART determinations. The range of estimated benefits, costs, and resulting net benefits for BART reflects the uncertainty concerning States responses to BART and represents EPA's best estimates of the benefit-cost outcomes of alternative compliance scenarios.

The annualized cost of BART, as quantified here, is EPA's best assessment of the cost of actions States are likely to take to comply with the rule. The EGU portion of these costs are generated from rigorous economic modeling of changes in the power sector due to the BART rule and guidelines. This type of analysis using IPM has undergone peer review and been upheld in Federal courts. The direct cost includes, but is not limited to, capital investments in pollution controls, operating expenses of the pollution controls, investments in new generating sources, and additional fuel expenditures. The EPA believes that these costs reflect, as closely as possible, the additional costs of the BART rule and guidelines to industry. However, there may exist certain costs that EPA has not quantified in these estimates. These costs may include costs of transitioning to the BART, such as the costs associated with the retirement of smaller or less efficient EGUs, employment shifts as workers are retrained at the same company or re-employed elsewhere in the economy. Costs may be understated since an optimization model was employed that assumes cost minimization, and the regulated community may not react in the same manner to comply with the rule. Although EPA has not quantified these potential additional costs, the Agency believes that they are small compared to the quantified costs of the program on the power sector. The annualized cost estimates presented are the best and most accurate based upon available information.

The non-EGU portion of these costs are generated from extensive cost modeling based on applying illustrative regulatory scenarios to the non-EGU source categories. These costs represent potential impacts to non-EGU sources from State-imposed BART requirements. The direct cost includes, but is not limited to, capital investments in pollution controls, operating and maintenance expenses of the pollution controls, and additional fuel expenditures. The EPA believes that these costs reflect, as closely as possible, the potential additional costs of the BART rule and guidelines to industries with non-EGU sources. However, there

may exist certain costs that EPA has not quantified in these estimates. These costs may include costs of transitioning to the BART rule and guidelines, such as the costs associated with the retirement of smaller or less efficient non-EGUs, employment shifts as workers are retrained at the same company or re-employed elsewhere in the economy, and costs associated with applying both SO_2 and NO_X controls at one facility at the same time. Costs may be understated since the non-EGU cost modeling presumed a least-cost approach, and the potentially regulated community may not react in the same manner to comply with the rules. Although EPA has not quantified these costs, the Agency believes that they are small compared to the quantified costs of the program on industries with potentially affected non-EGU sources. The annualized cost estimates presented are the best and most accurate based upon available information. In a separate analysis, EPA estimates the indirect costs and impacts of higher electricity prices and costs applicable to the non-EGU sectors on the entire economy [*see* Regulatory Impact Analysis for the Final Clean Visibility Rule, Appendix A (June 2005)].

The costs presented here are EPA's best estimate of the direct private costs of the BART rule and guidelines. For purposes of benefit-cost analysis of this rule, EPA has also estimated the additional costs of BART using alternate discount rates for calculating the social costs, parallel to the range of discount rates used in the estimates of the benefits of BART (3 percent and 7 percent). Using these alternate discount rates, the social costs of BART range from $0.3 to $2.9 billion in 2015. (Note the portion of these annual costs associated with non-EGU sources represents incremental private cost estimates that are used as a proxy for the social costs of the rule.)

Every benefit-cost analysis examining the potential effects of a change in environmental protection requirements is limited to some extent by data gaps, limitations in model capabilities (such as geographic coverage), and uncertainties in the underlying scientific and economic studies used to configure the benefit and cost models. Gaps in the scientific literature often result in the inability to estimate quantitative changes in health and environmental effects. Gaps in the economics literature often result in the inability to assign economic values even to those health and environmental outcomes that can be quantified. While uncertainties in the underlying scientific and economics literatures (that may result in overestimation or underestimation of benefits) are discussed in detail in the economic analyses and its supporting documents and references, the key uncertainties which have a bearing on the results of the benefit-cost analysis of this rule include the following:

- Uncertainty concerning actions States will undertake to comply with BART;
- EPA's inability to quantify potentially significant benefit categories;
- Uncertainties in population growth and baseline incidence rates;
- Uncertainties in projection of emissions inventories and air quality into the future;
- Uncertainty in the estimated relationships of health and welfare effects to changes in pollutant concentrations including the shape of the C–R function, the size of the effect estimates, and the relative toxicity of the many components of the PM mixture;
- Uncertainties in exposure estimation; and
- Uncertainties associated with the effect of potential future actions to limit emissions.

Despite these uncertainties, we believe the benefit-cost analysis provides a reasonable indication of the expected economic benefits of the rulemaking in future years under a set of reasonable assumptions.

In valuing reductions in premature fatalities associated with PM, we used a value of $5.5 million per statistical life. This represents a central value consistent with a range of values from $1 to $10 million suggested by recent meta-analyses of the wage-risk value of statistical life (VSL) literature.[87]

The benefits estimates generated for this rule are subject to a number of assumptions and uncertainties, that are discussed throughout the Regulatory Impact Analysis document [Regulatory Impact Analysis for the Final Clean Air Visibility Rule (April 2005)]. As Table IV–2 indicates, total benefits are driven primarily by the reduction in premature fatalities each year. Elaborating on the previous uncertainty discussion, some key assumptions underlying the primary estimate for the premature mortality category include the following:

(1) EPA assumes inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. Plausible biological mechanisms for this effect have been hypothesized for the endpoints included in the primary analysis and the weight of the available epidemiological evidence supports an assumption of causality.

(2) EPA assumes all fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because the proportion of certain components in the PM mixture produced via precursors emitted from EGUs may differ significantly from direct PM released from automotive engines and other industrial sources, but no clear scientific grounds exist for supporting differential effects estimates by particle type.

(3) EPA assumes the C–R function for fine particles is approximately linear within the range of ambient concentrations under consideration. In the PM Criteria Document, EPA recognizes that for individuals and specific health responses there are likely threshold levels, but there remains little evidence of thresholds for PM-related effects in populations.[88] Where potential threshold levels have been suggested, they are at fairly low levels with increasing uncertainty about effects at lower ends of the $PM_{2.5}$ concentration ranges. Thus, EPA estimates include health benefits from reducing the fine particles in areas with varied concentrations of PM, including both regions that are in attainment with fine particle standard and those that do not meet the standard.

The EPA recognizes the difficulties, assumptions, and inherent uncertainties in the overall enterprise. The analyses upon which the BART rule and guidelines are based were selected from the peer-reviewed scientific literature. We used up-to-date assessment tools, and we believe the results are highly useful in assessing this rule.

There are a number of health and environmental effects that we were unable to quantify or monetize. A complete benefit-cost analysis of BART requires consideration of all benefits and costs expected to result from the rule, not just those benefits and costs which could be expressed here in dollar terms. A listing of the benefit categories that were not quantified or monetized in our estimate are provided in Table IV–4. These effects are denoted by ''B'' in Table IV–3 above, and are additive to the estimates of benefits.

[87] Mrozek, J.R. and L.O. Taylor, *What determines the value of a life? A Meta Analysis,* Journal of Policy Analysis and Management 21 (2), pp. 253–270.

[88] U.S. EPA. (2004). Air Quality Criteria for Particulate Matter. Research Triangle Park, NC: National Center for Environmental Assessment-RTP Office; Report No. EPA/600/P–99/002aD.

4. What Are the Unquantified and Unmonetized Benefits of BART Emissions Reductions?

Important benefits beyond the human health and welfare benefits resulting from reductions in ambient levels of $PM_{2.5}$ and ozone are expected to occur from this rule. These other benefits occur both directly from NO_X and SO_2 emissions reductions, and indirectly through reductions in co-pollutants such as mercury. These benefits are listed in Table IV–4. Some of the more important examples include: Reductions in NO_X and SO_2 emissions required by BART will reduce acidification and, in the case of NO_X, eutrophication of water bodies. Reduced nitrate contamination of drinking water is another possible benefit of the rule. This final rule will also reduce acid and particulate deposition that cause damages to cultural monuments, as well as, soiling and other materials damage.

To illustrate the important nature of benefit categories we are currently unable to monetize, we discuss two categories of public welfare and environmental impacts related to reductions in emissions required by BART: reduced acid deposition and reduced eutrophication of water bodies.

a. What Are the Benefits of Reduced Deposition of Sulfur and Nitrogen to Aquatic, Forest, and Coastal Ecosystems?

Atmospheric deposition of sulfur and nitrogen, more commonly known as acid rain, occurs when emissions of SO_2 and NO_X react in the atmosphere (with water, oxygen, and oxidants) to form various acidic compounds. These acidic compounds fall to earth in either a wet form (rain, snow, and fog) or a dry form (gases and particles). Prevailing winds can transport acidic compounds hundreds of miles, across State borders. Acidic compounds (including small particles such as sulfates and nitrates) cause many negative environmental effects, including acidification of lakes and streams, harm to sensitive forests, and harm to sensitive coastal ecosystems.

i. Acid Deposition and Acidification of Lakes and Streams

The extent of adverse effects of acid deposition on freshwater and forest ecosystems depends largely upon the ecosystem's ability to neutralize the acid. The neutralizing ability [key indicator is termed Acid Neutralizing Capacity (ANC)] depends largely on the watershed's physical characteristics: geology, soils, and size. Waters that are sensitive to acidification tend to be located in small watersheds that have few alkaline minerals and shallow soils. Conversely, watersheds that contain alkaline minerals, such as limestone, tend to have waters with a high ANC. Areas especially sensitive to acidification include portions of the Northeast (particularly, the Adirondack and Catskill Mountains, portions of New England, and streams in the mid-Appalachian highlands) and southeastern streams.

ii. Acid Deposition and Forest Ecosystem Impacts

Current understanding of the effects of acid deposition on forest ecosystems focuses on the effects of ecological processes affecting plant uptake, retention, and cycling of nutrients within forest ecosystems. Recent studies indicate that acid deposition is at least partially responsible for decreases in base cations (calcium, magnesium, potassium, and others) from soils in the northeastern and southeastern United States. Losses of calcium from forest soils and forested watersheds have now been documented as a sensitive early indicator of soil response to acid deposition for a wide range of forest soils in the United States.

In red spruce stands, a clear link exists between acid deposition, calcium supply, and sensitivity to abiotic stress. Red spruce uptake and retention of calcium is impacted by acid deposition in two main ways: leaching of important stores of calcium from needles and decreased root uptake of calcium due to calcium depletion from the soil and aluminum mobilization. These changes increase the sensitivity of red spruce to winter injuries under normal winter conditions in the Northeast, result in the loss of needles, slow tree growth, and impair the overall health and productivity of forest ecosystems in many areas of the eastern United States. In addition, recent studies of sugar maple decline in the Northeast demonstrate a link between low base cation availability, high levels of aluminum and manganese in the soil, and increased levels of tree mortality due to native defoliating insects.

Although sulfate is the primary cause of base cation leaching, nitrate is a significant contributor in watersheds that are nearly nitrogen saturated. Base cation depletion is a cause for concern because of the role these ions play in surface water acid neutralization and their importance as essential nutrients for tree growth (calcium, magnesium and potassium).

This regulatory action will decrease acid deposition in the transport region and is likely to have positive effects on the health and productivity of forest systems in the region.

iii. Coastal Ecosystems

Since 1990, a large amount of research has been conducted on the impact of nitrogen deposition to coastal waters. Nitrogen is often the limiting nutrient in coastal ecosystems. Increasing the levels of nitrogen in coastal waters can cause significant changes to those ecosystems. In recent decades, human activities have accelerated nitrogen nutrient inputs, causing excessive growth of algae and leading to degraded water quality and associated impairments of estuarine and coastal resources.

Atmospheric deposition of nitrogen is a significant source of nitrogen to many estuaries. The amount of nitrogen entering estuaries due to atmospheric deposition varies widely, depending on the size and location of the estuarine watershed and other sources of nitrogen in the watershed. There are a few estuaries where atmospheric deposition of nitrogen contributes well over 40 percent of the total nitrogen load; however, in most estuaries for which estimates exist, the contribution from atmospheric deposition ranges from 15–30 percent. The area of the country with the highest air deposition rates (30 percent deposition rates) includes many estuaries along the northeast seaboard from Massachusetts to the Chesapeake Bay and along the central Gulf of Mexico coast.

In 1999, National Oceanic and Atmospheric Administration (NOAA) published the results of a 5-year national assessment of the severity and extent of estuarine eutrophication. An estuary is defined as the inland arm of the sea that meets the mouth of a river. The 138 estuaries characterized in the study represent more than 90 percent of total estuarine water surface area and the total number of U.S. estuaries. The study found that estuaries with moderate to high eutrophication represented 65 percent of the estuarine surface area.

Eutrophication is of particular concern in coastal areas with poor or stratified circulation patterns, such as the Chesapeake Bay, Long Island Sound, and the Gulf of Mexico. In such areas, the ''overproduced'' algae tends to sink to the bottom and decay, using all or most of the available oxygen and thereby reducing or eliminating populations of bottom-feeder fish and shellfish, distorting the normal population balance between different aquatic organisms, and in extreme cases, causing dramatic fish kills. Severe and persistent eutrophication often directly impacts human activities. For example,

fishery resource losses can be caused directly by fish kills associated with low dissolved oxygen and toxic blooms. Declines in tourism occur when low dissolved oxygen causes Noxious smells and floating mats of algal blooms create unfavorable aesthetic conditions. Risks to human health increase when the toxins from algal blooms accumulate in edible fish and shellfish, and when toxins become airborne, causing respiratory problems due to inhalation. According to the NOAA report, more than half of the nation's estuaries have moderate to high expressions of at least one of these symptoms'an indication that eutrophication is well developed in more than half of U.S. estuaries.

This rule is anticipated to reduce nitrogen deposition in the nation. Thus, reductions in the levels of nitrogen deposition will have a positive impact upon current eutrophic conditions in estuaries and coastal areas in the country.

5. Are There Health or Welfare Disbenefits of the BART That Have Not Been Quantified?

In contrast to the additional benefits of the rule discussed above, it is also possible that this rule will result in disbenefits in some areas of the region. Current levels of nitrogen deposition in these areas may provide passive fertilization for forest and terrestrial ecosystems where nutrients are a limiting factor and for some croplands.

The effects of ozone and PM on radiative transfer in the atmosphere can also lead to effects of uncertain magnitude and direction on the penetration of ultraviolet light and climate. Ground level ozone makes up a small percentage of total atmospheric ozone (including the stratospheric layer) that attenuates penetration of ultraviolet—b (UVb) radiation to the ground. The EPA's past evaluation of the information indicates that potential disbenefits would be small, variable, and with too many uncertainties to attempt quantification of relatively small changes in average ozone levels over the course of a year (EPA, 2005a). The EPA's most recent provisional assessment of the currently available information indicates that potential but unquantifiable benefits may also arise from ozone-related attenuation of UVb radiation (EPA, 2005b). Sulfate and nitrate particles also scatter UVb, which can decrease exposure of horizontal surfaces to UVb, but increase exposure of vertical surfaces. In this case as well, both the magnitude and direction of the effect of reductions in sulfate and nitrate particles are too uncertain to quantify (EPA, 2004). Ozone is a greenhouse gas, and sulfates and nitrates can reduce the amount of solar radiation reaching the earth, but EPA believes that we are unable to quantify any net climate-related disbenefit or benefit associated with the combined ozone and PM reductions in this rule.

B. Paperwork Reduction Act

Today's rule clarifies, but does not modify the information collection requirements for BART. Therefore, this action does not impose any new information collection burden. However, the OMB has previously approved the information collection requirements contained in the existing regulations [40 CFR Part 51] under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0421, EPA ICR number 1813.04. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by calling (202) 566–1672.

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

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administrations' 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.

Table IV–5 lists potentially impacted BART industry source categories and the current applicable small business criteria established by the Small Business Administration.

TABLE IV–5. POTENTIALLY AFFECTED BART SOURCE CATEGORIES AND SMALL BUSINESS SIZE STANDARDS

NAICS [a]	Description	Size standard [b]
221112 [c,d]	Fossil fuel-fired electric utility steam generating units	electric output ≤ 4 million megawatt hours.
212112	Bituminous Coal Underground Mining	500 Employees.
311221	Wet Corn Milling	750 Employees.
311311	Sugarcane Mills	500 Employees.
311313	Beet Sugar Manufacturing	750 Employees.
31214	Distilleries	750 Employees.
321212	Softwood Veneer and Plywood Manufacturing	500 Employees.
322121	Paper (except Newsprint) Mills (pt)	750 Employees.
325188	All Other Basic Inorganic Chemical Manufacturing (pt)	1,000 Employees.
325221	Cellulosic Organic Fiber Manufacturing	1,000 Employees.
325222	Noncellulosic Organic Fiber Manufacturing	1,000 Employees.
325182	Carbon Black Manufacturing (pt)	500 Employees.
327213	Glass Container Manufacturing	750 Employees.
327212	Other Pressed and Blown Glass and Glassware Manufacturing	750 Employees.

TABLE IV–5. POTENTIALLY AFFECTED BART SOURCE CATEGORIES AND SMALL BUSINESS SIZE STANDARDS—Continued

NAICS [a]	Description	Size standard [b]
32731	Cement Manufacturing	750 Employees.
32741	Lime Manufacturing	500 Employees.
331111	Iron and Steel Mills	1,000 Employees.
331315	Aluminum Sheet, Plate, and Foil Manufacturing	750 Employees.
331319	Other Aluminum Rolling and Drawing	750 Employees.
22121	Natural Gas Distribution	500 Employees.

[a] North American Industry Classification System.
[b] Small Business Administration Size Criteria.
[c] Include NAICS categories for source categories that own and operate electric generating units only.
[d] Federal, State, or local government-owned and operated establishments are classified according to the activity in which they are engaged.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any direct requirements on small entities. The rule would apply to States, not to small entities.

Courts have interpreted the RFA to require a regulatory flexibility analysis only when small entities will be subject to the requirements of the rule. See *Motor and Equip. Mfrs. Ass'n* v. *Nichols,* 142 F. 3d 449 (D.C. Cir., 1998); *United Distribution Cos.* v. *FERC,* 88 F. 3d 1105, 1170 (D.C. Cir., 1996); *Mid-Tex Elec. Co-op, Inc.* v. *FERC,* 773 F . 2d 327, 342 (D.C. Cir., 1985) (agency's certification need only consider the rule's impact on entities subject to the rule).

BART requirements in the regional haze rule require BART determinations for a select list of major stationary sources defined by section 169A(g)(7) of the CAA. However, as noted in the proposed and final regional haze rules, the State's determination of BART for regional haze involves some State discretion in considering a number of factors set forth in section 169A(g)(2), including the costs of compliance.

Further, the final regional haze rule allows States to adopt alternative measures in lieu of requiring the installation and operation of BART at these major stationary sources. As a result, the potential consequences of the BART provisions of the regional haze rule (as clarified in today's rule) at specific sources are speculative. Any requirements for BART will be established by State rulemakings. The States would accordingly exercise substantial intervening discretion in implementing the BART requirements of the regional haze rule and today's guidelines.

EPA has undertaken an illustrative analysis to assess the potential small business impacts of BART based upon EPA's assessment of the actions States may take to comply with the BART rule and guidelines.

For this final rule, the engineering analysis conducted for the rulemaking identified 491 EGU units potentially affected by the outcome of this rule. Using unit ORIS [89] numbers and the Energy Information Administration's publicly available 2002 electric generator databases (Form EIA 860 and Form EIA 861), we identified utility names, nameplate capacity for affected units, and net electricity generation potentially affected by this rule. After identifying these units, we excluded units that are located in CAIR regions in order to identify those units most likely affected by the BART regulatory program. After an assessment of the ownership of these remaining units, we identified 2 potentially affected small entities in the EGU sector. We used a cost-to-sales approach (comparison of expected annual costs of emission controls to annual sales revenue or government entity budgets for the affected small entity) to assess the potential impacts of BART for these affected entities. Using data from the cost analysis, EPA found one of these small entities may experience a cost-to-sales ratio of 3 percent of sales. The other affected small entity in the EGU sector does not face additional compliance costs associated with the rule.

The engineering analysis conducted for the rulemaking identified over 2,000 records associated with affected non-EGU units (all source categories listed in table IV–5 other than EGUs—NAICS 221112) potentially affected by the rule. Using publicly available sales and employment databases, plant names, and locations, we identified 279 entities and potential owners. In order to classify affected ultimate entities as small or large, EPA collected information on facility names, parent company sales, and parent company employment data. Data were compared with the appropriate size standard and entities were classified as small or large according to Small Business Administration's definitions. For example, ultimate parent companies of cement producers with employment exceeding 750 employees were classified as large companies. This process identified 36 small companies and 195 large companies potentially impacted as a result promulgating this rule. The remaining 48 entities were either government-owned (25 entities, primarily state universities) or parent ownership could not be definitively identified using available databases (23 entities).

Using the cost-to-sales approach described above, EPA found that five non-EGU source category small entities may potentially be affected at or above 3 percent. Two entities may be affected between one and three percent, and the remaining small entity cost-to-sales ratios are below one percent. The median cost-to-sales ratio for non-EGU source category small entities is estimated to be 0.3 percent and could potentially range from 0 to 20 percent. As previously discussed this analysis is illustrative and based upon EPA's assessment of actions States are likely to take as a result of the BART rule and guidelines promulgated today.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (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 UMRA, 2 U.S.C. 1532, EPA generally must prepare a written statement, including a cost-benefit analysis, for any proposed or final rule that ''includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more * * * in any one year.'' A ''Federal

[89] An ORIS code is a 4 digit number assigned by the Energy Information Administration (EIA) at the U.S. Department of Energy to power plants owned by utilities.

mandate'' is defined under section 421(6), 2 U.S.C. 658(6), to include a ''Federal intergovernmental mandate.'' A ''Federal intergovernmental mandate,'' in turn, is defined to include a regulation that ''would impose an enforceable duty upon State, local, or tribal governments,'' section 421(5)(A)(I), 2 U.S.C. 658(5)(A)(I). A ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector,'' with certain exceptions, section 421(7)(A), 2 U.S.C. 658(7)(A).

Before promulgating an EPA rule for which a written statement is needed under section 202 of UMRA, section 205, 2 U.S.C. 1535, of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective, or least burdensome alternative that achieves the objectives of the rule.The RIA prepared by EPA and placed in the docket for this rulemaking is consistent with the requirements of section 202 of the UMRA. Furthermore, EPA is not directly establishing any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments. Thus, EPA is not obligated to develop under section 203 of the UMRA a small government agency plan. Further, EPA carried out consultations with the governmental entities affected by this rule in a manner consistent with the intergovernmental consultation provisions of section 204 of the UMRA.

The EPA also believes that today's rule meets the UMRA requirement in section 205 to select the least costly and burdensome alternative in light of the statutory mandate for BART. As explained above, we are promulgating the BART rule and guidelines following the D.C. Circuit's remand of the BART provisions in the 1999 regional haze rule. The 1999 regional haze rule provides substantial flexibility to the States, allowing them to adopt alternative measures such as a trading program in lieu of requiring the installation and operation of BART. The provisions governing such alternative measures were affected by a more recent decision of the D.C. Circuit and will be revised in a separate rulemaking process. Today's rule will not restrict the ability of the States to adopt such alternatives measures once those revisions to the regional haze rule have been made final. This will provide an alternative to BART that gives States the ability to choose the least costly and least burdensome alternative. Today's rule also allows States affected by the Clean Air Interstate Rule to utilize emission reductions achieved by EGUs under that rule to satisfy BART requirements for those sources. This will provide those States with another cost effective and less burdensome alternative to BART.

The EPA is not reaching a final conclusion as to the applicability of UMRA to today's rulemaking action. The reasons for this are discussed in the 1999 regional haze rule (64 FR 35762) and in the 2001 BART guidelines proposal (66 FR 38111–38112). Notwithstanding this, the discussion in chapter 9 of the RIA constitutes the UMRA statement that would be required by UMRA if its statutory provisions applied. Consequently, we continue to believe that it is not necessary to reach a conclusion as to the applicability of the UMRA requirements.

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.'' Such policies are 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.'' Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless EPA consults with State and local officials early in the process of developing the regulation.

We have concluded that today's action, promulgating the BART guidelines, will not have federalism implications, as specified in section 6 of the Executive Order 13132 (64 FR 43255, August 10, 1999) because it will not have substantial direct effects on the States, nor substantially alter the relationship or the distribution of power and responsibilities between the States and the Federal government. Nonetheless, we consulted with a wide scope of State and local officials, including the National Governors Association, the National League of Cities, the National Conference of State Legislatures, the U. S. Conference of Mayors, the National Association of Counties, the Council of State Governments, the International City/County Management Association, and the National Association of Towns and Townships during the course of developing this rule.

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 does not have Tribal implications as defined by Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. Furthermore, this rule does not affect the relationship or distribution of power and responsibilities between the Federal government and Indian Tribes. The CAA and the TAR establish the relationship of the Federal government and Tribes in developing plans to address air quality issues, and this rule does nothing to modify that relationship. This rule does not have Tribal implications, and Executive Order 13175 does not apply to this rulemaking.

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, Section 5–501 of the Order directs the Agency to evaluate the environmental health or safety effects of the planned rule on children and to explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health and safety risks, such that the analysis required under section 5–501 of the

Order has the potential to influence the regulation. The BART rule and guidelines are not subject to the Executive Order because the rule and guidelines do not involve decisions on environmental health or safety risks that may disproportionately affect children. The EPA believes that the emissions reductions from the control strategies considered in this rulemaking will further improve air quality and will further improve children's health.

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

We have conducted a Regulatory Impact Analysis for this rule, that includes an analysis of energy impacts and is contained in the docket (Docket No. OAR–2002–0076). This 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 it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not a ''significant energy action,'' because it will have less than a 1 percent impact on the cost of energy production and does not exceed other factors described by OMB that may indicate a significant adverse effect. (See, ''Guidance for Implementing E.O. 13211,'' OMB Memorandum 01–27 (July 13, 2001) *http://www.whitehouse.gov/omb/memoranda/m01–27.html.)* Specifically, the presumptive requirements for EGUs for this rule, when fully implemented, are expected have a 0.25 percent impact on the cost of energy production for the nation in 2015. States must use the guidelines in making BART determinations for power plants with a generating capacity in excess of 750 MW. Our analysis evaluates the impact of the presumptive requirements for these sources and does not consider any possible additional controls for EGU sources or non-EGU sources that States may require. Although States may choose to use the guidelines in establishing BART limits for non-EGUs , ultimately States will determine the sources subject to BART and the appropriate level of control for such sources.

We are finalizing today's rule following the D.C. Circuit's remand of the BART provisions in the 1999 regional haze rule. The 1999 regional haze rule provides substantial flexibility to the States, allowing them to adopt alternative measures such as a trading program in lieu of requiring the installation and operation of BART. The provisions governing such alternative measures were affected by a more recent decision of the D.C. Circuit and will be revised in a separate rulemaking process. This rulemaking will not restrict the ability of the States to adopt alternative measures once those revisions to the regional haze rule have been made final. This will provide an alternative to BART that reduces the overall cost of the regulation and its impact on the energy supply. Today's rule also allows States affected by the Clean Air Interstate Rule to utilize emission reductions achieved by EGUs under that rule to satisfy BART requirements for those sources. This will provide those States with another cost effective and less burdensome alternative to BART. The BART rule itself offers flexibility by offering the choice of meeting SO_2 requirements between an emission rate and a removal rate.

For a State that chooses to require case-by-case BART, today's rule would establish presumptive levels of controls for SO_2 and NO_X for certain EGUs that the State finds are subject to BART. Based on its consideration of various factors set forth in the regulations; however, a State may conclude that a different level of control is appropriate. The States will accordingly exercise substantial intervening discretion in implementing the final rule. Additionally, we have assessed that the compliance dates for the rule will provide adequate time for EGUs to install the required emission controls.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer 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 (VCS) 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 VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the EPA decides not to use VCS.

This action does not involve technical standards; thus, EPA did not consider the use of any VCS.

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

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' requires federal agencies to consider the impact of programs, policies, and activities on minority populations and low-income populations. According to EPA guidance,[90] agencies are to assess whether minority or low-income populations face risks or a rate of exposure to hazards that are significant and that ''appreciably exceed or is likely to appreciably exceed the risk or rate to the general population or to the appropriate comparison group.'' (EPA, 1998)

In accordance with Executive Order 12898, the Agency has considered whether this rule may have disproportionate negative impacts on minority or low income populations. Negative impacts to these sub-populations that appreciably exceed similar impacts to the general population are not expected because the Agency expects this rule to lead to reductions in air pollution emissions and exposures generally.

K. Congressional Review Act

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

List of Subjects in 40 CFR Part 51

Environmental protection, Air pollution control, Administrative practice and procedure, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping

[90] U.S. Environmental Protection Agency, 1998. Guidance for Incorporating Environmental Justice Concerns in EPA's NEPA Compliance Analyses. Office of Federal Activities, Washington, D.C., April, 1998.

requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 15, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, part 51 of chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

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

Authority: 23 U.S.C. 101; 42 U.S.C. 7410–7671q.

■ 2. Section 51.302 is amended by revising paragraph (c)(4)(iii) to read as follows:

§ 51.302 Implementation control strategies for reasonably attributable visibility impairment.

* * * * *

(c) * * *

(4) * * *

(iii) BART must be determined for fossil-fuel fired generating plants having a total generating capacity in excess of 750 megawatts pursuant to ''Guidelines for Determining Best Available Retrofit Technology for Coal-fired Power Plants and Other Existing Stationary Facilities'' (1980), which is incorporated by reference, exclusive of appendix E to the Guidelines, except that options more stringent than NSPS must be considered. Establishing a BART emission limitation equivalent to the NSPS level of control is not a sufficient basis to avoid the analysis of control options required by the guidelines. This document is EPA publication No. 450/3–80–009b and has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is for sale from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. It is also available for inspection from the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/index.html.*

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■ 3. Section 51.308 is amended by revising paragraph (b), removing and reserving paragraph (c), revising paragraphs (e)(1)(ii), (e)(3), and (e)(4), and adding paragaphs (e)(5) and (6) to read as follows:

§ 51.308 Regional haze program requirements.

* * * * *

(b) *When are the first implementation plans due under the regional haze program?* Except as provided in § 51.309(c), each State identified in § 51.300(b)(3) must submit, for the entire State, an implementation plan for regional haze meeting the requirements of paragraphs (d) and (e) of this section no later than December 17, 2007.

(c) [Reserved]

* * * * *

(e) * * *

(1) * * *

(ii) A determination of BART for each BART-eligible source in the State that emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any mandatory Class I Federal area. All such sources are subject to BART.

(A) The determination of BART must be based on an analysis of the best system of continuous emission control technology available and associated emission reductions achievable for each BART-eligible source that is subject to BART within the State. In this analysis, the State must take into consideration the technology available, the costs of compliance, the energy and nonair quality environmental impacts of compliance, any pollution control equipment in use at the source, the remaining useful life of the source, and the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

(B) The determination of BART for fossil-fuel fired power plants having a total generating capacity greater than 750 megawatts must be made pursuant to the guidelines in appendix Y of this part (Guidelines for BART Determinations Under the Regional Haze Rule).

(C) *Exception.* A State is not required to make a determination of BART for SO_2 or for NO_X if a BART-eligible source has the potential to emit less than 40 tons per year of such pollutant(s), or for PM_{10} if a BART-eligible source emits less than 15 tons per year of such pollutant.

* * * * *

(3) A State which opts under 40 CFR 51.308(e)(2) to implement an emissions trading program or other alternative measure rather than to require sources subject to BART to install, operate, and maintain BART may satisfy the final step of the demonstration required by that section as follows: If the distribution of emissions is not substantially different than under BART, and the alternative measure results in greater emission reductions, then the alternative measure may be deemed to achieve greater reasonable progress. If the distribution of emissions is significantly different, the State must conduct dispersion modeling to determine differences in visibility between BART and the trading program for each impacted Class I area, for the worst and best 20 percent of days. The modeling would demonstrate ''greater reasonable progress'' if both of the following two criteria are met:

(i) Visibility does not decline in any Class I area, and

(ii) There is an overall improvement in visibility, determined by comparing the average differences between BART and the alternative over all affected Class I areas.

(4) A State that opts to participate in the Clean Air Interstate Rule cap-and-trade and trade program under part 96 AAA–EEE need not require affected BART-eligible EGU's to install, operate, and maintain BART. A State that chooses this option may also include provisions for a geographic enhancement to the program to address the requirement under § 51.302(c) related to BART for reasonably attributable impairment from the pollutants covered by the CAIR cap-and-trade program.

(5) After a State has met the requirements for BART or implemented emissions trading program or other alternative measure that achieves more reasonable progress than the installation and operation of BART, BART-eligible sources will be subject to the requirements of paragraph (d) of this section in the same manner as other sources.

(6) Any BART-eligible facility subject to the requirement under paragraph (e) of this section to install, operate, and maintain BART may apply to the Administrator for an exemption from that requirement. An application for an exemption will be subject to the requirements of § 51.303(a)(2)–(h).

* * * * *

■ 4. Appendix Y to Part 51 is added to read as follows:

Appendix Y to Part 51—Guidelines for BART Determinations Under the Regional Haze Rule

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I. Introduction and Overview

A. What is the purpose of the guidelines?

The Clean Air Act (CAA), in sections 169A and 169B, contains requirements for the protection of visibility in 156 scenic areas across the United States. To meet the CAA's requirements, we published regulations to protect against a particular type of visibility impairment known as ''regional haze.'' The regional haze rule is found in this part at 40 CFR 51.300 through 51.309. These regulations require, in 40 CFR 51.308(e), that certain types of existing stationary sources of air pollutants install best available retrofit technology (BART). The guidelines are designed to help States and others (1) identify those sources that must comply with the BART requirement, and (2) determine the level of control technology that represents BART for each source.

B. What does the CAA require generally for improving visibility?

Section 169A of the CAA, added to the CAA by the 1977 amendments, requires States to protect and improve visibility in certain scenic areas of national importance. The scenic areas protected by section 169A are ''the mandatory Class I Federal Areas * * * where visibility is an important value.'' In these guidelines, we refer to these as ''Class I areas.'' There are 156 Class I areas, including 47 national parks (under the jurisdiction of the Department of Interior—National Park Service), 108 wilderness areas (under the jurisdiction of the Department of the Interior—Fish and Wildlife Service or the Department of Agriculture—U.S. Forest Service), and one International Park (under the jurisdiction of the Roosevelt-Campobello International Commission). The Federal Agency with jurisdiction over a particular Class I area is referred to in the CAA as the Federal Land Manager. A complete list of the Class I areas is contained in 40 CFR 81.401 through 81.437, and you can find a map of the Class I areas at the following Internet site: *http://www.epa.gov/ttn/oarpg/t1/fr_notices/classimp.gif*.

The CAA establishes a national goal of eliminating man-made visibility impairment from all Class I areas. As part of the plan for achieving this goal, the visibility protection provisions in the CAA mandate that EPA issue regulations requiring that States adopt measures in their State implementation plans (SIPs), including long-term strategies, to provide for reasonable progress towards this national goal. The CAA also requires States to coordinate with the Federal Land Managers as they develop their strategies for addressing visibility.

C. What is the BART requirement in the CAA?

1. Under section 169A(b)(2)(A) of the CAA, States must require certain existing stationary sources to install BART. The BART provision applies to ''major stationary sources'' from 26 identified source categories which have the potential to emit 250 tons per year or more of any air pollutant. The CAA requires only sources which were put in place during a specific 15-year time interval to be subject to BART. The BART provision applies to sources that existed as of the date of the 1977 CAA amendments (that is, August 7, 1977) but which had not been in operation for more than 15 years (that is, not in operation as of August 7, 1962).

2. The CAA requires BART review when any source meeting the above description ''emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in any Class I area. In identifying a level of control as BART, States are required by section 169A(g) of the CAA to consider:

(a) The costs of compliance,

(b) The energy and non-air quality environmental impacts of compliance,

(c) Any existing pollution control technology in use at the source,

(d) The remaining useful life of the source, and

(e) The degree of visibility improvement which may reasonably be anticipated from the use of BART.

3. The CAA further requires States to make BART emission limitations part of their SIPs. As with any SIP revision, States must provide an opportunity for public comment on the BART determinations, and EPA's action on any SIP revision will be subject to judicial review.

D. What types of visibility problems does EPA address in its regulations?

1. We addressed the problem of visibility in two phases. In 1980, we published regulations addressing what we termed ''reasonably attributable'' visibility impairment. Reasonably attributable visibility impairment is the result of emissions from one or a few sources that are generally located in close proximity to a specific Class I area. The regulations addressing reasonably attributable visibility impairment are published in 40 CFR 51.300 through 51.307.

2. On July 1, 1999, we amended these regulations to address the second, more common, type of visibility impairment known as ''regional haze.'' Regional haze is the result of the collective contribution of many sources over a broad region. The regional haze rule slightly modified 40 CFR 51.300 through 51.307, including the addition of a few definitions in § 51.301, and added new §§ 51.308 and 51.309.

E. What are the BART requirements in EPA's regional haze regulations?

1. In the July 1, 1999 rulemaking, we added a BART requirement for regional haze. We amended the BART requirements in 2005. You will find the BART requirements in 40 CFR 51.308(e). Definitions of terms used in 40 CFR 51.308(e)(1) are found in 40 CFR 51.301.

2. As we discuss in detail in these guidelines, the regional haze rule codifies and clarifies the BART provisions in the CAA. The rule requires that States identify and list ''BART-eligible sources,'' that is, that States identify and list those sources that fall within the 26 source categories, were put in place during the 15-year window of time from 1962 to 1977, and have potential

emissions greater than 250 tons per year. Once the State has identified the BART-eligible sources, the next step is to identify those BART-eligible sources that may ''emit any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility.'' Under the rule, a source which fits this description is ''subject to BART.'' For each source subject to BART, 40 CFR 51.308(e)(1)(ii)(A) requires that States identify the level of control representing BART after considering the factors set out in CAA section 169A(g), as follows:

—States must identify the best system of continuous emission control technology for each source subject to BART taking into account the technology available, the costs of compliance, the energy and non-air quality environmental impacts of compliance, any pollution control equipment in use at the source, the remaining useful life of the source, and the degree of visibility improvement that may be expected from available control technology.

3. After a State has identified the level of control representing BART (if any), it must establish an emission limit representing BART and must ensure compliance with that requirement no later than 5 years after EPA approves the SIP. States may establish design, equipment, work practice or other operational standards when limitations on measurement technologies make emission standards infeasible.

F. What is included in the guidelines?

1. The guidelines provide a process for making BART determinations that States can use in implementing the regional haze BART requirements on a source-by-source basis, as provided in 40 CFR 51.308(e)(1). States must follow the guidelines in making BART determinations on a source-by-source basis for 750 megawatt (MW) power plants but are not required to use the process in the guidelines when making BART determinations for other types of sources.

2. The BART analysis process, and the contents of these guidelines, are as follows:

(a) *Identification of all BART-eligible sources.* Section II of these guidelines outlines a step-by-step process for identifying BART-eligible sources.

(b) *Identification of sources subject to BART.* As noted above, sources ''subject to BART'' are those BART-eligible sources which ''emit a pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any Class I area.'' We discuss considerations for identifying sources subject to BART in section III of the guidance.

(c) *The BART determination process.* For each source subject to BART, the next step is to conduct an analysis of emissions control alternatives. This step includes the identification of available, technically feasible retrofit technologies, and for each technology identified, an analysis of the cost of compliance, the energy and non-air quality environmental impacts, and the degree of visibility improvement in affected Class I areas resulting from the use of the control technology. As part of the BART analysis, the State should also take into account the remaining useful life of the source and any existing control technology present at the source. For each source, the State will determine a ''best system of continuous emission reduction'' based upon its evaluation of these factors. Procedures for the BART determination step are described in section IV of these guidelines.

(d) *Emissions limits.* States must establish emission limits, including a deadline for compliance, consistent with the BART determination process for each source subject to BART. Considerations related to these limits are discussed in section V of these guidelines.

G. Who is the target audience for the guidelines?

1. The guidelines are written primarily for the benefit of State, local and Tribal agencies, and describe a process for making the BART determinations and establishing the emission limitations that must be included in their SIPs or Tribal implementation plans (TIPs). Throughout the guidelines, which are written in a question and answer format, we ask questions ''How do I * * *?'' and answer with phrases ''you should * * *, you must * * *'' The ''you'' means a State, local or Tribal agency conducting the analysis. We have used this format to make the guidelines simpler to understand, but we recognize that States have the authority to require source owners to assume part of the analytical burden, and that there will be differences in how the supporting information is collected and documented. We also recognize that data collection, analysis, and rule development may be performed by Regional Planning Organizations, for adoption within each SIP or TIP.

2. The preamble to the 1999 regional haze rule discussed at length the issue of Tribal implementation of the requirements to submit a plan to address visibility. As explained there, requirements related to visibility are among the programs for which Tribes may be determined eligible and receive authorization to implement under the ''Tribal Authority Rule'' (''TAR'') (40 CFR 49.1 through 49.11). Tribes are not subject to the deadlines for submitting visibility implementation plans and may use a modular approach to CAA implementation. We believe there are very few BART-eligible sources located on Tribal lands. Where such sources exist, the affected Tribe may apply for delegation of implementation authority for this rule, following the process set forth in the TAR.

H. Do EPA regulations require the use of these guidelines?

Section 169A(b) requires us to issue guidelines for States to follow in establishing BART emission limitations for fossil-fuel fired power plants having a capacity in excess of 750 megawatts. This document fulfills that requirement, which is codified in 40 CFR 51.308(e)(1)(ii)(B). The guidelines establish an approach to implementing the requirements of the BART provisions of the regional haze rule; we believe that these procedures and the discussion of the requirements of the regional haze rule and the CAA should be useful to the States. For sources other than 750 MW power plants, however, States retain the discretion to adopt approaches that differ from the guidelines.

II. How to Identify BART-Eligible Sources

This section provides guidelines on how to identify BART-eligible sources. A BART-eligible source is an existing stationary source in any of 26 listed categories which meets criteria for startup dates and potential emissions.

A. What are the steps in identifying BART-eligible sources?

Figure 1 shows the steps for identifying whether the source is a ''BART-eligible source:''

Step 1: Identify the emission units in the BART categories,

Step 2: Identify the start-up dates of those emission units, and

Step 3: Compare the potential emissions to the 250 ton/yr cutoff.

Figure 1. How to determine whether a source is BART-eligible:

Step 1: Identify emission units in the BART categories

Does the plant contain emissions units in one or more of the 26 source categories?

➜ No ➜ Stop

➜ Yes ➜ Proceed to Step 2

Step 2: Identify the start-up dates of these emission units

Do any of these emissions units meet the following two tests?

In existence on August 7, 1977

AND

Began operation after August 7, 1962

➜ No ➜ Stop

➜ Yes ➜ Proceed to Step 3

Step 3: Compare the potential emissions from these emission units to the 250 ton/yr cutoff

Identify the ''stationary source'' that includes the emission units you identified in Step 2.

Add the current potential emissions from all the emission units identified in Steps 1 and 2 that are included within the ''stationary source'' boundary.

Are the potential emissions from these units 250 tons per year or more for any visibility-impairing pollutant?

➜ No ➜ Stop

➜ Yes ➜ These emissions units comprise the ''BART-eligible source.''

1. Step 1: Identify Emission Units in the BART Categories

1. The BART requirement only applies to sources in specific categories listed in the CAA. The BART requirement does not apply to sources in other source categories, regardless of their emissions. The listed categories are:

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

(2) Coal cleaning plants (thermal dryers),

(3) Kraft pulp mills,

(4) Portland cement plants,

(5) Primary zinc smelters,

(6) Iron and steel mill plants,

(7) Primary aluminum ore reduction plants,

(8) Primary copper smelters,
(9) Municipal incinerators capable of charging more than 250 tons of refuse per day,
(10) Hydrofluoric, sulfuric, and nitric acid plants,
(11) Petroleum refineries,
(12) Lime plants,
(13) Phosphate rock processing plants,
(14) Coke oven batteries,
(15) Sulfur recovery plants,
(16) Carbon black plants (furnace process),
(17) Primary lead smelters,
(18) Fuel conversion plants,
(19) Sintering plants,
(20) Secondary metal production facilities,
(21) Chemical process plants,
(22) Fossil-fuel boilers of more than 250 million BTUs per hour heat input,
(23) Petroleum storage and transfer facilities with a capacity exceeding 300,000 barrels,
(24) Taconite ore processing facilities,
(25) Glass fiber processing plants, and
(26) Charcoal production facilities.

2. Some plants may have emission units from more than one category, and some emitting equipment may fit into more than one category. Examples of this situation are sulfur recovery plants at petroleum refineries, coke oven batteries and sintering plants at steel mills, and chemical process plants at refineries. For Step 1, you identify all of the emissions units at the plant that fit into one or more of the listed categories. You do not identify emission units in other categories.

Example: A mine is collocated with an electric steam generating plant and a coal cleaning plant. You would identify emission units associated with the electric steam generating plant and the coal cleaning plant, because they are listed categories, but not the mine, because coal mining is not a listed category.

3. The category titles are generally clear in describing the types of equipment to be listed. Most of the category titles are very broad descriptions that encompass all emission units associated with a plant site (for example, ''petroleum refining'' and ''kraft pulp mills''). This same list of categories appears in the PSD regulations. States and source owners need not revisit any interpretations of the list made previously for purposes of the PSD program. We provide the following clarifications for a few of the category titles:

(1) *''Steam electric plants of more than 250 million BTU/hr heat input.''* Because the category refers to ''plants,'' we interpret this category title to mean that boiler capacities should be aggregated to determine whether the 250 million BTU/hr threshold is reached. This definition includes only those plants that generate electricity for sale. Plants that cogenerate steam and electricity also fall within the definition of ''steam electric plants''. Similarly, combined cycle turbines are also considered ''steam electric plants'' because such facilities incorporate heat recovery steam generators. Simple cycle turbines, in contrast, are not ''steam electric plants'' because these turbines typically do not generate steam.

Example: A stationary source includes a steam electric plant with three 100 million BTU/hr boilers. Because the aggregate capacity exceeds 250 million BTU/hr for the ''plant,'' these boilers would be identified in Step 2.

(2) *''Fossil-fuel boilers of more than 250 million BTU/hr heat input.''* We interpret this category title to cover only those boilers that are individually greater than 250 million BTU/hr. However, an individual boiler smaller than 250 million BTU/hr should be subject to BART if it is an integral part of a process description at a plant that is in a different BART category—for example, a boiler at a Kraft pulp mill that, in addition to providing steam or mechanical power, uses the waste liquor from the process as a fuel. In general, if the process uses any by-product of the boiler and the boiler's function is to serve the process, then the boiler is integral to the process and should be considered to be part of the process description.

Also, you should consider a multi-fuel boiler to be a ''fossil-fuel boiler'' if it burns any amount of fossil fuel. You may take federally and State enforceable operational limits into account in determining whether a multi-fuel boiler's fossil fuel capacity exceeds 250 million Btu/hr.

(3) *''Petroleum storage and transfer facilities with a capacity exceeding 300,000 barrels.''* The 300,000 barrel cutoff refers to total facility-wide tank capacity for tanks that were put in place within the 1962–1977 time period, and includes gasoline and other petroleum-derived liquids.

(4) *''Phosphate rock processing plants.''* This category descriptor is broad, and includes all types of phosphate rock processing facilities, including elemental phosphorous plants as well as fertilizer production plants.

(5) *''Charcoal production facilities.''* We interpret this category to include charcoal briquet manufacturing and activated carbon production.

(6) *''Chemical process plants.''* and pharmaceutical manufacturing. Consistent with past policy, we interpret the category ''chemical process plants'' to include those facilities within the 2-digit Standard Industrial Classification (SIC) code 28. Accordingly, we interpret the term ''chemical process plants'' to include pharmaceutical manufacturing facilities.

(7) *''Secondary metal production.''* We interpret this category to include nonferrous metal facilities included within SIC code 3341, and secondary ferrous metal facilities that we also consider to be included within the category ''iron and steel mill plants.''

(8) *''Primary aluminum ore reduction.''* We interpret this category to include those facilities covered by 40 CFR 60.190, the new source performance standard (NSPS) for primary aluminum ore reduction plants. This definition is also consistent with the definition at 40 CFR 63.840.

2. Step 2: Identify the Start-Up Dates of the Emission Units

1. Emissions units listed under Step 1 are BART-eligible only if they were ''in existence'' on August 7, 1977 but were not ''in operation'' before August 7, 1962.

What does ''in existence on August 7, 1977'' mean?

2. The regional haze rule defines ''in existence'' to mean that:

''the owner or operator has obtained all necessary preconstruction approvals or permits required by Federal, State, or local air pollution emissions and air quality laws or regulations and either has (1) begun, or caused to begin, a continuous program of physical on-site construction of the facility or (2) entered into binding agreements or contractual obligations, which cannot be canceled or modified without substantial loss to the owner or operator, to undertake a program of construction of the facility to be completed in a reasonable time.'' 40 CFR 51.301.

As this definition is essentially identical to the definition of ''commence construction'' as that term is used in the PSD regulations, the two terms mean the same thing. *See* 40 CFR 51.165(a)(1)(xvi) and 40 CFR 52.21(b)(9). Under this definition, an emissions unit could be ''in existence'' even if it did not begin operating until several years after 1977.

Example: The owner of a source obtained all necessary permits in early 1977 and entered into binding construction agreements in June 1977. Actual on-site construction began in late 1978, and construction was completed in mid-1979. The source began operating in September 1979. The emissions unit was ''in existence'' as of August 7, 1977.

Major stationary sources which commenced construction AFTER August 7, 1977 (*i.e.*, major stationary sources which were not ''in existence'' on August 7, 1977) were subject to new source review (NSR) under the PSD program. Thus, the August 7, 1977 ''in existence'' test is essentially the same thing as the identification of emissions units that were grandfathered from the NSR review requirements of the 1977 CAA amendments.

3. Sources are not BART-eligible if the only change at the plant during the relevant time period was the addition of pollution controls. For example, if the only change at a copper smelter during the 1962 through 1977 time period was the addition of acid plants for the reduction of SO_2 emissions, these emission controls would not by themselves trigger a BART review.

What does ''in operation before August 7, 1962'' mean?

An emissions unit that meets the August 7, 1977 ''in existence'' test is not BART-eligible if it was in operation before August 7, 1962. ''In operation'' is defined as ''engaged in activity related to the primary design function of the source.'' This means that a source must have begun actual operations by August 7, 1962 to satisfy this test.

Example: The owner or operator entered into binding agreements in 1960. Actual on-site construction began in 1961, and construction was complete in mid-1962. The source began operating in September 1962. The emissions unit *was not* ''in operation'' before August 7, 1962 and is therefore subject to BART.

What is a ''reconstructed source?'

1. Under a number of CAA programs, an existing source which is completely or

substantially rebuilt is treated as a new source. Such ''reconstructed'' sources are treated as new sources as of the time of the reconstruction. Consistent with this overall approach to reconstructions, the definition of BART-eligible facility (reflected in detail in the definition of ''existing stationary facility'') includes consideration of sources that were in operation before August 7, 1962, but were reconstructed during the August 7, 1962 to August 7, 1977 time period.

2. Under the regional haze regulations at 40 CFR 51.301, a reconstruction has taken place if ''the fixed capital cost of the new component exceeds 50 percent of the fixed capital cost of a comparable entirely new source.'' The rule also states that ''[a]ny final decision as to whether reconstruction has occurred must be made in accordance with the provisions of §§ 60.15 (f)(1) through (3) of this title.'' ''[T]he provisions of §§ 60.15(f)(1) through (3)'' refers to the general provisions for New Source Performance Standards (NSPS). Thus, the same policies and procedures for identifying reconstructed ''affected facilities'' under the NSPS program must also be used to identify reconstructed ''stationary sources'' for purposes of the BART requirement.

3. You should identify reconstructions on an emissions unit basis, rather than on a plantwide basis. That is, you need to identify only the reconstructed emission units meeting the 50 percent cost criterion. You should include reconstructed emission units in the list of emission units you identified in Step 1. You need consider as possible reconstructions only those emissions units with the potential to emit more than 250 tons per year of any visibility-impairing pollutant.

4. The ''in operation'' and ''in existence'' tests apply to reconstructed sources. If an emissions unit was reconstructed and began actual operation before August 7, 1962, it is not BART-eligible. Similarly, any emissions unit for which a reconstruction ''commenced'' after August 7, 1977, is not BART-eligible.

How are modifications treated under the BART provision?

1. The NSPS program and the major source NSR program both contain the concept of modifications. In general, the term ''modification'' refers to any physical change or change in the method of operation of an emissions unit that results in an increase in emissions.

2. The BART provision in the regional haze rule contains no explicit treatment of modifications or how modified emissions units, previously subject to the requirement to install best available control technology (BACT), lowest achievable emission rate (LAER) controls, and/or NSPS are treated under the rule. As the BART requirements in the CAA do not appear to provide any exemption for sources which have been modified since 1977, the best interpretation of the CAA visibility provisions is that a subsequent modification does not change a unit's construction date for the purpose of BART applicability. Accordingly, if an emissions unit began operation before 1962, it is not BART-eligible if it was modified between 1962 and 1977, so long as the modification is not also a ''reconstruction.'' On the other hand, an emissions unit which began operation within the 1962–1977 time window, but was modified after August 7, 1977, is BART-eligible. We note, however, that if such a modification was a major modification that resulted in the installation of controls, the State will take this into account during the review process and may find that the level of controls already in place are consistent with BART.

3. Step 3: Compare the Potential Emissions to the 250 Ton/Yr Cutoff

The result of Steps 1 and 2 will be a list of emissions units at a given plant site, including reconstructed emissions units, that are within one or more of the BART categories and that were placed into operation within the 1962–1977 time window. The third step is to determine whether the total emissions represent a current potential to emit that is greater than 250 tons per year of any single visibility impairing pollutant. Fugitive emissions, to the extent quantifiable, must be counted. In most cases, you will add the potential emissions from all emission units on the list resulting from Steps 1 and 2. In a few cases, you may need to determine whether the plant contains more than one ''stationary source'' as the regional haze rule defines that term, and as we explain further below.

What pollutants should I address?

Visibility-impairing pollutants include the following:

(1) Sulfur dioxide (SO_2),

(2) Nitrogen oxides (NO_X), and

(3) Particulate matter.

You may use PM_{10} as an indicator for particulate matter in this intial step. [Note that we do not recommend use of total suspended particulates (TSP) as in indicator for particulate matter.] As emissions of PM_{10} include the components of $PM_{2.5}$ as a subset, there is no need to have separate 250 ton thresholds for PM_{10} and $PM_{2.5}$; 250 tons of PM_{10} represents at most 250 tons of $PM_{2.5}$, and at most 250 tons of any individual particulate species such as elemental carbon, crustal material, etc.

However, if you determine that a source of particulate matter is BART-eligible, it will be important to distinguish between the fine and coarse particle components of direct particulate emissions in the remainder of the BART analysis, including for the purpose of modeling the source's impact on visibility. This is because although both fine and coarse particulate matter contribute to visibility impairment, the long-range transport of fine particles is of particular concern in the formation of regional haze. Thus, for example, air quality modeling results used in the BART determination will provide a more accurate prediction of a source's impact on visibility if the inputs into the model account for the relative particle size of any directly emitted particulate matter (*i.e.* PM_{10} vs. $PM_{2.5}$).

You should exercise judgment in deciding whether the following pollutants impair visibility in an area:

(4) Volatile organic compounds (VOC), and

(5) Ammonia and ammonia compounds.

You should use your best judgment in deciding whether VOC or ammonia emissions from a source are likely to have an impact on visibility in an area. Certain types of VOC emissions, for example, are more likely to form secondary organic aerosols than others.[1] Similarly, controlling ammonia emissions in some areas may not have a significant impact on visibility. You need not provide a formal showing of an individual decision that a source of VOC or ammonia emissions is not subject to BART review. Because air quality modeling may not be feasible for individual sources of VOC or ammonia, you should also exercise your judgement in assessing the degree of visibility impacts due to emissions of VOC and emissions of ammonia or ammonia compounds. You should fully document the basis for judging that a VOC or ammonia source merits BART review, including your assessment of the source's contribution to visibility impairment.

What does the term ''potential'' emissions mean?

The regional haze rule defines potential to emit as follows:

''Potential to emit'' means the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the source to emit a pollutant including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable. Secondary emissions do not count in determining the potential to emit of a stationary source.

The definition of ''potential to emit'' means that a source which actually emits less than 250 tons per year of a visibility-impairing pollutant is BART-eligible if its emissions would exceed 250 tons per year when operating at its maximum capacity given its physical and operational design (and considering all federally enforceable and State enforceable permit limits.)

Example: A source, while operating at one-fourth of its capacity, emits 75 tons per year of SO_2. If it were operating at 100 percent of its maximum capacity, the source would emit 300 tons per year. Because under the above definition such a source would have ''potential'' emissions that exceed 250 tons per year, the source (if in a listed category and built during the 1962–1977 time window) would be BART-eligible.

How do I identify whether a plant has more than one ''stationary source?''

1. The regional haze rule, in 40 CFR 51.301, defines a stationary source as a ''building, structure, facility or installation which emits or may emit any air pollutant.''[2]

[1] *Fine particles: Overview of Atmospheric Chemistry, Sources of Emissions, and Ambient Monitoring Data,* Memorandum to Docket OAR 2002–006, April 1, 2005.

[2] **Note:** Most of these terms and definitions are the same for regional haze and the 1980 visibility regulations. For the regional haze rule we use the term ''BART-eligible source'' rather than ''existing stationary facility'' to clarify that only a limited subset of existing stationary sources are subject to BART.

The rule further defines ''building, structure or facility'' as:

all of the pollutant-emitting activities which belong to the same industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same person (or persons under common control). Pollutant-emitting activities must be considered as part of the same industrial grouping if they belong to the same Major Group (*i.e.*, which have the same two-digit code) as described in the Standard Industrial Classification Manual, 1972 as amended by the 1977 Supplement (U.S. Government Printing Office stock numbers 4101–0066 and 003–005–00176–0, respectively).

2. In applying this definition, it is necessary to determine which facilities are located on ''contiguous or adjacent properties.'' Within this contiguous and adjacent area, it is also necessary to group those emission units that are under ''common control.'' We note that these plant boundary issues and ''common control'' issues are very similar to those already addressed in implementation of the title V operating permits program and in NSR.

3. For emission units within the ''contiguous or adjacent'' boundary and under common control, you must group emission units that are within the same industrial grouping (that is, associated with the same 2-digit SIC code) in order to define the stationary source.[3] For most plants on the BART source category list, there will only be one 2-digit SIC that applies to the entire plant. For example, all emission units associated with kraft pulp mills are within SIC code 26, and chemical process plants will generally include emission units that are all within SIC code 28. The ''2-digit SIC test'' applies in the same way as the test is applied in the major source NSR programs.[4]

4. For purposes of the regional haze rule, you must group emissions from all emission units put in place within the 1962–1977 time period that are within the 2-digit SIC code, even if those emission units are in different categories on the BART category list.

Examples: A chemical plant which started operations within the 1962 to 1977 time period manufactures hydrochloric acid (within the category title ''Hydrochloric, sulfuric, and nitric acid plants'') and various organic chemicals (within the category title ''chemical process plants''). All of the emission units are within SIC code 28 and, therefore, all the emission units are considered in determining BART eligibility of the plant. You sum the emissions over all of these emission units to see whether there are more than 250 tons per year of potential emissions.

A steel mill which started operations within the 1962 to 1977 time period includes a sintering plant, a coke oven battery, and various other emission units. All of the emission units are within SIC code 33. You sum the emissions over all of these emission units to see whether there are more than 250 tons per year of potential emissions.

4. Final Step: Identify the Emissions Units and Pollutants That Constitute the BART-Eligible Source

If the emissions from the list of emissions units at a stationary source exceed a potential to emit of 250 tons per year for any visibility-impairing pollutant, then that collection of emissions units is a BART-eligible source.

Example: A stationary source comprises the following two emissions units, with the following potential emissions:

Emissions unit A
200 tons/yr SO_2
150 tons/yr NO_X
25 tons/yr PM

Emissions unit B
100 tons/yr SO_2
75 tons/yr NO_X
10 tons/yr PM

For this example, potential emissions of SO_2 are 300 tons/yr, which exceeds the 250 tons/yr threshold. Accordingly, the entire ''stationary source'', that is, emissions units A and B, may be subject to a BART review for SO_2, NO_X, and PM, even though the potential emissions of PM and NO_X at each emissions unit are less than 250 tons/yr each.

Example: The total potential emissions, obtained by adding the potential emissions of all emission units in a listed category at a plant site, are as follows:

200 tons/yr SO_2
150 tons/yr NO_X
25 tons/yr PM

Even though total emissions exceed 250 tons/yr, no individual regulated pollutant exceeds 250 tons/yr and this source is not BART-eligible.

Can States establish de minimis levels of emissions for pollutants at BART-eligible sources?

In order to simplify BART determinations, States may choose to identify de minimis levels of pollutants at BART-eligible sources (but are not required to do so). De minimis values should be identified with the purpose of excluding only those emissions so minimal that they are unlikely to contribute to regional haze. Any de minimis values that you adopt must not be higher than the PSD applicability levels: 40 tons/yr for SO_2 and NO_X and 15 tons/yr for PM_{10}. These de minimis levels may only be applied on a plant-wide basis.

III. How to Identify Sources ''Subject to BART''

Once you have compiled your list of BART-eligible sources, you need to determine whether (1) to make BART determinations for all of them or (2) to consider exempting some of them from BART because they may not reasonably be anticipated to cause or contribute to any visibility impairment in a Class I area. If you decide to make BART determinations for all the BART-eligible sources on your list, you should work with your regional planning organization (RPO) to show that, collectively, they cause or contribute to visibility impairment in at least one Class I area. You should then make individual BART determinations by applying the five statutory factors discussed in Section IV below.

On the other hand, you also may choose to perform an initial examination to determine whether a particular BART-eligible source or group of sources causes or contributes to visibility impairment in nearby Class I areas. If your analysis, or information submitted by the source, shows that an individual source or group of sources (or certain pollutants from those sources) is not reasonably anticipated to cause or contribute to any visibility impairment in a Class I area, then you do not need to make BART determinations for that source or group of sources (or for certain pollutants from those sources). In such a case, the source is not ''subject to BART'' and you do not need to apply the five statutory factors to make a BART determination. This section of the Guideline discusses several approaches that you can use to exempt sources from the BART determination process.

A. What Steps Do I Follow To Determine Whether a Source or Group of Sources Cause or Contribute to Visibility Impairment for Purposes of BART?

1. How Do I Establish a Threshold?

One of the first steps in determining whether sources cause or contribute to visibility impairment for purposes of BART is to establish a threshold (measured in deciviews) against which to measure the visibility impact of one or more sources. A single source that is responsible for a 1.0 deciview change or more should be considered to ''cause'' visibility impairment; a source that causes less than a 1.0 deciview change may still contribute to visibility impairment and thus be subject to BART.

Because of varying circumstances affecting different Class I areas, the appropriate threshold for determining whether a source ''contributes to any visibility impairment'' for the purposes of BART may reasonably differ across States. As a general matter, any threshold that you use for determining whether a source ''contributes'' to visibility impairment should not be higher than 0.5 deciviews.

In setting a threshold for ''contribution,'' you should consider the number of emissions sources affecting the Class I areas at issue and the magnitude of the individual sources' impacts.[5] In general, a larger number of sources causing impacts in a Class I area may warrant a lower contribution threshold. States remain free to use a threshold lower than 0.5 deciviews if they conclude that the

[3] We recognize that we are in a transition period from the use of the SIC system to a new system called the North American Industry Classification System (NAICS). For purposes of identifying BART-eligible sources, you may use either 2-digit SICS or the equivalent in the NAICS system.

[4] **Note:** The concept of support facility used for the NSR program applies here as well. Support facilities, that is facilities that convey, store or otherwise assist in the production of the principal product, must be grouped with primary facilities even when the facilities fall wihin separate SIC codes. For purposes of BART reviews, however, such support facilities (a) must be within one of the 26 listed source categories and (b) must have been in existence as of August 7, 1977, and (c) must not have been in operation as of August 7, 1962.

[5] We expect that regional planning organizations will have modeling information that identifies sources affecting visibility in individual class I areas.

location of a large number of BART-eligible sources within the State and in proximity to a Class I area justify this approach.[6]

2. What Pollutants Do I Need to Consider?

You must look at SO_2, NO_X, and direct particulate matter (PM) emissions in determining whether sources cause or contribute to visibility impairment, including both PM_{10} and $PM_{2.5}$. Consistent with the approach for identifying your BART-eligible sources, you do not need to consider less than de minimis emissions of these pollutants from a source.

As explained in section II, you must use your best judgement to determine whether VOC or ammonia emissions are likely to have an impact on visibility in an area. In addition, although as explained in Section II, you may use PM_{10} an indicator for particulate matter in determining whether a source is BART-eligible, in determining whether a source contributes to visibility impairment, you should distinguish between the fine and coarse particle components of direct particulate emissions. Although both fine and coarse particulate matter contribute to visibility impairment, the long-range transport of fine particles is of particular concern in the formation of regional haze. Air quality modeling results used in the BART determination will provide a more accurate prediction of a source's impact on visibility if the inputs into the model account for the relative particle size of any directly emitted particulate matter (i.e. PM_{10} vs. $PM_{2.5}$).

3. What Kind of Modeling Should I Use To Determine Which Sources and Pollutants Need Not Be Subject to BART?

This section presents several options for determining that certain sources need not be subject to BART. These options rely on different modeling and/or emissions analysis approaches. They are provided for your guidance. You may also use other reasonable approaches for analyzing the visibility impacts of an individual source or group of sources.

Option 1: Individual Source Attribution Approach (Dispersion Modeling)

You can use dispersion modeling to determine that an individual source cannot reasonably be anticipated to cause or contribute to visibility impairment in a Class I area and thus is not subject to BART. Under this option, you can analyze an individual source's impact on visibility as a result of its emissions of SO_2, NO_X and direct PM emissions. Dispersion modeling cannot currently be used to estimate the predicted impacts on visibility from an individual source's emissions of VOC or ammonia. You may use a more qualitative assessment to determine on a case-by-case basis which sources of VOC or ammonia emissions may be likely to impair visibility and should therefore be subject to BART review, as explained in section II.A.3. above.

You can use CALPUFF[7] or other appropriate model to predict the visibility impacts from a single source at a Class I area. CALPUFF is the best regulatory modeling application currently available for predicting a single source's contribution to visibility impairment and is currently the only EPA-approved model for use in estimating single source pollutant concentrations resulting from the long range transport of primary pollutants.[8] It can also be used for some other purposes, such as the visibility assessments addressed in today's rule, to account for the chemical transformation of SO_2 and NO_X.

There are several steps for making an individual source attribution using a dispersion model:

1. *Develop a modeling protocol.* Some critical items to include in the protocol are the meteorological and terrain data that will be used, as well as the source-specific information (stack height, temperature, exit velocity, elevation, and emission rates of applicable pollutants) and receptor data from appropriate Class I areas. We recommend following EPA's *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts*[9] for parameter settings and meteorological data inputs. You may use other settings from those in IWAQM, but you should identify these settings and explain your selection of these settings.

One important element of the protocol is in establishing the receptors that will be used in the model. The receptors that you use should be located in the nearest Class I area with sufficient density to identify the likely visibility effects of the source. For other Class I areas in relatively close proximity to a BART-eligible source, you may model a few strategic receptors to determine whether effects at those areas may be greater than at the nearest Class I area. For example, you might chose to locate receptors at these areas at the closest point to the source, at the highest and lowest elevation in the Class I area, at the IMPROVE monitor, and at the approximate expected plume release height. If the highest modeled effects are observed at the nearest Class I area, you may choose not to analyze the other Class I areas any further as additional analyses might be unwarranted.

You should bear in mind that some receptors within the relevant Class I area may be less than 50 km from the source while other receptors within that same Class I area may be greater than 50 km from the same source. As indicated by the Guideline on Air Quality Models, 40 CFR part 51, appendix W, this situation may call for the use of two different modeling approaches for the same Class I area and source, depending upon the State's chosen method for modeling sources less than 50 km. In situations where you are assessing visibility impacts for source-receptor distances less than 50 km, you should use expert modeling judgment in determining visibility impacts, giving consideration to both CALPUFF and other appropriate methods.

In developing your modeling protocol, you may want to consult with EPA and your regional planning organization (RPO). Up-front consultation will ensure that key technical issues are addressed before you conduct your modeling.

2. *With the accepted protocol and compare the predicted visibility impacts with your threshold for ''contribution.''* You should calculate daily visibility values for each receptor as the change in deciviews compared against natural visibility conditions. You can use EPA's ''Guidance for Estimating Natural Visibility Conditions Under the Regional Haze Rule,'' EPA–454/B–03–005 (September 2003) in making this calculation. To determine whether a source may reasonably be anticipated to cause or contribute to visibility impairment at Class I area, you then compare the impacts predicted by the model against the threshold that you have selected.

The emissions estimates used in the models are intended to reflect steady-state operating conditions during periods of high capacity utilization. We do not generally recommend that emissions reflecting periods of start-up, shutdown, and malfunction be used, as such emission rates could produce higher than normal effects than would be typical of most facilities. We recommend that States use the 24 hour average actual emission rate from the highest emitting day of the meteorological period modeled, unless this rate reflects periods start-up, shutdown, or malfunction. In addition, the monthly average relative humidity is used, rather than the daily average humidity—an approach that effectively lowers the peak values in daily model averages.

For these reasons, if you use the modeling approach we recommend, you should compare your ''contribution'' threshold against the 98th percentile of values. If the 98th percentile value from your modeling is less than your contribution threshold, then you may conclude that the source does not contribute to visibility impairment and is not subject to BART.

Option 2: Use of Model Plants To Exempt Individual Sources With Common Characteristics

Under this option, analyses of model plants could be used to exempt certain BART-eligible sources that share specific characteristics. It may be most useful to use this type of analysis to identify the types of small sources that do not cause or contribute to visibility impairment for purposes of BART, and thus should not be subject to a BART review. Different Class I areas may have different characteristics, however, so

[6] Note that the contribution threshold should be used to determine whether an individual source is reasonably anticipated to contribute to visibility impairment. You should not aggregate the visibility effects of multiple sources and compare their collective effects against your contribution threshold because this would inappropriately create a ''contribute to contribution'' test.

[7] The model code and its documentation are available at no cost for download from *http://www.epa.gov/scram001/tt22.htm#calpuff.*

[8] The Guideline on Air Quality Models, 40 CFR part 51, appendix W, addresses the regulatory application of air quality models for assessing criteria pollutants under the CAA, and describes further the procedures for using the CALPUFF model, as well as for obtaining approval for the use of other, nonguideline models.

[9] *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts,* U.S. Environmental Protection Agency, EPA–454/R–98–019, December 1998.

you should use care to ensure that the criteria you develop are appropriate for the applicable cases.

In carrying out this approach, you could use modeling analyses of representative plants to reflect groupings of specific sources with important common characteristics. Based on these analyses, you may find that certain types of sources are clearly anticipated to cause or contribute to visibility impairment. You could then choose to categorically require those types of sources to undergo a BART determination. Conversely, you may find based on representative plant analyses that certain types of sources are not reasonably anticipated to cause or contribute to visibility impairment. To do this, you may conduct your own modeling to establish emission levels and distances from Class I areas on which you can rely to exempt sources with those characteristics. For example, based on your modeling you might choose to exempt all NO_X-only sources that emit less than a certain amount per year and are located a certain distance from a Class I area. You could then choose to categorically exempt such sources from the BART determination process.

Our analyses of visibility impacts from model plants provide a useful example of the type of analyses that can be used to exempt categories of sources from BART.[10] In our analyses, we developed model plants (EGUs and non-EGUs), with representative plume and stack characteristics, for use in considering the visibility impact from emission sources of different sizes and compositions at distances of 50, 100 and 200 kilometers from two hypothetical Class I areas (one in the East and one in the West). As the plume and stack characteristics of these model plants were developed considering the broad range of sources within the EGU and non-EGU categories, they do not necessarily represent any specific plant. However, the results of these analyses are instructive in the development of an exemption process for any Class I area.

In preparing our analyses, we have made a number of assumptions and exercised certain modeling choices; some of these have a tendency to lend conservatism to the results, overstating the likely effects, while others may understate the likely effects. On balance, when all of these factors are considered, we believe that our examples reflect realistic treatments of the situations being modeled. Based on our analyses, we believe that a State that has established 0.5 deciviews as a contribution threshold could reasonably exempt from the BART review process sources that emit less than 500 tons per year of NO_X or SO_2 (or combined NO_X and SO_2), as long as these sources are located more than 50 kilometers from any Class I area; and sources that emit less than 1000 tons per year of NO_X or SO_2 (or combined NO_X and SO_2) that are located more than 100 kilometers from any Class I area. You do, however, have the option of showing other thresholds might also be appropriate given your specific circumstances.

[10] CALPUFF Analysis in Support of the June 2005 Changes to the Regional Haze Rule, U.S. Environmental Protection Agency, June 15, 2005, Docket No. OAR–2002–0076.

Option 3: Cumulative Modeling To Show That No Sources in a State Are Subject to BART

You may also submit to EPA a demonstration based on an analysis of overall visibility impacts that emissions from BART-eligible sources in your State, considered together, are not reasonably anticipated to cause or contribute to any visibility impairment in a Class I area, and thus no source should be subject to BART. You may do this on a pollutant by pollutant basis or for all visibility-impairing pollutants to determine if emissions from these sources contribute to visibility impairment.

For example, emissions of SO_2 from your BART-eligible sources may clearly cause or contribute to visibility impairment while direct emissions of $PM_{2.5}$ from these sources may not contribute to impairment. If you can make such a demonstration, then you may reasonably conclude that none of your BART-eligible sources are subject to BART for a particular pollutant or pollutants. As noted above, your demonstration should take into account the interactions among pollutants and their resulting impacts on visibility before making any pollutant-specific determinations.

Analyses may be conducted using several alternative modeling approaches. First, you may use the CALPUFF or other appropriate model as described in Option 1 to evaluate the impacts of individual sources on downwind Class I areas, aggregating those impacts to determine the collective contribution of all BART-eligible sources to visibility impairment. You may also use a photochemical grid model. As a general matter, the larger the number of sources being modeled, the more appropriate it may be to use a photochemical grid model. However, because such models are significantly less sensitive than dispersion models to the contributions of one or a few sources, as well as to the interactions among sources that are widely distributed geographically, if you wish to use a grid model, you should consult with the appropriate EPA Regional Office to develop an appropriate modeling protocol.

IV. The BART Determination: Analysis of BART Options

This section describes the process for the analysis of control options for sources subject to BART.

A. What factors must I address in the BART review?

The visibility regulations define BART as follows:

Best Available Retrofit Technology (BART) means an emission limitation based on the degree of reduction achievable through the application of the best system of continuous emission reduction for each pollutant which is emitted by . . . [a BART-eligible source]. The emission limitation must be established, on a case-by-case basis, taking into consideration the technology available, the costs of compliance, the energy and non-air quality environmental impacts of compliance, any pollution control equipment in use or in existence at the source, the remaining useful life of the source, and the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

The BART analysis identifies the best system of continuous emission reduction taking into account:

(1) The available retrofit control options,

(2) Any pollution control equipment in use at the source (which affects the availability of options and their impacts),

(3) The costs of compliance with control options,

(4) The remaining useful life of the facility,

(5) The energy and non-air quality environmental impacts of control options

(6) The visibility impacts analysis.

B. What is the scope of the BART review?

Once you determine that a source is subject to BART for a particular pollutant, then for each affected emission unit, you must establish BART for that pollutant. The BART determination must address air pollution control measures for each emissions unit or pollutant emitting activity subject to review.

Example: Plantwide emissions from emission units within the listed categories that began operation within the ''time window'' for BART[11] are 300 tons/yr of NO_X, 200 tons/yr of SO_2, and 150 tons/yr of primary particulate. Emissions unit A emits 200 tons/yr of NO_X, 100 tons/yr of SO_2, and 100 tons/yr of primary particulate. Other emission units, units B through H, which began operating in 1966, contribute lesser amounts of each pollutant. For this example, a BART review is required for NO_X, SO_2, and primary particulate, and control options must be analyzed for units B through H as well as unit A.

C. How does a BART review relate to Maximum Achievable Control Technology (MACT) Standards under CAA section 112, or to other emission limitations required under the CAA?

For VOC and PM sources subject to MACT standards, States may streamline the analysis by including a discussion of the MACT controls and whether any major new technologies have been developed subsequent to the MACT standards. We believe that there are many VOC and PM sources that are well controlled because they are regulated by the MACT standards, which EPA developed under CAA section 112. For a few MACT standards, this may also be true for SO_2. Any source subject to MACT standards must meet a level that is as stringent as the best-controlled 12 percent of sources in the industry. Examples of these hazardous air pollutant sources which effectively control VOC and PM emissions include (among others) secondary lead facilities, organic chemical plants subject to the hazardous organic NESHAP (HON), pharmaceutical production facilities, and equipment leaks and wastewater operations at petroleum refineries. We believe that, in many cases, it will be unlikely that States will identify emission controls more stringent than the MACT standards without

[11] That is, emission units that were in existence on August 7, 1977 and which began actual operation on or after August 7, 1962.

identifying control options that would cost many thousands of dollars per ton. Unless there are new technologies subsequent to the MACT standards which would lead to cost-effective increases in the level of control, you may rely on the MACT standards for purposes of BART.

We believe that the same rationale also holds true for emissions standards developed for municipal waste incinerators under CAA section 111(d), and for many NSR/PSD determinations and NSR/PSD settlement agreements. However, we do not believe that technology determinations from the 1970s or early 1980s, including new source performance standards (NSPS), should be considered to represent best control for existing sources, as best control levels for recent plant retrofits are more stringent than these older levels.

Where you are relying on these standards to represent a BART level of control, you should provide the public with a discussion of whether any new technologies have subsequently become available.

D. What Are the Five Basic Steps of a Case-by-Case BART Analysis?

The five steps are:

STEP 1—Identify All [12] Available Retrofit Control Technologies,

STEP 2— Eliminate Technically Infeasible Options,

STEP 3— Evaluate Control Effectiveness of Remaining Control Technologies,

STEP 4— Evaluate Impacts and Document the Results, and

STEP 5—Evaluate Visibility Impacts.

1. STEP 1: How do I identify all available retrofit emission control techniques?

1. Available retrofit control options are those air pollution control technologies with a practical potential for application to the emissions unit and the regulated pollutant under evaluation. Air pollution control technologies can include a wide variety of available methods, systems, and techniques for control of the affected pollutant. Technologies required as BACT or LAER are available for BART purposes and must be included as control alternatives. The control alternatives can include not only existing controls for the source category in question but also take into account technology transfer of controls that have been applied to similar source categories and gas streams. Technologies which have not yet been applied to (or permitted for) full scale operations need not be considered as available; we do not expect the source owner to purchase or construct a process or control device that has not already been demonstrated in practice.

2. Where a NSPS exists for a source category (which is the case for most of the categories affected by BART), you should include a level of control equivalent to the NSPS as one of the control options.[13] The NSPS standards are codified in 40 CFR part 60. We note that there are situations where NSPS standards do not require the most stringent level of available control for all sources within a category. For example, post-combustion NO_X controls (the most stringent controls for stationary gas turbines) are not required under subpart GG of the NSPS for Stationary Gas Turbines. However, such controls must still be considered available technologies for the BART selection process.

3. Potentially applicable retrofit control alternatives can be categorized in three ways.

- Pollution prevention: use of inherently lower-emitting processes/practices, including the use of control techniques (*e.g.* low-NO_X burners) and work practices that prevent emissions and result in lower ''production-specific'' emissions (note that it is not our intent to direct States to switch fuel forms, *e.g.* from coal to gas),
- Use of (and where already in place, improvement in the performance of) add-on controls, such as scrubbers, fabric filters, thermal oxidizers and other devices that control and reduce emissions after they are produced, and
- Combinations of inherently lower-emitting processes and add-on controls.

4. In the course of the BART review, one or more of the available control options may be eliminated from consideration because they are demonstrated to be technically infeasible or to have unacceptable energy, cost, or non-air quality environmental impacts on a case-by-case (or site-specific) basis. However, at the outset, you should initially identify all control options with potential application to the emissions unit under review.

5. We do not consider BART as a requirement to redesign the source when considering available control alternatives. For example, where the source subject to BART is a coal-fired electric generator, we do not require the BART analysis to consider building a natural gas-fired electric turbine although the turbine may be inherently less polluting on a per unit basis.

6. For emission units subject to a BART review, there will often be control measures or devices already in place. For such emission units, it is important to include control options that involve improvements to existing controls and not to limit the control options only to those measures that involve a complete replacement of control devices.

Example: For a power plant with an existing wet scrubber, the current control efficiency is 66 percent. Part of the reason for the relatively low control efficiency is that 22 percent of the gas stream bypasses the scrubber. A BART review identifies options for improving the performance of the wet scrubber by redesigning the internal components of the scrubber and by eliminating or reducing the percentage of the gas stream that bypasses the scrubber. Four control options are identified: (1) 78 percent control based upon improved scrubber performance while maintaining the 22 percent bypass, (2) 83 percent control based upon improved scrubber performance while reducing the bypass to 15 percent, (3) 93 percent control based upon improving the scrubber performance while eliminating the bypass entirely, (this option results in a ''wet stack'' operation in which the gas leaving the stack is saturated with water) and (4) 93 percent as in option 3, with the addition of an indirect reheat system to reheat the stack gas above the saturation temperature. You must consider each of these four options in a BART analysis for this source.

7. You are expected to identify potentially applicable retrofit control technologies that represent the full range of demonstrated alternatives. Examples of general information sources to consider include:

- The EPA's Clean Air Technology Center, which includes the RACT/BACT/LAER Clearinghouse (RBLC);
- State and Local Best Available Control Technology Guidelines—many agencies have online information—for example South Coast Air Quality Management District, Bay Area Air Quality Management District, and Texas Natural Resources Conservation Commission;
- Control technology vendors;
- Federal/State/Local NSR permits and associated inspection/performance test reports;
- Environmental consultants;
- Technical journals, reports and newsletters, air pollution control seminars; and
- The EPA's NSR bulletin board—*http://www.epa.gov/ttn/nsr;*
- Department of Energy's Clean Coal Program—technical reports;
- The NO_X Control Technology ''Cost Tool''—Clean Air Markets Division Web page—*http://www.epa.gov/airmarkets/arp/nox/controltech.html;*
- Performance of selective catalytic reduction on coal-fired steam generating units—final report. OAR/ARD, June 1997 (also available at *http://www.epa.gov/airmarkets/arp/nox/controltech.html*);
- Cost estimates for selected applications of NO_X control technologies on stationary combustion boilers. OAR/ARD June 1997. (Docket for NO_X SIP Call, A–96–56, item II–A–03);
- Investigation of performance and cost of NO_X controls as applied to group 2 boilers. OAR/ARD, August 1996. (Docket for Phase II NO_X rule, A–95–28, item IV–A–4);
- Controlling SO_2 Emissions: A Review of Technologies. EPA–600/R–00–093, USEPA/ORD/NRMRL, October 2000; and
- The OAQPS Control Cost Manual.

You are expected to compile appropriate information from these information sources.

8. There may be situations where a specific set of units within a fenceline constitutes the

[12] In identifying ''all'' options, you must identify the most stringent option and a reasonable set of options for analysis that reflects a comprehensive list of available technologies. It is not necessary to list all permutations of available control levels that exist for a given technology—the list is complete if it includes the maximum level of control each technology is capable of achieving.

[13] In EPA's 1980 BART guidelines for reasonably attributable visibility impairment, we concluded that NSPS standards generally, at that time, represented the best level sources could install as BART. In the 20 year period since this guidance was developed, there have been advances in SO_2 control technologies as well as technologies for the control of other pollutants, confirmed by a number of recent retrofits at Western power plants. Accordingly, EPA no longer concludes that the NSPS level of controls automatically represents ''the best these sources can install.'' Analysis of the BART factors could result in the selection of a NSPS level of control, but you should reach this conclusion only after considering the full range of control options.

logical set to which controls would apply and that set of units may or may not all be BART-eligible. (For example, some units in that set may not have been constructed between 1962 and 1977.)

9. If you find that a BART source has controls already in place which are the most stringent controls available (note that this means that all possible improvements to any control devices have been made), then it is not necessary to comprehensively complete each following step of the BART analysis in this section. As long these most stringent controls available are made federally enforceable for the purpose of implementing BART for that source, you may skip the remaining analyses in this section, including the visibility analysis in step 5. Likewise, if a source commits to a BART determination that consists of the most stringent controls available, then there is no need to complete the remaining analyses in this section.

2. STEP 2: How do I determine whether the options identified in Step 1 are technically feasible?

In Step 2, you evaluate the technical feasibility of the control options you identified in Step 1. You should document a demonstration of technical infeasibility and should explain, based on physical, chemical, or engineering principles, why technical difficulties would preclude the successful use of the control option on the emissions unit under review. You may then eliminate such technically infeasible control options from further consideration in the BART analysis.

In general, what do we mean by technical feasibility?

Control technologies are technically feasible if either (1) they have been installed and operated successfully for the type of source under review under similar conditions, or (2) the technology could be applied to the source under review. Two key concepts are important in determining whether a technology could be applied: ''availability'' and ''applicability.'' As explained in more detail below, a technology is considered ''available'' if the source owner may obtain it through commercial channels, or it is otherwise available within the common sense meaning of the term. An available technology is ''applicable'' if it can reasonably be installed and operated on the source type under consideration. A technology that is available and applicable is technically feasible.

What do we mean by ''available'' technology?

1. The typical stages for bringing a control technology concept to reality as a commercial product are:

- Concept stage;
- Research and patenting;
- Bench scale or laboratory testing;
- Pilot scale testing;
- Licensing and commercial demonstration; and
- Commercial sales.

2. A control technique is considered available, within the context presented above, if it has reached the stage of licensing and commercial availability. Similarly, we do not expect a source owner to conduct extended trials to learn how to apply a technology on a totally new and dissimilar source type. Consequently, you would not consider technologies in the pilot scale testing stages of development as ''available'' for purposes of BART review.

3. Commercial availability by itself, however, is not necessarily a sufficient basis for concluding a technology to be applicable and therefore technically feasible. Technical feasibility, as determined in Step 2, also means a control option may reasonably be deployed on or ''applicable'' to the source type under consideration.

Because a new technology may become available at various points in time during the BART analysis process, we believe that guidelines are needed on when a technology must be considered. For example, a technology may become available during the public comment period on the State's rule development process. Likewise, it is possible that new technologies may become available after the close of the State's public comment period and before submittal of the SIP to EPA, or during EPA's review process on the SIP submittal. In order to provide certainty in the process, all technologies should be considered if available before the close of the State's public comment period. You need not consider technologies that become available after this date. As part of your analysis, you should consider any technologies brought to your attention in public comments. If you disagree with public comments asserting that the technology is available, you should provide an explanation for the public record as to the basis for your conclusion.

What do we mean by ''applicable'' technology?

You need to exercise technical judgment in determining whether a control alternative is applicable to the source type under consideration. In general, a commercially available control option will be presumed applicable if it has been used on the same or a similar source type. Absent a showing of this type, you evaluate technical feasibility by examining the physical and chemical characteristics of the pollutant-bearing gas stream, and comparing them to the gas stream characteristics of the source types to which the technology had been applied previously. Deployment of the control technology on a new or existing source with similar gas stream characteristics is generally a sufficient basis for concluding the technology is technically feasible barring a demonstration to the contrary as described below.

What type of demonstration is required if I conclude that an option is not technically feasible?

1. Where you conclude that a control option identified in Step 1 is technically infeasible, you should demonstrate that the option is either commercially unavailable, or that specific circumstances preclude its application to a particular emission unit. Generally, such a demonstration involves an evaluation of the characteristics of the pollutant-bearing gas stream and the capabilities of the technology. Alternatively, a demonstration of technical infeasibility may involve a showing that there are unresolvable technical difficulties with applying the control to the source (*e.g.*, size of the unit, location of the proposed site, operating problems related to specific circumstances of the source, space constraints, reliability, and adverse side effects on the rest of the facility). Where the resolution of technical difficulties is merely a matter of increased cost, you should consider the technology to be technically feasible. The cost of a control alternative is considered later in the process.

2. The determination of technical feasibility is sometimes influenced by recent air quality permits. In some cases, an air quality permit may require a certain level of control, but the level of control in a permit is not expected to be achieved in practice (*e.g.*, a source has received a permit but the project was canceled, or every operating source at that permitted level has been physically unable to achieve compliance with the limit). Where this is the case, you should provide supporting documentation showing why such limits are not technically feasible, and, therefore, why the level of control (but not necessarily the technology) may be eliminated from further consideration. However, if there is a permit requiring the application of a certain technology or emission limit to be achieved for such technology, this usually is sufficient justification for you to assume the technical feasibility of that technology or emission limit.

3. Physical modifications needed to resolve technical obstacles do not, in and of themselves, provide a justification for eliminating the control technique on the basis of technical infeasibility. However, you may consider the cost of such modifications in estimating costs. This, in turn, may form the basis for eliminating a control technology (see later discussion).

4. Vendor guarantees may provide an indication of commercial availability and the technical feasibility of a control technique and could contribute to a determination of technical feasibility or technical infeasibility, depending on circumstances. However, we do not consider a vendor guarantee alone to be sufficient justification that a control option will work. Conversely, lack of a vendor guarantee by itself does not present sufficient justification that a control option or an emissions limit is technically infeasible. Generally, you should make decisions about technical feasibility based on chemical, and engineering analyses (as discussed above), in conjunction with information about vendor guarantees.

5. A possible outcome of the BART procedures discussed in these guidelines is the evaluation of multiple control technology alternatives which result in essentially equivalent emissions. It is not our intent to encourage evaluation of unnecessarily large numbers of control alternatives for every emissions unit. Consequently, you should use judgment in deciding on those alternatives for which you will conduct the detailed impacts analysis (Step 4 below). For example, if two or more control techniques result in control levels that are essentially identical, considering the uncertainties of emissions factors and other parameters

pertinent to estimating performance, you may evaluate only the less costly of these options. You should narrow the scope of the BART analysis in this way only if there is a negligible difference in emissions and energy and non-air quality environmental impacts between control alternatives.

3. STEP 3: How do I evaluate technically feasible alternatives?

Step 3 involves evaluating the control effectiveness of all the technically feasible control alternatives identified in Step 2 for the pollutant and emissions unit under review.

Two key issues in this process include:

(1) Making sure that you express the degree of control using a metric that ensures an ''apples to apples'' comparison of emissions performance levels among options, and

(2) Giving appropriate treatment and consideration of control techniques that can operate over a wide range of emission performance levels.

What are the appropriate metrics for comparison?

This issue is especially important when you compare inherently lower-polluting processes to one another or to add-on controls. In such cases, it is generally most effective to express emissions performance as an average steady state emissions level per unit of product produced or processed.

Examples of common metrics:

• Pounds of SO_2 emissions per million Btu heat input, and

• Pounds of NO_X emissions per ton of cement produced.

How do I evaluate control techniques with a wide range of emission performance levels?

1. Many control techniques, including both add-on controls and inherently lower polluting processes, can perform at a wide range of levels. Scrubbers and high and low efficiency electrostatic precipitators (ESPs) are two of the many examples of such control techniques that can perform at a wide range of levels. It is not our intent to require analysis of each possible level of efficiency for a control technique as such an analysis would result in a large number of options. It is important, however, that in analyzing the technology you take into account the most stringent emission control level that the technology is capable of achieving. You should consider recent regulatory decisions and performance data (*e.g.*, manufacturer's data, engineering estimates and the experience of other sources) when identifying an emissions performance level or levels to evaluate.

2. In assessing the capability of the control alternative, latitude exists to consider special circumstances pertinent to the specific source under review, or regarding the prior application of the control alternative. However, you should explain the basis for choosing the alternate level (or range) of control in the BART analysis. Without a showing of differences between the source and other sources that have achieved more stringent emissions limits, you should conclude that the level being achieved by those other sources is representative of the achievable level for the source being analyzed.

3. You may encounter cases where you may wish to evaluate other levels of control in addition to the most stringent level for a given device. While you must consider the most stringent level as one of the control options, you may consider less stringent levels of control as additional options. This would be useful, particularly in cases where the selection of additional options would have widely varying costs and other impacts.

4. Finally, we note that for retrofitting existing sources in addressing BART, you should consider ways to improve the performance of existing control devices, particularly when a control device is not achieving the level of control that other similar sources are achieving in practice with the same device. For example, you should consider requiring those sources with electrostatic precipitators (ESPs) performing below currently achievable levels to improve their performance.

4. STEP 4: For a BART review, what impacts am I expected to calculate and report? What methods does EPA recommend for the impacts analysis?

After you identify the available and technically feasible control technology options, you are expected to conduct the following analyses when you make a BART determination:

Impact analysis part 1: Costs of compliance,

Impact analysis part 2: Energy impacts, and

Impact analysis part 3: Non-air quality environmental impacts.

Impact analysis part 4: Remaining useful life.

In this section, we describe how to conduct each of these three analyses. You are responsible for presenting an evaluation of each impact along with appropriate supporting information. You should discuss and, where possible, quantify both beneficial and adverse impacts. In general, the analysis should focus on the direct impact of the control alternative.

a. Impact analysis part 1: how do I estimate the costs of control?

1. To conduct a cost analysis, you:

(1) Identify the emissions units being controlled,

(2) Identify design parameters for emission controls, and

(3) Develop cost estimates based upon those design parameters.

2. It is important to identify clearly the emission units being controlled, that is, to specify a well-defined area or process segment within the plant. In some cases, multiple emission units can be controlled jointly. However, in other cases, it may be appropriate in the cost analysis to consider whether multiple units will be required to install separate and/or different control devices. The analysis should provide a clear summary list of equipment and the associated control costs. Inadequate documentation of the equipment whose emissions are being controlled is a potential cause for confusion in comparison of costs of the same controls applied to similar sources.

3. You then specify the control system design parameters. Potential sources of these design parameters include equipment vendors, background information documents used to support NSPS development, control technique guidelines documents, cost manuals developed by EPA, control data in trade publications, and engineering and performance test data. The following are a few examples of design parameters for two example control measures:

Control device	Examples of design parameters
Wet Scrubbers ..	Type of sorbent used (lime, limestone, etc.). Gas pressure drop. Liquid/gas ratio.
Selective Catalytic Reduction.	Ammonia to NO_X molar ratio. Pressure drop. Catalyst life.

4. The value selected for the design parameter should ensure that the control option will achieve the level of emission control being evaluated. You should include in your analysis documentation of your assumptions regarding design parameters. Examples of supporting references would include the EPA OAQPS *Control Cost Manual* (see below) and background information documents used for NSPS and hazardous pollutant emission standards. If the design parameters you specified differ from typical designs, you should document the difference by supplying performance test data for the control technology in question applied to the same source or a similar source.

5. Once the control technology alternatives and achievable emissions performance levels have been identified, you then develop estimates of capital and annual costs. The basis for equipment cost estimates also should be documented, either with data supplied by an equipment vendor (*i.e.*, budget estimates or bids) or by a referenced source (such as the *OAQPS Control Cost Manual,* Fifth Edition, February 1996, EPA 453/B–96–001).[14] In order to maintain and improve consistency, cost estimates should be based on the *OAQPS Control Cost Manual,* where possible.[15] The *Control Cost Manual* addresses most control technologies in sufficient detail for a BART analysis. The cost analysis should also take into account any site-specific design or other conditions identified above that affect the cost of a particular BART technology option.

[14] The *OAQPS Control Cost Manual* is updated periodically. While this citation refers to the latest version at the time this guidance was written, you should use the version that is current as of when you conduct your impact analysis. This document is available at the following Web site: *http://www.epa.gov/ttn/catc/dir1/cs1ch2.pdf.*

[15] You should include documentation for any additional information you used for the cost calculations, including any information supplied by vendors that affects your assumptions regarding purchased equipment costs, equipment life, replacement of major components, and any other element of the calculation that differs from the *Control Cost Manual.*

b. What do we mean by cost effectiveness?

Cost effectiveness, in general, is a criterion used to assess the potential for achieving an objective in the most economical way. For purposes of air pollutant analysis, ''effectiveness'' is measured in terms of tons of pollutant emissions removed, and ''cost'' is measured in terms of annualized control costs. We recommend two types of cost-effectiveness calculations—average cost effectiveness, and incremental cost effectiveness.

c. How do I calculate average cost effectiveness?

Average cost effectiveness means the total annualized costs of control divided by annual emissions reductions (the difference between baseline annual emissions and the estimate of emissions after controls), using the following formula:

Average cost effectiveness (dollars per ton removed) = *Control option annualized cost*[16]

Baseline annual emissions—Annual emissions with Control option

Because you calculate costs in (annualized) dollars per year ($/yr) and because you calculate emissions rates in tons per year (tons/yr), the result is an average cost-effectiveness number in (annualized) dollars per ton ($/ton) of pollutant removed.

d. How do I calculate baseline emissions?

1. The baseline emissions rate should represent a realistic depiction of anticipated annual emissions for the source. In general, for the existing sources subject to BART, you will estimate the anticipated annual emissions based upon actual emissions from a baseline period.

2. When you project that future operating parameters (*e.g.*, limited hours of operation or capacity utilization, type of fuel, raw materials or product mix or type) will differ from past practice, and if this projection has a deciding effect in the BART determination, then you must make these parameters or assumptions into enforceable limitations. In the absence of enforceable limitations, you calculate baseline emissions based upon continuation of past practice.

3. For example, the baseline emissions calculation for an emergency standby generator may consider the fact that the source owner would not operate more than past practice of 2 weeks a year. On the other hand, baseline emissions associated with a base-loaded turbine should be based on its past practice which would indicate a large number of hours of operation. This produces a significantly higher level of baseline emissions than in the case of the emergency/standby unit and results in more cost-effective controls. As a consequence of the dissimilar baseline emissions, BART for the two cases could be very different.

e. How do I calculate incremental cost effectiveness?

1. In addition to the average cost effectiveness of a control option, you should also calculate incremental cost effectiveness. You should consider the incremental cost effectiveness in combination with the average cost effectiveness when considering whether to eliminate a control option. The incremental cost effectiveness calculation compares the costs and performance level of a control option to those of the next most stringent option, as shown in the following formula (with respect to cost per emissions reduction):

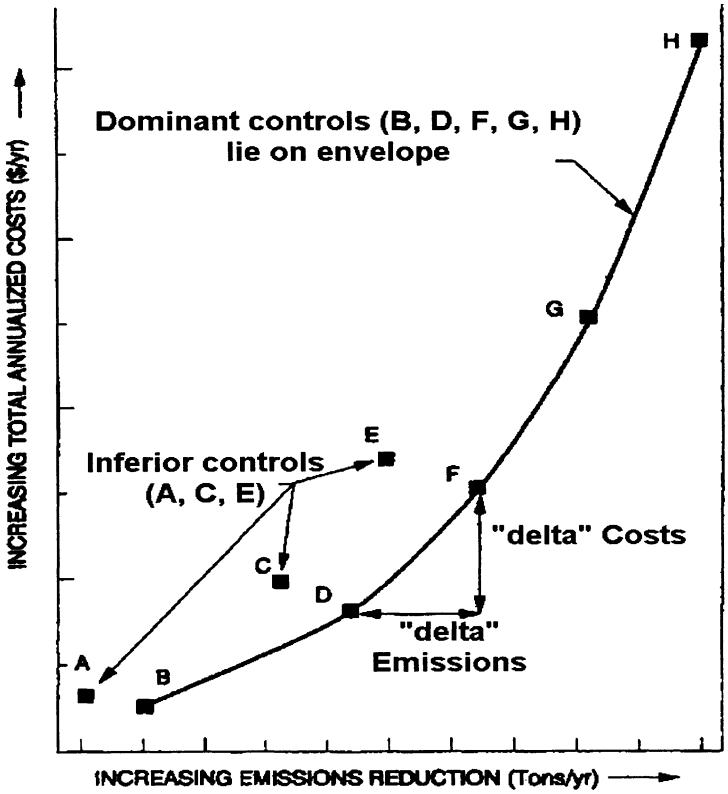
Incremental Cost Effectiveness (dollars per incremental ton removed) = (Total annualized costs of control option) − (Total annualized costs of next control option) ÷ (Control option annual emissions) − (Next control option annual emissions)

Example 1: Assume that Option F on Figure 2 has total annualized costs of $1 million to reduce 2000 tons of a pollutant, and that Option D on Figure 2 has total annualized costs of $500,000 to reduce 1000 tons of the same pollutant. The incremental cost effectiveness of Option F relative to Option D is ($1 million − $500,000) divided by (2000 tons − 1000 tons), or $500,000 divided by 1000 tons, which is $500/ton.

Example 2: Assume that two control options exist: Option 1 and Option 2. Option 1 achieves a 1,000 ton/yr reduction at an annualized cost of $1,900,000. This represents an average cost of ($1,900,000/1,000 tons) = $1,900/ton. Option 2 achieves a 980 tons/yr reduction at an annualized cost of $1,500,000. This represents an average cost of ($1,500,000/980 tons) = $1,531/ton. The incremental cost effectiveness of Option 1 relative to Option 2 is ($1,900,000 − $1,500,000) divided by (1,000 tons − 980 tons). The adoption of Option 1 instead of Option 2 results in an incremental emission reduction of 20 tons per year at an additional cost of $400,000 per year. The incremental cost of Option 1, then, is $20,000 per ton − 11 times the average cost of $1,900 per ton. While $1,900 per ton may still be deemed reasonable, it is useful to consider both the average and incremental cost in making an overall cost-effectiveness finding. Of course, there may be other differences between these options, such as, energy or water use, or non-air environmental effects, which also should be considered in selecting a BART technology.

2. You should exercise care in deriving incremental costs of candidate control options. Incremental cost-effectiveness comparisons should focus on annualized cost and emission reduction differences between ''dominant'' alternatives. To identify dominant alternatives, you generate a graphical plot of total annualized costs for total emissions reductions for all control alternatives identified in the BART analysis, and by identifying a ''least-cost envelope'' as shown in Figure 2. (A ''least-cost envelope'' represents the set of options that should be dominant in the choice of a specific option.)

[16] Whenever you calculate or report annual costs, you should indicate the year for which the costs are estimated. For example, if you use the year 2000 as the basis for cost comparisons, you would report that an annualized cost of $20 million would be: $20 million (year 2000 dollars).



Example: Eight technically feasible control options for analysis are listed. These are represented as A through H in Figure 2. The dominant set of control options, B, D, F, G, and H, represent the least-cost envelope, as we depict by the cost curve connecting them. Points A, C and E are inferior options, and you should not use them in calculating incremental cost effectiveness. Points A, C and E represent inferior controls because B will buy more emissions reductions for less money than A; and similarly, D and F will buy more reductions for less money than C and E, respectively.

3. In calculating incremental costs, you:

(1) Array the control options in ascending order of annualized total costs,

(2) Develop a graph of the most reasonable smooth curve of the control options, as shown in Figure 2. This is to show the ''least-cost envelope'' discussed above; and

(3) Calculate the incremental cost effectiveness for each dominant option, which is the difference in total annual costs between that option and the next most stringent option, divided by the difference in emissions, after controls have been applied, between those two control options. For example, using Figure 2, you would calculate incremental cost effectiveness for the difference between options B and D, options D and F, options F and G, and options G and H.

4. A comparison of incremental costs can also be useful in evaluating the viability of a specific control option over a range of efficiencies. For example, depending on the capital and operational cost of a control device, total and incremental cost may vary significantly (either increasing or decreasing) over the operational range of a control device. Also, the greater the number of possible control options that exist, the more weight should be given to the incremental costs vs. average costs. It should be noted that average and incremental cost effectiveness are identical when only one candidate control option is known to exist.

5. You should exercise caution not to misuse these techniques. For example, you may be faced with a choice between two available control devices at a source, control A and control B, where control B achieves slightly greater emission reductions. The average cost (total annual cost/total annual emission reductions) for each may be deemed to be reasonable. However, the incremental cost (total annual $cost_{A-B}$/total annual emission $reductions_{A-B}$) of the additional emission reductions to be achieved by control B may be very great. In such an instance, it may be inappropriate to choose control B, based on its high incremental costs, even though its average cost may be considered reasonable.

6. In addition, when you evaluate the average or incremental cost effectiveness of a control alternative, you should make reasonable and supportable assumptions regarding control efficiencies. An unrealistically low assessment of the emission reduction potential of a certain technology could result in inflated cost-effectiveness figures.

f. What other information should I provide in the cost impacts analysis?

You should provide documentation of any unusual circumstances that exist for the source that would lead to cost-effectiveness estimates that would exceed that for recent retrofits. This is especially important in cases where recent retrofits have cost-effectiveness values that are within what has been considered a reasonable range, but your analysis concludes that costs for the source being analyzed are not considered reasonable. (A reasonable range would be a range that is consistent with the range of cost effectiveness values used in other similar permit decisions over a period of time.)

Example: In an arid region, large amounts of water are needed for a scrubbing system. Acquiring water from a distant location could greatly increase the cost per ton of emissions reduced of wet scrubbing as a control option.

g. What other things are important to consider in the cost impacts analysis?

In the cost analysis, you should take care not to focus on incomplete results or partial calculations. For example, large capital costs for a control option alone would not preclude selection of a control measure if large emissions reductions are projected. In such a case, low or reasonable cost effectiveness numbers may validate the option as an appropriate BART alternative irrespective of the large capital costs. Similarly, projects with relatively low capital costs may not be cost effective if there are few emissions reduced.

h. Impact analysis part 2: How should I analyze and report energy impacts?

1. You should examine the energy requirements of the control technology and determine whether the use of that technology results in energy penalties or benefits. A source owner may, for example, benefit from the combustion of a concentrated gas stream rich in volatile organic compounds; on the other hand, more often extra fuel or electricity is required to power a control

device or incinerate a dilute gas stream. If such benefits or penalties exist, they should be quantified to the extent practicable. Because energy penalties or benefits can usually be quantified in terms of additional cost or income to the source, the energy impacts analysis can, in most cases, simply be factored into the cost impacts analysis. The fact of energy use in and of itself does not disqualify a technology.

2. Your energy impact analysis should consider only direct energy consumption and not indirect energy impacts. For example, you could estimate the direct energy impacts of the control alternative in units of energy consumption at the source (*e.g.*, BTU, kWh, barrels of oil, tons of coal). The energy requirements of the control options should be shown in terms of total (and in certain cases, also incremental) energy costs per ton of pollutant removed. You can then convert these units into dollar costs and, where appropriate, factor these costs into the control cost analysis.

3. You generally do not consider indirect energy impacts (such as energy to produce raw materials for construction of control equipment). However, if you determine, either independently or based on a showing by the source owner, that the indirect energy impact is unusual or significant and that the impact can be well quantified, you may consider the indirect impact.

4. The energy impact analysis may also address concerns over the use of locally scarce fuels. The designation of a scarce fuel may vary from region to region. However, in general, a scarce fuel is one which is in short supply locally and can be better used for alternative purposes, or one which may not be reasonably available to the source either at the present time or in the near future.

5. Finally, the energy impacts analysis may consider whether there are relative differences between alternatives regarding the use of locally or regionally available coal, and whether a given alternative would result in significant economic disruption or unemployment. For example, where two options are equally cost effective and achieve equivalent or similar emissions reductions, one option may be preferred if the other alternative results in significant disruption or unemployment.

i. Impact analysis part 3: How do I analyze ''non-air quality environmental impacts?''

1. In the non-air quality related environmental impacts portion of the BART analysis, you address environmental impacts other than air quality due to emissions of the pollutant in question. Such environmental impacts include solid or hazardous waste generation and discharges of polluted water from a control device.

2. You should identify any significant or unusual environmental impacts associated with a control alternative that have the potential to affect the selection or elimination of a control alternative. Some control technologies may have potentially significant secondary environmental impacts. Scrubber effluent, for example, may affect water quality and land use. Alternatively, water availability may affect the feasibility and costs of wet scrubbers. Other examples of secondary environmental impacts could include hazardous waste discharges, such as spent catalysts or contaminated carbon. Generally, these types of environmental concerns become important when sensitive site-specific receptors exist or when the incremental emissions reductions potential of the more stringent control is only marginally greater than the next most-effective option. However, the fact that a control device creates liquid and solid waste that must be disposed of does not necessarily argue against selection of that technology as BART, particularly if the control device has been applied to similar facilities elsewhere and the solid or liquid waste is similar to those other applications. On the other hand, where you or the source owner can show that unusual circumstances at the proposed facility create greater problems than experienced elsewhere, this may provide a basis for the elimination of that control alternative as BART.

3. The procedure for conducting an analysis of non-air quality environmental impacts should be made based on a consideration of site-specific circumstances. If you propose to adopt the most stringent alternative, then it is not necessary to perform this analysis of environmental impacts for the entire list of technologies you ranked in Step 3. In general, the analysis need only address those control alternatives with any significant or unusual environmental impacts that have the potential to affect the selection of a control alternative, or elimination of a more stringent control alternative. Thus, any important relative environmental impacts (both positive and negative) of alternatives can be compared with each other.

4. In general, the analysis of impacts starts with the identification and quantification of the solid, liquid, and gaseous discharges from the control device or devices under review. Initially, you should perform a qualitative or semi-quantitative screening to narrow the analysis to discharges with potential for causing adverse environmental effects. Next, you should assess the mass and composition of any such discharges and quantify them to the extent possible, based on readily available information. You should also assemble pertinent information about the public or environmental consequences of releasing these materials.

j. Impact analysis part 4: What are examples of non-air quality environmental impacts?

The following are examples of how to conduct non-air quality environmental impacts:

(1) *Water Impact*

You should identify the relative quantities of water used and water pollutants produced and discharged as a result of the use of each alternative emission control system. Where possible, you should assess the effect on ground water and such local surface water quality parameters as ph, turbidity, dissolved oxygen, salinity, toxic chemical levels, temperature, and any other important considerations. The analysis could consider whether applicable water quality standards will be met and the availability and effectiveness of various techniques to reduce potential adverse effects.

(2) *Solid Waste Disposal Impact*

You could also compare the quality and quantity of solid waste (*e.g.*, sludges, solids) that must be stored and disposed of or recycled as a result of the application of each alternative emission control system. You should consider the composition and various other characteristics of the solid waste (such as permeability, water retention, rewatering of dried material, compression strength, leachability of dissolved ions, bulk density, ability to support vegetation growth and hazardous characteristics) which are significant with regard to potential surface water pollution or transport into and contamination of subsurface waters or aquifers.

(3) *Irreversible or Irretrievable Commitment of Resources*

You may consider the extent to which the alternative emission control systems may involve a trade-off between short-term environmental gains at the expense of long-term environmental losses and the extent to which the alternative systems may result in irreversible or irretrievable commitment of resources (for example, use of scarce water resources).

(4) *Other Adverse Environmental Impacts*

You may consider significant differences in noise levels, radiant heat, or dissipated static electrical energy of pollution control alternatives. Other examples of non-air quality environmental impacts would include hazardous waste discharges such as spent catalysts or contaminated carbon.

k. How do I take into account a project's ''remaining useful life'' in calculating control costs?

1. You may decide to treat the requirement to consider the source's ''remaining useful life'' of the source for BART determinations as one element of the overall cost analysis. The ''remaining useful life'' of a source, if it represents a relatively short time period, may affect the annualized costs of retrofit controls. For example, the methods for calculating annualized costs in EPA's *OAQPS Control Cost Manual* require the use of a specified time period for amortization that varies based upon the type of control. If the remaining useful life will clearly exceed this time period, the remaining useful life has essentially no effect on control costs and on the BART determination process. Where the remaining useful life is less than the time period for amortizing costs, you should use this shorter time period in your cost calculations.

2. For purposes of these guidelines, the remaining useful life is the difference between:

(1) The date that controls will be put in place (capital and other construction costs incurred before controls are put in place can be rolled into the first year, as suggested in EPA's *OAQPS Control Cost Manual*); you are conducting the BART analysis; and

(2) The date the facility permanently stops operations. Where this affects the BART determination, this date should be assured by a federally- or State-enforceable restriction preventing further operation.

3. We recognize that there may be situations where a source operator intends to shut down a source by a given date, but wishes to retain the flexibility to continue

operating beyond that date in the event, for example, that market conditions change. Where this is the case, your BART analysis may account for this, but it must maintain consistency with the statutory requirement to install BART within 5 years. Where the source chooses not to accept a federally enforceable condition requiring the source to shut down by a given date, it is necessary to determine whether a reduced time period for the remaining useful life changes the level of controls that would have been required as BART.

If the reduced time period does change the level of BART controls, you may identify, and include as part of the BART emission limitation, the more stringent level of control that would be required as BART if there were no assumption that reduced the remaining useful life. You may incorporate into the BART emission limit this more stringent level, which would serve as a contingency should the source continue operating more than 5 years after the date EPA approves the relevant SIP. The source would not be allowed to operate after the 5-year mark without such controls. If a source does operate after the 5-year mark without BART in place, the source is considered to be in violation of the BART emissions limit for each day of operation.

5. Step 5: How should I determine visibility impacts in the BART determination?

The following is an approach you may use to determine visibility impacts (the degree of visibility improvement for each source subject to BART) for the BART determination. Once you have determined that your source or sources are subject to BART, you must conduct a visibility improvement determination for the source(s) as part of the BART determination. When making this determination, we believe you have flexibility in setting absolute thresholds, target levels of improvement, or *de minimis* levels since the deciview improvement must be weighed among the five factors, and you are free to determine the weight and significance to be assigned to each factor. For example, a 0.3 deciview improvement may merit a stronger weighting in one case versus another, so one ''bright line'' may not be appropriate. [Note that if sources have elected to apply the most stringent controls available, consistent with the discussion in section E. step 1. below, you need not conduct, or require the source to conduct, an air quality modeling analysis for the purpose of determining its visibility impacts.]

Use CALPUFF,[17] or other appropriate dispersion model to determine the visibility improvement expected at a Class I area from the potential BART control technology applied to the source. Modeling should be conducted for SO_2, NO_X, and direct PM emissions ($PM_{2.5}$ and/or PM_{10}). If the source is making the visibility determination, you should review and approve or disapprove of the source's analysis before making the expected improvement determination. There are several steps for determining the visibility impacts from an individual source using a dispersion model:

- Develop a modeling protocol.

Some critical items to include in a modeling protocol are meteorological and terrain data, as well as source-specific information (stack height, temperature, exit velocity, elevation, and allowable and actual emission rates of applicable pollutants), and receptor data from appropriate Class I areas. We recommend following EPA's *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts*[18] for parameter settings and meteorological data inputs; the use of other settings from those in IWAQM should be identified and explained in the protocol.

One important element of the protocol is in establishing the receptors that will be used in the model. The receptors that you use should be located in the nearest Class I area with sufficient density to identify the likely visibility effects of the source. For other Class I areas in relatively close proximity to a BART-eligible source, you may model a few strategic receptors to determine whether effects at those areas may be greater than at the nearest Class I area. For example, you might chose to locate receptors at these areas at the closest point to the source, at the highest and lowest elevation in the Class I area, at the IMPROVE monitor, and at the approximate expected plume release height. If the highest modeled effects are observed at the nearest Class I area, you may choose not to analyze the other Class I areas any further as additional analyses might be unwarranted.

You should bear in mind that some receptors within the relevant Class I area may be less than 50 km from the source while other receptors within that same Class I area may be greater than 50 km from the same source. As indicated by the *Guideline on Air Quality Models,* this situation may call for the use of two different modeling approaches for the same Class I area and source, depending upon the State's chosen method for modeling sources less than 50 km. In situations where you are assessing visibility impacts for source-receptor distances less than 50 km, you should use expert modeling judgment in determining visibility impacts, giving consideration to both CALPUFF and other EPA-approved methods.

In developing your modeling protocol, you may want to consult with EPA and your regional planning organization (RPO). Up-front consultation will ensure that key technical issues are addressed before you conduct your modeling.

- For each source, run the model, at pre-control and post-control emission rates according to the accepted methodology in the protocol.

Use the 24-hour average actual emission rate from the highest emitting day of the meteorological period modeled (for the pre-control scenario). Calculate the model results for each receptor as the change in deciviews compared against natural visibility conditions. Post-control emission rates are calculated as a percentage of pre-control emission rates. For example, if the 24-hr pre-control emission rate is 100 lb/hr of SO_2, then the post control rate is 5 lb/hr if the control efficiency being evaluated is 95 percent.

- Make the net visibility improvement determination.

Assess the visibility improvement based on the modeled change in visibility impacts for the pre-control and post-control emission scenarios. You have flexibility to assess visibility improvements due to BART controls by one or more methods. You may consider the frequency, magnitude, and duration components of impairment. Suggestions for making the determination are:

- Use of a comparison threshold, as is done for determining if BART-eligible sources should be subject to a BART determination. Comparison thresholds can be used in a number of ways in evaluating visibility improvement (*e.g.* the number of days or hours that the threshold was exceeded, a single threshold for determining whether a change in impacts is significant, or a threshold representing an x percent change in improvement).
- Compare the 98th percent days for the pre- and post-control runs.

Note that each of the modeling options may be supplemented with source apportionment data or source apportionment modeling.

E. How do I select the ''best'' alternative, using the results of Steps 1 through 5?

1. Summary of the Impacts Analysis

From the alternatives you evaluated in Step 3, we recommend you develop a chart (or charts) displaying for each of the alternatives:

(1) Expected emission rate (tons per year, pounds per hour);

(2) Emissions performance level (*e.g.*, percent pollutant removed, emissions per unit product, lb/MMBtu, ppm);

(3) Expected emissions reductions (tons per year);

(4) Costs of compliance—total annualized costs ($), cost effectiveness ($/ton), and incremental cost effectiveness ($/ton), and/or any other cost-effectiveness measures (such as $/deciview);

(5) Energy impacts;

(6) Non-air quality environmental impacts; and

(7) Modeled visibility impacts.

2. Selecting a ''best'' alternative

1. You have discretion to determine the order in which you should evaluate control options for BART. Whatever the order in which you choose to evaluate options, you should always (1) display the options evaluated; (2) identify the average and incremental costs of each option; (3) consider the energy and non-air quality environmental impacts of each option; (4) consider the remaining useful life; and (5) consider the modeled visibility impacts. You should provide a justification for adopting the technology that you select as the ''best'' level of control, including an explanation of the

[17] The model code and its documentation are available at no cost for download from *http://www.epa.gov/scram001/tt22.htm#calpuff.*

[18] *Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts,* U.S. Environmental Protection Agency, EPA–454/R–98–019, December 1998.

CAA factors that led you to choose that option over other control levels.

2. In the case where you are conducting a BART determination for two regulated pollutants on the same source, if the result is two different BART technologies that do not work well together, you could then substitute a different technology or combination of technologies.

3. In selecting a ''best'' alternative, should I consider the affordability of controls?

1. Even if the control technology is cost effective, there may be cases where the installation of controls would affect the viability of continued plant operations.

2. There may be unusual circumstances that justify taking into consideration the conditions of the plant and the economic effects of requiring the use of a given control technology. These effects would include effects on product prices, the market share, and profitability of the source. Where there are such unusual circumstances that are judged to affect plant operations, you may take into consideration the conditions of the plant and the economic effects of requiring the use of a control technology. Where these effects are judged to have a severe impact on plant operations you may consider them in the selection process, but you may wish to provide an economic analysis that demonstrates, in sufficient detail for public review, the specific economic effects, parameters, and reasoning. (We recognize that this review process must preserve the confidentiality of sensitive business information). Any analysis may also consider whether other competing plants in the same industry have been required to install BART controls if this information is available.

4. Sulfur dioxide limits for utility boilers

You must require 750 MW power plants to meet specific control levels for SO_2 of either 95 percent control or 0.15 lbs/MMBtu, for each EGU greater than 200 MW that is currently uncontrolled unless you determine that an alternative control level is justified based on a careful consideration of the statutory factors. Thus, for example, if the source demonstrates circumstances affecting its ability to cost-effectively reduce its emissions, you should take that into account in determining whether the presumptive levels of control are appropriate for that facility. For a currently uncontrolled EGU greater than 200 MW in size, but located at a power plant smaller than 750 MW in size, such controls are generally cost-effective and could be used in your BART determination considering the five factors specified in CAA section 169A(g)(2). While these levels may represent current control capabilities, we expect that scrubber technology will continue to improve and control costs continue to decline. You should be sure to consider the level of control that is currently best achievable at the time that you are conducting your BART analysis.

For coal-fired EGUs with existing post-combustion SO_2 controls achieving less than 50 percent removal efficiencies, we recommend that you evaluate constructing a new FGD system to meet the same emission limits as above (95 percent removal or 0.15 lb/mmBtu), in addition to the evaluation of scrubber upgrades discussed below. For oil-fired units, regardless of size, you should evaluate limiting the sulfur content of the fuel oil burned to 1 percent or less by weight.

For those BART-eligible EGUs with pre-existing post-combustion SO_2 controls achieving removal efficiencies of at least 50 percent, your BART determination should consider cost effective scrubber upgrades designed to improve the system's overall SO_2 removal efficiency. There are numerous scrubber enhancements available to upgrade the average removal efficiencies of all types of existing scrubber systems. We recommend that as you evaluate the definition of ''upgrade,'' you evaluate options that not only improve the design removal efficiency of the scrubber vessel itself, but also consider upgrades that can improve the overall SO_2 removal efficiency of the scrubber system. Increasing a scrubber system's reliability, and conversely decreasing its downtime, by way of optimizing operation procedures, improving maintenance practices, adjusting scrubber chemistry, and increasing auxiliary equipment redundancy, are all ways to improve average SO_2 removal efficiencies.

We recommend that as you evaluate the performance of existing wet scrubber systems, you consider some of the following upgrades, in no particular order, as potential scrubber upgrades that have been proven in the industry as cost effective means to increase overall SO_2 removal of wet systems:

(a) Elimination of Bypass Reheat;

(b) Installation of Liquid Distribution Rings;

(c) Installation of Perforated Trays;

(d) Use of Organic Acid Additives;

(e) Improve or Upgrade Scrubber Auxiliary System Equipment;

(f) Redesign Spray Header or Nozzle Configuration.

We recommend that as you evaluate upgrade options for dry scrubber systems, you should consider the following cost effective upgrades, in no particular order:

(a) Use of Performance Additives;

(b) Use of more Reactive Sorbent;

(c) Increase the Pulverization Level of Sorbent;

(d) Engineering redesign of atomizer or slurry injection system.

You should evaluate scrubber upgrade options based on the 5 step BART analysis process.

5. Nitrogen oxide limits for utility boilers

You should establish specific numerical limits for NO_X control for each BART determination. For power plants with a generating capacity in excess of 750 MW currently using selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) for part of the year, you should presume that use of those same controls year-round is BART. For other sources currently using SCR or SNCR to reduce NO_X emissions during part of the year, you should carefully consider requiring the use of these controls year-round as the additional costs of operating the equipment throughout the year would be relatively modest.

For coal-fired EGUs greater than 200 MW located at greater than 750 MW power plants and operating without post-combustion controls (*i.e.* SCR or SNCR), we have provided presumptive NO_X limits, differentiated by boiler design and type of coal burned. You may determine that an alternative control level is appropriate based on a careful consideration of the statutory factors. For coal-fired EGUs greater than 200 MW located at power plants 750 MW or less in size and operating without post-combustion controls, you should likewise presume that these same levels are cost-effective. You should require such utility boilers to meet the following NO_X emission limits, unless you determine that an alternative control level is justified based on consideration of the statutory factors. The following NO_X emission rates were determined based on a number of assumptions, including that the EGU boiler has enough volume to allow for installation and effective operation of separated overfire air ports. For boilers where these assumptions are incorrect, these emission limits may not be cost-effective.

TABLE 1.—PRESUMPTIVE NO_X EMISSION LIMITS FOR BART-ELIGIBLE COAL-FIRED UNITS.[19]

Unit type	Coal type	NO_X presumptive limit (lb/mmbtu)[20]
Dry-bottom wall-fired	Bituminous	0.39
	Sub-bituminous	0.23
	Lignite	0.29
Tangential-fired	Bituminous	0.28
	Sub-bituminous	0.15
	Lignite	0.17
Cell Burners	Bituminous	0.40
	Sub-bituminous	0.45
Dry-turbo-fired	Bituminous	0.32
	Sub-bituminous	0.23
Wet-bottom tangential-fired	Bituminous	0.62

MostEGUs can meet these presumptive NO_X limits through the use of current combustion control technology, *i.e.* the careful control of combustion air and low-NO_X burners. For units that cannot meet these limits using such technologies, you should consider whether advanced combustion control technologies such as rotating opposed fire air should be used to meet these limits.

Because of the relatively high NO_X emission rates of cyclone units, SCR is more cost-effective than the use of current combustion control technology for these units. The use of SCRs at cyclone units burning bituminous coal, sub-bituminous coal, and lignite should enable the units to cost-effectively meet NO_X rates of 0.10 lbs/mmbtu. As a result, we are establishing a presumptive NO_X limit of 0.10 lbs/mmbtu based on the use of SCR for coal-fired cyclone units greater than 200 MW located at 750 MW power plants. As with the other presumptive limits established in this guideline, you may determine that an alternative level of control is appropriate based on your consideration of the relevant statutory factors. For other cyclone units, you should review the use of SCR and consider whether these post-combustion controls should be required as BART.

For oil-fired and gas-fired EGUs larger than 200MW, we believe that installation of current combustion control technology to control NO_X is generally highly cost-effective and should be considered in your determination of BART for these sources. Many such units can make significant reductions in NO_X emissions which are highly cost-effective through the application of current combustion control technology.[21]

V. Enforceable Limits/Compliance Date

To complete the BART process, you must establish enforceable emission limits that reflect the BART requirements and require compliance within a given period of time. In particular, you must establish an enforceable emission limit for each subject emission unit at the source and for each pollutant subject to review that is emitted from the source. In addition, you must require compliance with the BART emission limitations no later than 5 years after EPA approves your regional haze SIP. If technological or economic limitations in the application of a measurement methodology to a particular emission unit make a conventional emissions limit infeasible, you may instead prescribe a design, equipment, work practice, operation standard, or combination of these types of standards. You should consider allowing sources to ''average'' emissions across any set of BART-eligible emission units within a fenceline, so long as the emission reductions from each pollutant being controlled for BART would be equal to those reductions that would be obtained by simply controlling each of the BART-eligible units that constitute BART-eligible source.

You should ensure that any BART requirements are written in a way that clearly specifies the individual emission unit(s) subject to BART regulation. Because the BART requirements themselves are ''applicable'' requirements of the CAA, they must be included as title V permit conditions according to the procedures established in 40 CFR part 70 or 40 CFR part 71.

Section 302(k) of the CAA requires emissions limits such as BART to be met on a continuous basis. Although this provision does not necessarily require the use of continuous emissions monitoring (CEMs), it is important that sources employ techniques that ensure compliance on a continuous basis. Monitoring requirements generally applicable to sources, including those that are subject to BART, are governed by other regulations. See, *e.g.*, 40 CFR part 64 (compliance assurance monitoring); 40 CFR 70.6(a)(3) (periodic monitoring); 40 CFR 70.6(c)(1) (sufficiency monitoring). Note also that while we do not believe that CEMs would necessarily be required for all BART sources, the vast majority of electric generating units potentially subject to BART already employ CEM technology for other programs, such as the acid rain program. In addition, emissions limits must be enforceable as a practical matter (contain appropriate averaging times, compliance verification procedures and recordkeeping requirements). In light of the above, the permit must:

- Be sufficient to show compliance or noncompliance (*i.e.*, through monitoring times of operation, fuel input, or other indices of operating conditions and practices); and
- Specify a reasonable averaging time consistent with established reference methods, contain reference methods for determining compliance, and provide for adequate reporting and recordkeeping so that air quality agency personnel can determine the compliance status of the source; and
- For EGUS, specify an averaging time of a 30-day rolling average, and contain a definition of ''boiler operating day'' that is consistent with the definition in the proposed revisions to the NSPS for utility boilers in 40 CFR Part 60, subpart Da.[22] You should consider a boiler operating day to be any 24-hour period between 12:00 midnight and the following midnight during which any fuel is combusted at any time at the steam generating unit. This would allow 30-day rolling average emission rates to be calculated consistently across sources.

[FR Doc. 05–12526 Filed 7–5–05; 8:45 am]

BILLING CODE 6560–50–P

[19] No Cell burners, dry-turbo-fired units, nor wet-bottom tangential-fired units burning lignite were identified as BART-eligible, thus no presumptive limit was determined. Similarly, no wet-bottom tangential-fired units burning sub-bituminous were identified as BART-eligible.

[20] These limits reflect the design and technological assumptions discussed in the technical support document for NO_X limits for these guidelines. See *Technical Support Document for BART NO_X Limits for Electric Generating Units and Technical Support Document for BART NO_X* Limits for Electric Generating Units Excel Spreadsheet, Memorandum to Docket OAR 2002–0076, April 15, 2005.

[21] See *Technical Support Document for BART NO_X Limits for Electric Generating Units* and *Technical Support Document for BART NO_X Limits for Electric Generating Units Excel Spreadsheet,* Memorandum to Docket OAR 2002–0076, April 15, 2005.

[22] 70 FR 9705, February 28, 2005.

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