12–9–04 Thursday
Vol. 69 No. 236 Dec. 9, 2004

Pages 71339–71690

Federal Register

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.archives.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara,* available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via e-mail at *gpoaccess@gpo.gov.* The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 69 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

What's NEW!

Federal Register Table of Contents via e-mail

Subscribe to FEDREGTOC, to receive the **Federal Register** Table of Contents in your e-mail every day.

If you get the HTML version, you can click directly to any document in the issue.

To subscribe, go to **http://listserv.access.gpo.gov** and select:

Online mailing list archives
FEDREGTOC-L
Join or leave the list

Then follow the instructions.

What's NEW!

Regulations.gov, the award-winning Federal eRulemaking Portal

Regulations.gov is the one-stop U.S. Government web site that makes it easy to participate in the regulatory process.

Try this fast and reliable resource to find all rules published in the *Federal Register* that are currently open for public comment. Submit comments to agencies by filling out a simple web form, or use available e-mail addresses and web sites.

The Regulations.gov e-democracy initiative is brought to you by NARA, GPO, EPA and their eRulemaking partners.

Visit the web site at: **http://www.regulations.gov**

Contents

Federal Register

Vol. 69, No. 236

Thursday, December 9, 2004

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

7852.....71689

7 CFR

354.....71660

11 CFR

Proposed Rules:

300.....71388

14 CFR

39 (8 documents) 71339, 71340, 71342, 71344, 71347, 71349, 71351, 71353

15 CFR

732.....71356
734.....71356
740.....71356
742.....71356
744.....71356
772.....71356

18 CFR

11.....71364

21 CFR

1 (2 documents) 71562, 71655
11.....71562

27 CFR

9.....71372

30 CFR

938 (2 documents) 71528, 71551

35 CFR

Ch. I.....71375

40 CFR

52.....71375

Proposed Rules:

52.....71390
60.....71472
272.....71391

45 CFR

Proposed Rules:

650.....71395

47 CFR

2.....71380
15.....71380
64.....71383
73 (7 documents) 71384, 71385, 71386, 71387

Proposed Rules:

73.....71396

Rules and Regulations

Federal Register
Vol. 69, No. 236
Thursday, December 9, 2004

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19767; Directorate Identifier 2004–NM–139–AD; Amendment 39–13900; AD 2004–25–12]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all EMBRAER Model EMB–135 and –145 series airplanes. This AD requires a one-time inspection of each passenger service unit (PSU) to determine the serial number of the printed circuit board (PCB) installed in each PSU, replacement of the PCB if necessary, related investigative actions, and other specified actions. This AD is prompted by reports that PSUs on two airplanes emitted smoke. We are issuing this AD to prevent failure of a PSU, which could result in smoke or fire in the airplane's passenger cabin.

DATES: This AD becomes effective January 13, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of January 13, 2005.

ADDRESSES: For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), PO Box 343–CEP 12.225, Sao Jose dos Campos–SP, Brazil. You can examine this information at 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/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or 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.

FOR FURTHER INFORMATION CONTACT: *Technical information:* 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.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

Examining the 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 DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for all EMBRAER Model EMB–135 and –145 series airplanes. The proposed AD was published in the **Federal Register** on September 9, 2004 (69 FR 54596), to require a one-time inspection of each passenger service unit (PSU) to determine the serial number of the printed circuit board (PCB) installed in each PSU, replacement of the PCB if necessary, related investigative actions, and other specified actions.

Comments

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

Request To Limit Applicability

The commenter requests that we limit the applicability to airplanes having serial numbers (S/Ns) up to and including 828. The commenter states that it has received information from the airplane manufacturer that the PSUs on airplanes having S/N 829 and subsequent will be inspected during production.

We partially agree with the commenter's request. We do not agree to revise the applicability statement of paragraph (a) of this AD. We note that paragraph (h) of this AD prohibits the installation of an affected part with an affected S/N. This prohibition should apply to all airplanes, including those with S/Ns 829 and subsequent, which will have been inspected in production. Therefore, the applicability statement of this AD continues to identify all EMBRAER Model EMB–135 and –145 series airplanes, so that paragraph (h) will prohibit installing an affected part on all of these airplanes. However, we agree that airplanes that have been inspected during production do not need to be inspected as required by paragraph (f) of this AD. Therefore, we have revised paragraph (f) of this AD to apply only to airplanes having S/Ns 001 through 828 inclusive.

Conclusion

We have carefully reviewed the available data, including the comment that has 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 affects about 539 airplanes of U.S. registry. The required actions take about 3 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the AD for U.S. operators is $105,105, or $195 per airplane.

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in

Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged 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 AD.

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:

2004–25–12 Empresa Brasileira De Aeronautica S.A. (EMBRAER): Amendment 39–13900. Docket No. FAA–2004–19767; Directorate Identifier 2004–NM–139–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective January 13, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all EMBRAER Model EMB–135 and –145 series airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports that passenger service units (PSUs) on two airplanes emitted smoke. We are issuing this AD to prevent failure of a PSU, which could result in smoke or fire in the airplane's passenger cabin.

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 Inspection

(f) For airplanes having serial numbers (S/Ns) 001 through 828 inclusive: Within 90 days after the effective date of this AD, inspect each PSU in the passenger cabin and lavatory to determine the part number (P/N) and S/N of the printed circuit board (PCB) installed in the PSU, is in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 145–25–0277, Change 02, dated June 28, 2004.

(1) If the PCB is not P/N 7277220–501 with S/N 2108 through 6008 inclusive: Before further flight, do the applicable related investigative actions and other specified actions in accordance with the Accomplishment Instructions of the service bulletin. No further action is required by this paragraph.

(2) If the PCB is P/N 7277220–501 with S/N 2108 through 6008 inclusive: Before further flight, replace the PCB with a new or serviceable PCB having a S/N that is not within the range of 2108 through 6008 inclusive, and do the applicable related investigative actions and other specified actions, in accordance with the Accomplishment Instructions of the service bulletin.

Note 1: EMBRAER Service Bulletin 145–25–0277, Change 02, refers to C&D Aerospace Service Bulletin 7130000–25–79, Revision 2, dated June 17, 2004, as an additional source of service information for doing the required inspection, replacement, and related investigative actions, as applicable. The EMBRAER service bulletin includes the C&D Aerospace service bulletin.

Actions Done Previously

(g) Inspections, replacements, and related investigative actions done before the effective date of this AD in accordance with EMBRAER Service Bulletin 145–25–0277, dated October 22, 2003; or Change 01, dated November 28, 2003; are acceptable for compliance with the corresponding action required by this AD.

Parts Installation

(h) As of the effective date of this AD, no person may install a PCB having P/N 7277220–501 with S/N 2108 through 6008 inclusive, on any PSU on any airplane.

Returning Parts Not Required

(i) Where EMBRAER Service Bulletin 145–25–0277, Change 02, dated June 28, 2004, specifies to return any PCB with a subject S/N to C&D Aerospace, this AD does not require that action.

Alternative Methods of Compliance (AMOCs)

(j) 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

(k) Brazilian airworthiness directive 2004–05–02, dated June 2, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(l) You must use EMBRAER Service Bulletin 145–25–0277, Change 02, dated June 28, 2004, 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. For copies of the service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), PO Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26918 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004–NM–33–AD; Amendment 39–13898; AD 2004–25–10]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–300 and –400ER Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 767–300 and –400ER series airplanes, that requires replacing the tie rods for the waste tank cradle, related investigative actions, corrective actions, and special retrofit action if necessary. This action is necessary to prevent possible failure of the main deck floor stanchions and consequent collapse of the main floor during an emergency landing, which could result in passenger injury and impede passenger evacuation from the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective January 13, 2005.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 13, 2005.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at 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/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Susan 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: 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 Boeing Model 767–300 and –400ER series airplanes was published in the **Federal Register** on June 16, 2004 (69 FR 33597). That action proposed to require replacing the tie rods for the waste tank cradle, related investigative actions, corrective actions, and special retrofit action if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comment received.

Request To Revise ''Parts Installation'' Section

One commenter requests that we revise paragraph (c) of the proposed AD from ''* * * on any airplane'' to ''* * * on any airplane applicable for this AD.'' The commenter requests this change in order for the paragraph to be consistent with the rest of the document and to avoid possible misinterpretation.

We agree with the commenter's request to revise paragraph (c) of the AD. All of the requirements stated in this AD are applicable only to the airplanes listed in the applicability statement. However, the phrasing of paragraph (c) in the proposed AD may confuse or mislead some operators. Therefore, we have revised paragraph (c) of this AD to clarify that the paragraph applies to any airplane ''to which this AD applies.''

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 97 airplanes of the affected design in the worldwide fleet. The FAA estimates that 42 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per airplane to accomplish the required actions, and that the average labor rate is $65 per work hour. Required parts will cost approximately $2,471 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $109,242, or $2,601 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. The manufacturer may cover the cost of replacement parts associated with this AD, subject to warranty conditions. Manufacturer warranty remedies may also be available for labor costs associated with this AD. As a result, the costs attributable to the AD may be less than stated above.

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:

2004–25–10 Boeing: Amendment 39–13898. Docket 2004–NM–33–AD.

Applicability: Model 767–300 series airplanes, as listed in Boeing Alert Service Bulletin 767–38A0062, dated August 15, 2002; and Model 767–400ER series airplanes, as listed in Boeing Alert Service Bulletin 767–38A0063, dated August 15, 2002; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the main deck floor stanchions and consequent collapse of the main floor during an emergency landing, which could result in passenger injury and impede passenger evacuation from the airplane, accomplish the following:

Replacement and Related Investigative and Corrective Actions and Retrofit Action

(a) Within 18 months after the effective date of this AD: Replace the four tie rods for the waste tank cradle with new tie rods and do all applicable related investigative actions, corrective actions, and special retrofit actions by accomplishing all the actions in the Accomplishment Instructions of Boeing Alert Service Bulletins 767–38A0062 (for Model 767–300 series airplanes) and 767–38A0063 (for Model 767–400ER series airplanes), both dated August 15, 2002; as applicable. Do the actions in accordance with the applicable service bulletin except as provided by paragraph (b) of this AD. Accomplish any related investigative, corrective, or special retrofit action before further flight.

(b) If any deformation, crack, or other damage is found during any related investigative action required by paragraph (a) of this AD, and the bulletin specifies contacting Boeing for appropriate action: Before further flight, perform the special retrofit action per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. For a retrofit method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

Parts Installation

(c) As of the effective date of this AD, no person may install any tie rod for the waste tank cradle having part number 251T0100–1401, 251T0100–1402, 251T0100–1403, or 251T0100–1404, on any airplane to which this AD applies.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, Seattle ACO, FAA, is authorized to approve alternative methods of compliance (AMOCs) for this AD.

Incorporation by Reference

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing Alert Service Bulletin 767–38A0062, dated August 15, 2002; and Boeing Alert Service Bulletin 767–38A0063, dated August 15, 2002; as applicable. 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. Copies may be obtained from Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at 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/code_of_federal_regulations/ibr_locations.html.*

Effective Date

(f) This amendment becomes effective on January 13, 2005.

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26917 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19023; Directorate Identifier 2004–NM–123–AD; Amendment 39–13899; AD 2004–25–11]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Model A318, A319, A320, and A321 series airplanes. This AD requires removing two maintenance lights in the hydraulics bay, disconnecting the wiring for the lights, and modifying the switches. This AD is prompted by underlying safety issues involved in fuel tank explosions on several large transport airplanes. We are issuing this AD to prevent an ignition source for fuel vapor in the hydraulics bay, which could result in fire or explosion in the adjacent center wing fuel tank.

DATES: This AD becomes effective January 13, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of January 13, 2005.

ADDRESSES: For service information identified in this AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. You can examine this information at 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/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or 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.

FOR FURTHER INFORMATION CONTACT:

Technical information: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

Examining the 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 DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for certain Airbus Model A318, A319, A320, and A321 series airplanes. The proposed AD was published in the **Federal Register** on September 7, 2004 (69 FR 54055), to require removing two maintenance lights in the hydraulics bay, disconnecting the wiring for the lights, and modifying the switches.

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.

Request To Include a Terminating Action

One commenter states that it has no objection to the proposed AD but requests that we revise the proposed AD to include a terminating action that includes installation of an explosion-proof lighting system.

We acknowledge the commenter's request but do not concur. The commenter's request did not include any technical information about an explosion-proof lighting system, nor did it describe the procedures associated with installing such a system. Further, we do not know of any service information at this time that provides procedures for installing this type of system. Once such service information is available and approved, we may consider approving a request for an alternative method of compliance

(AMOC) for the requirements of this AD. No change has been made to the final rule.

Request To Provide Option of Deactivating Power

One commenter requests that we revise the proposed AD to include an option that would allow an operator to deactivate the power to the subject maintenance lights by modifying certain switch wiring. The commenter notes that this modification would reduce the cost of deactivating the existing lights and allow easier installation when replacement lights are available. The commenter states that this modification ''would equally address the unsafe condition.''

We do not concur with the commenter's request. The commenter did not provide any information on how it plans to modify the wiring to deactivate power to the subject maintenance lights. We may approve a request for an AMOC for the requirements of this AD if the commenter submits this request with technical data supporting its request. No change has been made to the final rule.

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 as proposed.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Remove lights, disconnect wires, and modify switches	3	$65	$70	$265	648	$171,720

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged with promoting safety 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 AD.

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:

2004–25–11 Airbus: Amendment 39–13899. Docket No. FAA–2004–19023; Directorate Identifier 2004–NM–123–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective January 13, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A318, A319, A320, and A321 series airplanes; certificated in any category; except those airplanes on which Airbus Modification 33518 has been accomplished in production.

Unsafe Condition

(d) This AD was prompted by underlying safety issues involved in fuel tank explosions on several large transport airplanes. We are issuing this AD to prevent an ignition source for fuel vapor in the hydraulics bay, which could result in fire or explosion in the center wing fuel tank.

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

(f) Within 19 months after the effective date of this AD, remove maintenance lights 9LL and 10LL from the hydraulics bay, disconnect the wiring for the lights, and modify the 12LL switches. Do the actions in accordance with Airbus Service Bulletin A320–92–1032, dated March 8, 2004.

Alternative Methods of Compliance (AMOCs)

(g) 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

(h) French airworthiness directive F–2004–073, dated May 26, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(i) You must use Airbus Service Bulletin A320–92–1032, dated March 8, 2004, 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. For copies of the service information, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26916 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–64–AD; Amendment 39–13891; AD 2004–25–04]

RIN 2120–AA64

Airworthiness Directives; Mooney Aircraft Corporation Models M20B, M20C, M20D, M20E, M20F, M20G, and M20J Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA adopts a new airworthiness directive (AD) for all Mooney Aircraft Corporation (Mooney) Models M20B, M20C, M20D, M20E, M20F, M20G, and M20J airplanes equipped with an O & N Bladder Fuel Cell installed per Supplemental Type Certificate (STC) SA2277CE or STC SA2350CE. The STCs apply to all the affected airplane models except for Model M20B airplanes. Model M20B airplanes could have one of the STCs incorporated by field approval. This AD requires you to inspect the drain valve to assure that it is inserted fully into the drain nipple and modify any drain valve found not to be inserted fully into the drain nipple. This AD also requires certain modifications and replacements on the affected fuel cells to reduce the chances of water/ice contamination. This AD is the result of reports of rainwater entering the fuel bladders and the information from the subsequent evaluation of the fuel systems. The actions specified by this AD are intended to assist in preventing water from entering the fuel bladders, which could result in rough engine operation or complete loss of engine power.

DATES: This AD becomes effective on January 21, 2005.

As of January 21, 2005, the Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulation.

ADDRESSES: You may get the service information identified in this AD from O & N Aircraft Modifications Inc., 210 Windsock Lane, Seamans Airport, Factoryville, PA 18419; telephone: (717) 945–3769; facsimile: (717) 945–7282.

You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–64–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Paul O. Pendleton, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4143; facsimile: (316) 946–4107.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The FAA has received a report of water being trapped in the fuel bladders on Mooney Models M20C, M20D, M20E, M20F, M20G, and M20J airplanes that are equipped with an O & N Bladder Fuel Cell installed per Supplemental Type Certificate (STC) SA2277CE or STC SA2350CE. The STCs apply to all of the above-referenced airplane models except for the Mooney Model M20B airplanes; the Model M20B airplanes could have one of the STCs incorporated by field approval.

Evaluation of this problem shows that improper installation of the fuel bladder drains and fuel caps could allow rainwater to enter the fuel bladders if the fuel cap was defective.

The evaluation also revealed additional installation problems and design deficiencies, including:

—Inadequate installation of the foam filler that supports the fuel bladders;

—Inadequate engine crankcase breather vent and primary fuel vent ice protection; and

—Fuel caps that have the sealing surface below the fuel tank opening.

What is the potential impact if FAA took no action? If not prevented, water entering the fuel bladders could result in rough engine operation or complete loss of engine power.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to all Mooney Aircraft Corporation (Mooney) Models M20B, M20C, M20D, M20E, M20F, M20G, and M20J airplanes equipped with an O & N Bladder Fuel Cell installed per Supplemental Type Certificate (STC) SA2277CE or STC SA2350CE. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 9, 1998 (63 FR 54401). The NPRM proposed to require you to inspect the drain valve to assure that it was inserted fully into the drain nipple and modify any drain valve found not fully inserted into the drain nipple. The NPRM also proposed to require you to incorporate the design changes specified in O & N Aircraft Modifications Inc. Mandatory Service Bulletin No. ON–100, dated February 1, 1998.

Comments

Was the public invited to comment? We provided the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and FAA's response to each comment:

Comment Issue No. 1: Remove the Requirement To Replace the Flush Style Fuel Cap With a Raised Style Fuel Cap

What is the commenter's concern? The FAA received 18 comments with each commenter stating that requiring replacement of the flush style fuel caps with raised style fuel caps is unnecessary.

Most commenters, which are owners and operators of the affected model airplanes, state that they have never experienced getting a single drop of water in the fuel tanks with the O&N flush style fuel caps. Many of these airplanes are washed frequently with high-pressure hoses and are parked outside in the rain, sleet, and snow.

The commenters express no problems with the flush style fuel caps because of proper maintenance and proper operating procedures.

Several commenters state that all high performance airplanes have flush style fuel caps. They further comment that, if the FAA wants these fuel caps replaced on the affected Mooney airplanes because they pose an unsafe condition, then the FAA should mandate this on all airplanes with flush style fuel caps.

The commenters also communicate that this replacement would cause a financial burden with no gain in safety.

The commenters want the fuel cap replacement requirement removed from the AD.

What is FAA's response to the concern? We are requiring you to replace the flush style fuel caps with raised style caps because the sealing surface of the flush style fuel caps is below the fuel tank opening.

However, based on the comments received, we have developed ''Pilot Operating Procedures for Pre-flight Fuel System Check.'' Inserting these procedures into the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) would serve as an alternative method of compliance (AMOC) for replacing the flush style fuel caps.

Based on these comments, we will change the final rule AD to incorporate these procedures as an AMOC to replacing the fuel caps.

Comment Issue No. 2: Revise or Remove the Proposed AD

What is the commenter's concern? The notice of proposed rulemaking (NPRM) states that improper installation of the fuel bladder drains and fuel caps could allow rainwater to enter the fuel bladders.

Several commenters do not feel they should be penalized because of improper installation of the fuel bladders and the flush fuel cap that an unauthorized independent fixed base operator did. The commenters express that no reported problems exist with water in the fuel system on O&N bladder systems installed at an authorized installation center.

Most commenters state that the proposed AD is unnecessary, could cause significant damage to the existing fuel bladder tanks, and could cause a financial burden to the owners and operators with no gain in safety.

These commenters want the proposed AD withdrawn.

One commenter wants the proposed AD revised to include a proper inspection by licensed FAA personnel to prevent the reoccurrence of any improper installation.

Several commenters want the applicability of the AD revised to exclude airplanes that had the O&N bladder system installed at an authorized O&N facility.

What is FAA's response to the concern? The FAA does not concur that the AD is not necessary. As earlier stated, our evaluation of the problem reveals installation and design deficiencies on the fuel bladder drains and fuel caps. Our determination on this issue is that the actions of the AD are necessary to ensure that the unsafe condition does not continue to exist or develop on the affected type design airplanes.

As stated before, the incorporation of the ''Pilot Operating Procedures for Pre-flight Fuel System Check'' as an AMOC for the fuel cap replacement requirement will alleviate a percentage of the commenters' concerns.

Comment Issue No. 3: Remove Requirement To Install an Anti-Ice Mast

What is the commenter's concern? One commenter states these airplanes are not certificated to fly into known icing conditions.

Another commenter states that, since anti-icing masts are not normally found on general aviation aircraft, there is no reason to add it to the affected Mooney airplanes. The commenter further expresses that the anti-ice mast is unproven and untested on Mooney airplanes and could actually impede vent performance under normal and icing conditions. The commenter also states that, if the FAA believes that the risk of vent icing is inordinately high, the FAA should then issue an AD for all registered aircraft.

The commenters want the final rule AD revised to remove the requirement to install an anti-ice mast forward of the vent tubes.

What is FAA's response to the concern? The FAA does not concur. As stated earlier, this is one of the areas where we found installation or design deficiencies that needed action to remove an unsafe condition. Therefore, we have determined that this portion of the AD is valid and necessary to address the unsafe condition.

We are not changing the final rule AD action based on these comments.

Comment Issue No. 4: Crank Case Vent Hole Is Unrelated to the O&N Bladder Fuel Cells

What is the commenter's concern? The commenter states that, if Mooney airplanes with the bladder fuel cells installed need to have this vent hole drilled in the engine's crankcase breathers, the FAA should then include all piston-powered airplanes.

What is FAA's response to the concern? To this date, FAA has not received data indicating that the condition exists on any other installations other the Mooney airplanes with the O&N fuel cap installation. If our continued evaluation reveals such a condition, we will consider further rulemaking action on other type design aircraft.

We are not changing the final rule AD action based on these comments.

Conclusion

What is FAA's final determination on this issue? We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed except for the changes discussed above and minor editorial corrections. We have determined that these changes and minor corrections:

—Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and

—Do not add any additional burden upon the public than was already proposed in the NPRM.

Changes to 14 CFR Part 39—Effect on the AD

How does the revision to 14 CFR part 39 affect this AD? On July 10, 2002, the FAA published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

How many airplanes does this AD impact? We estimate that this AD affects 300 airplanes in the U.S. registry.

What is the cost impact of this AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the inspection and modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operations
8 work hours × $65 per hour = $520	$200	$520 + $200 = $750	$720 × 300 = $216,000.

Authority for This Rulemaking

What authority does FAA have for issuing this rulemaking action? 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 AD.

Regulatory Findings

Will this AD impact various entities? 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.

Will this AD involve a significant rule or regulatory action? 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 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 summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include ''AD Docket No. 98–CE–64–AD'' in your request.

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 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. FAA amends § 39.13 by adding a new AD to read as follows:

2004–25–04 Mooney Aircraft Corporation: Amendment 39–13891; Docket No. 98–CE–64–AD.

When Does This AD Become Effective?

(a) This AD becomes effective on January 21, 2005.

What Other ADs Are Affected By This Action?

(b) None.

What Airplanes Are Affected by This AD?

(c) This AD affects Models M20C, M20D, M20E, M20F, M20G, and M20J airplanes, all serial numbers, that are:

(1) certificated in any category;

(2) equipped with an O & N Bladder Fuel Cell installed per Supplemental Type Certificate (STC) SA2277CE or STC SA2350CE; and

(3) This AD affects Model M20B airplanes, all serial numbers, that are certificated in any category and have any of the STCs referenced in paragraph (c)(2) incorporated by field approval.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of reports of rain water entering the fuel bladders and the information from the subsequent evaluation of the fuel systems. The actions specified in this AD are intended to assist in preventing water from entering the fuel bladders, which could result in rough engine operation or complete loss of engine power.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) On both the left and right wing, inspect the drain valve to assure that it was inserted fully into the drain nipple	Within the next 12 months after January 21, 2005 (the effective date of this AD), unless already done (see Note 1)	Follow O & N Aircraft Modifications Inc. Mandatory Service Bulletin No. ON–100, dated February 1, 1998.
(2) Modify any drain valve found not to be inserted fully into the drain nipple	Prior to further flight after the inspection required in paragraph (e)(1) of this AD, unless already done (see Note 1).	Follow O & N Aircraft Modifications Inc. Mandatory Service Bulletin No. ON–100, dated February 1, 1998.
(3) On both the left and right wing do the following: (i) Install a foam wedge to reduce the amount of trapped fluids in the center fuel cell; (ii) Install an anti-ice mast forward of the vent tubes to prevent icing of the fuel tank vents; (iii) Drill a vent hole to prevent icing of the engine's crankcase breathers; and (iv) Replace the flush style fuel caps and adapters with raised style caps and adapters. Follow the instructions in paragraph (f) of this AD as an alternative method of compliance for replacing the flush style fuel caps	Within the next 12 months after January 21, 2005 (the effective date of this AD), unless already done (see Note 1).	Follow O & N Aircraft Modifications Inc. Mandatory Service Bulletin No. ON–100, dated February 1, 1998.

Note 1: All kits installed by (or obtained from) O&N Aircraft Modifications Inc. after February 1, 1998, incorporate the actions of this AD. If you have one of these kits installed, you may take ''unless already done'' credit for the actions of this AD.

What Is the Alternate Method of Compliance (AMOC) for Replacing the Flush Style Fuel Caps as Required in Paragraph (e)(3)(iv) of This AD?

(f) Instead of replacing the flush style fuel caps as required in paragraph (e)(3)(iv) of this AD, you may do a preflight fuel system check prior to each flight. To do this, you must insert the following ''Pilot Operating Procedures—Preflight Fuel System Check'' (paragraphs (f)(1), (f)(2), (f)(3), and (f)(4) of this AD) into the Limitation Section of the FAA-approved Airplane Flight Manual (AFM):

(1) Place a suitable container under the fuel strainer drain outlet prior to operating the strainer drain control for at least 4 seconds. Check strainer to ensure drain is closed.(2) Inspect the fluid drained from the fuel strainer and each wing tank quick drain for evidence of fuel contamination in the form of water, rust, sludge, ice, or any other substance not compatible with fuel. Also check for proper fuel grade before the first flight of each day and after each refueling. If any contamination is detected, comply with paragraph (f)(4) of this AD.

(3) Repeat steps in paragraph (f)(1) and (f)(2) of this AD on each wing tank quick drain.

(4) If the airplane has been exposed to rain, sleet, or snow, or if the wing fuel tanks or fuel strainer drains produce water or other contamination, you must purge the airplane fuel system to the extent necessary to ensure that there is no water, ice, or other fuel contamination.

May I Request Another AMOC for This AD?

(g) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Wichita Aircraft Certification Office (ACO), FAA. For information on any already approved alternative methods of compliance, contact Paul O. Pendleton, Aerospace Engineer, FAA, Wichita ACO, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4143; facsimile: (316) 946–4107.

Does This AD Incorporate Any Material by Reference?

(h) You must do the actions required by this AD following the instructions in O & N Aircraft Modifications Inc. Mandatory Service Bulletin No. ON–100, dated February 1, 1998. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may get a copy from O & N Aircraft Modifications Inc., 210 Windsock Lane, Seamans Airport, Factoryville, PA 18419. You may review copies at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or at 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/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on December 1, 2004.

David A. Downey,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26915 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19228; Directorate Identifier 2004–NM–77–AD; Amendment 39–13897; AD 2004–25–09]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 707 Airplanes and Model 720 and 720B Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Boeing Model 707 airplanes and Model 720 and 720B series airplanes. This AD requires repetitive inspections of the left and right support ribs for the main landing gear (MLG) trunnion, related investigative/corrective actions if necessary, and other specified actions. This AD is prompted by reports of in-service cracking of the support ribs for the MLG trunnion. We are issuing this AD to detect and correct corrosion and cracking of the support ribs for the MLG trunnion, which could result in collapse of the MLG.

DATES: This AD becomes effective January 13, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of January 13, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. You can examine this information at 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/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or 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.

FOR FURTHER INFORMATION CONTACT: *Technical information:* Candice Gerretsen, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6428; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

Examining the 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 DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for all Boeing Model 707 airplanes and Model 720 and 720B series airplanes. That action, published in the **Federal Register** on October 4, 2004 (69 FR 59151), proposed to require repetitive inspections of the left and right support ribs for the main landing gear (MLG) trunnion, related investigative/corrective actions if necessary, and other specified actions.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that was submitted on the proposed AD. The commenter, the manufacturer, supports the proposed AD.

Conclusion

We have carefully reviewed the available data, including the comment that has been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 227 airplanes of the affected design worldwide. The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection, per inspection cycle.	6	$65	None	$390, per inspection cycle.	32	$12,480, per inspection cycle.

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged 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 AD.

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):

2004–25–09 Boeing: Amendment 39–13897. Docket No. FAA–2004–19228; Directorate Identifier 2004–NM–77–AD.

Effective Date

(a) This AD becomes effective January 13, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; and Model 707–300, –300B, –300C, and –400 airplanes; and Model 720 and 720B series airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of in-service cracking of the support ribs for the main landing gear (MLG) trunnion. We are issuing this AD to detect and correct corrosion and cracking of the support ribs for the MLG trunnion, which could result in collapse of the MLG.

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 Bulletin References

(f) The term ''alert service bulletin,'' as used in this AD, means the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3510, dated January 15, 2004.

Repetitive Detailed Inspection and Corrective Action

(g) Within 6 months after the effective date of this AD: Do a detailed inspection for corrosion and cracking of the left and right support ribs of the MLG trunnion. Do the inspection in accordance with all of the actions in Part I of the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 6 months.

(h) If any corrosion or cracking is found during any inspection required by paragraph (g) of this AD: Before further flight, do all applicable related investigative and corrective actions, and the other specified actions, in accordance with the alert service bulletin; except, where the alert service bulletin specifies to contact Boeing, before further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Repetitive High Frequency Eddy Current (HFEC) Inspection and Corrective Action

(i) Within 12 months after the effective date of this AD: Do a HFEC inspection for cracking of the left and right support ribs of the MLG trunnion. Do the inspection in accordance with all of the actions in Part II of the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 12 months.

(j) If cracking is found during any inspection required by paragraph (i) of this AD: Before further flight, repair the cracked area in accordance with a method approved by the Manager, Seattle ACO; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Material Incorporated by Reference

(l) You must use Boeing 707 Alert Service Bulletin A3510, dated January 15, 2004, 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. For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26794 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19811; Directorate Identifier 2004–NM–201–AD; Amendment 39–13893; AD 2004–25–05]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR series airplanes. This AD requires repetitive inspections to detect cracks and fractures of the strut front spar chord assembly at each strut location, and repair if necessary. This AD is prompted by a report of a fractured front spar chord assembly for strut No. 3, which resulted in the loss of the strut upper link load path. We are issuing this AD to prevent loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane.

DATES: Effective December 27, 2004.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of December 27, 2004.

We must receive comments on this AD by February 7, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this 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.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207. You can examine this information at 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/code_of_federal_regulations/ibr_locations.html.*

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–2004–19811; the directorate identifier for this docket is 2004–NM–201–AD.

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Examining the Dockets

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.

FOR FURTHER INFORMATION CONTACT: Technical information: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6437; fax (425) 917–6590. *Plain language information:* Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION: We have received a report indicating that the front spar chord assembly for strut No. 3 fractured on a Boeing Model 747–200B series airplane that had accumulated a total of 16,604 flight cycles and 79,013 flight hours. The front spar chord assembly fractured 4.37 inches forward of the upper link attach lug. The manufacturer's analysis showed that the fitting fractured as the result of fatigue at a critical stress area. Fracture of the front spar chord assembly will result in the loss of the strut upper link load path. Loss of the upper link load path would result in the transfer of additional loads to the diagonal brace load path, which could result in fracture of the diagonal brace. This condition, if not corrected, could result in in-flight separation of the strut and engine from the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin (ASB) 747–54A2224, dated September 30, 2004. The ASB describes procedures for accomplishing detailed and high frequency eddy current (HFEC) inspections of the strut front spar chord assembly for cracks and fractures at each strut location. The ASB also specifies, if any crack or fracture is found, to contact the manufacturer for additional instructions and repair. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of This AD

The unsafe condition described previously is likely to exist or develop on other airplanes of the same type design. Therefore, we are issuing this AD to prevent loss of the strut upper link load path and consequent fracture

of the diagonal brace, which could result in in-flight separation of the strut and engine from the airplane. This AD requires accomplishing the actions specified in the service information described previously, except as discussed under ''Difference Between the AD and the ASB.''

Difference Between the AD and the ASB

The ASB specifies that you may contact the manufacturer for instructions on how to repair certain conditions, but this AD requires you to repair those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the type certification basis of the airplane, and that have been approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make those findings.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19811; Directorate Identifier 2004–NM–201–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the 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 AD. 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.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications with you. You can get more information about plain language at *http://www/faa.gov/language* and *http://www.plainlanguage.gov.*

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 the 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 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):

2004–25–05 Boeing: Amendment 39–13893. Docket No. FAA–2004–19811; Directorate Identifier 2004–NM–201–AD.

Effective Date

(a) This AD becomes effective December 27, 2004.

Applicability

(b) This AD applies to Boeing 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SP, and 747SR series airplanes; as listed in Boeing Alert Service Bulletin (ASB) 747–54A2224, dated September 30, 2004; certificated in any category.

Unsafe Condition

(c) This AD was prompted by a report of a fractured front spar chord assembly for strut No. 3, which resulted in the loss of the strut upper link load path. The FAA is issuing this AD to prevent loss of the strut upper link load path and consequent fracture of the diagonal brace, which could result in in-flight separation of the strut and engine.

Compliance

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

Detailed and High Frequency Eddy Current (HFEC) Inspections

(e) Within 90 days after the effective date of this AD, perform detailed and HFEC inspections to detect any cracks or fractures of the front spar chord assembly for struts Number 1 through 4 inclusive, in accordance with Boeing ASB 747–54A2224, dated September 30, 2004.

(f) Accomplishment of the detailed and HFEC inspections in accordance with Boeing 747 Fleet Team Digest 747–FTD–54–04002, dated April 15, 2004, May 4, 2004, June 1, 2004, July 12, 2004, or July 28, 2004; or Boeing Message 1–C6ELC (Service Request ID No.: 218724992), dated April 14, 2004; before the effective date of this AD, is considered acceptable for compliance with the requirements of paragraph (e) of this AD.

Repetitive Inspections

(g) For airplanes on which no crack or fracture is detected: At the times specified in Table 1—Repetitive Intervals of this AD, perform the detailed and HFEC inspections required by paragraph (e) of this AD at the intervals specified in Table 1.

TABLE 1.—REPETITIVE INTERVALS

For Airplanes identified in Boeing ASB 747–54A2224, dated September 30, 2004, as—	At intervals not to exceed—
Group 1	1,000 flight cycles or 18 months, whichever occurs first.
Group 2 and Group 3.	1,200 flight cycles or 18 months, whichever occurs first.
Group 4 and Group 6.	1,500 flight cycles or 18 months, whichever occurs first.
Group 5	2,000 flight cycles or 18 months, whichever occurs first.

Corrective Action

(h) If any crack or fracture is found during any inspection required by this AD, and the bulletin specifies contacting Boeing for appropriate action: Before further flight, repair the crack or fracture according to a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance (AMOCs)

(i)(1) 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.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Material Incorporated by Reference

(j) You must use Boeing Alert Service Bulletin 747–54A2224, dated September 30, 2004, 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. For copies of the service information, contact Boeing Commercial Airplanes, PO Box 3707, Seattle, Washington 98124–2207. You can review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC; or at 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/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26793 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19816; Directorate Identifier 2004–NM–231–AD; Amendment 39–13895; AD 2004–25–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330 and A340 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Model A330 and A340 series airplanes. This AD requires regularly performing a complete electrical shutdown of the airplane to reset the integrated standby instrument system (ISIS). This AD also provides an optional terminating action. This AD is prompted by reports indicating that an airplane lost the ISIS, then, during the same flight, lost all electronic instrument system (EIS) display units. We are issuing this AD to prevent loss of the ISIS, which, if combined with loss of all EIS display units, could reduce the flightcrew's situational awareness and contribute to loss of control of the airplane or impact with obstacles or terrain.

DATES: Effective December 27, 2004.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of December 27, 2004.

We must receive comments on this AD by February 7, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this 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.
- 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 AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. You can examine this information at 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/code_of_federal_regulations/ibr_locations.html.*

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–2004–19816; the directorate identifier for this docket is 2004–NM–231–AD.

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

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.

FOR FURTHER INFORMATION CONTACT: *Technical information:* 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.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION: The Direction Generale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus Model A330 and A340

series airplanes. The DGAC advises that an Airbus Model A340 series airplane lost the integrated standby instrument system (ISIS). During the same flight, all electronic instrument system (EIS) display units were also lost. Investigation revealed that the ISIS failure is caused by a time-counter fault that occurs after 145 hours of continuous power supply to the ISIS. Loss of the ISIS, if combined with loss of all EIS display units, could reduce the flightcrew's situational awareness and contribute to loss of control of the airplane or impact with obstacles or terrain.

The subject ISIS on certain Airbus Model A340 series airplanes is also installed on certain Airbus Model A330 series airplanes. Therefore, airplanes of both of these models may be subject to the identified unsafe condition.

Relevant Service Information

Airbus has issued Service Bulletins A330–34–3141 (for Airbus Model A330 series airplanes), A340–34–4145 (for Airbus Model A340–200 and –300 series airplanes), and A340–34–5016 (for Airbus Model A340–541 and –642 airplanes); all dated June 8, 2004. The service bulletins describe procedures for replacing the ISIS with an improved ISIS, which eliminates the need to regularly reset the ISIS. The actions specified in the service information, if accomplished, are intended to adequately address the unsafe condition.

Airbus Service Bulletins A330–34–3141, A340–34–4145, and A340–34–5016 refer to Thales Service Bulletin C16221D–34–002 as an additional source of service information.

FAA's Determination and Requirements of This AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. According to this bilateral airworthiness agreement, the DGAC has kept us informed of the situation described above. We have examined the DGAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are issuing this AD to prevent loss of the ISIS, which, if combined with loss of all EIS display units, could reduce the flightcrew's situational awareness and contribute to loss of control of the airplane or impact with obstacles or terrain. This AD requires regularly performing a complete electrical shutdown of the airplane to reset the ISIS. This AD also provides an option for replacing the existing ISIS with an improved ISIS, which constitutes terminating action for the requirement to regularly perform a complete electrical shutdown.

Differences Between the AD and French Emergency Airworthiness Directive

This AD differs from the French emergency airworthiness directive in that this AD does not allow resetting the circuit breaker as a means of resetting the ISIS. This AD instead requires a complete electrical shutdown of the airplane, which the French emergency airworthiness directive provides as an alternative means of resetting the ISIS. The decision to not allow resetting the circuit breaker is based on FAA policy that pulling circuit breakers is not an acceptable means of routinely removing electrical power from airplane systems. This policy is based on the fact that use of a circuit breaker as a switch will degrade the ability of the circuit breaker to trip at its rated current trip point.

The applicability of French Emergency Airworthiness Directive UF–2004–167 excludes airplanes that accomplished Airbus Service Bulletin A330–34–3141, A340–34–4145, or A340–34–5016 in service. However, we have not excluded those airplanes in the applicability of this AD. Rather, this AD specifies that accomplishing the applicable service bulletin is an optional terminating action for the requirement to regularly reset the ISIS. This requirement ensures that the actions specified in this AD are accomplished on all affected airplanes.

Interim Action

We consider this AD interim action. We are currently considering requiring the optional terminating action specified in this AD, which eliminates the need to regularly perform a complete electrical shutdown of the airplane. However, the planned compliance time for this installation would allow enough time to provide notice and opportunity for public comment on the merits of the modification.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19816; Directorate Identifier 2004–NM–231–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the 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 AD. 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.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications with you. You can get more information about plain language at *http://www/faa.gov/language* and *http://www.plainlanguage.gov.*

Authority for This Rulemaking

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

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, the FAA is charged 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 AD.

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 the 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 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):

2004–25–07 Airbus: Amendment 39–13895. Docket No. FAA–2004–19816; Directorate Identifier 2004–NM–231–AD.

Effective Date

(a) This AD becomes effective December 27, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330 and A340 series airplanes, certificated in any category; on which Airbus Modification 47244 (reference Airbus Service Bulletin A330–34–3120 or A340–34–4138) has been done, and on which Airbus Modification 52423 has not been done.

Unsafe Condition

(d) This AD was prompted by a report indicating that an airplane lost the integrated standby instrument system (ISIS), then, during the same flight, lost all electronic instrument system (EIS) display units. The FAA is issuing this AD to prevent loss of the ISIS, which, if combined with loss of all EIS display units, could reduce the flightcrew's situational awareness and contribute to loss of control of the airplane or impact with obstacles or terrain.

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.

Requirement for Complete Electrical Shutdown

(f) Within 3 days after the effective date of this AD, or within 5 days after the last ISIS reset or complete electrical shutdown of the airplane, whichever is first, perform a complete electrical shutdown of the airplane to reset the ISIS. Repeat the electrical shutdown of the airplane at intervals not to exceed 5 days, until the actions in paragraph (g) of this AD are done.

Note 1: This AD does not allow resetting the circuit breaker as a means of resetting the ISIS.

Optional Terminating Action

(g) Replacing the existing ISIS, part number (P/N) C16221DB04, with an improved ISIS, P/N C16221WA01, in accordance with Airbus Service Bulletin A330–34–3141 (for Airbus Model A330 series airplanes), A340–34–4145 (for Airbus Model A340–200 and –300 series airplanes), or A340–34–5016 (for Airbus Model A340–541 and –642 airplanes); all dated June 8, 2004; as applicable; terminates the requirements of paragraph (f) of this AD.

Note 2: Airbus Service Bulletins A330–34–3141, A340–34–4145, and A340–34–5016 refer to Thales Service Bulletin C16221D–34–002 as an additional source of service information.

Alternative Methods of Compliance (AMOCs)

(h) 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

(i) French Emergency Airworthiness Directive UF–2004–167, dated October 19, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(j) If the optional terminating action in paragraph (g) of this AD is accomplished, you must use Airbus Service Bulletin A330–34–3141, dated June 8, 2004; Airbus Service Bulletin A340–34–4145, dated June 8, 2004; or Airbus Service Bulletin A340–34–5016, dated June 8, 2004; as applicable; to perform the actions that are specified in paragraph (g) of this AD. The Director of the Federal Register approves the incorporation by reference of these document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. You can review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC; or at 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/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on November 30, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26791 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19556; Directorate Identifier 2004–CE–37–AD; Amendment 39–13887; AD 2004–24–11]

RIN 2120–AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Model Duo-Discus Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Schempp-Hirth (SCHEMPP–HIRTH) Flugzeugbau GmbH Model Duo-Discus gliders. This AD requires you to do a one-time inspection of the bonding of the spar cap and spar web and repair any defective bonding of the spar cap and spar web. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to detect and correct failure of the bonding of the spar cap and spar web, which, if not detected and corrected, could result in an in-flight wing failure.

DATES: This AD becomes effective on December 30, 2004.

As of December 30, 2004, the Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulation.

We must receive any comments on this AD by January 3, 2005.

ADDRESSES: Use one of the following to submit comments on this 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 20590–001.
- *Fax:* 1–202–493–2251.
- *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.

To get the service information identified in this AD, contact Schempp-Hirth Flugzeugbau GmbH, Postfach 1443, 73222 Kircheim/Teck, Federal Republic of Germany; telephone: 49 7021 7298–0; facsimile: 49 7021 7298–199.

To view the comments to this AD, go to *http://dms.dot.gov*. The docket number is FAA–2004–19556.

FOR FURTHER INFORMATION CONTACT: Gregory Davison, Aerospace Engineer, FAA, Small Airplane Directorate, Room 301, 901 Locust, Kansas City, Missouri 64106; telephone: (816) 329–4130; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, reported to FAA that an in-flight failure of the wing structure at maneuvering loads had occurred on a SCHEMPP-HIRTH Model Duo-Discus glider within the serial number range of 165 through 389. Analysis indicated failure in the bonding of the spar cap and spar web.

This condition caused us to issue AD 2003–16–51, Amendment 39–13282 (68 FR 50055, August 20, 2003). AD 2003–16–51 requires you to do a one-time inspection of the bonding of the spar cap and spar web and repair any defective bonding of the spar cap and spar web.

The LBA notified us of additional reports of bonding problems of the spar cap and spar web on Model Duo-Discus gliders, serial numbers 1 through 164.

What is the potential impact if FAA took no action? This condition, if not detected and corrected, could cause the spar cap and spar web to fail. This failure could result in an in-flight wing failure.

Is there service information that applies to this subject? SCHEMPP-HIRTH has issued Technical Note No. 396–9, dated January 30, 2004, and Appendix to Technical Note No. 396–9, dated January 30, 2004.

What are the provisions of this service information? This service information includes procedures for:

—Inspecting the bonding of the spar cap and spar web; and

—Repairing any defective bonding of the spar cap and spar web.

What action did the LBA take? The LBA classified this service information as mandatory and issued German AD Number D–2004–084, dated February 4, 2004, to ensure the continued airworthiness of these gliders in Germany.

Did the LBA inform the United States under the bilateral airworthiness agreement? These SCHEMPP-HIRTH Model Duo-Discus gliders are manufactured in Germany and are type-certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Under this bilateral airworthiness agreement, the LBA has kept us informed of the situation described above.

FAA's Determination and Requirements of This AD

What has FAA decided? We have examined the LBA's findings, reviewed all available information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Since the unsafe condition described previously is likely to exist or develop on these SCHEMPP–HIRTH Model Duo-Discus gliders (serial numbers 1 through 164) of the same type design that are registered in the United States, we are issuing this AD to detect and correct failure of the bonding of the spar cap and spar web, which if not detected and corrected, could result in an in-flight wing failure.

What does this AD require? This AD requires you to incorporate the actions in the previously-referenced service bulletin.

How does the revision to 14 CFR part 39 affect this AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Comments Invited

Will I have the opportunity to comment before you issue the rule? This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include the docket number, ''FAA–2004–19556; Directorate Identifier 2004–CE–37–AD'' at the beginning of your 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 AD.

Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). This is docket number FAA–2004–19556. 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*.

Are there any specific portions of this AD I should pay attention to? We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend this AD in light of those comments and contacts.

Docket Information

Where can I go to view the docket information? You may view the AD docket that contains the AD, any comments received, and any final disposition in person at the DMS Docket Offices between 9 a.m. and 5 p.m. (eastern standard time), Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5227) is located on the plaza level

of the Department of Transportation NASSIF Building at the street address stated in **ADDRESSES**. You may also view the AD docket on the Internet at *http://dms.dot.gov*. The comments will be available in the AD docket shortly after the DMS receives them.

Regulatory Findings

Will this AD impact various entities? 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.

Will this AD involve a significant rule or regulatory action? 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 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 summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include ''Docket No. FAA–2004–19556; Directorate Identifier 2004–CE–37–AD'' in your request.

This rulemaking is promulgated under the authority in Subtitle VII, Part A, Subpart III, Section 44701, General requirements. Under that section, the FAA is charged with prescribing minimum standards required in the interest of safety for the design of aircraft. This regulation is within the scope of that authority since it corrects an unsafe condition in the design of the aircraft caused by defective bonding of the spar cap to the spar web.

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 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2004–24–11 Schempp-Hirth Flugzeugbau GmbH: Amendment 39–13887; Docket No. FAA–2004–19556; Directorate Identifier 2004–CE–37–AD.

When Does This AD Become Effective?

(a) This AD becomes effective on December 30, 2004.

Are Any Other ADs Affected by This Action?

(b) None.

What Gliders Are Affected by This AD?

(c) This AD affects Model Duo-Discus gliders, serial numbers 1 through 164, that are certificated in any category

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to detect and correct failure of the bonding of the spar cap and spar web, which, if not detected and corrected, could result in an in-flight failure of the wing.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) Inspect the bonding between the spar cap and the spar web for defects.	Within the next 10 hours time-in-service (TIS) after December 30, 2004 (the effective date of this AD).	Follow SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Technical Note No. 396–9, dated January 30, 2004; and SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Appendix to Technical Note No. 396–9, dated January 30, 2004.
(2) Repair any defect in the bonding between the spar cap and the spar web.	Prior to further flight after the inspection required by paragraph (e)(1) of this AD.	Follow SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Technical Note No. 396–9, dated January 30, 2004; SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Appendix to Technical Note No. 396–9, dated January 30, 2004; and the applicable maintenance manual.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, FAA. For information on any already approved alternative methods of compliance, contact Gregory Davison, Aerospace Engineer, FAA, Small Airplane Directorate, Room 301, 901 Locust, Kansas City, Missouri 64106; telephone: (816) 329–4130; facsimile: (816) 329–4090.

Is There Other Information That Relates to This Subject?

(g) German AD Number D–2004–084, dated February 4, 2004, also addresses the subject of this AD.

Does This AD Incorporate Any Material by Reference?

(h) You must do the actions required by this AD following the instructions in SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Technical Note No. 396–9, dated January 30, 2004; and SCHEMPP–HIRTH Flugzeugbau GmbH. Kircheim/Teck Appendix to Technical Note No. 396–9, dated January 30, 2004. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get a copy of this service information, contact Schempp-Hirth Flugzeugbau GmbH, Postfach 1443, 73222 Kircheim/Teck, Federal Republic of Germany; telephone: 49 7021 7298–0; facsimile: 49 7021 7298–199. To review copies of this service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* or call (202) 741–6030. To view the AD docket, go to the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001 or on the Internet at *http://*

dms.dot.gov. The docket number is FAA–2004–19556.

Issued in Kansas City, Missouri, on November 26, 2004.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26640 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR parts 732, 734, 740, 742, 744, and 772

[Docket No. 041022290–4290–01]

RIN 0694–AD19

Encryption Export and Reexport Controls Revisions

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule revises: the criteria for determining if a foreign made item incorporating U.S. origin encryption is subject to the Export Administration Regulations; the notification requirements for beta test encryption software and certain ''publicly available'' encryption software; and the review and reporting requirements for exports and reexports of certain encryption items under License Exception ENC that are neither ''publicly available'' nor eligible for ''mass market'' treatment. It also makes technical changes.

DATES: This rule is effective December 9, 2004.

ADDRESSES: Send comments concerning this rule via e-mail to *rpd2@bis.doc.gov*, fax to (202) 482–3355 or to Regulatory Policy Division, Bureau of Industry and Security, Room 2705, U.S. Department of Commerce, Washington, DC 20230. Refer to regulatory identification number 0694–AD19 in all comments.

FOR FURTHER INFORMATION CONTACT: Norman LaCroix, Director, Information Technology Controls Division, Office of National Security and Technology Transfer Controls, (202) 482–4439.

SUPPLEMENTARY INFORMATION: This rule removes the requirement to make a separate request for *de minimis* eligibility when submitting a review request for some encryption commodities and software under License Exception ENC. Foreign made items incorporating U.S. origin encryption items that have met specified notification or review requirements under mass market, License Exception TSU or License Exception ENC procedures will be treated like foreign made items that incorporate other U.S. origin items, in determining *de minimis* eligibility. This rule removes certain reporting requirements in License Exception TMP regarding beta test encryption software. This rule reduces the notification requirements for exports and reexports of certain ''publicly available'' encryption software that has been posted to the Internet pursuant to License Exception TSU by removing the requirement to notify the U.S. Government of updates or modifications if the Internet location has not changed. This rule simplifies License Exception ENC review requirements for exports and reexports of eligible encryption items, by implementing a uniform 30 day period for most encryption reviews and by clarifying the criteria by which licensing requirements to certain ''government end-users'' are determined. In connection with this 30 day period associated with the initial U.S. Government technical review of an encryption item, this rule authorizes BIS to, at any time, require additional technical information about an encryption item submitted for review and, if the information is not furnished, to suspend or revoke authorization to use License Exception ENC with respect to the item for which the information is sought. This rule also expands the list of countries to which certain encryption items may be sent immediately, once a review request is submitted to the U.S. Government. The list (Supplement No. 3 to part 740) now covers all current members of the European Union (EU), to include those countries that joined the EU on May 1, 2004. This rule updates and clarifies several encryption review requirements in License Exception ENC and clarifies the definition of the term ''hold without action'' in the Export Administration Regulations. This rule also makes some technical changes, and revises the e-mail address of the ENC Encryption Request Coordinator from *enc@ncsc.mil* to *enc@nsa.gov* to match the current e-mail address of that organization.

Although this rule is issued in final form and there is no formal comment period, comments on this rule are welcomed on an ongoing basis.

Determining When a Foreign Made Item Is Subject to the EAR

Section 734.4 of the EAR describes situations under which foreign made items are not subject to the Export Administration Regulations because the U.S. origin items that they incorporate are less than a defined ''*de minimis*'' percentage of their content. This rule removes the requirement for U.S. firms to request eligibility for *de minimis* treatment when submitting their encryption commodity or software for review to obtain authorization for export and reexport under License Exception ENC (§ 740.17 of the EAR). As a result, foreign made items containing most U.S. origin encryption commodities or software that have met the notification, review or determination requirements specified in revised § 734.4(b) are now treated, for purposes of *de minimis* calculations, in the same way as foreign made items that incorporate other U.S. origin dual-use items. However, there is no *de minimis* eligibility for encryption technology controlled under Export Control Classification Number (ECCN) 5E002, or for foreign made items going to a destination in Country Group E:1 when the foreign item contains U.S. origin restricted encryption content described in § 740.17(b)(2) of the EAR (*e.g.* network infrastructure commodities and software controlled under ECCNs 5A002 and 5D002, cryptanalytic items, and ECCN 5D002 encryption source code that is not ''publicly available'' as that term is used in License Exception TSU, § 740.13(e)(1) of the EAR). This rule also makes conforming changes to § 732.2(d) to reflect these new *de minimis* procedures.

Exports of Beta Test Encryption Software Under License Exception TMP

This rule removes the requirements to report the names and addresses of testing consignees by removing § 740.9(c)(8)(ii). It restructures, but makes no other substantive changes to § 740.9(c)(8). It retains the notification requirements of that paragraph and changes an e-mail address.

Exports of Certain ''Publicly Available'' Encryption Software Under License Exception TSU

For ''publicly available'' encryption software that has been posted to the Internet after notification to BIS and the ENC Encryption Request Coordinator under § 740.13(e), this rule removes the requirement to provide notice of updates or modifications made to the encryption software at the previously notified location. This rule makes no other substantive changes to this section, but substantially reorganizes it.

License Exception ENC Review Requirements for Certain Encryption Items That Are Neither Publicly Available Nor Determined by BIS To Be Eligible for ''Mass Market'' Treatment

This rule clarifies the scope of License Exception ENC by replacing, throughout § 740.17, the phrase (and its variants) ''encryption items controlled under ECCN 5A002, 5D002 or 5E002, and 'information security' test, inspection, and production equipment controlled under ECCN 5B002'' with a list of the specific ECCNs (including the sub-paragraph number, where needed for clarity) that identify which items subject to the EAR are eligible for this license exception. It consolidates the provisions and restrictions that apply to the entire license exception, in a revised introductory paragraph and a new paragraph (f), respectively. It removes repetitive references to such provisions and restrictions from various paragraphs. It also replaces the ''Grandfathering'' paragraph (former § 740.17(d)(2)) with specific information in paragraphs (a), (b)(2), and (b)(3) describing the extent to which prior U.S. Government reviews may be used to satisfy current License Exception ENC encryption review requirements.

This rule retains the basic structure of License Exception ENC, by addressing exports and reexports to countries listed in Supplement No. 3 to part 740 in paragraph (a) and exports to other countries in paragraph (b). Paragraph (b) continues to be further subdivided, providing separate provisions for exports and reexports to: Subsidiaries of U.S. companies (paragraph (b)(1)); non-''government end-users'' for certain restricted items (as described in paragraph (b)(2)); and both ''government end-users'' and non-''government end-users'' for all other items (paragraph (b)(3)). However, important substantive changes and clarifications are made to all of these paragraphs. Those changes and clarifications are discussed below.

Exports, Reexports and Technical Assistance to Countries Listed in Supplement No. 3 to Part 740 (§ 740.17(a))

This rule revises § 740.17(a) so that the section not only continues to authorize the export and reexport of encryption items under specified circumstances, but also allows the provision of technical assistance related to encryption items (as described in § 744.9 of the EAR), when the technical assistance is provided to end-users located or headquartered in Canada or in countries listed in Supplement No. 3 to part 740. This rule also removes the specific reference in this paragraph to the prohibition on exports or reexports of encryption source code and technology to nationals of countries listed in Country Group E:1 in Supplement No. 1 to part 740 of the EAR, as such general restrictions on the use of License Exception ENC have been consolidated into a new paragraph (f). It also divides paragraph (a) into three paragraphs designated § 740.17 (a)(1), § 740.17 (a)(2), and § 740.17(a)(3).

Section 740.17(a)(1) eliminates the requirement that the U.S. Government review the encryption items and related technical assistance prior to their being provided for internal company use in the development of new products by private sector end-users that are headquartered in Canada or in countries listed in Supplement No. 3 to part 740. However, it retains the requirement that such new product encryption items developed by those end-users be reviewed by the U.S. Government before the finished products are transferred to others. It also defines ''private sector end-user'' for the purposes of this paragraph.

Section 740.17(a)(2) states that certain items reviewed and authorized for export and reexport prior to October 19, 2000 are authorized for continued export and reexport under revised § 740.17(a), without additional U.S. Government review.

Section § 740.17(a)(3) retains the existing License Exception ENC provisions requiring submission of an encryption review request to BIS and the ENC Encryption Request Coordinator before export or reexport of: Finished encryption products to end-users located in countries listed in Supplement No. 3 to part 740; finished products to foreign subsidiaries and offices of end-users headquartered in Canada or in countries listed in Supplement No. 3 to part 740; and other encryption items (including technology and related technical assistance) to end-users located in, but not headquartered in, countries listed in Supplement No. 3 to part 740.

Export and Reexports to Other Countries (§ 740.17(b))

This rule makes no substantive changes to paragraph (b)(1), which deals with exports and reexports to subsidiaries of U.S. companies, but substantially reorganizes it. As with paragraph (a), the rule also removes the specific reference in this paragraph to the prohibition on exports or reexports of encryption source code and technology to nationals of countries listed in Country Group E:1 in Supplement No. 1 to part 740 of the EAR, as such general restrictions on the use of License Exception ENC have been consolidated into a new paragraph (f).

This rule replaces the previous illustrative descriptions of ''retail'' and other ''equivalent functionality'' encryption commodities and software (eligible for export and reexport to both ''government end-users'' and non-''government end-users'' in paragraph (b)(3)), with an exclusive list in paragraph (b)(2) of those encryption commodities and software that are eligible only to non- ''government end-users''. Except for commodities and software that provide an ''open cryptographic interface'' or that are specified in paragraph (b)(2), all encryption products eligible for License Exception ENC qualify under paragraph (b)(3), thereby removing the need for ''retail'' or other ''equivalent functionality'' considerations.

This rule also replaces the requirement for obtaining specific U.S. Government authorization before exporting or reexporting under paragraph (b)(3) with a 30 day waiting period, calculated in calendar days beginning with the date that an encryption review request for the commodity or software is registered with BIS. For encryption reviews that are not completed by BIS within this 30 day period, the exporter may ship after the waiting period has elapsed. As with similar requirements in the current rule, the 30 day waiting period does not include any time that BIS places the review request on ''hold without action''. Upon completion of BIS's review, BIS will provide written notice of the provisions, if any, of § 740.17 under which the encryption item may be exported or reexported.

This rule also removes the word ''retail'' from § 740.17(b)(3), except in paragraph (b)(3)(ii)(A), which describes the extent to which items previously classified as ''retail'' may be exported and reexported under paragraph (b)(3) without further U.S. Government review. BIS believes that these changes will help readers more readily distinguish the procedure for making certain non-''mass-market'' encryption commodities and software eligible for export and reexport under License Exception ENC from the procedure by which ''mass market'' encryption commodities and software are removed from the scope of ECCNs 5A002 or 5D002 pursuant to § 742.15(b)(2) of the EAR.

Reporting Requirements (§ 740.17(e))

This rule clarifies that the semi-annual reporting requirements of License Exception ENC apply to exports

from the United States to all destinations except Canada, and to reexports from Canada to other foreign destinations. In conformance with the revisions to § 740.17(b)(3), under paragraph (e)(4) (''Exclusions from reporting requirements'') this rule removes the word ''retail'' and the phrase ''designed for, bundled with, or pre-loaded on single CPU computers, laptops or hand-held devices.''

Other Changes to License Exception ENC

This rule eliminates all references to requesting eligibility for *de minimis* treatment from License Exception ENC because such special requests are no longer required due to the changes in §§ 734.4(a)(2) and 734.4(b) made by this rule. This rule revises § 740.17(d) by changing the title from ''Review requirements'' to ''Review request procedures'' to more accurately reflect its contents. This rule also substantially reorganizes paragraph (d)(3) and institutes an e-mail notification procedure in place of the previous requirement that product key length increases authorized under this paragraph be certified to BIS and the ENC Encryption Request Coordinator in a letter from a corporate official.

Lastly, this rule contains a new provision authorizing BIS to contact the submitter of a review request at any time, even after the 30-day waiting periods prescribed in §§ 740.17(b)(2)(ii) or 740.17(b)(3)(ii)(B) have passed, to request additional information about an encryption item. If the submitter does not supply the requested information within 14 days after receiving the request from BIS, BIS may suspend or revoke the submitter's right to use License Exception ENC for the item about which the additional information is sought. If the submitter requests additional time to collect the information before the date it is due to BIS, BIS may grant up to an additional 14 days if BIS concludes that such additional time is necessary.

Supplement No. 3 to Part 740

This rule adds Cyprus, Estonia, Latvia, Lithuania, Malta, Slovakia and Slovenia to Supplement No. 3 to part 740 because those countries were admitted to the European Union on May 1, 2004 and were not previously listed in this supplement. (Although the Czech Republic, Hungary and Poland were also admitted to the European Union on May 1, 2004, these three countries were previously listed in Supplement No. 3 to part 740.) This supplement identifies the countries that are eligible to receive both ''mass-market'' encryption products and non- ''mass-market'' encryption items from the United States, immediately after the U.S. origin items are registered with BIS for review (*i.e.*, without a 30 day waiting period) under § 740.17(a) or § 742.15(b)(2) of the EAR. The addition of these countries to Supplement No. 3 continues the United States Government's practice of authorizing such immediate exports and reexports of encryption items to countries in the European Union's license-free zone. This rule also changes the title of this supplement from ''License Exception ENC country group.'' to ''Countries eligible for the provisions of § 740.17(a).'' The revised title more accurately describes the supplement, which lists the countries that are relevant to the provisions of § 740.17(a) but does not set forth any geographic limitation on the use of other provisions of License Exception ENC.

Section 742.15

This rule adds to § 742.15(b)(1) the e-mail addresses of BIS and the ENC Encryption Request Coordinator to which advance notifications of exports and reexports of encryption items controlled under ECCNs 5A992, 5D992 or 5E992 must be sent if a person wishes to export or reexport such items without a license under this section.

Supplement No. 6 to Part 742

To expedite the handling of encryption review requests and reduce the need for U.S. Government requests for additional information from submitters, this rule revises paragraph (c)(8) to require that similar information be provided regarding third-party encryption hardware components as is currently required for software components. This rule also revises paragraph (c)(11) by eliminating the word ''retail'' in conformance with the revisions to § 740.17(b)(3).

Section 744.9

This rule updates the paragraph pertaining to ''Restrictions on Technical Assistance by U.S. Persons with Respect to Encryption Items'' by replacing a previous reference to ''classification request'' with ''encryption review request'', and by adding references to § 740.17(a)(1) and § 740.17(a)(3) in conformance with the revisions to License Exception ENC.

Section 772.1—Definition of ''Hold Without Action''

This rule adds a sentence to the end of the definition to make clear that, unlike the procedure for license applications, BIS is not restricted to the circumstances described in § 750.4(c) of the EAR when determining that an encryption review request may be placed on ''hold without action'' status.

Administrative Changes

This rule revises the e-mail address of the ENC Encryption Request Coordinator wherever it appears in § 740.9, § 740.13, and § 740.17 from *enc@ncsc.mil* to *enc@nsa.gov* to reflect the current e-mail address of that organization. In § 740.17(e)(5)(i), this rule revises the mailing address of the BIS office to which semi-annual License Exception ENC reports are sent, to reflect the current name of that office.

Although the Export Administration Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), as extended by the Notice of August 6, 2004, 69 FR 48763 (August 10, 2004) continues the Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements:

1. This rule has been determined to be significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains collections of information subject to the PRA. These collections have been approved by OMB under control number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748, and control number 0694–0104 ''Encryption Items Under the Jurisdiction of the Department of Commerce, Forms BIS 742R and 742S'' which carries a total estimated burden of 2,830 hours among an estimated 680 respondents. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to David Rostker, OMB Desk Officer, by e-mail at *david_rostker@omb.eop.gov* or by fax to 202.395.285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

3. This rule does not contain policies with Federalism implications as this term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C.

553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (Sec. 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this rule is being issued in final form.

List of Subjects

15 CFR Parts 732 and 740

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

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 772

Exports.

■ Accordingly, parts 732, 734, 740, 742, 744 and 772 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

PART 732—[AMENDED]

■ 1. The authority citation for part 732 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

■ 2. In § 732.2 revise the introductory text of paragraph (d) to read as follows.

§ 732.2 Steps regarding scope of the EAR.

* * * * *

(d) *Step 4: Foreign-made items incorporating less than the de minimis level of U.S. parts, components, and materials.* This step is appropriate only for items that are made outside the United States and not currently in the United States. Special requirements and restrictions apply to items that incorporate U.S. origin encryption items (see § 734.4(a)(2) and (b) of the EAR).

* * * * *

PART 734—[AMENDED]

■ 3. The authority citation for part 734 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004); Notice of November 4, 2004, 69 FR 64637 (November 8, 2004).

■ 4. In § 734.4 revise paragraph (a)(2), add paragraph (b), and revise the introductory texts of paragraphs (c) and (d) to read as follows:

§ 734.4 De Minimis U.S. Content.

(a) * * *

(2) Foreign produced encryption technology that incorporates U.S. origin encryption technology controlled by ECCN 5E002 is subject to the EAR regardless of the amount of U.S. origin content.

* * * * *

(b) *Special requirements for certain encryption items.* Foreign made items that incorporate U.S. origin items that are listed in this paragraph are subject to the EAR unless they meet the *de minimis* level and destination requirements of paragraph (c) or (d) of this section and the requirements of this paragraph.

(1) The U.S. origin commodities or software, if controlled under ECCNs 5A002.a.1, .a.2, .a.5, or .a.6, or 5D002, must have been:

(i) Authorized for license exception TSU because of having met the notification requirements of § 740.13(e) of the EAR (ECCN 5D002 only);

(ii) Authorized for License Exception ENC by BIS after a review pursuant to § 740.17(b)(3) of the EAR; or

(iii) Authorized for License Exception ENC by BIS after a review pursuant to § 740.17(b)(2), and the foreign made product will not be sent to any destination in Country Group E:1 in Supplement No. 1 to part 740 of the EAR.

(2) The U.S. origin encryption items, if controlled under ECCNs 5A992, 5D992, or 5E992 must:

(i) Have met the notification requirements of § 742.15(b)(1) of the EAR; or

(ii) Have been determined by BIS to be ''mass market'' commodities or software after a review in accordance with § 742.15(b)(2) of the EAR (ECCNs 5A992 and 5D992 only); or

(iii) Be an item described in § 742.15(b)(3)(ii) or § 742.15(b)(3)(iii) of the EAR.

Note to paragraph (b): See supplement No. 2 to this part for *de minimis* calculation procedures and reporting requirements.

(c) Except as provided in paragraphs(a) and (b)(1)(iii) and subject to the provisions of paragraphs (b)(1)(i), (b)(1)(ii) and (b)(2) of this section, the following reexports are not subject to the EAR when made to a terrorist-supporting country listed in Country Group E:1 (see Supplement No. 1 to part 740 of the EAR).

* * * * *

(d) Except as provided in paragraph (a) of this section and subject to the provisions of paragraph (b) of this section, the following reexports are not subject to the EAR when made to countries other than those described in paragraph (c) of this section.

* * * * *

PART 740—[AMENDED]

■ 5. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec. 901–911, Pub. L. 106–387; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

■ 6. In § 740.9, revise paragraph (c)(8) to read as follows:

§ 740.9 Temporary imports, exports, and reexports (TMP).

* * * * *

(c) * * *

(8) *Notification of beta test encryption software.* For beta test encryption software eligible under this license exception you must, by the time of export or reexport, submit the information described in paragraphs (a) through (e) of Supplement No. 6 to part 742 of the EAR by e-mail to BIS at *crypt@bis.doc.gov* and to the ENC Encryption Request Coordinator at *enc@nsa.gov.*

■ 7. In § 740.13, revise paragraph (e) as follows.

§ 740.13 Technology and software—unrestricted (TSU).

* * * * *

(e) *Encryption source code (and corresponding object code).*

(1) *Scope and eligibility.* This paragraph (e) authorizes exports and reexports, without review, of encryption source code controlled by ECCN 5D002 that, if not controlled by ECCN 5D002, would be considered publicly available under § 734.3(b)(3) of the EAR. Such

source code is eligible for License Exception TSU under this paragraph (e) even if it is subject to an express agreement for the payment of a licensing fee or royalty for commercial production or sale of any product developed using the source code. This paragraph also authorizes the export and reexport of the corresponding object code (*i.e.*, that which is compiled from source code that is authorized for export and reexport under this paragraph) if both the object code and the source code from which it is compiled would be considered publicly available under § 734.3(b)(3) of the EAR, if they were not controlled under ECCN 5D002.

(2) *Restrictions.* This paragraph (e) does not authorize:

(i) Export or reexport of any encryption software controlled under ECCN 5D002 that does not meet the requirements of paragraph (e)(1), even if the software incorporates or is specially designed to use other encryption software that meets the requirements of paragraph (e)(1) of this section; or

(ii) Any knowing export or reexport to a country listed in Country Group E:1 in Supplement No. 1 to part 740 of the EAR.

(3) *Notification requirement.* You must notify BIS and the ENC Encryption Request Coordinator via e-mail of the Internet location (*e.g.*, URL or Internet address) of the source code or provide each of them a copy of the source code at or before the time you take action to make the software publicly available as that term is described in § 734.3(b)(3) of the EAR. If you elect to meet this requirement by providing copies of the source code to BIS and the ENC Encryption Request Coordinator, you must provide additional copies to each of them each time the cryptographic functionality of the software is updated or modified. If you elect to provide the Internet location of the source code, you must notify BIS and the ENC Encryption Request Coordinator each time the Internet location is changed, but you are not required to notify them of updates or modifications made to the encryption software at the previously notified location. In all instances, submit the notification or copy to *crypt@bis.doc.gov* and to *enc@nsa.gov.*

Note to paragraph (e). Posting encryption source code and corresponding object code on the Internet (*e.g.*, FTP or World Wide Web site) where it may be downloaded by anyone neither establishes ''knowledge'' of a prohibited export or reexport for purposes of this paragraph, nor triggers any ''red flags'' necessitating the affirmative duty to inquire under the ''Know Your Customer'' guidance provided in Supplement No. 3 to part 732 of the EAR.

■ 8. In § 740.17, revise the introductory text and paragraphs (a), (b), (d) and (e), and add paragraph (f) to read as follows:

§ 740.17 Encryption software and commodities (ENC).

Subject to the eligibility criteria and restrictions described in paragraphs (a), (b) and (f) of this section, License Exception ENC is available for the export and reexport of: commodities and software controlled by ECCNs 5A002.a.1, .a.2, .a.5, and .a.6, 5B002, and 5D002 that do not meet the ''mass market'' criteria of the Cryptography Note (Note 3) of Category 5, part 2 (''Information Security'') of the Commerce Control List (Supplement No. 1 to part 774 of the EAR); technology controlled by ECCN 5E002; and certain technical assistance as described in § 744.9 of the EAR. The initial export or reexport of an encryption commodity or software under paragraphs (b)(2) or (b)(3) of this section is subject to a 30 day waiting period, as described in paragraph (d)(2) of this section. In addition, persons exporting or reexporting under paragraphs (a), (b)(2) or (b)(3) of this section must file the semi-annual reports required by paragraph (e) of this section. Review request procedures for encryption items eligible for License Exception ENC are described in paragraph (d) of this section (*e.g.*, for items that have not previously been reviewed, or for items that have been reviewed but for which the cryptographic functionality has been changed). See § 742.15(b)(2) of the EAR for similar review procedures for ''mass market'' encryption commodities and software.

(a) *Exports, reexports, and technical assistance to countries listed in Supplement No. 3 to this part.* This paragraph (a) authorizes export or reexport of items controlled under ECCNs 5A002.a.1, .a.2, .a.5, or .a.6, 5B002, 5D002, or 5E002, and provision of technical assistance described in § 744.9 of the EAR, to end-users in countries listed in Supplement No. 3 to part 740 of the EAR. This paragraph also authorizes exports or reexports to foreign subsidiaries and offices of end-users headquartered in Canada or in countries listed in Supplement No. 3 to part 740. In addition, the transaction must meet the terms of paragraphs (a)(1), (a)(2), or (a)(3) of this section.

(1) *Internal development of new products.* No prior review is required for exports or reexports of U.S. origin encryption items or related technical assistance under this paragraph (a) to private sector end-users that are headquartered in Canada or in countries listed in Supplement No. 3 to part 740, for internal use for the development of new products by those end-users and their offices or subsidiaries. Any encryption item produced or developed with an item exported or reexported under this paragraph (a)(1) is subject to the EAR and requires review and authorization before any sale or retransfer outside of the private sector end-user that developed it. In this paragraph (a)(1), private sector end-user means:

(i) An individual who is not acting on behalf of any foreign government; or

(ii) A commercial firm (including its subsidiary and parent firms, and other subsidiaries of the same parent) that is not wholly owned by, or otherwise controlled by or acting on behalf of, any foreign government.

(2) *Items previously reviewed by the U.S. Government.* No additional U.S. Government review is required under this paragraph (a) for export or reexport of encryption commodities or software or parts or components thereof that, prior to October 19, 2000, were authorized for export or reexport under a license or Encryption Licensing Arrangement, or were reviewed and authorized for export and reexport to entities other than U.S. subsidiaries under License Exception ENC. No additional U.S. Government review is required under this paragraph for export or reexport of encryption technology that, prior to October 19, 2000, was approved for export or reexport under a license or Encryption Licensing Arrangement.

(3) *Other transactions.* For any use not described in paragraph (a)(1) of this section, before you export or reexport any item or related technical assistance that has not been previously reviewed by the U.S. Government and authorized under this paragraph (a), you must submit a review request in accordance with paragraph (d) of this section.

(b) *Exports and reexports to countries not listed in supplement No. 3 to this part.* (1) *Encryption items for U.S. subsidiaries.* This paragraph (b)(1) authorizes export, or reexport or items controlled under ECCNs 5A002.a.1, .a.2, .a.5, or .a.6, 5B002, 5D002 or 5E002:

(i) To any ''U.S. subsidiary''; and

(ii) By a U.S. company and its subsidiaries to foreign nationals who are employees, contractors or interns of a U.S. company or its subsidiaries if the items are for internal company use, including the development of new products.

(iii) *General restriction.* All items produced or developed with commodities, software or technology exported under this paragraph (b)(1) are

subject to the EAR and require review and authorization before sale or transfer outside the U.S. company and its subsidiaries.

(2) *Encryption commodities and software restricted to non-''government end-users.''* This paragraph (b)(2) authorizes the export and reexport of items described in § 740.17(b)(2)(iii) of the EAR that do not provide an ''open cryptographic interface'' and that are controlled by ECCNs 5A002.a.1, .a.2, .a.5, or .a.6, or 5D002 to individuals, commercial firms, and other entities that are not ''government end-users'' and that are not located in a country listed in Supplement No. 3 to this part. In addition, the transaction must meet the provisions of either § 740.17(b)(2)(i) or (ii) of the EAR.

(i) *Commodities and software previously reviewed by the U.S. Government.* No additional U.S. Government review is required under this paragraph (b)(2) for export or reexports of encryption commodities or software or parts or components thereof that, prior to October 19, 2000, were authorized for export or reexport under a license or Encryption Licensing Arrangement, or were reviewed and authorized for export and reexport to entities other than U.S. subsidiaries under License Exception ENC.

(ii) *Other commodities and software not previously reviewed.* Before exporting or reexporting any item that has not been reviewed by the U.S. Government and authorized under this paragraph (b)(2), you must submit a review request in accordance with paragraph (d) of this section and wait until 30 days after that request is registered (as defined in § 750.4(a)(2) of the EAR) with BIS. Days during which the review request is on ''hold without action'' status are not counted towards fulfilling the 30 day waiting period.

(iii) The encryption commodities, software and components eligible for export or reexport under this paragraph (b)(2) (see paragraph (b)(3) of this section for commodities, software and components not listed in this paragraph (b)(2)(iii)) are:

(A) Network infrastructure commodities and software, and parts and components thereof (including commodities and software necessary to activate or enable cryptographic functionality in network infrastructure products) providing secure Wide Area Network (WAN), Metropolitan Area Network (MAN), Virtual Private Network (VPN), satellite, cellular or trunked communications meeting any of the following with key lengths exceeding 64-bits for symmetric algorithms:

(*1*) Aggregate encrypted WAN, MAN, VPN or backhaul throughput (includes communications through wireless network elements such as gateways, mobile switches, controllers, *etc.*) greater than 44 Mbps.; or

(*2*) Wire (line), cable or fiber-optic WAN, MAN or VPN single-channel input data rate exceeding 44 Mbps; or

(*3*) Maximum number of concurrent encrypted data tunnels or channels exceeding 250; or

(*4*) Air-interface coverage (*e.g.*, through base stations, access points to mesh networks, bridges, *etc.*) exceeding 1,000 meters, where any of the following applies:

(*i*) Maximum data rates exceeding 5 Mbps (at operating ranges beyond 1,000 meters); or

(*ii*) Maximum number of concurrent full-duplex voice channels exceeding 30; or

(*iii*) Substantial support is required for installation or use.

(B) Encryption source code that would not be eligible for export or reexport under License Exception TSU because it is not publicly available as that term is used in § 740.13(e)(1) of the EAR.

(C) Encryption commodities or software that do not provide an ''open cryptographic interface'', but that have:

(*1*) Been modified or customized for government end-user(s) or government end-use (*e.g.* to secure departmental, police, state security, or emergency response communications); or

(*2*) Cryptographic functionality that has been modified or customized to customer specification; or

(*3*) Cryptographic functionality or ''encryption component'' (except encryption software that would be considered publicly available, as that term is used in § 740.13(e)(1) of the EAR) that is user-accessible and can be easily changed by the user.

(D) ''Cryptanalytic items''; or

(E) Encryption commodities and software that provide functions necessary for quantum cryptography; or

(F) Encryption commodities and software that have been modified or customized for computers controlled by ECCN 4A003.

(3) *Encryption commodities, software and components available to both ''government end-users'' and to non-''government end-users''.* This paragraph authorizes export and reexport of commodities, software and components controlled by ECCNs 5A002.a.1, .a.2, .a.5, or .a.6, 5B002, or 5D002. To be eligible under this paragraph (b)(3) the requirements of paragraphs (b)(3)(i) and (b)(3)(ii) must be met.

(i) The commodities or software must *not:*

(A) Provide an ''open cryptographic interface''; or

(B) Be listed in paragraph (b)(2) of this section.

(ii) *Review and authorization requirement.* (A) *Commodities and software previously reviewed by the U.S. Government.* Encryption commodities, software and components reviewed and authorized by BIS for export and reexport as ''retail'' commodities or software under this paragraph (b)(3) prior to December 9, 2004 do not require additional review or authorization for export or reexport under this paragraph.

(B) *Other commodities and software not previously reviewed.* Before exporting or reexporting any item that has not been reviewed by the U.S. Government and authorized under this paragraph (b)(3), you must submit a review request in accordance with paragraph (d) of this section and wait until 30 days after that request is registered (as defined in § 750.4(a)(2) of the EAR) with BIS. Days during which the review request is on ''hold without action'' are not counted towards fulfilling the 30 day waiting period.

(4) *Exemptions from the 30 day waiting period and review requirements.* (i) *Exemptions from the 30 day waiting period.* Items listed in this paragraph (b)(4)(i) may be exported or reexported under authority of paragraphs (b)(2) or (b)(3) immediately upon filing the review requests required by those paragraphs provided all other requirements for export or reexport under the paragraph being relied upon are met.

(A) Encryption commodities and software (including key management products) with key lengths not exceeding 64 bits for symmetric algorithms, 1024 bits for asymmetric key exchange algorithms, and 160 bits for elliptic curve algorithms;

(B) Encryption source code that would not be considered publicly available for export or reexport under License Exception TSU, provided that a copy of your source code is included in the review request to BIS and the ENC Encryption Request Coordinator.

(ii) *Exemptions from the review requirement.* The following products do not require review under this license exception, but remain subject to the EAR (including all terms and provisions of this license exception, and all licensing requirements that may apply to a particular item or transaction for reasons other than encryption):

(A) Commodities and software that would not otherwise be controlled under Category 5 (telecommunications

and ''information security'') of the Commerce Control List, but that are controlled under ECCN 5A002 or 5D002 only because they incorporate components or software that provide short-range wireless encryption functions (*e.g.*, with an operating range typically not exceeding 100 meters);

(B) Foreign products developed with or incorporating U.S.-origin encryption source code, components or toolkits (or otherwise designed to operate with U.S. products, *e.g.*, via signing), provided that the U.S.-origin encryption items (and related technical assistance, as described in § 744.9 of the EAR) have previously been reviewed and authorized by BIS and the cryptographic functionality has not been changed.

* * * * *

(d) *Review request procedures.* To request review of your encryption items under License Exception ENC (*e.g.*, for items that have not previously been reviewed, or for items that have been reviewed but for which the cryptographic functionality has been changed), you must submit to BIS and to the ENC Encryption Request Coordinator the information described in paragraph (d)(1) of this section and in paragraphs (a) through (e) of Supplement No. 6 to part 742 of the EAR (Guidelines for Submitting Review Requests for Encryption Items).

(1) *Instructions for requesting review.* Review requests must be submitted on Form BIS–748P (Multipurpose Application), or its electronic equivalent, as described in § 748.3 of the EAR. To ensure that your review request is properly routed, insert the phrase ''License Exception ENC'' in Block 9 (Special Purpose) of the paper or electronic application. Also, place an ''X'' in the box marked ''Classification Request'' in Block 5 (Type of Application) of Form BIS–748P or select ''Commodity Classification'' if filing electronically. Neither the electronic nor paper forms provide a separate Block to check for the submission of encryption review requests. Failure to properly complete these items may delay consideration of your review request. Review requests that are not submitted electronically to BIS should be mailed to the address indicated on the BIS–748P form. See paragraph (e)(5)(ii) of this section for the mailing address for the ENC Encryption Request Coordinator.

(2) *Action by BIS.* Upon completion of its review, BIS will send you written notice of the provisions, if any, of this section under which your items may be exported or reexported. If BIS has not, within 30 days of registration of a complete review request from you, informed you that your item is not authorized for License Exception ENC, you may export or reexport under the applicable provisions of License Exception ENC. BIS may hold your review request without action if necessary to obtain additional information or for any other reason necessary to ensure an accurate determination with respect to ENC eligibility. Time on such ''hold without action'' status shall not be counted towards fulfilling the 30 day waiting period specified in this paragraph and in paragraphs (b)(2) and (b)(3) of this section. BIS may require you to supply additional relevant technical information about your encryption item(s) or information that pertains to their eligibility for License Exception ENC at any time, before or after the expiration of the 30 day waiting period specified in this paragraph and in paragraphs (b)(2) and (b)(3) of this section. If you do not supply such information within 14 days after receiving a request for it from BIS, BIS may return your review request(s) without action or otherwise suspend or revoke your eligibility to use License Exception ENC for that item(s). At your request, BIS may grant you up to an additional 14 days to provide the requested information. Any request for such an additional number of days must be made prior to the date by which the information was otherwise due to be provided to BIS, and may be approved if BIS concludes that additional time is necessary.

(3) *Key length increases.* Commodities and software that are modified only to upgrade the key length used for confidentiality or key exchange algorithms (after having been reviewed and authorized for License Exception ENC by BIS) may be exported or reexported under the previously authorized provision of License Exception ENC without further review, provided:

(i) The exporter or reexporter certifies to BIS and the ENC Encryption Request Coordinator that no change to the encryption functionality has been made other than to upgrade the key length for confidentiality or key exchange algorithms;

(ii) The certification includes the original authorization number issued by BIS and the date of issuance;

(iii) The certification is received by BIS and the ENC Encryption Request Coordinator before the export or reexport of the upgraded product; and

(iv) The certification is e-mailed to *crypt@bis.doc.gov* and *enc@nsa.gov.*

(e) *Reporting requirements.* (1) *Semi-annual reporting requirement.* Semi-annual reporting is required for exports to all destinations other than Canada, and for reexports from Canada, under this license exception. Certain encryption items and transactions are excluded from this reporting requirement (see paragraph (e)(4) of this section). For instructions on how to submit your reports, see paragraph (e)(5) of this section.

(2) *General information required.* Exporters must include all of the following applicable information in their reports:

(i) For items exported (or reexported from Canada) to a distributor or other reseller, including subsidiaries of U.S. firms, the name and address of the distributor or reseller, the item and the quantity exported or reexported and, if collected by the exporter as part of the distribution process, the end-user's name and address;

(ii) For items exported (or reexported from Canada) to individual consumers through direct sale (provided the transaction is not exempted from reporting under paragraph (e)(4)(iii) or (e)(4)(iv) of this section), the name and address of the recipient, the item, and the quantity exported;

(iii) For exports of ECCN 5E002 items to be used for technical assistance that are not released by § 744.9 of the EAR, the name and address of the end-user; and

(iv) For each item, the authorization number and the name of the item(s) exported (or reexported from Canada).

(3) *Information on foreign manufacturers and products that use encryption items.* For direct sales or transfers, under License Exception ENC, of encryption components, source code, general purpose toolkits, equipment controlled under ECCN 5B002, technology, or items that provide an ''open cryptographic interface'' to foreign developers or manufacturers when intended for use in foreign products developed for commercial sale, you must submit the names and addresses of the manufacturers using these encryption items and, if you know when the product is made available for commercial sale, a non-proprietary technical description of the foreign products for which these encryption items are being used (*e.g.*, brochures, other documentation, descriptions or other identifiers of the final foreign product; the algorithm and key lengths used; general programming interfaces to the product, if known; any standards or protocols that the foreign product adheres to; and source code, if available).

(4) *Exclusions from reporting requirements.* Reporting is not required for the following items and transactions:

(i) Any encryption item exported or reexported under paragraph (a)(1) or (b)(1) of this section;

(ii) Encryption commodities or software with a symmetric key length not exceeding 64 bits;

(iii) Encryption commodities and software authorized under paragraph (b)(3) of this section, exported (or reexported from Canada) to individual consumers;

(iv) Encryption items exported (or reexported from Canada) via free and anonymous download;

(v) Encryption items from or to a U.S. bank, financial institution or its subsidiaries, affiliates, customers or contractors for banking or financial operations;

(vi) Items that incorporate components limited to providing short-range wireless encryption functions;

(vii) General purpose operating systems, or desktop applications (*e.g.*, e-mail, browsers, games, word processing, data base, financial applications or utilities) authorized under paragraph (b)(3) of this section;

(viii) Client Internet appliance and client wireless LAN cards; or

(ix) Foreign products developed by bundling or compiling of source code.

(5) *Submission requirements.* You must submit the reports required under this section, semi-annually, to BIS and to the ENC Encryption Request Coordinator, unless otherwise provided in this paragraph (e)(5). For exports occurring between January 1 and June 30, a report is due no later than August 1 of that year. For exports occurring between July 1 and December 31, a report is due no later than February 1 the following year. These reports must be provided in electronic form. Recommended file formats for electronic submission include spreadsheets, tabular text or structured text. Exporters may request other reporting arrangements with BIS to better reflect their business models. Reports may be sent electronically to BIS at *crypt@bis.doc.gov* and to the ENC Encryption Request Coordinator at *enc@nsa.gov*, or disks and CDs containing the reports may be sent to the following addresses:

(i) Department of Commerce, Bureau of Industry and Security, Office of National Security and Technology Transfer Controls, 14th Street and Pennsylvania Ave., NW., Room 2705, Washington, DC 20230, Attn: Encryption Reports, and

(ii) Attn: ENC Encryption Request Coordinator, 9800 Savage Road, Suite 6131, Ft. Meade, MD 20755–6000.

(f) *Restrictions.* Notwithstanding any language elsewhere in this section, License Exception ENC does not authorize:

(1) Any export or reexport of any ''cryptanalytic item'' to any ''government end-user'' (as that definition is applied to encryption items); or

(2) Any export or reexport of any ''open cryptographic interface'' item to any end-user not located in or headquartered in Canada or in countries listed in Supplement No. 3 part 740 of the EAR; or

(3) Any export or reexport to, or provision of any service in any country listed in Country Group E:1 in Supplement No. 1 to part 740 of the EAR; or

(4) Furnishing source code or technology to any national of a country listed in Country Group E:1.

■ 9. Revise Supplement No. 3 to part 740 to read as follows:

Supplement No. 3 to Part 740—Countries Eligible for the Provisions of § 740.17(a)

Austria.
Australia.
Belgium.
Cyprus.
Czech Republic.
Estonia.
Denmark.
Finland.
France.
Germany.
Greece.
Hungary.
Ireland.
Italy.
Japan.
Latvia.
Lithuania.
Luxembourg.
Malta.
Netherlands.
New Zealand.
Norway.
Poland.
Portugal.
Slovakia.
Slovenia.
Spain.
Sweden.
Switzerland.
United Kingdom.

PART 742—AMENDED

■ 10. The authority citation for part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; Sec 1503, Pub.L. 108–11,117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004); Notice of November 4, 2004, 69 FR 64637 (November 8, 2004).

■ 11. In § 742.15, revise the first sentence of paragraph (b)(1) and the last sentence of the introductory text to paragraph (b)(2) to read as follows:

§ 742.15 Encryption items.

* * * * *

(b) * * *

(1) *Notification requirement for specified encryption items.* You may export or reexport encryption items controlled under ECCNs 5A992, 5D992, or 5E992 and identified in paragraphs (b)(1)(i) or (b)(1)(ii) of this section to most destinations without a license (NLR: No License Required), provided that you have submitted to BIS and to the ENC Encryption Request Coordinator at *crypt@bis.doc.gov* and *enc@nsa.gov*, by the time of export, the information described in paragraphs (a) through (e) of Supplement No. 6 to this part. * * *

* * * * *

(2) *Review requirement for mass market encryption commodities and software exceeding 64 bits.* * * * Encryption commodities and software that are described in § 740.17(b)(2) of the EAR do not qualify for mass market treatment.

* * * * *

■ 12. In part 742, Supplement Number 6, revise paragraphs (c)(8) and (c)(11) to read as follows:

Supplement No. 6 to Part 742—Guidelines for Submitting Review Requests for Encryption Items

* * * * *

(c) * * *

(8) Describe the cryptographic functionality that is provided by third-party hardware or software encryption components (if any). Identify the manufacturers of the hardware or software components, including specific part numbers and version information as needed to describe the product. Describe whether the encryption software components (if any) are statically or dynamically linked.

* * * * *

(11) For products that meet the requirements of § 740.17(b)(3)—

Encryption commodities, software and components available to both ''government end-users'' and to non-''government end-users''—describe how they are not restricted by the provisions of § 740.17(b)(2).

* * * * *

PART 744—[AMENDED]

■ 13. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004); Notice of November 4, 2004, 69 FR 64637 (November 8, 2004).

■ 14. In § 744.9, revise paragraph (a) to read:

§ 744.9 Restrictions on technical assistance by U.S. persons with respect to encryption items.

(a) *General prohibition.* No U.S. person may, without authorization from BIS, provide technical assistance (including training) to foreign persons with the intent to aid a foreign person in the development or manufacture outside the United States of encryption commodities and software that, if of United States origin, would be controlled for EI reasons under ECCN 5A002 or 5D002. Technical assistance may be exported and reexported immediately to nationals of the countries listed in Supplement 3 to part 740 of the EAR (except for technical assistance to government end-users for cryptanalytic items), provided that the exporter has submitted to BIS a completed encryption review request by the time of export (as described in § 740.17(a)(3) of the EAR, for technical assistance not otherwise authorized under § 740.17(a)(1) of the EAR). Note that this prohibition does not apply if the U.S. person providing the assistance has a license or is otherwise entitled to export the encryption commodities and software in question to the foreign person(s) receiving the assistance. Note in addition that the mere teaching or discussion of information about cryptography, including, for example, in an academic setting or in the work of groups or bodies engaged in standards development, by itself would not establish the intent described in this section, even where foreign persons are present.

* * * * *

PART 772—[AMENDED]

■ 15. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

■ 16. In § 772.1, add a sentence to the end of the definition of ''hold without action'' to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Hold Without Action (HWA). * * * Encryption review requests may be placed on hold without action status as provided in § 740.17(d)(2) and § 742.15(b)(2) of the EAR.

Dated: December 2, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–26992 Filed 12–8–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM05–3–000]

Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands

December 3, 2004.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; update of Federal land use fees.

SUMMARY: In accordance with the Commission's regulations, the Commission by its designee, the Executive Director, is updating its schedule of fees for the use of government lands. The yearly update is based on the most recent schedule of fees for the use of linear rights-of-way prepared by the United States Forest Service. Since the next fiscal year will cover the period from October 1, 2004 through September 30, 2005 the fees in this notice will become effective October 1, 2004. The fees will apply to fiscal year 2005 annual charges for the use of government lands.

The Commission has concluded, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB that this rule is not a ''major rule'' as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C 804(2).

DATES: *Effective Date:* October 1, 2004.

FOR FURTHER INFORMATION CONTACT: Fannie Kingsberry, Division of Financial Services, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; (202) 502–6108.

SUPPLEMENTARY INFORMATION: Document Availability: 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. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in the eLibrary (formerly FERRIS). The full text of this document is available on eLibrary in PDF and MSWord 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.

User assistance is available for eLibrary and the FERC's Web site during normal business hours by contacting FERC Online Support by telephone at (866) 208–3676 (toll free) or for TTY, (202) 502–8659, or by e-mail at *FERCOnlineSupport@ferc.gov.*

List of Subjects in 18 CFR Part 11

Electric power, Reporting and recordkeeping requirements.

Thomas R. Herlihy,

Executive Director, Office of the Executive Director.

■ Accordingly, the Commission, effective October 1, 2004, amends part 11 of chapter I, Title 18 of the Code of Federal Regulations, as follows:

PART 11—[AMENDED]

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 791a–825r; 42 U.S.C. 7101–7352.

■ 2. In part 11, Appendix A is revised to read as follows.

Appendix A to Part 11—Fee Schedule for FY 2005

State	County	(Fee/acre/yr)
Alabama	All Counties	$27.23
Arkansas	All Counties	20.43
Arizona	Apache	6.79
	Cochise	
	Gila	
	Graham	
	La Paz	
	Mohave	
	Navajo	
	Pima	
	Yavapai	
	Yuma	
	Coconino (North of Colorado R.)	
	Coconino (South of Colorado R.)	27.23
	Greenlee	
	Maricopa	
	Pinal	
	Santa Cruz	
California	Imperial	13.61
	Inyo	
	Lassen	
	Modoc	
	Riverside	
	San Bernardino	
	Siskiyou	20.43
	Alameda	34.03
	Alpine	
	Amador	
	Butte	
	Calaveras	
	Colusa	
	Contra Costa	
	Del Norte	
	El Dorado	34.03
	Fresno	
	Glenn	
	Humboldt	
	Kern	
	Kings	
	Lake	
	Madera	
	Mariposa	
	Mendicino	
	Merced	
	Mono	
	Napa	
	Nevada	
	Placer	
	Plumas	
	Sacramento	
	San Benito	
	San Joaquin	
	Santa Clara	
	Shasta	
	Sierra	
	Solano	
	Sonoma	
	Stanislaus	
	Sutter	
	Tehama	
	Trinity	
	Tulare Kings	
	Tuolumne	
	Yolo	
	Yuba	
	Los Angeles	40.86
	Marin	
	Monterey	
	Orange	
	San Diego	
	San Francisco	
	San Luis Obispo	
	San Mateo	
	Santa Barbara	

State	County	(Fee/acre/yr)
	Santa Cruz	
	Ventura	
Colorado	Adams	6.79
	Arapahoe	
	Bent	
	Cheyenne	
	Crowley	
	Elbert	
	El Paso	
	Huerfano	
	Kiowa	
	Kit Carson	
	Lincoln	
	Logan	
	Moffat	
	Montezuma	
	Morgan	
	Pueblo	
	Sedgewick	
	Washington	
	Weld	
	Yuma	
	Baca	13.61
	Bloomfield	
	Dolores	
	Garfield	
	Las Animas	
	Mesa	
	Montrose	
	Otero	
	Prowers	
	Rio Blanco	
	Routt	
	San Miguel	
	Alamosa	27.23
	Archuleta	
	Boulder	
	Chaffee	
	Clear Creek	
	Conejos	
	Costilla	
	Custer	
	Denver	
	Delta	
	Douglas	
	Eagle	27.23
	Fremont	
	Gilpin	
	Grand	
	Gunnison	
	Hinsdale	
	Jackson	
	Jefferson	
	Lake	
	La Plata	
	Larimer	
	Mineral	
	Ouray	
	Park	
	Pitkin	
	Rio Grande	
	Saguache	
	San Juan	
	Summit	
	Teller	
Connecticut	All Counties	6.79
Florida	Baker	40.86
	Bay	
	Bradford	
	Calhoun	
	Clay	
	Columbia	
	Dixie	
	Duval	

State	County	(Fee/acre/yr)
	Escambia	
	Franklin	
	Gadsden	
	Gilchrist	
	Gulf	
	Hamilton	
	Holmes	
	Jackson	
	Jefferson	
	Lafayette	
	Leon	
	Liberty	
	Madison	
	Nassau	
	Okaloosa	40.86
	Santa Rosa	
	Suwannee	
	Taylor	
	Union	
	Wakulla	
	Walton	
	Washington	
	All Other Counties	68.05
Georgia	All Counties	40.86
Idaho	Cassia	6.79
	Gooding	
	Jerome	
	Lincoln	
	Minidoka	
	Oneida	
	Owyhee	
	Power	
	Twin Falls	
	Ada	20.43
	Adams	
	Bannock	
	Bear Lake	
	Benewah	
	Bingham	
	Blaine	
	Boise	
	Bonner	
	Bonneville	
	Boundary	
	Butte	
	Camas	
	Canyon	
	Caribou	
	Clark	
	Clearwater	
	Custer	
	Elmore	
	Franklin	
	Fremont	
	Gem	
	Idaho	20.43
	Kootenai	
	Latah	
	Lemhi	
	Lewis	
	Madison	
	Nez Perce	
	Payette	
	Shoshone	
	Teton	20.43
	Valley	
	Washington	
Illinois	All Counties	20.43
Indiana	All Counties	34.03
Kansas	Morton	13.61
	All Other Counties	6.79
Kentucky	All Counties	20.43
Louisiana	All Counties	40.86
Maine	All Counties	20.43

State	County	(Fee/acre/yr)
Michigan	Alger	20.43
	Baraga	
	Chippewa	
	Delta	
	Dickinson	
	Gogebic	
	Houghton	
	Iron	
	Keweenaw	
	Luce	
	Macking	
	Marquette	
	Menominee	
	Ontonagon	
	Schoolcraft	
	All Other Counties	27.23
Minnesota	All Counties	20.43
Mississippi	All Counties	27.23
Missouri	All Counties	20.43
Montana	Big Horn	6.79
	Blaine	
	Carter	
	Cascade	
	Chouteau	
	Custer	
	Daniels	
	McCone	
	Meagher	
	Dawson	
	Fallon	
	Fergus	
	Garfield	
	Glacier	
	Golden Valley	
	Hill	
	Judith Basin	
	Liberty	
	Musselshell	
	Petroleum	
	Phillips	
	Pondera	
	Power River	
	Prairie	
	Richland	
	Roosevelt	
	Rosebud	
	Sheridan	
	Teton	
	Toole	
	Treasure	
	Valley	
	Wheatland	
	Wibaux	
	Yellowstone	
	Beaverhead	20.43
	Broadwater	
	Carbon	
	Deer Lodge	20.43
	Flathead	
	Gallatin	
	Granite	
	Jefferson	
	Lake	
	Lewis & Clark	
	Lincoln	
	Madison	
	Mineral	
	Missoula	
	Park	
	Powell	
	Ravalli	
	Sanders	
	Silver Bow	
	Stillwater	

State	County	(Fee/acre/yr)
	Sweet Grass	
Nebraska	All Counties	6.79
Nevada	Churchilll	3.40
	Clark	
	Elko	
	Esmeralda	
	Eureka	
	Humboldt	
	Lander	
	Lincoln	
	Lyon	
	Mineral	
	Nye	
	Pershing	
	Washoe	
	White Pine	
	Carson City	34.03
	Douglas	
	Story	
New Hampshire	All Counties	20.43
New Mexico	Chaves	6.79
	Curry	
	De Baca	
	Dona Ana	6.79
	Eddy	
	Grant	
	Guadalupe	
	Harding	
	Hidalgo	
	Lea	
	Luna	
	McKinley	
	Otero	
	Quay	
	Roosevelt	
	San Juan	
	Socorro	
	Torrence	
	Rio Arriba	13.61
	Sandoual	
	Union	
	Bernalillo	27.23
	Catron	
	Cibola	
	Colfax	
	Lincoln	
	Los Alamos	
	Mora	
	San Miguel	
	Santa Fe	
	Sierra	
	Taos	
	Valencia	
New York	All Counties	27.23
North Carolina	All Counties	40.86
North Dakota	All Counties	6.79
Ohio	All Counties	27.23
Oklahoma	Beaver	13.61
	Cimarron	
	Roger Mills	
	Texas	
	De Flore	20.43
	McCurtain	
	All Other Counties	6.79
Oregon	Harney	6.79
	Lake	
	Malheur	
	Baker	13.61
	Crook	
	Deschutes	
	Gilliam	
	Grant	
	Jefferson	
	Klamath	

State	County	(Fee/acre/yr)
	Morrow	
	Sherman	
	Umatilla	
	Union	
	Wallowa	
	Wasco	
	Wheeler	
	Coos	20.43
	Curry	
	Douglas	
	Jackson	
	Josephine	
	Benton	27.23
	Clackamas	
	Clatsop	
	Columbia	
	Hood River	
	Lane	
	Lincoln	
	Linn	
	Marion	
	Multnomah	
	Polk	
	Tillamook	
	Washington	
	Yamhill	
Pennsylvania	All Counties	27.23
Puerto Rico	All	40.86
South Carolina	All Counties	40.86
South Dakota	Butte	20.43
	Custer	
	Fall river	
	Lawrence	
	Mead	
	Pennington	
	All Other Counties	6.79
Tennessee	All Counties	27.23
Texas	Culberson	6.79
	El Paso	
	Hudspeth	
	All Other Counties	40.86
Utah	Beaver	6.79
	Box Elder	
	Carbon	
	Duchesne	
	Emery	
	Garfield	
	Grand	
	Iron	
	Juab	
	Kane	
	Millard	
	San Juan	
	Tooele	
	Uintah	
	Wayne	
	Washington	13.61
	Cache	20.43
	Daggett	
	Davis	
	Morgan	
	Piute	
	Rich	20.43
	Salt Lake	
	Sanpete	
	Sevier	
	Summit	
	Utah	
	Wasatch	
	Weber	
Vermont	All Counties	27.23
Virginia	All Counties	27.23
Washington	Adams	13.61
	Asotin	

State	County	(Fee/acre/yr)
	Benton	
	Chelan	
	Columbia	
	Douglas	
	Franklin	
	Garfield	
	Grant	
	Kititas	
	Klickitat	
	Lincoln	
	Okanogan	
	Spokane	
	Walla Walla	
	Whitman	
	Yakima	
	Ferry	20.43
	Pend Oreille	
	Stevens	
	Clallam	27.23
	Clark	
	Cowlitz	
	Grays Harbor	
	Island	
	Jefferson	
	King	
	Kitsap	
	Lewis	
	Mason	
	Pacific	27.23
	Pierce.	
	San Juan	
	Skagit	
	Skamania	
	Snohomish	
	Thurston	
	Wahkiakum	
	Whatcom	
West Virginia	All Counties	27.23
Wisconsin	All Counties	20.43
Wyoming	Albany	6.79
	Campbell	
	Carbon	
	Converse	
	Goshen	
	Hot Springs	
	Johnson	
	Laramie	
	Lincoln	
	Natrona	
	Niobrara	
	Platte	
	Sheridan	
	Sweetwater	
	Freemont	
	Sublette	
	Uinta	
	Washakie	
	Big Horn	20.43
	Crook	
	Park	
	Teton	
	Weston	
All Other Zones		6.06

[FR Doc. 04–27017 Filed 12–8–04; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[TTB T.D.–20; Re: Notice No. 19]

RIN 1513–AA59

Establishment of the Yamhill-Carlton District Viticultural Area (2002R–216P)

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

ACTION: Final rule; Treasury decision.

SUMMARY: This Treasury decision establishes the Yamhill-Carlton District viticultural area in Yamhill and Washington Counties, Oregon. The new Yamhill-Carlton District viticultural area is entirely within the existing Willamette Valley viticultural area. We designate viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: *Effective Date:* February 7, 2005.

FOR FURTHER INFORMATION CONTACT: N. A. Sutton, Program Manager, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., #158, Petaluma, CA 94952; telephone 415–271–1254.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (the FAA Act, 27 U.S.C. 201 *et seq.*) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity and prohibits the use of misleading information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers these regulations.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that supports setting the boundary of the proposed viticultural area as the petition specifies;
- Evidence relating to the geographical features, such as climate, soils, elevation, and physical features, that distinguish the proposed viticultural area from surrounding areas;
- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area's boundary prominently marked.

Yamhill-Carlton District Petition

General Background

TTB received a petition from Alex Sokol-Blosser, Secretary of the North Willamette Valley AVA Group, on behalf of Yamhill-Carlton District winegrowers, proposing a new viticultural area to be called the ''Yamhill-Carlton District.'' Ken Wright was the author of the petition. The proposed Yamhill-Carlton District viticultural area is located about 35 miles southwest of Portland, Oregon, and 25 miles inland from the Pacific Ocean. The proposed area is wholly within Yamhill and Washington Counties in northwestern Oregon and is entirely within the existing Willamette Valley viticultural area (27 CFR 9.90). As of the 2002 Yamhill-Carlton District petition, there were 26 vineyards within the area, with about 650 acres planted to grapes.

The proposed Yamhill-Carlton District viticultural area is distinguished primarily by elevation, soil, and climate. Within the viticultural area's described boundary the defined viticultural area is limited to elevations between 200 feet and 1,000 feet, yielding size of 8,500 acres. A precedent exists for elevation as a distinguishing factor with the establishment of the Mendocino Ridge viticultural area in Mendocino County, California, which includes land only at or above the 1,200-foot elevation (*see* 27 CFR 9.158 and T.D. ATF–392 at 62 FR 55512, October 27, 1997).

Name Evidence

This viticultural area is locally known as the ''Yamhill-Carlton District,'' according to the petition. The viticultural area surrounds the towns of Yamhill and Carlton, Oregon, which lie 3 miles apart along State Route 47 in Yamhill County. While the two towns operate independently, they have had strong ties since their separate incorporations over 100 years ago. The hyphenated expression of the cities' names has been used since 1853 with the establishment of the Yamhill-Carlton Pioneer Cemetery.

In modern times, the Yamhill-Carlton Union High School has existed since 1955 and operates under the supervision of the Yamhill-Carlton School District. The two cities share a newspaper, the Carlton-Yamhill Review. The USGS Carlton map identifies the towns of Yamhill and Carlton and the Yamhill-Carlton Pioneer Cemetery.

Boundary Evidence

Geographically, the Yamhill-Carlton District viticultural area is a south-facing bowl containing a series of horseshoe-shaped eroded hills composed of sedimentary parent material. To the area's west is the higher-elevation Coast Range, to the south is a cooler maritime-influenced area, and to the east and north are natural lowland drainages. The area's western boundary is based on the change to sedimentary soils from the volcanic soils of the Coast Range. The higher elevations of the coastal hills to the west, generally ranging from 1,000–2,000 feet, are much cooler and have proven unsuitable for grape growing.

At the viticultural area's southwestern boundary, the area's almost purely sedimentary parent material changes to a mix of basalt, slate, and sedimentary material. The southern boundary transitions to a valley floor that contains deep soils composed of Willamette silts. The frost-prone nature of this lower elevation region, combined with its high soil permeability and fertility, makes it unsuitable for production of quality vinifera grape varieties.

Abbey and Kuehne Roads serve as the Yamhill-Carlton District viticultural area's eastern border and mark the change from its sedimentary soils to the volcanic soils of the Dundee Hills. Millican Creek, a natural drainage between the viticultural area and the Dundee Hills, runs along this boundary line, flowing from north to south and eventually joining the Yamhill River near the town of Lafayette. Chehalem Creek's drainage system separates the Yamhill-Carlton District from Ribbon Ridge and the Chehalem Mountains to the northeast. The Yamhill-Carlton District's sedimentary soils are generally coarser in texture and subject to more faulting, uplifts, and erosion than the Ribbon Ridge sedimentary soils.

The Wapato Lake Bed, a large, low drainage area on the northeastern boundary of the Yamhill-Carlton District, separates it from the Chehalem Mountains. The soils of these two viticultural regions are vastly different. The Yamhill-Carlton District has highly eroded sedimentary parent material, while the Chehalem Mountains, which lie across the Wapato Lake Bed, have soils formed from wind-blown mixed material and overlying basalt. The northern border of the Yamhill-Carlton District viticultural area coincides with the low elevation Patton Valley with its predominately wind-blown soil.

In modern times, two vineyards can lay claim to being first planted in the Yamhill-Carlton viticultural area. In 1974, Roy and Betty Wahle planted 8 acres of vinifera grapes, and, that same year, Pat and Joe Campbell of Elk Cove Vineyards also planted an 8-acre vineyard. In 1977, Elk Grove Estate produced the first commercial wine in the Yamhill-Carlton area, and, as of 2002, there were 10 commercial wineries in the area.

Distinguishing Features

Soils

The most significant feature separating the Yamhill-Carlton District viticultural area from nearby grape-growing regions is the area's predominant ancient sedimentary soils. Wines made from grapes grown in these sedimentary soils often contain distinct aromatic flavors (coffee, cocoa, anis, cedar, tobacco) not found in the same wine varietals grown in different soils, according to the petition. Also, the petition adds that the wines made from grapes grown in these ancient sedimentary soils are consistently lower in acid than wines made from grapes grown in basaltic or wind-blown soils.

According to ''The Roadside Geology of Oregon'' (David Alt and Donald W. Hyndman), the soils of the Yamhill-Carlton District, formed in the Eocene era, are derived from marine sediments and ocean floor volcanic basalt that have a high water-holding capacity with moderate to high erosion levels. Alan Campbell of NW Vineyards prepared a vineyard soils map of Yamhill County, Oregon, which shows that the western hills of the Yamhill-Carlton District comprise two soils groups, Willakenzie on the lower elevation slopes and Peavine on the upper slopes. Peavine soils dominate the northern section of the viticultural area, while its eastern slopes comprise Wellsdale and Willakenzie soil series.

The sedimentary soils of the Yamhill-Carlton District viticultural area are millions of years older than the soils in the surrounding areas. In contrast, younger volcanic-based soils formed in the Miocene Era dominate in the Eola Hills (south of the Yamhill-Carlton District), Chehalem Mountains (north and east of the Yamhill-Carlton District), and Dundee Hills (southeast of the Yamhill-Carlton District).

The Eola Hills have predominately basalt soil series (Neika, Gelderman, Ritner), which are characterized by their low water capacity, slow permeability, and moderate erosion level. The Chehalem Mountains have a combination of Columbia River basalt, ocean sedimentation, and wind-blown loess derivation soil types. The Dundee Hills contain soils mainly derived from Columbia River basalt lavas (largely based on the Jory series), which are moderately fertile and well drained, with slight to moderate erosion levels. The Ribbon Ridge region, immediately east of the Yamhill-Carlton District viticultural area, also contains primarily sedimentary soils. However, these were formed in the Oligocene Era and are younger, finer, and more uniform than the sedimentary soils of the Yamhill-Carlton District.

The floor of the Willamette Valley, at elevations of 200 feet or below, contains fine-grained soils deposited as a result of the Missoula floods, which occurred 12,000 years ago. These Willamette silt soils have greater depth, fertility, and water-holding capacity than soils of the viticultural area. The fertility and water-holding capacity of these low-elevation soils extends the vegetative period of the vine and delays the ripening of vines planted in the Willamette valley.

Elevation

Within the Yamhill-Carlton District viticultural area's boundary, which is described in the regulatory text below, only land from 200 feet to 1,000 feet in elevation is included within the viticultural area. At elevations below 200 feet, the low valley floors are prone to frost. Conversely, at elevations greater than 1,000 feet, the higher terrain is significantly cooler and lacks the necessary heat to properly ripen wine grapes.

Climate

The climate of the Yamhill-Carlton District viticultural area is distinct from the surrounding areas. It is bordered on the west by the mountains of the Coast Range, which have a colder climate as measured in degree-days (a heat summation obtained by totaling each day's temperature above 50 degrees Fahrenheit during the growing season), and which are unsuitable for production of vinifera wine grape varietals. Also, temperatures in the Yamhill-Carlton District annually average 18.3 days above 90° F, while the Coast Range has only 2 such days, making it a significantly cooler growing area.

The Coast Range is also wetter than the Yamhill-Carlton viticultural area. According to data obtained from the Oregon Climate Service, average rainfall for the Yamhill-Carlton District is 42 inches, while the Coast Range receives between 80 and 110 inches per year.

The regions immediately south of the Yamhill-Carlton area are influenced by the cooling effect of weather systems flowing inland from the Pacific Ocean through the Van Duzer Corridor, a mountain gap in the Coast Range, at Dallas, Oregon. This corridor funnels cooling marine summer breezes east toward Salem, which substantially lowers the average temperature during the growing season. This marine cooling effect quickly dissipates as it moves north towards the Yamhill-Carlton District.

The Yamhill-Carlton District has a 42-inch average annual rainfall, as compared to 49.1 inches for Dallas, Oregon, to the south at the Van Duzer Corridor. Also, Dallas, Oregon, has 51 fewer degree-days than McMinnville, Oregon (which is at the southern border of the Yamhill-Carlton District), and 186 fewer degree-days than Forest Grove, Oregon (which lies 6 miles north of the viticultural area).

The Patton Valley, a large, low area just north of the Yamhill-Carlton District, has an annual rainfall average difference of about 2 inches when compared with the Yamhill-Carlton District viticultural area. However, the 30-year average temperature data show the area north of Patton Valley to have 135 more degree-days than the Yamhill-Carlton District.

Boundary Description

See the narrative boundary description of the viticultural area in the regulatory text published at the end of this notice.

Maps

The petitioner(s) provided the required maps, and we list them below in the regulatory text.

Notice of Proposed Rulemaking

TTB published a notice of proposed rulemaking regarding the establishment of the Yamhill-Carlton District viticultural area in the October 7, 2003, **Federal Register** as Notice No. 19 (68 FR 57845). In that notice, TTB requested comments by December 8, 2003, from all interested persons. We received one comment supporting the establishment of the Yamhill-Carlton District viticultural area.

After careful review, TTB finds that the evidence submitted with the petition supports the establishment of the proposed viticultural area. Therefore, under the authority of the Federal Alcohol Administration Act and part 4 of our regulations, we establish the ''Yamhill-Carlton District'' viticultural area in Oregon, effective 60 days from this document's publication date.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. With the establishment of this viticultural area and its inclusion in part 9 of the TTB regulations, its name, ''Yamhill-Carlton District,'' is recognized as a name of viticultural significance. Consequently, wine bottlers using ''Yamhill-Carlton District'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, must ensure that the product is eligible to use the viticultural area's name as an appellation of origin.

For a wine to be eligible to use as an appellation of origin the name of a viticultural area specified in part 9 of the TTB regulations, at least 85 percent of the grapes used to make the wine must have been grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible to use the viticultural area name as an appellation of origin and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the viticultural area name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label.

Different rules apply if a wine has a brand name containing a viticultural area name that was used as a brand name on a label approved before July 7, 1986. *See* 27 CFR 4.39(i)(2) for details.

Regulatory Analyses and Notices

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of a viticultural area name is the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This rule is not a significant regulatory action as defined by Executive Order 12866 (58 FR 51735). Therefore, it requires no regulatory assessment.

Drafting Information

N.A. Sutton of the Regulations and Procedures Division drafted this document.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, we amend 27 CFR, chapter 1, part 9 as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Amend subpart C by adding § 9.183 to read as follows:

§ 9.183 Yamhill-Carlton District.

(a) *Name.* The name of the viticultural area described in this section is ''Yamhill-Carlton District''.

(b) *Approved maps.* The appropriate maps for determining the boundary of the Yamhill-Carlton District viticultural area are eight 1:24,000 Scale U.S.G.S. topography maps. They are titled:

(1) Gaston Quadrangle, Oregon, 1956, revised 1992;

(2) Laurelwood Quadrangle, Oregon, 1956, revised 1992;

(3) Dundee Quadrangle, Oregon, 1956, revised 1993;

(4) Carlton Quadrangle, Oregon—Yamhill Co., 1957, revised 1992;

(5) Fairdale Quadrangle, Oregon-Yamhill Co., 1979;

(6) McMinnville Quadrangle, Oregon—Yamhill Co., 1957, revised 1992;

(7) Muddy Valley Quadrangle, Oregon—Yamhill Co., 1979, revised 1992; and

(8) Turner Creek Quadrangle, Oregon, 1979.

(c) *Boundary.* The Yamhill-Carlton District viticultural area is located in Yamhill and Washington Counties, Oregon, and is entirely within the Willamette Valley viticultural area. The Yamhill-Carlton District viticultural area is limited to lands at or above 200 feet in elevation and at or below 1,000 feet in elevation within its boundary, which is described as follows—

(1) The point of beginning is on the Gaston map in the village of Gaston at the intersection of Gaston Road East (E. Main Street within Gaston) and the 200-foot elevation line, approximately 225 feet west of State Route 47, section 49, T1S, R4W. From this beginning point, proceed southerly and then southeasterly about 8.15 miles along the meandering 200-foot elevation line (crossing to and from the Laurelwood map in sections 12 and 13, T2S, R4W, and then returning to the Laurelwood map) to the 200-foot elevation line's intersection with Spring Hill Road, section 58, T2S, R3W (Laurelwood Quadrangle); then

(2) Proceed south 1.1 miles on Spring Hill Road, which becomes North Valley Road at Laughlin Road, crossing onto the Dundee map, to the road's intersection with the 200-foot elevation line, section 30, T2S, R3W (Dundee Quadrangle); then

(3) Proceed northerly then southerly for approximately 5 miles along the 200-foot elevation line, crossing over to and back from the Laurelwood map, to the 200-foot elevation line's intersection with State Route 240, section 47, T3S, R3W (Dundee Quadrangle); then

(4) Proceed straight west for 0.2 mile on State Route 240 to its intersection with Kuehne Road at the 207-foot benchmark, section 47, T3S, R3W (Dundee Quadrangle); then

(5) Proceed southerly for about 1.9 miles on Kuehne Road to its intersection with Abbey Road, section 50, T3S, R3W (Dundee Quadrangle); then

(6) Proceed southerly 1.4 miles on Abbey Road to its intersection with the 200-foot elevation line, north of the 174-foot elevation point, section 52, T3S, R3W (Dundee Quadrangle); then

(7) Proceed southwesterly for about 2.1 miles along the meandering 200-foot elevation line to Lafayette Cemetery on the Carlton map in section 1, T4S, R4W, and turning northerly along the 200-foot elevation line, continue along the elevation line for about 6 miles, crossing to and from the Dundee map, to the 200-foot elevation line's intersection with Stag Hollow Road, north of Hendricks Road and 190-foot elevation point, section 24, T3S, R4W (Carlton Quadrangle); then

(8) Continue westerly along the meandering 200-foot elevation line, turning northeasterly as the elevation line passes through the Carlton Lakes State Wildlife Refuge, then westerly as the elevation line crosses Stag Hollow Creek in section 47, T3S, R4W, then southerly as the elevation line crosses the North Yamhill River on the Fairdale map in section 43, T2S, R5W, then, returning to the Carlton map, continue southerly on the 200-foot elevation line to its intersection with Meadow Lake Road near the southwest corner of section 55, T3S, R4W (Carlton Quadrangle);

(9) Continue westerly along the meandering 200-foot elevation line, crossing onto the Fairdale map, to the elevation line's intersection with the 123°17′30″ longitude line (north of Panther Creek) in the western extension of section 22, T3S, R5W (Fairdale Quadrangle); then

(10) Proceed 0.2 mile straight south along the 123°17′30″ longitude line, crossing Panther Creek, to the line's intersection with the 200-foot elevation line south of the creek in the western extension of section 22, T3S, R5W (Fairdale Quadrangle); then

(11) Proceed easterly and then southeasterly along the meandering 200-foot elevation line, crossing onto the Carlton map, then the McMinnville map, to the elevation line's third intersection with an unnamed light-duty road, southwest of the Henderson Benchmark in section 87, T4S, R4W (McMinnville Quadrangle);

(12) Continue southerly and then westerly along the meandering 200-foot elevation line, crossing onto the Muddy Valley map, to the elevation line's intersection with Baker Creek Road (very near Baker Creek Road's intersection with High Heaven Road) in section 54, T4S, R5W (Muddy Valley Quadrangle); then

(13) Proceed west-southwest for 0.8 mile on Baker Creek Road to its intersection with the 123°17′30″ longitude line in Happy Valley, section 54, T4S, R5W (Muddy Valley Quadrangle); then

(14) Proceed straight north 13.4 miles on the 123°17′30″ longitude line, passing through the Fairdale map and crossing onto the Turner Creek map, to the longitude line's intersection with the 1,000-foot elevation line in the northwestern quadrant of section 10, T2S, R5W, approximately one mile diagonally northwest of the footbridge in Menefee Park (Turner Creek Quadrangle); then

(15) Proceed easterly and then northerly for 4.1 miles along the meandering 1,000-foot elevation line to its intersection with the Washington-Yamhill County line at northern boundary of section 3, T2S, R5W (also the common T1S/T2S boundary line) (Turner Creek Quadrangle); then

(16) Proceed straight east 3.9 miles along the Washington-Yamhill County line, crossing onto the Gaston map, to the county line's intersection with South Road, just east of Mt. Richmond Road, section 60, T2S, R4W (Gaston Quadrangle); then

(17) Proceed east-northeast for 1.8 miles on South Road to its intersection with the 200-foot elevation line, 0.3 mile west of the Gaging Station, section 34, T1S, R4W (Gaston Quadrangle); then

(18) Proceed easterly 1.9 miles along the 200-foot elevation line and return to the beginning point within the village of Gaston.

Signed: November 1, 2004.

Arthur J. Libertucci,

Administrator.

Approved: November 18, 2004.

Timothy E. Skud,

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

[FR Doc. 04–27016 Filed 12–8–04; 8:45 am]

BILLING CODE 4810–31–P

PANAMA CANAL COMMISSION

35 CFR Chapter I

Panama Canal Regulations

Vacation of Title

Editorial Note: Under section 121 of Public Law 108–309, the Panama Canal Commission (PCC) and its Office of Transition Administration (OTA) terminated on October 1, 2004. A letter from the General Attorney for the PCC OTA to the Office of the Federal Register has confirmed that PCC regulations should be removed from the Code of Federal Regulations (CFR).

Therefore, the Director of the Federal Register, pursuant to his authority to maintain an orderly system of codification under 44 U.S.C. 1510 and 1 CFR 8.2 hereby removes from the CFR, Title 35, Chapter I consisting of Parts 1 to 299.

Accordingly, Title 35 of the Code of Federal Regulations is hereby vacated.

[FR Doc. 04–55526 Filed 12–8–04; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MN–0002; FRL–7846–7]

Approval and Promulgation of Implementation Plans: Minnesota: Minneapolis-St. Paul Carbon Monoxide Maintenance Plan Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the Minnesota State Implementation Plan (SIP) for the maintenance of the Carbon Monoxide (CO) ambient air quality standards (NAAQS) submitted on November 10, 2004. Specifically, EPA is approving Minnesota's revised 1996 and 2009 CO emissions inventories and 2009 Motor Vehicle Emissions Budgets (MVEB) recalculated using MOBILE6 for the Minneapolis-St. Paul CO maintenance area.

DATES: This rule is effective on January 24, 2005, unless EPA receives relevant adverse written comments by January 10, 2005. If adverse comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. R05–OAR–2004–MN–0002 by one of the following methods:

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

E-mail: bortzer.jay@epa.gov.

Fax: (312) 886–5824.

Mail: You may send written comments to: J. Elmer Bortzer, Chief, Air Programs Branch (AR–18J),

Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: J. Elmer Bortzer, Chief, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

Instructions: Direct your comments to Docket ID No.R05–OAR–2004–MN–0002. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov, or e-mail. The Federal regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is published in the proposed rule section of this **Federal Register**.

Docket: All documents in the docket are listed in an index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (We recommend that you telephone Michael Leslie, Environmental Engineer, at (312) 353–6680 before visiting the Region 5 office.) This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Leslie, Environmental Engineer, Criteria Pollutants Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6680, *leslie.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is organized as follows:

I. General Information

A. Does This Action Apply to Me?

This action is a non-regulatory planning document designed to ensure that ambient concentrations of CO in the Minneapolis-St. Paul area are maintained at levels that comply with the NAAQS.

B. How Can I Get Copies of This Document and Other Related Information?

1. The Regional Office has established an electronic public rulemaking file available for inspection at Regional Material in EDocket (RME) under RME ID No. R05–OAR–2004–MN–0002, and a hard copy file which is available for inspection at the Regional Office. The official public file 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 rulemaking file does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Air Programs Branch, Air and Radiation Division, EPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the regulations.gov Web site located at *http://www.regulations.gov* where you can find, review, and submit comments on Federal rules that have been published in the **Federal Register**, the government's legal newspaper, and are open for comment.

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 at the EPA Regional Office, 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 the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

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 rulemaking identification number by including the text ''Public comment on proposed rulemaking Region 5 Air Docket ''R05–OAR–2004–MN–0002'' 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.

For detailed instructions on submitting public comments and on what to consider as you prepare your comments see the **ADDRESSES** section and the section I General Information of the **SUPPLEMENTARY INFORMATION** section of the related proposed rule which is

published in the Proposed Rules section of this **Federal Register**.

II. Background

The Minnesota Pollution Control Agency (MPCA) is required to develop and periodically update a maintenance plan to ensure that ambient concentrations of CO in the Minneapolis-St. Paul area are maintained at levels that comply with the NAAQS. The CO Maintenance Plan for Minneapolis-St. Paul is a component of Minnesota's SIP for the NAAQS. The CO maintenance plan established a MVEB which is used in transportation conformity.

On January 29, 2002, EPA officially released the MOBILE6 motor vehicle emissions factor model (67 FR 4254). The primary purpose of this submittal is to use the MOBILE6 model to help MPCA update the CO Maintenance Plan's MVEB. The on-road mobile, point and area, and non-road portions of the maintenance plan's CO emissions inventory have been updated as well.

III. What Is the MOBILE Model and MOBILE6?

MOBILE is an EPA emissions factor model used for estimating pollution from on-road motor vehicles. MOBILE calculates emissions of volatile organic compounds (VOCs), nitrogen oxides (NO_X) and carbon monoxide (CO) from passenger cars, motorcycles, buses, and light-duty and heavy-duty trucks. The model accounts for changes in vehicle emission standards, changes in vehicle populations and activity, and variation in local conditions such as temperature, humidity, fuel quality, and air quality programs.

MOBILE is used to calculate current and future inventories of motor vehicle emissions at the national and local level. Inventories based on MOBILE are also used to meet the federal Clean Air Act's SIP and transportation conformity requirements.

MOBILE6 is the first major update of the MOBILE model since 1993. The MOBILE model was first developed in 1978. It has been updated many times to reflect changes in the vehicle fleet and fuels, to incorporate EPA's growing understanding of vehicle emissions, and to cover new emissions regulations and modeling needs. Although some minor updates were made in 1996 with the release of MOBILE5b, MOBILE6 is the first major revision to MOBILE since MOBILE5a was released in 1993.

IV. What Is Transportation Conformity?

Transportation conformity means that the level of emissions from the transportation sector (cars, trucks and buses) must be consistent with the requirements in the SIP to attain and maintain the air quality standards. The Clean Air Act, in section 176(c), requires conformity of transportation plans, programs and projects to an implementation plan's purpose of attaining and maintaining the National Ambient Air Quality Standards. EPA published rules (40 CFR part 93 subpart A) establishing criteria and procedures for determining whether transportation plans, programs and projects funded or approved under title 23 U.S.C. or the Federal Transit Act conform to the SIP.

The transportation conformity rules require a CO maintenance area, such as Minneapolis-St. Paul, to compare the actual projected emissions from cars, trucks and buses on the highway network, to the MVEB established by a maintenance plan. The Minneapolis-St. Paul area has an approved CO maintenance plan. This submittal established the new MVEB for transportation conformity purposes.

V. What Is a Motor Vehicle Emissions Budget?

An MVEB is the projected level of controlled emissions from the transportation sector (on-road mobile sources) that is estimated in the SIP. The SIP controls emissions through regulations, for example, on fuels and exhaust levels for cars. The emissions budget concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and how to revise the emissions budget. The transportation conformity rule allows changing the MVEB as long as the total level of emissions from all sources remains below the attainment level.

VI. What Is the Purpose and Content of Minnesota's Submittal?

In this submittal, Minnesota provided 1996 and 2009 CO emissions inventories based on the MOBILE6 model. The purpose of this submittal is to update the CO Maintenance Plan MVEB to reflect the updated inventories. EPA officially released the MOBILE6 motor vehicle emissions factor model on January 29, 2002 (67 FR 4254). The November 10, 2004, submittal demonstrates that the new levels of motor vehicle emissions calculated using MOBILE6 continue to support maintenance of the CO NAAQS for Minneapolis-St. Paul area.

VII. What Are the Revised CO Emissions Inventories?

The MPCA contracted with the Sonoma Technology Incorporated (STI) consultants to develop the emissions inventory for the maintenance plan. Table 1 below summarizes the revised CO emissions inventories in tons per winter day. EPA is approving these revised 2009 emissions inventories. The CO emission inventory includes on-road mobile sources, point and area sources, and non-road mobile sources.

TABLE 1.—MINNEAPOLIS-ST. PAUL CO EMISSIONS (TONS/WINTER DAY)

Source category	1996	2009
On-Road Mobile	1,872	1,311
Point and Area	297	127
Non-Road Mobile	337	418
Totals	2,506	1,856

On-Road Mobile Sources

On-road mobile sources represent the majority of CO emissions for the Minneapolis-St Paul CO maintenance area. The revised inventories were developed using the latest planning assumptions, including updated vehicle registration data and age distribution, vehicle miles traveled (VMT), speeds, fleet mix, and SIP control measures.

The VMT data used for the 1996 on-road mobile source inventories were generated from the data that was reported annually to the United States Department of Transportation's Highway Performance Monitoring System (HPMS). Because HPMS data are annual average daily traffic (AADT) data, these data need to be adjusted for wintertime inventories. The Minnesota Department of Transportation estimated a scaling factor of 0.87 for converting annual VMT to wintertime VMT, and this factor was applied to all HPMS data.

For future years, VMT data were estimated using a traffic demand model (TDM) recently developed by the Metropolitan Council. This model estimates VMT on freeways, including some but not all ramps and arterials and collectors. To estimate the total VMT on freeways (*i.e.*, including all ramps), a default assumption from MOBILE6 that total freeway VMT is 92% nonramp and 8% ramp was used.

For the 1996 emission inventory, the speeds were assumed for each functional class (interstate, arterial, and collectors), with the exception that local systems (urban and rural) were modeled as local roadways in MOBILE6, and therefore had fixed average speeds of 12.9 mph. Information was not available

to break the speed data down into separate averages for AM peak, PM peak, and off-peak periods, or to determine the statistical distribution of different speeds. For freeways and interstates, the speeds were assumed to be the VMT weighted average of ramp and nonramp speeds. The MOBILE6 defaults for freeway ramp VMT and freeway nonramp VMT were assumed.

The TDM calculates speeds for future years, but the speed calculation methods were not developed for purposes of emissions modeling. In most transportation models, speed is estimated primarily to allocate travel across the roadway network. Speed is used as a measure of impedance to travel rather than as a prediction of accurate travel times. For this reason, speed results from most travel demand models must be adjusted to properly estimate actual average speeds.

As a result, rather than using the speeds calculated by the TDM, speeds were calculated in accordance with EPA guidance. The EPA guidance identifies eight different methodologies for estimating speed of which one involves the use of a post-processor. For each TDM run, the post-processor was applied to each roadway link for each hour of the day. The number of roadway links differed among TDM runs; and therefore the interpolation of link-specific speed data between TDM runs (as was done for VMT data) would not have been straightforward for 2009 and 2019. The interagency consultation group decided that it was reasonable to estimate that 2009 average speeds would be approximately the same as those estimated from the 2010 TDM run, and 2019 average speeds would be approximately the same as those estimated from the 2020 TDM run. VMT weighted average speeds were calculated for each county, MOBILE6 roadway type (*i.e.*, freeway and arterial/collector), and time period (AM peak, PM peak, or off-peak).

The distribution of VMT across different vehicle types is referred to as the ''VMT mix.'' MOBILE6 includes default VMT mixes for past, current, and future years, taking into account projected changes in VMT mix over time. Although past VMT mix information could have been updated based on HPMS data, this is not possible for future years. For this reason, MOBILE6 defaults for VMT mix were used to generate emissions.

Although the MOBILE6 model includes default vehicle age distributions, which are usually assumed to not change over time, MOBILE6 results can depend heavily on the distribution of vehicle ages used. STI obtained vehicle registration data from the Minnesota Department of Public Safety. For each vehicle, these data included a vehicle identification number (VIN) and the county of registration. These data were used to determine age distributions for light-duty passenger vehicles and light-duty trucks (LDVs and LDTs) in the 8-county Minneapolis-St. Paul area. STI used MOBILE6 defaults for heavy-duty vehicle age distributions. Heavy-duty vehicle traffic in Minneapolis-St. Paul is likely to have a significant contribution from vehicles registered outside the eight counties, and possibly outside the state, thus indicating that national default data were more appropriate for heavy-duty vehicles than for light-duty vehicles.

For light-duty cars, the Minneapolis-St. Paul age distribution is very similar to the default national age distribution included in MOBILE6; but LDTs in the 8-county region were significantly newer than the MOBILE6 default age distribution with the exception that Class 1 LDTs were significantly older than the MOBILE6 default age distribution.

Point and Area Sources

The emission inventories for stationary and area sources were based on MPCA's emissions estimates for 1996 and 2002. Information gaps in the 2002 inventory were filled with estimates acquired from the Central Regional Air Planning Association, the Lake Michigan Air Directors' Consortium, and the preliminary draft version of the EPA's 2002 National Emission Inventory (NEI). Emissions were projected from 2002 forward to 2009 (and, when needed, back to 1996) by applying growth factors from EPA's Economic Growth Analysis System (EGAS) model or other appropriate growth surrogates. For example, STI applied survey data that indicated declining trends in the numbers of fireplaces per household and the consumption of wood per fireplace, as well as increasing trends in the estimated numbers of housing units (historical and forecasted) to project emissions for residential wood combustion. Finally, STI applied seasonal profiles to estimate emissions for a typical winter day.

The specific information sources used for 1996 and 2002 emissions estimates, growth projection factors, and seasonal profiles applied for each emissions source category (designated by source classification code [SCC]) were included in an appendix to the submittal. In addition, some of the stationary source estimates reflect local data.

Non-Road Sources

Non-road emissions result from the use of fuel in a diverse collection of vehicles and equipment such as recreational vehicles, agricultural equipment, and construction equipment. STI used the newest version of EPA's NONROAD model to estimate emissions from all non-road sources except commercial marine vessels (CMVs), locomotives, and aircraft. NONROAD was run for the 1996 and 2009 winters in the 8-county area, using weekday activity information. The most recent version of this model is NONROAD2004 released on May 11, 2004.

Some of the seasonal activity factors in NONROAD2004 were adjusted to account for local information. For the Minneapolis-St. Paul area, it was determined the wintertime activity for some types of lawn and garden equipment (and golf carts) should be 0%. Aircraft ground support equipment and terminal tractors are excluded from the non-road emissions because these emissions were included in MPCA's emission inventory for airports.

In winter, emissions from CMVs in the Minneapolis-St. Paul area are negligible due to frozen waterways. Year 2002 emissions from airport ground-support equipment at the Minneapolis-St. Paul airport and emissions from aircraft were acquired from the MPCA point source inventory. Emissions from ground-support equipment were projected to 1996 and 2009 by using EGAS growth factors. Emissions for aircraft were projected by using historical aircraft operations data, forecasts of operations by the Metropolitan Council, or forecasts of operations by the Federal Aviation Administration whenever available. Historical data and forecasts were not readily available for a few small airports; therefore, EGAS growth factors were applied instead. Aircraft at these airports accounted for approximately 12% of total emissions from aircraft in 2002.

Emissions from locomotives were estimated to be quite low (approximately one ton per winter day) in the 1998 Maintenance Plan, and a recent evaluation of locomotive emissions conducted by STI for calendar year 2002 confirmed that these emissions were approximately correct. Therefore, the 1996 locomotive emission estimates in the 1998 Maintenance Plan were retained. For 2009, locomotive emissions were assumed to be identical, since EPA has projected no growth in locomotive fuel usage and no CO emission reductions

associated with its locomotive emissions regulations.

VIII. What Is Minneapolis-St. Paul Revised Motor Vehicle Emissions Budget?

MPCA submitted an emissions inventory for the Minneapolis-St. Paul maintenance area for the base year of 1996. The year 1996 was selected for the inventory as no excursions or violations of the standard occurred. Emissions were then projected for 2009. The MOBILE6 emissions model was used for on-road mobile sources. These revised inventories were developed using the latest planning assumptions, including updated vehicle registration data from 1996 through 2009, VMT, speeds, fleet mix, and SIP control measures. The emission inventory amounts are shown in the table below.

TABLE 2.—MINNEAPOLIS-ST. PAUL CO EMISSIONS (TONS/WINTER DAY)

Source category	1996	2009
On-Road Mobile	1,872	1,311
Point and Area	297	127
Non-Road Mobile	337	418
Totals	2,506	1,856

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the level of emissions during one of the years in which the area met the air quality health standard. For example: The emissions from point, area and mobile sources for the Minneapolis-St. Paul area in 1996 equaled 2506 tons per winter day of CO. The projected emissions for 2009 totaled 1856 tons per winter day of CO from all sources. The safety margin for the Minneapolis-St. Paul area is the difference between these amounts, or 650 tons per winter day of CO.

Minnesota has submitted a complete and accurate emissions inventory of CO for the Minneapolis-St. Paul maintenance area and we are approving the emissions inventory. Based upon the updated emissions inventory, the revised maintenance plan contains a new budget (or limit) for motor vehicle emissions resulting from transportation plans for the Minneapolis-St. Paul maintenance area. We have reviewed the budget and have found that the budgets meet all of the adequacy criteria in section 93.118 of the transportation conformity rule. These criteria include: (1) The SIP was endorsed by the Governor (or his designee) and was subject to a state public hearing; (2) consultation among federal, state, and local agencies occurred; (3) the emissions budget is clearly identified and precisely quantified; (4) the MVEB, when considered together with all other emissions, is consistent with attainment; and (5) the MVEB is consistent with and clearly related to the emissions inventory and control strategy in the SIP. We are also required to consider comments submitted to the state at the public hearing. No significant comments were received by the state on the transportation conformity budget. The new area-wide CO budget is shown in the table below:

TABLE 3.—MINNEAPOLIS-ST. PAUL'S MOTOR VEHICLE EMISSIONS BUDGET

Source category	2009 CO emissions (tons/winter day)
On-Road Mobile	1,311
Safety Margin	650
Motor Vehicle Emissions Budget	1,961

This new MVEB is to be used in all subsequent conformity determinations concerning transportation plans in the Minneapolis-St. Paul maintenance area. We believe that the MVEB is consistent with the control measures identified in this maintenance plan and that this plan demonstrates maintenance with the CO standard.

The above demonstrates the 2009 emissions will still maintain the total emissions for the area at or below the maintenance level. For this reason, EPA is approving the new projected MVEB for 2009.

IX. EPA Action

EPA is approving the Minnesota SIP revision submitted on November 10, 2004. This submittal revises Minnesota's 1996 and 2009 CO emission inventories and 2009 MVEB using MOBILE6 for the Minneapolis-St. Paul CO maintenance area.

EPA is publishing this action without prior proposal, because EPA views this as a noncontroversial revision and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse written comments be filed. This action will be effective without further notice unless EPA receives relevant adverse written comments by January 10, 2005. Should the Agency receive such comment, we will publish a final rule informing the public that this action will not take effect. Any parties interested in commenting on this action should do so at this time. If we do not receive comments, this action will be effective on January 24, 2005. An effective date 45 days from the date of publication in the **Federal Register** has been selected in consideration of section 553 of the Administrative Procedure Act (5 U.S.C. 553). Section 553(d)allows us to make this action effective in 45 days because this action relieves a restriction on the funding of transportation projects in Minnesota which would occur and continue without the approval of this plan revision.

X. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

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.

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

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).

Regulatory Flexibility Act

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.*).

Unfunded Mandates Reform Act

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).

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

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).

Executive Order 13132: Federalism

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.

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

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.

National Technology Transfer Advancement Act

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.

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.*).

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).

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 February 7, 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.

Dated: November 30, 2004.

Bharat Mathur,

Acting Regional Administrator, Region 5.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart Y—Minnesota

■ 2. Section 52.1237 is amended by adding paragraph (d) to read as follows:

§ 52.1237 Control strategy: Carbon monoxide.

* * * * *

(d) Approval—On November 10, 2004, Minnesota submitted a revision to the Carbon Monoxide (CO) maintenance plan for the Minneapolis-St. Paul area. These plans revised 1996 and 2009 motor vehicle emission inventories and 2009 Motor Vehicle Emissions Budgets (MVEB) recalculated using the emissions factor model MOBILE6. The MVEB for transportation conformity purposes for the Minneapolis-St. Paul maintenance area is 1961 tons per winter day of CO.

[FR Doc. 04–27026 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 15

[ET Docket No. 01–278; FCC 04–262]

Radio Frequency Device Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document addresses three petitions for reconsideration of various aspects of the rule changes adopted in the *Second Report and Order and Memorandum Opinion and Order* (Second Report and Order) in this proceeding. In particular, the Commission: Grants a request to permit compliance information statements for self-authorized equipment to be provided in alternative formats; grants a request to permit longer duration transmissions during the setup of security systems; and denies a requests to permit electronic labeling of self-authorized equipment, to further relax the equipment authorization requirements for low frequency intentional radiators and to require foreign regulators to accept accreditations of United States laboratories.

DATES: Effective January 10, 2005.

FOR FURTHER INFORMATION CONTACT: Hugh VanTuyl, Office of Engineering and Technology, (202) 418–7506, TTY (202) 418–2989, e-mail: *Hugh.VanTuyl@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum Opinion and Order,* ET Docket No. 01–278, FCC 04–262, adopted November 5, 2004 and released November 9, 2004. The full text of this document is available on the Commission's Internet site at *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.

Summary of the Report and Order

1. In the *Second Report and Order,* 68 FR 68531, December 9, 2003, the Commission updated certain regulations contained in parts 2, 15, and 18 of the rules. Three parties filed petitions for reconsideration of the changes adopted in the *Second Report and Order.* Cisco Systems, Inc. (Cisco) requests that the Commission expand the scope of the rule changes that allows manufacturers to provide part 15 information statements in alternative forms to include the compliance information statement supplied with equipment authorized under the Declaration of Conformity (DoC) procedure. G.E. Interlogix, Inc. requests that the Commission reconsider its decision on remote control devices that prohibits installers of security systems from exceeding the five second limit on manual and automatic transmissions in § 15.231 during the equipment set-up process. The Information Technology Industry Council requests that the Commission: Make additional changes to the labeling requirements for self-authorized equipment to permit electronic labeling for equipment subject to DoC as it does for software defined radios; allow manufacturers to provide the compliance information in alternative forms for equipment authorized under the DoC procedure as is now permitted for part 15 information statements; extend the relaxed equipment authorization requirements for low-frequency, low-powered intentional radiators to higher frequencies; and insist that foreign regulators accept accreditations of United States laboratories, including manufacturers' laboratories.

DoC Compliance Information Statements

2. In their petitions, Cisco and ITI note that the rule changes adopted in the *Second Report and Order* that allow information statements to be supplied in alternative forms do not apply to the compliance information statements that are required by § 2.1077 to be supplied with equipment authorized under the DoC procedure. Cisco states that the omission of § 2.1077 from the same treatment of other information was not recognized by the industry during the filing of comments during the FCC proceeding. It states that in reviewing the requirements and comparing the various types of information, it cannot identify any good reason why the DoC compliance information statement should not be included among the documents that manufacturers can provide to end users over the Internet. Cisco further states that because manufacturers cannot provide this information over the Internet, manufacturers and users will bear the cost of providing the information with a product with no clear regulatory benefit to anyone. ITI requests that the Commission revise § 2.1077 to make the rule consistent with the revised part 15 rules for providing information statements in alternative formats.

3. The exclusion of DoC compliance statements from the same treatment as part 15 information statements was an inadvertent omission by the Commission that, as Cisco notes, was not recognized by industry at the time comments were filed in this proceeding. We agree with Cisco and ITI that permitting DoC compliance information statements to be provided in alternative formats will offer increased flexibility to manufacturers and result in cost savings to the industry. Accordingly, we are amending § 2.1077 of the rules to allow DoC compliance statements to be provided in formats other than paper, such as on a computer disk or over the Internet. Consistent with the Commission's actions in the *Second Report and Order* for part 15 information statements, we will allow compliance information statements to be provided in alterative forms only when the instruction manual is provided in the same alternative form and the user can reasonably be expected to have the capability to access information in that form. These requirements will help ensure that the DoC compliance information statement is accessible to all persons using a given device.

Remote Control Device Transmission Duration Limits

4. In the *Second Report and Order,* the Commission denied a request by G.E. Interlogix to modify § 15.231 of the rules to allow remote control devices to be operated with transmission durations greater than five seconds during equipment setup. In its petition for reconsideration, G.E. Interlogix states that it met with Commission representatives in January 2001 and discussed the problem of security systems requiring a lengthier setup period for new systems than could be accomplished within the five second period permitted under § 15.231. G.E. Interlogix states that it advised the Commission staff that while setup transmissions can, in theory, be performed in the manual mode, in practice, systems are designed for an automatic download of setup data and the five second transmission limitation can be too restrictive for certain sophisticated systems. It further advised that system setup generally occurs only once, but in rare cases such as a property changing hands or system failure, a system must be reinitialized. G.E. Interlogix submitted a copy of an interpretation letter issued by staff at the Commission's Laboratory stating that a transmission that exceeds the five second limit in § 15.231 is permissible to initiate a system, provided it occurs only once. G.E. Interlogix states that while its comments filed in response to the *NPRM* requested that the Commission codify this interpretation, it did not supply supportive data because it considered the request to be non-controversial. It states that setup transmissions used by all wireless security systems are not control signals in the strict sense, nor are they recognition codes, and the part 15 rules were never specifically designed to account for them. It further states that setup transmissions are not performed by the user of the security equipment and are not transmissions that occur during the functioning of the security system. Rather, they are transmissions that provide a system with the initial programming required for operation. GE Interlogix states that in a sophisticated security system the setup process can exceed five seconds because a low data rate is required to reliably transmit the setup information at the low signal levels permitted by the rules. It requests that the Commission: Reconsider its decision in the *Second Report and Order* and permit transmission of setup information for security systems in excess of five seconds, provided such transmissions are under the control of a professional installer, and clarify that data transmissions during a setup procedure are permitted under § 15.231. G.E. Interlogix notes that none of its systems use setup transmissions in excess of ten seconds.

5. The Commission denied G.E. Interlogix's request to modify § 15.231 in the *Second Report and Order* because it did not provide sufficient justification for a change to this rule section. Based upon the additional information supplied in G.E. Interlogix's petition, we are persuaded that there is, in some cases, a need to allow installers of complex security systems to initiate transmissions of greater than the five second duration permitted by § 15.231. We are therefore amending § 15.231 of the rules to allow setup transmissions, including data, of greater than the five second limit in § 15.231(a)(1) and (a)(2), provided such transmissions are under the control of a professional installer. To minimize the likelihood of interference

to authorized users of the spectrum, we will limit setup transmissions to no more than ten seconds, which G.E. Interlogix indicates is adequate for all of its systems. This action will allow manufacturers greater flexibility in the design of complex security systems while resulting in a negligible increase in interference potential for these systems because the longer duration transmissions are only five seconds longer than the rules currently allow and will generally occur only once per system.

Declaration of Conformity (DoC) Labeling

6. In the *Second Report and Order,* the Commission simplified the labeling requirements for equipment authorized under the DoC procedure. For most devices authorized under the DoC procedure, the changed rule requires that the label show the FCC logo and the equipment trade name and model number. The Commission also clarified in the *Second Report and Order* that the trade name and model number may be placed on the equipment in a location other than on the DoC label when necessary. In addition, the Commission denied a request by ITI and other parties to permit electronic labeling for equipment authorized under the DoC procedure. In denying ITI's request, the Commission stated that the part 2 rules permit electronic labeling for software defined radios because there is sometimes a need for a third party to change the identification number of a radio in the field when changes are made to the software that affect the device's operating frequency, modulation type or maximum output power. This permits the identification number to be changed without physical re-labeling of a radio. The Commission stated that none of the comments in this proceeding have shown that there is a similar need to allow this capability in equipment subject to DoC.

7. In its petition, ITI repeats its request that the Commission permit electronic labeling for equipment subject to DoC. It states that this change would reduce costs for products that already have displays because the identifying marks could be maintained in memory and displayed on startup or on demand while the product is operating. ITI further states that electronic labeling could be used by the Commission for product approval purposes such as the difficult administrative task of tracking grant notices.

8. The Commission considered and rejected ITI's request to allow electronic labeling of equipment subject to DoC in the *Second Report and Order*. ITI has not provided any new information in its petition that would lead us to change our decision on this subject. The revised DoC labeling rules require only the FCC logo, equipment trade name and model number on a device, and manufacturers already place a trade name and model number on virtually all devices made. Therefore, the DoC labeling requirement is not a significant burden. Further, there is not a need to change the identification information for devices subject to DoC after manufacture as there is for software defined radios where the operating parameters and FCC identification number may be changed post-manufacture. ITI has also not shown how electronic labeling could be used by the Commission for product approval purposes, such as tracking grant notices, because there is no grant notice for equipment subject to DoC. Accordingly, we decline to allow electronic labeling for equipment subject to DoC.

Other Matters

9. *Very low power intentional radiators.* In the *Second Report and Order*, the Commission changed the equipment authorization requirement from certification to verification for intentional radiators operating below 490 kHz in which all emissions are at least 40 dB below the part 15 limit.

10. The Commission stated that because the interference potential of such devices is extremely low, requiring certification seems to be an unnecessary burden on manufacturers. ITI states that it supports the Commission's decision to eliminate the certification requirement for very low powered intentional radiators, but requests that the Commission consider extending the verification process to higher frequency bands. However, ITI did not provide specific information on the operating parameters (*e.g.*, frequency range or output signal level) for intentional radiators that it believes should be subject to verification or provide technical justification for making changes to the authorization requirement for certain intentional radiators. Based on the lack of a specific request and record on this issue, we decline to make further changes to the authorization requirements for very low power intentional radiators at this time.

11. *Accreditation of test laboratories.* In the *Second Report and Order*, the Commission eliminated the requirement for an accredited laboratory to file a description of its measurement facilities with the Commission if the accrediting organization submitted certain information about the laboratory to the Commission. The purpose of this change was to reduce the burden on laboratories by eliminating the need to file duplicate information with both the Commission and an accrediting organization. ITI requests that in addition to this change, the Commission insist that foreign regulators also accept similar accreditations from U.S. laboratories, including manufacturer's laboratories, but it did not identify any specific rule changes that the Commission could make to accomplish this objective. This issue is more appropriately addressed in the context of negotiating mutual recognition agreements or arrangements (MRAs) with other administrations than in this proceeding. We therefore decline to make any rule changes concerning the acceptance of U.S. laboratory accreditations by foreign regulators.

Procedural Matters

12. *Final Regulatory Flexibility Certification.* The Regulatory Flexibility Act of 1980, as amended (RFA),[1] requires that a regulatory flexibility analysis be prepared for rulemaking proceedings, unless the agency certifies that ''the rule will not have a significant economic impact on a substantial number of small entities.'' [2] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [3] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[4] 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.

13. The *Second Report and Order* modified the rules to allow part 15 information statements to be provided to the user of equipment in alternative forms, such as on a CD–ROM or over the

[1] The Regulatory Flexibility Analysis, *see* 5 U.S.C. 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847 (1966) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[2] 5 U.S.C. 605(b).

[3] 5 U.S.C. 601(6).

[4] 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**.''

Internet. The *Second Report and Order* also denied a request by G.E. Interlogix to allow security system setup transmissions of greater duration than the five second limit currently in § 15.231(a) of the rules. A Final Regulatory Flexibility Analysis was incorporated in the *Second Report and Order*.[5] Following publication of the *Second Report and Order*, Cisco and ITI filed their petitions seeking to allow the compliance information statement for equipment authorized under the DoC procedure to be provided in alternative forms. G.E. Interlogix filed a petition requesting that the Commission reconsider its denial of G.E. Interlogix's request to permit longer duration transmissions during the setup of security systems. In the *Memorandum Opinion and Order* we are amending the rules to allow DoC compliance information statements to be included in alternative forms and to allow longer duration setup transmissions for security systems.

14. These amendments to the rules will affect manufacturers of radio frequency devices that are authorized under the DoC procedure and manufacturers of security systems, and it is the Commission's belief that many of these manufacturers are small businesses. The changes in the *Memorandum Opinion and Order* are deregulatory in nature because they eliminate the need for manufacturers to supply paper statements with equipment subject to DoC and allow greater flexibility in the setup of security systems. For this reason, these changes will not result in a ''significant economic burden'' on manufacturers. Therefore, we certify that the amendments included in the *Memorandum Opinion and Order* will not have a significant economic impact on a substantial number of small entities.

15. The Commission will send a copy of the *Memorandum Opinion and Order,* including a copy of this final certification, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996.[6] In addition, the *Memorandum Opinion and Order* and this certification will be sent to the Chief Counsel for Advocacy of the Small Business Administration.

Ordering Clauses

16. Pursuant to the authority contained in sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r), this *Memorandum Opinion and Order* is adopted and parts 2 and 15 of the Commission's Rules are amended as set forth in the attached appendix effective 30 days after publication in the **Federal Register**.

17. Pursuant to the authority contained in sections 4(i), 301, 302, 303(e), 303(f), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r), the motion for partial reconsideration filed by Cisco Systems, Inc. on September 12, 2003 is granted to the extent indicated herein.

18. Pursuant to the authority contained in sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r), the motion for reconsideration and clarification filed by the Information Technology Institute on September 17, 2003 is granted in part and denied in part to the extent indicated herein.

19. Pursuant to the authority contained in sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r), the petition for reconsideration filed by G.E. Interlogix, Inc. on January 8, 2004 is granted to the extent indicated herein.

20. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Memorandum Opinion and Order,* including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in Parts 2 and 15

Communications equipment.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Rule Changes

For the reasons set forth in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 15 to read as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

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

Authority: 47 U.S.C. 154, 302a, 303, and 336 unless otherwise noted.

■ 2. Section 2.1077 is amended by revising paragraph (c) to read as follows:

§ 2.1077 Compliance information.

* * * * *

(c) The compliance information statement shall be included in the user's manual or as a separate sheet. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.

PART 15—RADIO FREQUENCY DEVICES

■ 3. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336 and 544a.

■ 4. Section 15.231 is amended by adding paragraph (a)(5) to read as follows:

§ 15.231 Periodic operation in the band 40.66–40.70 MHz and above 70 MHz.

(a) * * *

■ (5) Transmission of set-up information for security systems may exceed the transmission duration limits in paragraphs (a)(1) and (a)(2) of this section, provided such transmissions are under the control of a professional installer and do not exceed ten seconds after a manually operated switch is released or a transmitter is activated automatically. Such set-up information may include data.

* * * * *

[FR Doc. 04–27048 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96–128; FCC 03–235]

The Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Federal Communications Commission received Office of Management and Budget (OMB) approval for the new public information collection, Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket 96–128, OMB Control Number 3060–1046. The

[5] *See* 68 FR 68531, 68541, December 9, 2003.

[6] *See* 5 U.S.C. 801(a)(1)(A).

Commission previously announced in a notice that OMB Control No. 3060–1046 and associated rules 47 CFR 64.1300, 64.1310, and 64.1320 became effective July 1, 2004 (69 FR 26825 May 14, 2004). By this document, we confirm that OMB Control No. 3060–1046 and the associated final rules 47 CFR 64.1300, 64.1310, and 64.1320 were effective on July 1, 2004.

DATES: The rules in 47 CFR 64.1300, 64.1310, 64.1320 published at 68 FR 62751 (November 6, 2003) became effective July 1, 2004.

FOR FURTHER INFORMATION CONTACT: Darryl Cooper Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–7131, or via the Internet at *darryl.cooper@fcc.gov* or Denise A. Coca, Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0574, or via the Internet at *denise.coca@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Federal Communications Commission has received OMB approval for a new information collection in Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket 96–128, 68 FR 62751, November 6, 2003, which adopts new rules that place liability to compensate a payphone service provider for payphone-originated calls on the facilities-based carrier, as defined in the rules, that completes these calls on switches that the carrier leases or owns. Through this document, the Commission confirms that it received OMB approval on May 5, 2004; OMB Control No. 3060–1046. Accordingly, the interim rules were vacated, and the effective date for this collection and associated final rules 47 CFR 64.1300, 64.1310, and 64.1320 was July 1, 2004.

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 the OMB control numbers and expiration dates should be directed to Paul J. Laurenzano, Federal Communications Commission, 445 12th Street, SW., Washington DC 20554, (202) 418–1359 or via the Internet at *plaurenz@fcc.gov.*

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27051 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3623, MB Docket No. 04–283, RM–10965]

Digital Television Broadcast Service; Kalispell, MT

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Montana State University, allots DTV channel *46 for noncommercial use at Kalispell, Montana. *See* 69 FR 47399, August 5, 2004. DTV channel *46 can be allotted to Kalispell, Montana, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 48–00–48 N. and 114–21–55 W. Since the community of Kalispell is located within 400 kilometers of the U.S.-Canadian border, concurrence from the Canadian government was obtained for this allotment. With this action, this proceeding is terminated.

DATES: Effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 04–283, adopted November 16, 2004, and released November 30, 2004. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 301–816–2820, facsimile 301–816–0169, or via e-mail *joshir@erols.com*.

This document does not contain [new or modified] information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Commission will send a copy of this Report & Order in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.622 [Amended]

■ 2. Section 73.622(b), the Table of Digital Television Allotments under Montana, is amended by adding DTV channel *46 at Kalispell.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 04–27043 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3622, MB Docket No. 04–260, RM–10616]

Television Broadcast Service and Digital Television Broadcast Service; Tulsa, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Global Education Development, Inc., Broadcasting for the Challenged, Inc., Faith That Pleases God Church, Creative Educational Media Corporation, Oral Roberts University, and the Community Television Educators, Inc., substitutes DTV channel *26 for channel *63 at Tulsa. *See* 69 FR 45664, July 30, 2004. DTV channel can be allotted to Tulsa, Oklahoma, in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 36–04–56 N. and 95–45–27 W. with a power of 200, HAAT of 94 meters and with a DTV service

population of 776 thousand. With this action, this proceeding is terminated.

DATES: Effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 04–260, adopted November 16, 2004, and released November 30, 2004. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 301–816–2820, facsimile 301–816–0169, or via-e-mail *joshir@erols.com*.

This document does not contain [new or modified] information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Pub. L. 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Pub. L. 107–198, *see* 44 U.S.C. 3506(c)(4).

The Commission will send a copy of this Report & Order in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.606 [Amended]

■ 2. Section 73.606(b), the Table of Television Allotments under Oklahoma is amended by removing TV channel *63 at Tulsa.

§ 73.622 [Amended]

■ 3. Section 73.622(b), the Table of Digital Television Allotments under Oklahoma is amended by adding DTV channel *26 at Tulsa.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 04–27044 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3621, MB Docket No. 04–187, RM–10967]

Digital Television Broadcast Service; Greenwood, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Mississippi Broadcasting Partners, substitutes DTV channel 32 for DTV channel 54 at Greenwood, Mississippi. *See* 69 FR 30857, June 1, 2004. DTV channel 32 can be allotted to Greenwood, Mississippi, in compliance with the principle community coverage requirements of section 73.625(a) at reference coordinates 33–22–23 N. and 90–32–25 W. with a power of 1000, HAAT of 610 meters and with a DTV service population of 743 thousand. With this action, this proceeding is terminated.

DATES: Effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 04–187, adopted November 16, 2004, and released November 30, 2004. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 301–816–2820, facsimile 301–816–0169, or via-e-mail *joshir@erols.com.*

This document does not contain [new or modified] information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Commission will send a copy of this Report & Order in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.622 [Amended]

■ 2. Section 73.622(b), the Table of Digital Television Allotments under Mississippi, is amended by removing DTV channel 54 and adding DTV channel 32 at Greenwood.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 04–27047 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3611; MB Docket No. 04–205, RM–10704]

Radio Broadcasting Service; Islamorada, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Paul B. Christensen, Esquire, allots Channel 283C2 at Islamorada, Florida, as the community's first local aural transmission service. *See* 69 FR 34114, published June 18, 2004. Channel 283C2 can be allotted to Islamorada in compliance with the Commission's minimum distance separation requirements, provided there is a site restriction of 0.9 kilometers (0.6 miles) southwest of the community. The reference coordinates for Channel 283C2 at Islamorada are 24–55–05 North Latitude and 80–38–04 West Longitude. A filing window for Channel 283C2 at Islamorada, Florida will not be opened at this time. Instead, the issue of opening a filing window for this

channel will be addressed by the Commission in a subsequent order.

DATES: Effective January 6, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 04–205, adopted November 17, 2004, and released November 22, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Florida, is amended by adding Islamorada, Channel 283C2.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–27040 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3514, MB Docket No. 02–376, RM–10617]

Radio Broadcasting Services; Sells, AZ

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document grants a petition filed by Rural Pima Broadcasting proposing the allotment of Channel 285 at Sells, Arizona, as its first local aural broadcast service. See 67 FR 78401, published December 24, 2002. This document also denies a counterproposal filed by Lakeshore Media, LLC proposing to substitute Channel 285C3 for Channel 285C2 at Willcox, and reallot Channel 285C3 from Willcox to Davis-Monthan Air Force Base, Arizona (''Davis-Monthan AFB''), as a first local aural transmission service. Lakeshore's counterproposal also included the allotment of Channels 283C2 and 245C2 at Willcox to provide service to unserved and underserved areas created by the reallotment of Channel 285C3 from Willcox to Davis-Monthan AFB. Channel 285A can be allotted at Sells at a site 9.3 kilometers (5.8 miles) south of the community at coordinates 31–49–44 NL and 111–53–28 WL. This site has received concurrence from the government of Mexico as a specially negotiated restricted allotment limited to 1.1 kW ERP and 100 m HAAT or the equivalent along the 123.2 degree azimuth toward Station XHNI(FM) Channel 286B, Nogales, Sonora, Mexico. *See* **SUPPLEMENTARY INFORMATION**.

DATES: Effective January 6, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order*, MB Docket No. 02–376, adopted November 17, 2004, and released November 22, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and 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).

Lakeshore's counterproposal is denied. Its proposal to allot Channels 282C2 and 245C2 at Willcox to avoid unserved and underserved areas as ''backfill'' allotments is precluded by the Commission's decision in *Pacific Broadcasting of Missouri, LLC*, 18 FCC Rcd 2291 (2003); *recon. den.* 19 FCC Rcd 10,950 (2004). Without the backfill allotments, the Lakeshore counterproposal would leave behind vast unserved and underserved areas, *i.e.*, white and gray area. The loss area resulting from Lakeshore's proposed substitution of Channel 285C3 for Channel 285C3 at Willcox and the reallotment of Channel 285C3 from Willcox to Davis-Monthan AFB would contain 8,560.3 square kilometers with a population of 13,842. An area of 2,142 square kilometers with a population of 2,846 would be left with no aural reception service, and an area of 1,068 square kilometers with a population of 1,022 would be left with one aural reception service.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by adding Sells, Channel 285A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–27041 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3613; MB Docket No. 04–204; RM–110661]

Radio Broadcasting Services; Birmingham, Alabama and Calhoun, GA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of SSR Communications Incorporated, allots Channel 233A to Calhoun, Georgia, as its first FM commercial aural broadcast service. To accommodate the proposal consistent with the minimum distance separation requirements of the Commission's rules, this document also grants the reclassification of WYSF(FM),

Birmingham, Alabama, to specify operation on Channel 233C0 in lieu of Channel 233C. No response was filed to the *Order to Show Cause* issued to Citadel Broadcasting Company, licensee of Station WYSF(FM), Birmingham, Alabama. Channel 233A at Calhoun can be allotted consistent with the minimum distance separation requirements of the Commission's Rules with a site restriction of 10.8 kilometers (6.7 miles) east of the community. The reference coordinates for Channel 233A at Calhoun are 34–31–48 NL and 84–50–19 WL. This site restriction will ensure full-spacing to Station WMUU(FM)'s licensed Channel 233C facilities at Greenville, South Carolina.

DATES: Effective January 6, 2005.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 04–204, adopted November 17, 2004, and released November 22, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and 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).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Alabama is amended by removing Channel 233C and by adding Channel 233C0 at Birmingham.

■ 3. Section 73.202(b), the Table of FM Allotments under Georgia is amended by adding Calhoun, Channel 233A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–27045 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3614; MB Docket No. 04–168, RM–10832]

Radio Broadcasting Services; Waitsburg, Washington

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Waitsburg Broadcasting Company, allots Channel 272A to Waitsburg, Washington, as its first local aural transmission service. *See* 69 FR 29254, May 21, 2004. Channel 272A can be allotted to Waitsburg, consistent with the minimum distance separation requirements of the Commission's Rules with a site restriction 12.3 kilometers (7.6 miles) east of the community at coordinates 46–17–41 NL and 117–59–47 WL. Although concurrence has been requested for Channel 272A at Waitsburg, notification has not been received. If a construction permit is granted prior to the receipt of formal concurrence in the allotment by the Canadian government, the construction permit will include the following condition: ''Operation with the facilities specified for Waitsburg herein is subject to modification, suspension or, termination without right to hearing, if found by the Commission to be necessary in order to conform to the U.S.-Canadian FM Broadcast Agreement.'' A filing window for Channel 272A at Waitsburg, Washington, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

DATES: Effective January 6, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC. 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 04–168, adopted November 17, 2004, and released November 22, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC, 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and 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).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Waitsburg, Channel 272A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–27046 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 69, No. 236
Thursday, December 9, 2004

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.

FEDERAL ELECTION COMMISSION

11 CFR Part 300

[Notice 2004–17]

Political Party Committees Donating Funds to Certain Tax-Exempt Organizations and Political Organizations

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission requests comments on proposed amendments to its rules governing limitations on national, State, district, and local political party committees making or directing donations to certain tax-exempt organizations and political organizations. These proposed rules would conform to the decision of the U.S. Supreme Court in *McConnell* v. *FEC,* which included a narrowing construction of section 101 of the Bipartisan Campaign Reform Act of 2002. The Commission has not made any final decisions on the issues presented in this rulemaking. Further information is provided in the **SUPPLEMENTARY INFORMATION** that follows.

DATES: Comments must be received on or before January 10, 2005. If the Commission receives sufficient requests to testify, it may hold a hearing on these proposed rules. Commenters wishing to testify at the hearing must so indicate in their written or electronic comments.

ADDRESSES: All comments should be addressed to Ms. Mai T. Dinh, Assistant General Counsel, and must be submitted in either electronic or written form. Commenters are strongly encouraged to submit comments electronically to ensure timely receipt and consideration. Electronic mail comments should be sent to *partytaxexempts@fec.gov,* and must include the full name, electronic mail address and postal service address of the commenter. Electronic mail comments that do not contain the full name, electronic mail address and postal service address of the commenter will not be considered. If the electronic mail comments include an attachment, the attachment must be in the Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments should be sent to (202) 219–3923, with printed copy follow-up to ensure legibility. Written comments and printed copies of faxed comments should be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. The Commission will post public comments on its Web site. If the Commission decides that a hearing is necessary, the hearing will be held in its ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Mai T. Dinh, Assistant General Counsel, or Mr. Albert J. Kiss, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Bipartisan Campaign Reform Act of 2002, Public Law 107–155, 116 Stat. 81 (Mar. 27, 2002) (''BCRA''), contained extensive and detailed amendments to the Federal Election Campaign Act of 1971 (''FECA'' or ''the Act''), as amended, 2 U.S.C. 431 *et seq.* The Supreme Court upheld most of BCRA in *McConnell* v. *FEC,* 540 U.S. 93, 124 S. Ct. 619 (2003). Under BCRA section 101(a), a national, State, district or local political party committee must not solicit any funds for, or make or direct donations to, certain tax-exempt organizations. 2 U.S.C. 441i(d). Section 441i(d)'s restrictions apply to solicitations for, and making or directing donations to, two types of tax-exempt organizations (''certain tax-exempt organizations''). These consist of (1) organizations described in 26 U.S.C. 501(c) that are exempt from tax under 26 U.S.C. 501(a) (or that have submitted an application for determination of tax exempt status under section 501(a)) and that make expenditures or disbursements in connection with an election for Federal office (including expenditures or disbursements for Federal election activity); and (2) political organizations described in 26 U.S.C. 527 (other than a political committee, a State, district or local committee of a political party, or the authorized campaign committee of a candidate for State or local office).

In 2002, the Commission promulgated rules at 11 CFR 300.11, 300.37, 300.50, and 300.51 implementing 2 U.S.C. 441i(d). *Explanation and Justification for Rules on Prohibited and Excessive Contributions: Non-Federal Funds or Soft Money,* 67 FR 49,064, 49,089–49,091, and 49,105–49,106 (July 29, 2002). Except for the title of each, the final rule at 11 CFR 300.11 is identical to the final rule at 11 CFR 300.50, and the final rule at 11 CFR 300.37 is identical to the final rule at 11 CFR 300.51. *Id.* at 49,106.

Subsequently, the Supreme Court upheld 2 U.S.C. 441i(d)'s prohibitions on the solicitation of funds for certain tax-exempt organizations. In a separate analysis, however, the Supreme Court stated that 2 U.S.C. 441i(d) raises overbreadth concerns ''if read to restrict donations from a party's federal account—*i.e.*, funds that have already been raised in compliance with FECA's source, amount and disclosure limitations.'' *McConnell,* 124 S. Ct. at 680–681. The Court found ''no evidence that Congress was concerned about, much less that it intended to prohibit, donations of money already fully regulated by FECA * * * [t]hus, political parties remain free to make or direct donations of money to any tax-exempt organization that has otherwise been raised in compliance with FECA.'' *Id.* at 681–682. Accordingly, the Commission now proposes to modify its regulations at 11 CFR 300.11, 300.37, 300.50 and 300.51 to provide that the prohibition on political party committees [1] making or directing donations to certain tax-exempt organizations is limited to donations of non-Federal funds and thus would not apply to donations of Federal funds to these organizations.

[1] These restrictions also apply to the national congressional campaign committees and to ''an entity that is directly or indirectly established, financed, maintained, or controlled by any such national, State, district, or local committee or its agent, and an officer or agent acting on behalf of any such party committee or entity * * *'' and references to political party committees in this Notice of Proposed Rulemaking also include these entities, agents and officers. *See* 2 U.S.C. 441i(d); 11 CFR 300.11(b), 300.37(b), 300.50(b), and 300.51(b); *see also* Advisory Opinion 2004–25 (concluding that the chairman of a national congressional campaign committee, under the facts presented, was acting in his personal capacity and not as an officer or agent of a national congressional campaign committee when donating his personal funds to organizations engaged in voter registration activity).

I. Proposed 11 CFR 300.11—Prohibitions on Fundraising For And Donating To Certain Tax-Exempt Organizations

The Commission proposes to revise 11 CFR 300.11 by modifying the prohibition in current section 300.11 on national party committees, making or directing any donations to certain tax-exempt organizations. As modified, section 300.11 would prohibit the making or directing of donations of non-Federal funds to these organizations. Section 300.2(k) defines ''non-Federal funds'' as funds that are not subject to the limitations and prohibitions of the Act. 11 CFR 300.2(k).

As revised, section 300.11 would be consistent with 2 U.S.C. 441i(a)(1) and 11 CFR 300.10, under which national party committees may not solicit, receive, or direct to another person a contribution, donation or transfer of funds or any other thing of value, or spend any funds, not subject to the amount limitations, source prohibitions and reporting requirements of the Act, because national party committees are barred from accepting non-Federal funds.

Although only national party committees are the subject of the prohibitions in section 300.11, current paragraph 300.11(b)(3) erroneously expands the scope of these restrictions to include ''an agent of a national, *State, district, or local party committee* of a political party'' [emphasis added]. Accordingly, the Commission also proposes to make a technical correction to paragraph 300.11(b)(3) which would strike the reference to a State, district, or local party committee.

II. Proposed 11 CFR 300.37—Prohibitions on Fundraising For And Donating To Certain Tax-Exempt Organizations

The Commission proposes revisions to 11 CFR 300.37, which applies to State, district and local party committees, that are similar to the proposed revisions to 11 CFR 300.11 discussed above. Under the draft amendments, a State, district, or local committee of a political party would be prohibited from soliciting any funds for, or making or directing any donations of non-Federal funds to, certain tax-exempt organizations.

The Commission invites comment on whether the Supreme Court's rationale for limiting section 441i(d)'s prohibition on directing or donating non-Federal funds applies to Levin funds. *See McConnell,* 124 S. Ct. at 680–682. Levin funds are funds that a State, district or local party committee of a political party raises itself pursuant to State law, and are limited to $10,000 per calendar year from any person other than foreign nationals and those prohibited from making a donation under State law. 2 U.S.C. 441i(b)(2)(A)(ii); 11 CFR 300.2(h) and (i). A State, district or local committee of a political party may spend Levin funds on ''[a]ny use that is lawful under the laws of the State in which the committee is organized'' other than two types of Federal election activities: (1) Public communications that promote, support, attack or oppose a Federal candidate and (2) services provided by certain party committee employees. 11 CFR 300.32(b)(2). The donation of Levin funds is subject to amount limitations, certain source prohibitions, and reporting requirements under the FECA, even though these amount limitations, source prohibitions and reporting requirements are different than those applicable to Federal funds. See, *e.g.*, 11 CFR 300.31(c) and (d) and 300.36(b). Thus, Levin funds may fall within the Supreme Court's description of funds ''already fully regulated by FECA,'' and ''otherwise * * * raised in compliance with FECA'' that are outside the Court's narrow construction of the prohibition in 2 U.S.C. 441i(d). However, the Commission has stated that Levin funds are a ''new type of non-Federal funds'' and are ''unlike Federal funds, which are fully subject to the Act's requirements, and unlike ordinary non-Federal funds because they are subject to certain additional requirements under BCRA.'' *Explanation and Justification to Final Rules; Prohibited and Excessive Contributions: Non-Federal Funds or Soft Money,* 67 FR 49,064, 49,065, and 49,085 (July 29, 2002). The Commission invites comments on whether State, district and local political party committees should be allowed to make or direct donations of Levin funds to certain tax-exempt organizations to the extent permitted by State law.

III. Proposed 11 CFR 300.50—Prohibited Fundraising by National Party Committees

For the reasons addressed above in the discussion of proposed section 300.11, the Commission proposes to revise 11 CFR 300.50 by modifying the prohibition in current section 300.50 on national party committees making or directing any donations to certain tax-exempt organizations. As modified, section 300.50 would prohibit national party committees from soliciting any funds for, or making or directing donations of non-Federal funds to, certain tax-exempt organizations.

The Commission also proposes to make a technical correction to 11 CFR 300.50(b)(3) that is similar to the proposed technical change to 11 CFR 300.11(b)(3) discussed above.

IV. Proposed 11 CFR 300.51—Prohibited Fundraising by State, District, or Local Party Committees

For the reasons addressed above in the discussion of proposed sections 300.11 and 300.37, the Commission proposes to revise 11 CFR 300.51 to provide a State, district, or local committee of a political party is prohibited from soliciting any funds for, or making or directing any donations of non-Federal funds to, certain tax-exempt organizations.

For the reasons addressed in the discussion of proposed section 300.37, the Commission invites comment on whether or not Levin funds should be subject to the section 300.51 prohibition.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

The Commission certifies that the attached proposed rules, if promulgated, would not have a significant economic impact on a substantial number of small entities. The basis for this certification is that the national, State, district and local party committees of the two major political parties are not small entities under 5 U.S.C. 601, and the number of other small entities to which the rules would apply is not substantial. Moreover, the proposed rules narrow the scope of certain restrictions applicable to the affected political party committees, and thus would not have a significant economic impact on the affected entities.

List of Subjects in 11 CFR Part 300

Campaign funds, Nonprofit organizations, Political committees and parties.

For the reasons set out in the preamble, the Federal Election Commission proposes to amend subchapter C of chapter I of title 11 of the *Code of Federal Regulations* as follows:

PART 300—NON-FEDERAL FUNDS

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

Authority: 2 U.S.C. 434(e), 438(a)(8), 441a(a), 441i, 453.

2. In § 300.11, the introductory text of paragraph (a) and paragraph (b)(3) would be revised to read as follows:

§ 300.11 Prohibitions on fundraising for and donating to certain tax-exempt organizations (2 U.S.C. 441i(d)).

(a) *Prohibitions.* A national committee of a political party, including a national congressional campaign committee, must not solicit any funds for, or make or direct any donations of non-Federal funds to, the following organizations:

* * * * *

(b) * * *

(3) An entity that is directly or indirectly established, financed, maintained or controlled by an agent of a national committee of a political party, including a national congressional campaign committee.

* * * * *

3. In § 300.37, the introductory text of paragraph (a) would be revised to read as follows:

§ 300.37 Prohibitions on fundraising for and donating to certain tax-exempt organizations (2 U.S.C. 441i(d)).

(a) *Prohibitions.* A State, district or local committee of a political party must not solicit any funds for, or make or direct any donations of non-Federal funds to:

* * * * *

4. In § 300.50, the introductory text of paragraph (a) and paragraph (b)(3) would be revised to read as follows:

§ 300.50 Prohibited fundraising by national party committees (2 U.S.C. 441i(d)).

(a) *Prohibitions on fundraising and donations.* A national committee of a political party, including a national congressional campaign committee, must not solicit any funds for, or make or direct donations of non-Federal funds to the following organizations:

* * * * *

(b) * * *

(3) An entity that is directly or indirectly established, financed, maintained or controlled by an agent of a national committee of a political party, including a national congressional campaign committee.

* * * * *

5. In § 300.51, the introductory text of paragraph (a) would be revised to read as follows:

§ 300.51 Prohibited fundraising by State, district, or local party committees (2 U.S.C. 441i(d)).

(a) *Prohibitions.* A State, district or local committee of a political party must not solicit any funds for, or make or direct any donations of non-Federal funds to:

* * * * *

Dated: December 3, 2004.

Ellen L. Weintraub,

Vice-Chair, Federal Election Commission.

[FR Doc. 04–27025 Filed 12–8–04; 8:45 am]

BILLING CODE 6715–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MN–0002; FRL–7846–8]

Approval and Promulgation of Implementation Plans: Minnesota: Minneapolis-St. Paul Carbon Monoxide Maintenance Plan Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Minnesota State Implementation Plan (SIP) for the maintenance of the Carbon Monoxide (CO) ambient air quality standard (NAAQS) submitted on November 10, 2004. Specifically, EPA is proposing approval of Minnesota's revised 2009 emissions inventories and 2009 Motor Vehicle Emissions Budgets (MVEB) recalculated using MOBILE6 for the Minneapolis-St. Paul CO maintenance area.

In the final rules section of this **Federal Register**, EPA is approving the SIP revision as a direct final rule without prior proposal, because EPA views this as a noncontroversial revision and anticipate 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 proposed rule, no further activity is contemplated in relation to this proposed rule. 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 on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before January 10, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2004–MN–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://docket.epa.gov/rmepub/index.jsp. Regional Material 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 on-line instructions for submitting comments.

E-mail: bortzer.jay@epa.gov.

Fax: (312) 886–5824.

Mail: You may send written comments to: J. Elmer Bortzer, Chief, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: J. Elmer Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Regional Material in EDocket (RME) ID No. R05–OAR–2004–MN–0002. EPA's policy is that all comments received will be included in the public docket without change, 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 Regional Material in EDocket (RME), regulations.gov, or e-mail. The EPA Regional Material in EDocket (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 docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of

encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the electronic docket are listed in the Regional Material in EDocket (RME) index at *http://www.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Michael Leslie at (312) 353–6680 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Michael Leslie, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), USEPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6680. *leslie.michael@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to me?

This action primarily applies to the transportation sector represented by Metropolitan Council, the Minnesota Department of Transportation and persons needing to travel in the Minneapolis-St. Paul metropolitan area.

B. What Should I Consider as I Prepare my Comments for EPA?

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

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

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

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

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

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

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

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

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

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

II. What Action is EPA Taking Today?

EPA is proposing to approve the Minnesota SIP revision submitted on November 10, 2004. This submittal revises Minnesota's 1996 and 2009 CO emission inventories and 2009 MVEB using MOBILE6 for the Minneapolis-St. Paul CO maintenance area.

III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information, see the Direct Final Rule which is located in the Rules section of this **Federal Register**. Copies of the request and the EPA's analysis are available electronically at Regional Material in EDocket (RME) or in hard copy at the above address. (Please telephone Michael Leslie at (312) 353–6680 before visiting the Region 5 Office.)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide.

Dated: November 30, 2004.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 04–27027 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 272

[FRL–7846–6]

Idaho: Incorporation by Reference of Approved State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Resource Conservation and Recovery Act, as amended (RCRA), allows EPA to authorize State hazardous waste management programs if EPA finds that such programs are equivalent and consistent with the Federal program and provide adequate enforcement of compliance. Title 40 of the Code of Federal Regulations (CFR) Part 272 is used by EPA to codify its decision to authorize individual State programs and incorporates by reference those provisions of the State statutes and regulations that are subject to EPA's inspection and enforcement authorities as authorized provisions of the State's program. This rule proposes to revise the codification of the Idaho authorized program.

DATES: Comments on this proposed action must be received by the close of business January 10, 2005. If EPA receives significant comments on this proposed action, EPA will respond to such comments in the **Federal Register** at the time EPA publishes a final rule.

ADDRESSES: Send written comments by mail to Jeff Hunt, U.S. EPA, Region 10, 1200 Sixth Avenue, Mail stop AWT–122, Seattle, WA 98101, or via e-mail to *hunt.jeff@epa.gov.* You can inspect the records related to this codification effort from 8:30 a.m. to 4 p.m. Monday through Friday in the EPA Region 10 Library, 1200 Sixth Avenue, Mail stop WCM–122, Seattle, WA 98101.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, U.S. EPA, Region 10, 1200 Sixth Avenue, Mail stop WCM–122, Seattle, WA 98101, e-mail: *hunt.jeff@epa.gov*, phone number (206) 553–0256.

SUPPLEMENTARY INFORMATION:

I. Incorporation by Reference

A. What Is Codification?

Codification is the process of including the statutes and regulations that comprise the State's authorized hazardous waste management program in the CFR. Section 3006(b) of RCRA, as amended, allows the Environmental Protection Agency (EPA) to authorize State hazardous waste management programs. The State regulations

authorized by EPA supplant the federal regulations concerning the same matter with the result that after authorization EPA enforces the authorized regulations. Infrequently, State statutory language which acts to regulate a matter is also authorized by EPA with the consequence that EPA enforces the authorized statutory provision. EPA does not authorize State enforcement authorities and does not authorize State procedural requirements. EPA codifies the authorized State program in 40 CFR part 272 and incorporates by reference State statutes and regulations that make up the approved program which is Federally enforceable in accordance with Sections 3007, 3008, 3013 and 7003 of RCRA, 42 U.S.C. 6927, 6928, 6934 and 6973, and any other applicable statutory and regulatory provisions.

Today's action proposes to codify EPA's authorization of revisions to Idaho's hazardous waste management program. This proposed codification reflects the State program in effect at the time EPA authorized revisions to the Idaho hazardous waste management program in a final rule dated March 10, 2004 (69 FR 11322). Notice and an opportunity for comment regarding the revisions to the authorized State program were provided to the public at the time those revisions were proposed. EPA is not reopening its decisions to authorize changes to the State's program nor is EPA requesting comment on those revisions.

B. What Is the History of the Authorization and Codification of Idaho's Hazardous Waste Management Program?

Idaho initially received final authorization for its hazardous waste management program, effective April 9, 1990 (55 FR 11015). Subsequently, EPA authorized revisions to the State's program effective June 5, 1992 (57 FR 11580), August 10, 1992 (57 FR 24757), June 11, 1995 (60 FR 18549), January 19, 1999 (63 FR 56086), July 1, 2002 (67 FR 44069), and March 10, 2004 (69 FR 11322). EPA first codified Idaho's authorized hazardous waste program effective February 4, 1991 (55 FR 50327), and updated the codification of Idaho's program on June 5, 1992 (57 FR 11580), August 10, 1992 (57 FR 24757), and August 24, 1999 (64 FR 34133). In this action, EPA is proposing to revise Subpart N of 40 CFR part 272, to include the recent authorization revision actions effective July 1, 2002 (67 FR 44069) and March 10, 2004 (69 FR 11322).

C. What Decisions Have We Proposed in This Action?

Today's action proposes to codify EPA's authorization of revisions to Idaho's hazardous waste management program. The proposed codification will incorporate by reference the most recent version of the State's authorized hazardous waste management regulations. This proposed action does not reopen any decision EPA previously made concerning the authorization of the State's hazardous waste management program. EPA is not requesting comments on its decisions published in the **Federal Register** notices referenced in section B of this document concerning revisions to the authorized program in Idaho.

EPA is proposing to incorporate by reference the authorized revisions to the Idaho hazardous waste program by revising subpart N of 40 CFR part 272. 40 CFR part 272, subpart N, § 272.651 currently incorporates by reference Idaho's authorized hazardous waste program, as amended, through 1999. Section 272.651 also references the demonstration of adequate enforcement authority, including procedural and enforcement provisions, which provide the legal basis for the State's implementation of the hazardous waste management program. In addition, § 272.651 references the Memorandum of Agreement, the Attorney General's Statement and the Program Description which were evaluated as part of the approval process of the hazardous waste management program in accordance with Subtitle C of RCRA.

D. What Is the Effect of Idaho's Codification on Enforcement?

EPA retains the authority under statutory provisions, including but not limited to, RCRA sections 3007, 3008, 3013 and 7003, and any other applicable statutory and regulatory provisions, to undertake inspections and enforcement actions and to issue orders in all authorized States. With respect to enforcement actions, EPA will rely on Federal sanctions, Federal inspection authorities, and Federal procedures rather than the State analogues to these provisions. Therefore, the EPA is not proposing to incorporate by reference Idaho's inspection and enforcement authorities nor are those authorities part of Idaho's approved State program which operates in lieu of the Federal program. 40 CFR 272.651(b)(2) lists these authorities for informational purposes, and also because EPA considered them in determining the adequacy of Idaho's enforcement authorities. This action proposes to revise this listing for informational purposes where these authorities have changed under Idaho's revisions to State law and were considered by EPA in determining the adequacy of Idaho's enforcement authorities. Idaho's authority to inspect and enforce the State's hazardous waste management program requirements continues to operate independently under State law.

E. What State Provisions Are Not Proposed as Part of the Codification?

The public is reminded that some provisions of Idaho's hazardous waste management program are not part of the federally authorized State program. These non-authorized provisions include:

(1) Provisions that are not part of the RCRA subtitle C program because they are ''broader in scope'' than RCRA subtitle C (see 40 CFR 271.1(i));

(2) Federal rules for which Idaho is not authorized, but which have been incorporated into the State regulations because of the way the State adopted federal regulations by reference;

(3) State procedural and enforcement authorities which are necessary to establish the ability of the program enforce compliance but which do not supplant the Federal statutory enforcement and procedural authorities.

State provisions that are ''broader in scope'' than the federal program are not incorporated by reference in 40 CFR part 272. For reference and clarity, 40 CFR 272.651(b)(3) currently lists the Idaho regulatory provisions which are ''broader in scope'' than the federal program and which are not part of the authorized program being incorporated by reference. This action proposes to update that list for ''broader in scope'' provisions EPA identified in recent authorization actions for revisions to the State program. While ''broader in scope'' provisions are not part of the authorized program and cannot be enforced by EPA, the State may enforce such provisions under State law.

Idaho has adopted but is not authorized for certain sections of the Post Closure rule (Standards Applicable to Owners and Operators of Closed and Closing Hazardous Waste Management Facilities: Post-Closure Permit Requirement and Closure Process; Final Rule) promulgated by EPA on October 22, 1998 (63 FR 56710). These unauthorized sections of the Post Closure rule include the State analogs to Federal citations 40 CFR 270.1(c)(7), 40 CFR 265.121, 40 CFR 265.110(c), and 40 CFR 265.118(c)(4). Additionally, Idaho is authorized for State analogs to Federal 40 CFR 264.90(e), 264.90(f), 264.110(c), 264.112(b)(8),

264.112(c)(2)(iv), 264.118(b)(4), 264.118(d)(2)(iv), 264.140(d), 265.90(f), 265.110(d), 265.112(b)(8), 265.118(c)(5), 265.140(d), 270.1(c) introductory text, and 270.28 except where those sections reference the use of enforceable documents in the context of the Post Closure rule. Idaho did not seek, nor receive, authorization for language in those sections which state as follows: ''* * * or in an enforceable document (as defined in 270.1(c)(7).'' Therefore, these Federal amendments included in Idaho's adoption by reference at IDAPA 58.01.05.000, *et seq.*, but which are not part of the State's authorized program will not be included in this proposed codification.

F. What Will Be the Effect of the Proposed Codification on Federal HSWA Requirements?

With respect to any requirement(s) pursuant to the Hazardous and Solid Waste Amendments of 1984 (HSWA) for which the State has not yet been authorized and which EPA has identified as taking effect immediately in States with authorized hazardous waste management programs, EPA will enforce those Federal HSWA standards until the State is authorized for those provisions.

The proposed Codification does not effect Federal HSWA requirements for which the State is not authorized. EPA has authority to implement HSWA requirements in all States, including States with authorized hazardous waste management programs, until the States become authorized for such requirements or prohibitions unless EPA has identified the HSWA requirement(s) as an optional or as a less stringent requirement of the Federal program. A HSWA requirement or prohibition, unless identified by EPA as optional or as less stringent, supersedes any less stringent or inconsistent State provision which may have been previously authorized by EPA (50 FR 28702, July 15, 1985).

Some existing State requirements may be similar to the HSWA requirements implemented by EPA. However, until EPA authorizes those State requirements, EPA enforces the HSWA requirements and not the State analogs.

II. Statutory and Executive Order Reviews

This action proposes to codify EPA-authorized hazardous waste management requirements pursuant to RCRA Section 3006 and imposes no requirements other than those imposed by State law (see Supplementary Information). Therefore, this proposed action complies with applicable executive orders and statutory provisions as follows:

1. *Executive Order 12866: Regulatory Planning Review*—The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993).

2. *Paperwork Reduction Act*—This proposed action does not impose an information collection burden under the Paperwork Reduction Act.

3. *Regulatory Flexibility Act*—This action proposes to codify Idaho's authorized hazardous waste management regulations in the CFR and does not impose new burdens on small entities. After considering the economic impacts of today's proposed rule on small entities under the Regulatory Flexibility Act, I certify that this action will not have a significant economic impact on a substantial number of small entities.

4. *Unfunded Mandates Reform Act*—Because this action proposes to codify pre-existing requirements under State law which EPA already approved under 40 CFR part 271 and does not impose any additional enforceable duty beyond that required by State law or existing Federal 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).

5. *Executive Order 13132: Federalism*—Executive Order 13132 does not apply to this proposed action because it will not have federalism implications (*i.e.* 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 action proposes to codify existing authorized State hazardous waste management program requirements without altering the relationship or the distribution of power and responsibilities established by RCRA.

6. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*—Executive Order 13175 does not apply to this proposed action because this action does not have tribal implications (*i.e.*, 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).

7. *Executive Order 13045: Protection of Children from Environmental Health and Safety Risks*—This proposed action is not subject to Executive Order 13045 because it is not economically significant and it does not make decisions based on environmental health or safety risks.

8. *Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use*—This proposed action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

9. *National Technology Transfer and Advancement Act (NTTAA)*—EPA previously addressed the non-applicability of the NTTAA in its final approvals to revisions of the State's authorized hazardous waste management program. See section B of this proposed rule for the citations to the **Federal Register** for EPA's approval of revisions to the State's authorized hazardous waste management program. Section 12(d) of the NTTAA does not apply to this action.

10. *Executive Order 12988*—EPA has taken the necessary steps in this proposed action to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

List of Subjects in 40 CFR Part 272

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Incorporation by reference, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This proposed action is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: November 22, 2004.

Ronald A. Kreizenbeck,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 272 as follows:

PART 272—APPROVED STATE HAZARDOUS WASTE MANAGEMENT PROGRAMS

1. The authority citation for part 272 continues to read as follows:

Authority: Secs. 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

2. Subpart N is amended by revising § 272.651 to read as follows:

§ 272.651 Idaho State-administered program: Final authorization.

(a) Pursuant to section 3006(b) of RCRA, 42 U.S.C. 6926(b), Idaho has final authorization for the following elements as submitted to EPA in Idaho's base program application for final authorization which was approved by EPA effective on April 9, 1990. Subsequent program revision applications were approved effective on June 5, 1992, August 10, 1992, June 11, 1995, January 19, 1999, July 1, 2002, and March 10, 2004.

(b) The State of Idaho has primary responsibility for enforcing its hazardous waste management program. However, EPA retains the authority to exercise its inspection and enforcement authorities in accordance with sections 3007, 3008, 3013, 7003 of RCRA, 42 U.S.C. 6927, 6928, 6934, 6973, and any other applicable statutory and regulatory provisions, regardless of whether the State has taken its own actions, as well as in accordance with other statutory and regulatory provisions.

(c) *State statutes and regulations.* (1) The Idaho statutes and regulations cited in this paragraph are incorporated by reference as part of the hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(i) The EPA Approved Idaho Statutory Requirements Applicable to the Hazardous Waste Management Program, March 2004.

(ii) The EPA Approved Idaho Regulatory Requirements Applicable to the Hazardous Waste Management Program, March 2004.

(2) EPA considered the following statutes and regulations in evaluating the State program but is not incorporating them herein for enforcement purposes:

(i) Idaho Code (I.C.) containing the General Laws of Idaho Annotated, Title 39, Chapter 44, ''Hazardous Waste Management'', published in 2002 by the Michie Company, Law Publishers: sections 39–4404; 39–4405 (except 39–4405(8)); 39–4406; 39–4407; 39–4408(4); 39–4409(2) (except first sentence); 39–4409(3); 39–4409(4) (first sentence); 39–4410; 39–4411(1); 39–4411(3); 39–4411(6); 39–4412 through 39–4416; 39–4418; 39–4419; 39–4421; 39–4422; and 39–4423(3)(a) and (b).

(ii) Idaho Code (I.C.) containing the General Laws of Idaho Annotated, Title 39, Chapter 58, ''Hazardous Waste Facility Siting Act'', published in 2002 by the Michie Company, Law Publishers: sections 39–5804; 39–5809; 39–5810; 39–5813(2); 39–5814; 39–5816; 39–5817; and 39–5818(1).

(iii) Idaho Code (I.C.) containing the General Laws of Idaho Annotated, Volume 2, Title 9, Chapter 3, ''Public Writings'', published in 1990 by the Michie Company, Law Publishers, Charlottesville, Virginia: sections 9–337(10); 9–337(11); 9–338; 9–339; and 9–344(2).

(iv) 2002 Cumulative Pocket Supplement to the Idaho Code (I.C.), Volume 2, Title 9, Chapter 3, ''Public Writing'', published in 2002 by the Michie Company, Law Publishers, Charlottesville, Virginia: sections 9–340A, 9–340B, and 9–343.

(v) Idaho Department of Environmental Quality Rules and Regulations, Idaho Administrative Code, IDAPA 58, Title 1, Chapter 5, ''Rules and Standards for Hazardous Waste'', as published July 2002: sections 58.01.05.000; 58.01.05.356.02 through 58.01.05.356.05; 58.01.05.800; 58.01.05.850; 58.01.05.996; 58.01.05.997; and 58.01.05.999.

(3) The following statutory and regulatory provisions are broader in scope than the Federal program, are not part of the authorized program, are not incorporated by reference, and are not federally enforceable:

(i) Idaho Code containing the General Laws of Idaho Annotated, Title 39, Chapter 44, ''Hazardous Waste Management'', published in 2002 by the Michie Company, Law Publishers: sections 39–4403(6) and (14); 39–4427; 39–4428 and 39–4429.

(ii) Idaho Code containing the General Laws of Idaho Annotated, Title 39, Chapter 58, ''Hazardous Waste Siting Act'', published in 2002 by the Michie Company, Law Publishers: section 39–5813(3).

(iii) Idaho Department of Environmental Quality Rules and Regulations, Idaho Administrative Code, IDAPA 58, Title 1, Chapter 5, ''Rules and Standards for Hazardous Waste'', as published July 2002: sections 58.01.05.355; and 58.01.05.500.

(4) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region 10 and the State of Idaho (IDEQ), signed by the EPA Regional Administrator on August 1, 2001, although not incorporated by reference, is referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(5) *Statement of Legal Authority.* The ''Attorney General's Statement for Final Authorization,'' signed by the Attorney General of Idaho on July 5, 1988 and revisions, supplements and addenda to that Statement, dated July 3, 1989, February 13, 1992, December 29, 1994, September 16, 1996, October 3, 1997, April 6, 2001, and September 11, 2002, although not incorporated by reference, are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(6) *Program Description.* The Program Description, and any other materials submitted as part of the original application or as supplements thereto, although not incorporated by reference, are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

3. Appendix A to part 272, State Requirements, is amended by revising the listing for ''Idaho'' to read as follows:

Appendix A to Part 272—State Requirements

* * * * *

Idaho

(a) The statutory provisions include:

Idaho Code containing the General Laws of Idaho Annotated, Title 39, Chapter 44, ''Hazardous Waste Management'', 2002: sections 39–4402; 39–4403 (except 39–4403(6) and (14)); 39–4408(1)–(3); 39–4409(1) (except fourth and fifth sentences); 39–4409(2) (first sentence); 39–4409(4) (except first sentence); 39–4409(5); 39–4409(6); 39–4409(7); 39–4409(8); 39–4411(2); 39–4411(4); 39–4411(5); 39–4423 (except 39–4423(3)(a) and (b)); and 39–4424.

Idaho Code containing the General Laws of Idaho Annotated, Title 39, Chapter 58, ''Hazardous Waste Facility Siting Act'', published in 2002 by the Michie Company, Law Publishers: sections 39–5802; 39–5803; 39–5808; 39–5811; 39–5813(1); and 39–5818(2).

Copies of the Idaho statutes that are incorporated by reference are available from Michie Company, Law Publishers, 1 Town Hall Square, Charlottesville, VA 22906–7587.

(b) The regulatory provisions include:

Idaho Department of Environmental Quality Rules and Regulations, Idaho Administrative Code, IDAPA 58, Title 1, Chapter 5, ''Rules and Standards for Hazardous Waste'', as published on July 2002: sections 58.01.05.001; 58.01.05.002; 58.01.05.003; 58.01.05.004; 58.01.05.005; 58.01.05.006; 58.01.05.007; 58.01.05.008; 58.01.05.009; 58.01.05.010; 58.01.05.011; 58.01.05.012; 58.01.05.013; 58.01.05.014; 58.01.05.015; 58.01.05.016; 58.01.05.356.01; and 58.01.05.998, except where any of those sections reference the use of enforceable documents in the context of the Post Closure rule. Idaho did not seek, nor receive, authorization for language in those sections which states as follows: ''* * * or in an enforceable document (as defined in 270.1(c)(7).'' Therefore, these Federal amendments included in Idaho's adoption by reference at IDAPA 58.01.05.000, *et seq.*, are not part of the State's authorized program. Nor does Idaho's authorized program include the Federal regulations at 40 CFR 270.1(c)(7), 40 CFR 265.121, 40 CFR 265.110(c) or 40 CFR

265.119(c)(4) because Idaho did not seek authorization for those sections.

* * * * *

[FR Doc. 04–27028 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL SCIENCE FOUNDATION

45 CFR Part 650

RIN 3145–AA44

Minor Amendments To Rule on Inventions and Patents Resulting From Grants, Cooperative Agreements, and Contracts

AGENCY: National Science Foundation.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action would amend the NSF Patents regulation to require grantees to use an electronic reporting and management system for inventions made with NSF assistance.

DATES: Comments must reach the NSF Patent Assistant on or before February 7, 2005.

ADDRESSES: All comments should be addressed to: NSF Patent Assistant at *patents@nsf.gov* or at Office of the General Counsel, National Science Foundation 4201 Wilson Boulevard, Arlington, VA 22230.

FOR FURTHER INFORMATION CONTACT: Robin Clay Fritsch, NSF Patent Assistant, at *patents@nsf.gov* or on (703) 292–8060 (voice) or (703) 292–9041 (facsimile).

SUPPLEMENTARY INFORMATION: This amendment would revise the current NSF patent regulation published as part 650 of title 45 of the Code of Federal Regulations to require NSF awardees to use the Edison Invention Information Management System maintained by the National Institutes of Health to handle NSF-assisted inventions. This is consistent with the Foundation's requirement that all proposals seeking NSF financial assistance and all reports on NSF-assisted projects be submitted electronically.

Submit electronic comments as an ASCII file avoiding the use of special characters and any form of encryption. Identify all comments sent electronically with subject line: Comments to Proposed Rulemaking.

Determinations

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), I have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. I certify under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This rule would possibly affect the following entities, some of which may be small entities: NSF grantees, including those funded under our Small Business Innovation Research and Small Business Technology Transfer Programs, and recipients of subcontracts under NSF grants.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 601 note), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Robin Clay Fritsch, NSF Patent Assistant, on (703) 292–8060 (voice), (703) 292–9041 (facsimile), or *patents@nsf.gov.*

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. I have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. This proposed rule would not result in such an expenditure.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

I have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, and determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action''

under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designed it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

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

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

List of Subjects in 45 CFR Part 650

Government procurement, Grant programs—science and technology, Inventions and patents, Nonprofit organizations, Small businesses.

Lawrence Rudolph,

General Counsel.

Accordingly, Title 45 of the Code of Federal Regulations part 650 is proposed to be amended as follows:

PART 650—PATENTS

1. The authority citation for Part 650 continues to read as follows:

Authority: 35 U.S.C. 200–212; 42 U.S.C. 1870(e) and 1871; and the Presidential Memorandum entitled ''Government Patent Policy'', issued February 18, 1983.

§ 650.4 [Amended]

2. The Patent Rights clause set forth in § 650.4(a) is amended:

A. By removing ''SEPTEMBER, 1997'' in its heading and adding in its place, ''FEBRUARY, 2005''.

B. By removing the words ''shall be in the form of a written report'' in paragraph (c)(1) and adding in its place, ''will be submitted via the iEdison Invention Information Management System maintained by the National Institutes of Health'';

C. By removing the words ''forward to NSF'' in paragraph (f)(5) and adding in its place, ''submit electronically to NSF via the iEdison Invention Information Management System maintained by the National Institutes of Health''; and

D. By revising paragraph (l) to read:

(l) *Communications.* All communications required by this Patents Rights clause must be submitted through the iEdison Invention Information Management System maintained by the National Institutes of Health unless prior permission for another form of submission is obtained from the Patent Assistant at *patents@nsf.gov* or at Office of the General Counsel, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

3. Section 650.19 is revised to read:

§ 650.19 Electronic invention handling.

(a) Grantees must use the iEdison Invention Information Management System maintained by the National Institutes of Health to disclose NSF subject inventions. Detailed instructions for use of that system are provided at *https://s-edison.info.nih.gov/iEdison/* and should be followed for NSF subject inventions except that:

(1) All communications required must be provided electronically as a PDF or TIFF file through iEdison unless prior permission for another form of submission is obtained from the Patent Assistant.

(2) NSF does not require either an Annual Utilization Report or a Final Invention Statement and Certification.

(b) Questions on use of iEdison and requests for persmission to submit material in other forms may be sent to the NSF Patent Assistant at *patents@nsf.gov* or at Office of the General Counsel, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

[FR Doc. 04–27034 Filed 12–8–04; 8:45 am]

BILLING CODE 7555–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3612; MB Docket No. 04–287, RM–11044]

Radio Broadcasting Services; Booneville, KY

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal.

SUMMARY: The Audio Division dismisses a Petition for Rule Making filed by Eastern Kentucky Educational Radio, requesting the allotment of Channel 227A at Booneville, Kentucky as that community's first local aural transmission service. *See* 69 FR 48443, August 10, 2004. Eastern Kentucky Educational Radio nor any other party, filed comments in support of the allotment of Channel 227A to Booneville, Kentucky. It is the Commission's policy to refrain from making a new allotment to a community absent a *bona fide* expression of interest.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 04–287, adopted November 17, 2004, and released November 22, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.*

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–27042 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 69, No. 236

Thursday, December 9, 2004

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matters of Technology Options (India) Pvt. Ltd. and Shivram Rao

On Wednesday, December 1, 2004, the **Federal Register** published the November 24, 2004 Decision and Order issued by the Under Secretary of Commerce, Bureau of Industry and Security (BIS), United States Department of Commerce, in the above-referenced matters (69 FR 69887). This notice corrects certain errors in connection with the publication of the Decision and Order. There is a minor error in the address listed for the respondents, Technology Options (India) Pvt. Ltd. and Shivram Rao, on pages 69887–69888. The correct address for both the respondents is ''Plot #168, Behind Maria Mansion, CST Road, Kalina, Mumbai 400 098 India'' rather than ''Pilot #168, Behind Maria Mansion, CST Road, Kalina, Mumbai 400 098 India.''

In addition, this notice corrects two additional publication errors that appear on page 69887. In the first sentence of the second paragraph of the Decision and Order, the correct spelling of ''Indira Ghandi Centre for Atomic Research'' is ''Indira Gandhi Centre for Atomic Research.'' Also in the same sentence, the correct spelling of ''mechanical fatigue rest system'' is ''mechanical fatigue test system.''

While the Administrative Law Judge's (ALJ) October 27, 2004 Recommended Decision and Order concerning Technology Options (India) Pvt. Ltd. (Docket # 04–BIS–02) was published as an attachment to the Under Secretary's Decision and Order, the October 27, 2004 Recommended Decision and Order of the ALJ concerning the second respondent, Shivram Rao (Docket # 04–BIS–03), was inadvertently not published. The Recommended and Decision Order of the ALJ related to Shivrm Rao, a portion of which has been redacted, shall hereby be published in the **Federal Register**.

Dated: December 3, 2004.

Kenneth I. Juster,

Under Secretary for Industry and Security.

Recommended Decision and Order on Motion for Default Order

[Docket No. 04–BIS–03]

On February 2, 2004, the Bureau of Industry and Security, United States Department of Commerce (BIS), issued a charging letter initiating this administrative enforcement proceeding against Shivram Rao (''RAO''). The charging letter alleged that Rao committed one violation of Section 764.2(d), one violation of Section 764.2(g), and two violations of Section 764.2(h) of the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (2004)) (the ''Regulations''),[1] issued under the Export Administration Act of 1979, as amended (50 USC app. §§ 2401–2420 (2000)) (the ''Act'').[2] In accordance with Section 766.7 of the Regulations, BIS moved for the issuance of an Order of Default against Rao, as Rao has not answered or otherwise responded to the charging letter as required by the Regulations.

A. Legal Basis for Issuing an Order of Default

Section 766.7 of the Regulations state that BIS may file a Motion for an Order of Default if a respondent fails to file a timely Answer to a charging letter. That section, entitled ''Default,'' provides in pertinent part:

Failure of the respondent to file an answer within the time provided constitutes a waiver of the respondent's right to appear and contest the allegations in the charging letter. In such event, the administrative law judge, on BIS's motion and without further notice to the respondent, shall find the facts to be as alleged in the charging letter and render an initial or recommended decision containing findings of fact and appropriate conclusions of law and issue or recommend an order imposing appropriate sanctions.

15 CFR Part 766.7 (2004):

Pursuant to Section 766.7 of the Regulations, a respondent must file an Answer to the charging letter ''within 30 days after being served with notice of the issuance of the charging letter'' initiating the proceeding.

B. Service of the Charging Letter

Section 766.3(b)(1) of the Regulations provides that notice of issuance of a charging letter shall be served on a respondent by mailing copy via registered or certified mail addressed to the respondent at the respondent's last known address. In accordance with that section, on February 2, 2004, BIS sent a notice of issuance of the charging letter by registered mail to Respondent Rao, at his last known address: Technology Options (India) Pvt. Ltd., Plot #168, Behind Maria Mansion, CST Road, Kalina, Mumbai 400 098, India. BIS also submitted evidence establishing that on February 2, 2004, BIS submitted evidence establishing that on February 16, 2004, Technology Options received the notice of issuance of a charging letter. These actions constitute service under the Regulations.

Section 766.6(a) of the regulations provides, in pertinent part, that ''[t]he respondent must answer the charging letter within 30 days after being served with notice of issuance of the charging letter[.]'' Since service was effected on February 16, 2004, Rao's Answer to the charging letter was due no later than March 16, 2004. Rao did not file an Answer to the Charging letter nor did Rao request an extension of time to answer the Charging letter under Section 766.16(b)(2). Accordingly, because Rao failed to answer or otherwise respond to the charging letter within thirty days from the date he received the notice of issuance of the charging letter, as required by Section 766.66 of the Regulations, Rao is in default.

[1] The violations charged occurred in 2000 and 2001. The Regulations governing the violations at issue are found in the 2000 and 2001 versions of the Code of Federal Regulations (15 CFR parts 730–774 (2000–2001)). The 2004 Regulations establish the procedures that apply to this matter.

[2] From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 CFR, 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706 (2000)) (IEEPA). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 6, 2004 (69 FR, 48763, August 10, 2004), has continued the Regulations in effect under IEEPA.

C. Summary of Violations

The charging letter filed by BIS included a total of four charges. Specifically, the charging letter alleged that from on or about April 1, 2000, through on or about August 31, 2001, Rao conspired with others, known and unknown, to export from the United States to the Indira Gandhi Centre for Atomic Research (''IGCAR'') a thermal mechanical fatigue test system (''fatigue test system'') and a universal testing machine, both items subject to the Regulations, without a BIS export license as required by Section 744.11 of the Regulations. *See* Gov't Ex. 3. At all relevant times, IGCAR was an organization listed on the Entity List set forth at Supplement No. 4 to Part 744 of the Regulations (''Entity List'').[3] In furtherance of the conspiracy, false documentation was submitted to the United States exporter that provided that a party other than IGCAR was the ultimate consignee for the items to be exported from the United States.

The charging letter further alleged that on or about June 13, 2000, in connection with the export of the fatigue test system and attempted export of the universal testing machine, Rao took actions to evade the Regulations. Specifically, Rao, with others, known and unknown, developed and employed a scheme by which the company with which Rao was affiliated, Technology Options (India) Pvt. Ltd. (''Technology Options''), would receive the export of the fatigue test system from the United States without a BIS license and then divert it to the true ultimate consignee, IGCAR, in violation of the Regulation.

The charging letter also alleged that on or about August 16, 2001, through on or about April 8, 2002, in connection with the export of the fatigue test system references above, Rao made false statements to the U.S. Government regarding its knowledge of an involvement in the export. Specifically, Rao made misleading and false statements to U.S. Foreign Commercial Service officers regarding the end user of the fatigue test system.

Pursuant to the default procedures set forth in Section 766.7 of the Regulations, I find the facts to be as alleged in the charging letter, and hereby determine that those facts establish that Rao committed one violations of Section 764.2(d), one violation of Section 764(g), and two violations of 764.2(h) of the regulations.

[3] The persons on the Entity List are end-users who have been determined to present an unacceptable risk of diversion to the development of weapons of mass destruction or the missiles used to delivery such weapons.

Section 764.3 of the Regulations estalbishes the sanctions that BIS may seek for the violations charged in this proceeding. The applicable sanctions are a civil monetary penalty, suspension from practice before the Department of Commerce, and a denial of export privileges under the Regulations. *See* 15 CFR Part 764.3 (2004).

Because Rao violated the Regulations by conspiring and engaging in transactions to evade the Regulations, BIS requests that I recommend to the Under Secretary of Commerce for Industry and Security[4] that Rao's export privileges be denied for fifteen (15) years. BIS has suggested this sanction because Rao has demonstrated a severe disregard for U.S. export control laws. Further, BIS believes that imposition of a civil penalty in this case may be ineffective, given the difficulty of collecting payment against a party outside of the United States. In light of these circumstances, BIS believes that the denial of Rao's export privileges for fifteen (15) years is an appropriate sanction.

Given the foregoing, I concur with BIS and recommend that the Under Secretary enter an Order denying Rao's export privileges for a period of fifteen (15) years.

The terms of the denial of export privileges against Rao should be consistent with the standard language used by BIS in such order. The language is:

[Portions of this Recommended Decision have been REDACTED]

Accordingly, I am referring this Recommended Decision and Order to the Under Secretary for review and final action for the agency, without further notice to the Respondent, as provided in Section 766.7 of the Regulations.

Within 30 days after receipt of this Recommended Decision and Order, the Under Secretary shall issue a written order affirming, modifying, or vacating the Recommended Decision and Order. *See* 15 CFR 766.22(c).

Done and dated this 27th of October at Baltimore, MD.

Joseph N. Ingolia,
Chief Administrative Law Judge.

Certificate of Service

I hereby certify that I served the Recommended Decision and Order by Federal Express to the following person:

Shivram Rao, Technology Options (India) Pvt. Ltd., Pilot #168, Behind Maria Mansion, CST Road, Kalina, Mumbai 400 098, India.

Done and dated this 28th day of October 2004, at Baltimore, Maryland.

Alyssa L. Paladino,

Law Clerk, ALJ Docketing Center, U.S. Coast Guard.

[FR Doc. 04–27059 Filed 12–8–04; 8:45 am]

BILLING CODE 3510–33–M

[4] Pursuant to Seciton 13(c)(1) of the Act and Section 766.17(b)(2) of the Regulations, in export control enforcement cases, the Administrative Law Judge makes recommended findings of fact and conclusions of law that the Under Secretary must affirm, modify or vacate. The Under Secretary's actions is the final decision for the agency.

DEPARTMENT OF COMMERCE

International Trade Administration

U.S. Microelectronics Trade Mission

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice to U.S. Microelectronics Trade Mission to Shanghai, China, March 14–17, 2005.

SUMMARY: The United States Department of Commerce, International Trade Administration, U.S. Commercial Service, Office of Global Trade Programs is organizing a microelectronics trade mission to China, March 14–17, 2005. This trade mission will take place during the renowned annual Shanghai exhibition Electronica and Productronica China 2005—co-located with SEMICON China. Participating firms will not only have pre-arranged one-on-one meetings scheduled for them by the U.S. Commercial Service in Shanghai, but will also have the opportunity to make additional business contacts at the exhibition. A similar microelectronics mission took place in March 2004.

FOR FURTHER INFORMATION CONTACT: Office of Global Trade Programs; Room 2012; Department of Commerce; Washington, DC 20230; Tel: (202) 482–4457; Fax: (202) 482–0178.

SUPPLEMENTARY INFORMATION: U.S. Microelectronics Trade Mission, Shanghai, China, March 14–17, 2005.

Mission Statement

I. Description Of The Mission

The United States Department of Commerce, International Trade Administration, U.S. Commercial Service, Office of Global Trade Programs is organizing a microelectronics trade mission to China, March 14–17, 2005. This trade mission will take place during the renowned annual Shanghai exhibition Electronica and Productronica China 2005—co-located with SEMICON China. Participating firms will not only have pre-arranged one-on-one meetings scheduled for

them by the U.S. Commercial Service in Shanghai, but will also have the opportunity to make additional business contacts at the exhibition. A similar microelectronics mission took place in March 2004.

Trade mission participants will include representatives from U.S. firms specializing in microelectronics design, manufacturing, and distribution, including semiconductor devices, integrated circuit design services, semiconductor manufacturing equipment, clean room equipment, and electronics packaging/interconnects.

II. Commercial Setting for the Mission

Microelectronics design, manufacturing, and distribution make the foundation for the rapid growth of e-commerce, web-enabled technologies, and wireless technologies that will be the major business prospects in the 21st century in Asia. Representing one of the largest and fastest growing information technology (IT) markets in the world, China's electronics sector and IT industry are expected to grow at an annual rate of 25 percent. The Chinese Government is strongly committed to the development of a domestic microelectronics industry to enable the adoption of IT nationwide and to improve economic productivity. China's tenth Five-Year Plan (2001–2005) addresses the development of the country's information industry (including microelectronics). These development trends indicate that China is emerging as a new and strong production base for electronic and IT products in Asia. With this rapid growth in the IT sector, China is forced to build its strong microelectronics industry primarily on imports and investment from foreign suppliers. Shanghai, Beijing, and Hong Kong are among the cities that lead China's IT industry growth.

III. Goals for the Mission

The goal is to assist U.S. microelectronics industry's small- to medium-sized enterprises (SMEs) in attaining their export business objectives in the Chinese market through participation in this trade mission, which will be centered around a major exhibition. Mission participants will gain first-hand market exposure; meet with government decision makers and potential agents, distributors, and business partners from the private sector; and obtain information that will help them position themselves to take advantage of the strong business opportunities in China's microelectronics market.

IV. Scenario for the Mission

The mission will focus primarily on Shanghai. The schedule includes site visits, and briefings by the U.S. and Chinese governments. The purpose of the site visits will be to provide a broad vision of the Chinese electronics/semiconductor industry, which will help the participants to better understand the Chinese market. China government briefings will bring the participants into the government's presence and acquaint them with trade opportunities available to them from the Chinese government's perspective. A SEMICON forum, which all of the participants will be invited to attend, will also be on the agenda. The dates of the trade exhibition are March 15–17. The U.S. Commercial Service in Shanghai will set aside time for pre-arranged individual business meetings for the mission participants. In addition, the participants will have the opportunity to conduct business with exhibitors at the show, as well as display company literature in a booth at the exhibition. No other types of exhibition items may be displayed. A hospitality reception for the participants will be held the evening of March 17.

Timetable

Saturday, March 12—Arrive Shanghai (optional); activities open
Sunday, March 13—Arrive Shanghai (optional); activities open
Monday, March 14—Breakfast briefing for participants with Commercial Service Shanghai staff; High-tech industry park meetings and/or site tours
Tuesday, March 15—SEMI association market briefing in morning; Attend exhibition in afternoon
Wednesday, March 16—Meeting with Shanghai government authorities and/or site visits in morning; Attend exhibition in afternoon
Thursday, March 17—Individual one-on-one meetings; Hospitality reception in evening
Friday, March 18—Participants may wish to have follow-up business visits/appointments, or depart for the U.S.
Saturday, March 19—Participants will depart for the United States

V. Criteria for Participant Selection

- Relevance of the company's business line to mission's scope and goals;
- Potential for business in the China market;
- Timeliness of the company's signed and completed application and participation agreement, and payment of the mission participation fee of $2,250 for the first company representative, and $500 each for additional representatives;
- Provision of adequate information on the company's products and/or services and communication of the company's primary objectives to facilitate appropriate matching with potential business partners;
- Certification that the company meets Departmental guidelines for participation, including certification that the company's products and/or services are manufactured or produced in the United States or if manufactured/produced outside the of the United States, the product/services must be marketed under the name of the U.S. firm and have U.S. content of at least fifty-one percent of the value of the finished good or service.

A minimum of eight and a maximum of twenty participating companies will be recruited in an open and public manner, including publication in the **Federal Register**; posting on the Internet; press releases to general and trade media; direct mail and broadcast fax; and notices by industry trade associations and other multiplier groups, and at industry meetings, symposiums, conferences, and trade shows.

Any partisan political activities (including political contributions) of an applicant are entirely irrelevant to the selection process. The $2,250 trade mission participation fee does not include the cost of travel, lodging and meals. Recruitment will begin immediately and will close on January 21, 2005.

Contact

Ms. Marlene Ruffin, Global Trade Programs, U.S. & Foreign Commercial Service, Room 2107, U.S. Department of Commerce, Washington, DC 20230, Phone: (202) 482–0570; Fax: (202) 482–0115; e-mail: *Marlene.Ruffin@mail.doc.gov.*

Dated: December 2, 2004.

Nancy Hesser,

Industry Sector Manager, Office of Trade Event Programs.

[FR Doc. E4–3588 Filed 12–8–04; 8:45 am]

BILLING CODE 3510–DR–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of an Import Limit for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in the People's Republic of China

December 3, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection adjusting a limit.

EFFECTIVE DATE: December 9, 2004.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Bureau of Customs and Border Protection website (*http://www.cbp.gov*), or call (202) 344–2650. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at *http://otexa.ita.doc.gov*.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limit for Group I is being increased for carryover.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 69 FR 4926, published on February 2, 2004). Also see 68 FR 65445 published on November 20, 2003.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 3, 2004.

Commissioner,
Bureau of Customs and Border Protection, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 14, 2003, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in China and exported during the twelve-month period which began on January 1, 2004 and extends through December 31, 2004.

Effective on December 9, 2004, you are directed to increase the limit for Group I, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Group I 200, 218, 219, 226, 237, 239pt. [2], 300/301, 313–315, 317/326, 331pt. [3], 333–336, 338/339, 340–342, 345, 347/348, 351, 352, 359–C [4], 359–V [5], 360–363, 410, 433–436, 438, 440, 442–444, 445/446, 447, 448, 611, 613–615, 617, 631pt. [6], 633–636, 638/639, 640–643, 644, 645/646, 647, 648, 651, 652, 659–C [7], 659–H [8], 659–S [9], 666pt. [10], 845 and 846, as a group.	1,218,629,752 square meters equivalent.

[1] The limit has not been adjusted to account for any imports exported after December 31, 2003.

[2] Category 239pt.: only HTS number 6209.20.5040 (diapers).

[3] Category 331pt.: all HTS numbers except 6116.10.1720, 6116.10.4810, 6116.10.5510, 6116.10.7510, 6116.92.6410, 6116.92.6420, 6116.92.6430, 6116.92.6440, 6116.92.7450, 6116.92.7460, 6116.92.7470, 6116.92.8800, 6116.92.9400 and 6116.99.9510.

[4] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010.

[5] Category 359–V: only HTS numbers 6103.19.2030, 6103.19.9030, 6104.12.0040, 6104.19.8040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.9044, 6110.90.9046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.9030, 6204.12.0040, 6204.19.8040, 6211.32.0070 and 6211.42.0070.

[6] Category 631pt.: all HTS numbers except 6116.10.1730, 6116.10.4820, 6116.10.5520, 6116.10.7520, 6116.93.8800, 6116.93.9400, 6116.99.4800, 6116.99.5400 and 6116.99.9530.

[7] Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[8] Category 659–H: only HTS numbers 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090.

[9] Category 659–S: only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[10] Category 666pt.: all HTS numbers except 5805.00.4010, 6301.10.0000, 6301.40.0010, 6301.40.0020, 6301.90.0010, 6302.53.0010, 6302.53.0020, 6302.53.0030, 6302.93.1000, 6302.93.2000, 6303.12.0000, 6303.19.0010, 6303.92.1000, 6303.92.2010, 6303.92.2020, 6303.99.0010, 6304.11.2000, 6304.19.1500, 6304.19.2000, 6304.91.0040, 6304.93.0000, 6304.99.6020, 6307.90.9884, 9404.90.8522 and 9404.90.9522.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
James C. Leonard III,
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc.E4–3589 Filed 12–8–04; 8:45 am]

BILLING CODE 3510–DS–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Wool Textile Products Produced or Manufactured in Romania

December 3, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection adjusting limits.

EFFECTIVE DATE: December 9, 2004.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Bureau of Customs and Border Protection website (*http://www.cbp.gov*), or call (202) 344-2650. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at *http://otexa.ita.doc.gov*.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limit for Category 443 is being increased for the undoing of special shift, reducing the limit for Category 447/448 to account for the special shift being returned to Category 443.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 69 FR 4926,

published on February 2, 2004). Also see 68 FR 55037, published on September 22, 2003.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 3, 2004.

Commissioner, Bureau of Customs and Border Protection,
Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on September 16, 2003, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, and man-made fiber textiles and textile products in the following categories, produced or manufactured in Romania and exported during the twelve-month period which began on January 1, 2004 and extends through December 31, 2004.

Effective on December 9, 2004, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
443	53,164 numbers.
447/448	32,808 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2003.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
James C. Leonard III,
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E4–3592 Filed 12–8–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0025]

Federal Acquisition Regulation; Submission for OMB Review; Buy American Act-Trade Agreements Act Certificate

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding extension to an existing OMB clearance (9000–0025).

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 the Buy American Act-Trade Agreements Act Certificate. A request for public comments was published at 69 FR 53685 on September 2, 2004. 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 January 10, 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 (V), 1800 F Street, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT Cecelia Davis, Contract Policy Division, GSA (202) 219–0202.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the Trade Agreements Act of 1979, unless specifically exempted by statute or regulation, agencies are required to evaluate offers over a certain dollar limitation not to supply an eligible product without regard to the restrictions of the Buy American. Offerors identify excluded end products on this certificate.

The contracting officer uses the information to identify the offered items which are domestic end products. Items having components of unknown origin are considered to have been mined, produced, or manufactured outside the United States or a designated country of the Act.

B. Annual Reporting Burden

Respondents: 1,140.
Responses Per Respondent: 10.
Total Responses: 11,400.
Hours Per Response: .167.
Total Burden Hours: 1,238.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (V), 1800 F Street, NW, Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0025, Buy American Act,-Trade Agreements Act Certificate, in all correspondence.

Dated: November 30, 2004

Laura Auletta

Director, Contract Policy Division.

[FR Doc. 04–26999 Filed 12–8–04; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0024]

Federal Acquisition Regulation; Submission for OMB Review; Buy American Act Certificate

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance (9000–0024).

SUMMARY: Under the provision 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 Buy American Act Certificate. A request for public comments was published at 69 FR 53421, September 1, 2004. 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 January 10, 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 (V), 1800 F Street, NW., Room 4035, Washington, DC 20405. Please cite OMB Control No. 9000–0024, Buy American Act Certificate, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Cecelia Davis, Contract Policy Division, GSA (202) 219–0202.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Buy American Act requires that only domestic end products be acquired for public use unless specifically authorized by statute or regulation, provided that the cost of the domestic products is reasonable.

The Buy American Act Certificate provides the contracting office with the information necessary to identify which products offered are domestic end products and which are of foreign origin. Components of unknown origin are considered to have been supplied from outside the United States.

B. Annual Reporting Burden

Respondents: 3,906.

Responses per Respondent: 15.

Total Responses: 58,590.

Hours per Response: .109.

Total Burden Hours: 6,361.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (V), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0024, Buy American Certificate, in all correspondence.

Dated: November 30, 2004.

Laura Auletta,

Director, Contract Policy Division.

[FR Doc. 04–27000 Filed 12–8–04; 8:45 am]

BILLING CODE 6820–EP–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0097]

Federal Acquisition Regulation; Submission for OMB Review; Information Reporting to the Internal Revenue Service (IRS) (Taxpayer Identification Number)

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance (9000–0097).

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 information reporting to the Internal Revenue Service (IRS) (taxpayer identification number). A request for public comments was published at 69 FR 53421 on September 1, 2004. 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 January 10, 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 (VR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No. 9000–0097, Information Reporting to the Internal Revenue Service (IRS) (Taxpayer Identification Number), in all correspondence.

FOR FURTHER INFORMATION CONTACT: Gerald Zaffos, Contract Policy Division, GSA (202) 208–6091.

SUPPLEMENTARY INFORMATION:

A. Purpose

Subpart 4.9, Information Reporting to the Internal Revenue Service (IRS), and the provision at 52.204–3, Taxpayer Identification, implement statutory and regulatory requirements pertaining to taxpayer identification and reporting.

B. Annual Reporting Burden

Respondents: 250,000.
Responses Per Respondent: 2.
Total Responses: 500,000.
Hours Per Response: .10.
Total Burden Hours: 50,000.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VR), Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0097, Information Reporting to the Internal Revenue Service (IRS) (Taxpayer Identification Number), in all correspondence.

Dated: November 30, 2004

Laura Auletta

Director, Contract Policy Division.

[FR Doc. 04–27002 Filed 12–8–04; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7321–018]

Erie Boulevard Hydropower, L.P.; Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and a Deadline or Submission of Final Amendments

December 3, 2004.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent license.

b. *Project No.:* 7321–018.

c. *Date Filed:* November 26, 2004.

d. *Applicant:* Erie Boulevard Hydropower, L.P.

e. *Name of Project:* Macomb Project.

f. *Location:* On the Salmon River in Franklin County, near Malone, New York. The project does not occupy Federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Jerry L. Sabattis, Erie Boulevard Hydropower, L.P., 225 Greenfield Parkway, Suite 201, Liverpool, NY 13088, (315) 413–2787.

i. FERC Contact: John Smith, (202) 502-8972 or *john.smith@ferc.gov.*

j. Cooperating Agencies: We are asking Federal, State, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in item l below.

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: January 24, 2005.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests and requests for cooperating agency status may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''eFiling'' link.

m. This application is not ready for environmental analysis at this time.

n. The existing Macomb Project consists of: (1) A 106-foot-long, 32-foot-high concrete gravity overflow-type dam having a spillway crest elevation of 570.7 feet above mean sea level; (2) a 38-foot-long, 25-foot-high intake structure along each bank; (3) a 6-foot-diameter, 60-foot-long, riveted-steel, gated waste tube along each bank; (4) a 14-acre reservoir with a net storage capacity of 14 acre-feet at the spillway crest elevation; (5) a 6.5-foot-diameter, 60-foot-long, riveted-steel, concrete-encased, gated pipeline along the left (south) bank; (6) a powerhouse containing one 1,000-kilowatt horizontal Francis turbine; (7) a 370-foot-long, 34.5-kilovolt transmission line; and (8) appurtenant facilities. The applicant estimates that the total average annual generation would be 5,660 megawatthours.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. With this notice, we are initiating consultation with the New York State Historic Preservation Officer (SHPO), as required by Section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. Procedural schedule and final amendments: The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Acceptance or Deficiency Letter, January 2005
Issue Scoping Document, February 2005
Notice of application is ready for environmental analysis, May 2005
Notice of the availability of the EA, November 2005
Ready for Commission's decision on the application, December 2005

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3563 Filed 12–8–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Settlement Agreement and Soliciting Comments

December 3, 2004.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement agreement on new license application.

b. *Project No.:* 2150–033.

c. *Date Filed:* November 30, 2004.

d. *Applicant:* Puget Sound Energy.

e. *Name of Project:* Baker River Project.

f. *Location:* On the Baker River, near the Town of Concrete, in Whatcom and Skagit Counties, Washington. The project occupies about 5,207 acres of lands within the Mt. Baker-Snoqualmie National Forest managed by the U.S. Forest Service.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602

h. *Applicant Contact:* Connie Freeland, Puget Sound Energy, P.O. Box 97034 PSE–09S Bellevue, WA 98009–9734; (425) 462–3556 or *connie.freeland@pse.com.*

i. *FERC Contact:* Steve Hocking, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426; (202) 502–8753 or *steve.hocking@ferc.gov.*

j. *Deadline for filing comments:* December 23, 2004. Reply comments: January 3, 2005.

All documents (original and eight copies) must be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please put the project name ''Baker River Project'' and project number ''P–2150–033'' on the first page of all documents.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's Web site *http://www.ferc.gov* under the ''e-Filing'' link.

k. The Baker River Project has two developments. The Upper Baker development consists of the following existing facilities: (1) A 312-foot-high by 1,200-foot-long concrete gravity dam impounding Baker Lake with a surface area of about 4,980 acres at a normal full pool elevation of 727.77 feet mean sea level (msl); (2) a 122-foot-long, 59-foot wide concrete and steel powerhouse at the base of the dam containing two turbine-generator units, Unit No. 1 with an authorized capacity of 52,400 kilowatts (kW) and Unit No. 2 with an authorized capacity of 38,300 kW; (3) a 115-foot-high by 1,200-foot-long earth and rock-fill dam, known as West Pass dike, located in a depression about 1,500 feet north of Upper Baker dam; (4) a 22-foot-high by 3,000-foot-long earth-filled dike, known as Pumping Pond dike, which impounds Depression Lake with a surface area of 44 acres at a normal full pool elevation of 699 feet msl; (5) a water recovery pumping station adjacent to Pumping Pond; (6) fish passage facilities and fish spawning facilities; and (7) appurtenant facilities.

The Lower Baker development consists of the following existing facilities: (1) A 285-foot-high by 550-foot-long concrete thick arch dam impounding Lake Shannon with a surface area of about 2,278 acres at a normal full pool elevation of 442.35 feet msl; (2) a concrete intake equipped with trashracks and gatehouse located at the dam's left abutment; (3) a 1,410-foot-long concrete and steel-lined pressure tunnel; (4) a concrete surge tank near the downstream end of the pressure tunnel; (5) a 90-foot-long, 66-foot-wide concrete and steel powerhouse containing one turbine-generator unit, Unit No. 3 with an authorized capacity of 79,330 kW; (6) a 750-foot-long, 115-kilovolt transmission line; (7) fish passage facilities including a 150-foot-long by 12-foot-high barrier dam; and (8) appurtenant facilities.

l. A copy of the settlement agreement is available for review in the Commission's Public Reference Room or may be viewed on the Commission's Web site *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3565 Filed 12–8–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER03–1102–003, ER03–1102–004, EL05–14–000]

California Independent System Operator Corporation; Notice of Technical Conference

December 3, 2004.

Take notice that a technical conference will be held on Wednesday, January 12, 2005, and Thursday, January 13, 2005, beginning at 9 a.m. (e.s.t.), in Room 3M–2B at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Pursuant to the Commission's October 28, 2004, Order,[1] the technical conference will afford the parties an opportunity to discuss the California Independent System Operator Corporation's (CAISO) proposed ''self-certification'' process and any party's alternate proposal on how best to achieve the CAISO's objective based upon the presentation of proposals at the technical conference. All proposals must be submitted within 30 days of the date of this notice. Parties must be prepared to discuss their proposals at the technical conference.

All interested persons and staff are permitted to attend.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3566 Filed 12–8–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Errata Notice

December 3, 2004.

In the matter of: 11978–002, 12037–001, 12191–001, 12195–001, 12226–001, 12237–001, 12242–001, 12243–001, 12263–001, 12268–001, 12277–001, 12278–001, 12281–001, 12294–001, 12364–002, and 12417–001; Symbiotics, LLC, Symbiotics, LLC, Prosser Creek Hydro, LLC, McCloud Hydro, LLC, Gillham Hydro, LLC, Nimrod Hydro, LLC, San Jacinto Hydro, LLC, Spavinaw Hydro, LLC, Great Salt Plains, LLC, Wappapello Hydro, LLC, GV Montgomery Hydro, LLC, KR 6 Hydro, LLC, Wilkins Hydro, LLC, Huntington Hydro, LLC, Rough River Hydro, LLC, Coralville Hydro, LLC.

On December 1, 2004, the Commission issued a ''Notice of Surrender of Preliminary Permits'' on December 1, 2004, in the above-reference docket numbers. This Errata Notice corrects the project number for Gillham Hydro, to read: 12226–001.

This correction is reflected in the caption above.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3564 Filed 12–8–04; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

OPP–2004–[0401]; FRL–7689–5

Pesticide Program Dialogue Committee, Pesticide Registration Improvement Act Process Improvement Workgroup; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Pesticide Program Dialogue Committee (PPDC), Pesticide Registration Improvement Act (PRIA) Process Improvement Workgroup will hold a public meeting on January 25, 2005. An agenda for this meeting is being developed and will be posted on EPA's website. The workgroup is developing advice and recommendations on topics related to EPA's registration process.

DATES: The meeting will be held on Tuesday, January 25, 2005 from 1:00 p.m. to 4 p.m.

ADDRESSES: The meeting will be held at EPA's Offices at 1801 S. Bell Street, Crystal Mall #2, Rm. 1126, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Rick Keigwin, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7618; fax number: (703) 308–4776; e-mail address: *keigwin.richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

[1] *California Indep. Sys. Operator Corp.*, 109 FERC ¶ 61,087 at P 52 (2004).

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 persons who are concerned about implementation of the Pesticide Registration Improvement Act (PRIA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug, and Cosmetic Act (FFDCA). Other potentially affected entities may include but are not limited to agricultural workers and farmers; pesticide industry trade associations; envrionmental, consumer and farmworker groups; pesticide users and growers; pest consultants; State, local and Tribal governments; academia; public health organizations; food processors; and the public. 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 anyquestions 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–2004–0401. 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

The Office of Pesticide Programs (OPP) is entrusted with the responsibility of ensuring the safety of the American food supply, protection and education of those who apply or are exposed to pesticides occupationally or through use of products, and the general protection of the environment and special ecosystems from potential risks posed by pesticides.

PPDC was established under the Federal Advisory Committee Act (FACA), Public Law 92-463, in September 1995 for a 2-year term and has been renewed every 2 years since that time. PPDC provides advice and recommendations to OPP on a broad range of pesticide regulatory, policy, and program implementation issues that are associated with evaluating and reducing risks from use of pesticides. The following sectors are represented on the PPDC: Pesticide industry and trade associations; environmental/public interest and consumer groups; farm worker organizations; pesticide user, grower, and commodity groups; Federal and State/local/Tribal governments; the general public; academia; and public health organizations. Copies of the PPDC charter are filed with appropriate committees of Congress and the Library of Congress and are available upon request.

List of Subjects

Environmental protection, Pesticides and pests

Dated: November 30, 2004.

Martha Monell

Acting Director, Office of Pesticide Programs.

[FR Doc. 04–27033 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0386; FRL–7687–8]

Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine ethyleneimine polymer; 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–2004–0386, must be received on or before January 10, 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: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: *gandhi.bipin@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 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–2004–0386. 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–2004–0386. 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–2004–0386. 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–2004–0386.

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–2004–0386. 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, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 30, 2004.

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 Cognis 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.

Cognis Corporation

PP 4E6868

EPA has received a pesticide petition (4E6868) from Cognis Corporation, 4900 Este Avenue, Cincinnati, OH 45234 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.960 to establish an exemption from the requirement of a tolerance for amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer, (CAS Reg. No. 192230–19–6) in or on all raw agricultural commodities when used as an inert ingredient in the pesticide formulations. 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*. Cognis is petitioning the Agency to exempt amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer from the requirement of a tolerance since this inert ingredient meets the exemption criteria for low-risk polymers under 40 CFR 723.250. Consequently, plant metabolism data are not necessary.

2. *Analytical method*. Since the petitioner is requesting a tolerance exemption, an analytical method for residues of the polymer in or on food crops is not required.

B. Toxicological Profile

When it can be determined that an inert ingredient meets the definition of an exempt or low-risk polymer (40 CFR 723.250) then the production of data is generally not required by EPA to establish a tolerance or an exemption from a tolerance. Cognis Corporation asserts that the data and information provided below are sufficient to establish the potential activity, toxicity and risks associated with amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer as an inert ingredient when applied to growing crops or raw agricultural commodities. Further, in the case of chemical substances described as polymers, EPA has established criteria, which when they are met or exceeded, are considered low-risk. These criteria are described in 40 CFR 723.250 and identify polymers that are relatively unreactive, stable, and typically not absorbed when compared to other chemical substances including some polymers.

The criteria described in 40 CFR 723.250, and addressed below, will generally exclude polymer chemicals that are not well-known and understood, and potentially present a significant risk of adverse effects. Therefore, the polymers that meet or exceed these criteria can be considered minimal or negligible risk.

As presented below, amides, from acetic acid, C5–9 carboxylic acids and

diethylenetriamine-ethyleneimine polymer conforms to the definition of a low-risk polymer as described in 40 CFR 723.250.

a. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

b. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer contain as the integral part of its composition, the atomic elements of hydrogen, oxygen, nitrogen, and carbon.

c. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer do not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

d. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are not designed nor reasonably anticipated to substantially depolymerize, degrade, or decompose.

e. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are manufactured from monomers that are listed in the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

f. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are not a water absorbing polymer.

g. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer do not contain any reactive functional groups.

h. The minimum number-average molecular weight of amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer is approximately 1,400 daltons. Substances with molecular weights greater than 400 daltons are generally not absorbed through the intact skin, and substances with molecular weights greater than 1,000 daltons are generally not absorbed through the intact gastrointestinal (GI). Chemicals not absorbed through the GI tract are incapable of eliciting a toxic response via these routes of exposure.

i. Amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer contain less than 10% oligomeric material below molecular weight of 500 daltons and less than 25% oligomeric material below 1,000 daltons.

C. Aggregate Exposure

1. *Dietary exposure.* Since amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are considered a low-risk polymer, there is a reasonable certainty of no harm from exposure to this polymer from food or drinking water or from aggregate exposure.

2. *Non-dietary exposure.* Since amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are considered a low-risk polymer, there is a reasonable certainty of no harm from exposure to this polymer from non-dietary means.

D. Cumulative Effects

At this time, there is no information to indicate that any toxic effects produced by amides, from acetic acid, C5-9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are cumulative with those of any other chemical. Given the compound's categorization as a low-risk polymer, and its proposed use in pesticide formulations, there is no expectation of increased risk due to cumulative exposure.

E. Safety Determination

1. *U.S. population.* Since amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are considered a low-risk polymer, no adverse effects of concern to the U.S. population are expected.

2. *Infants and children.* Since amides, from acetic acid, C5–9 carboxylic acids and diethylenetriamine-ethyleneimine polymer are considered a low-risk polymer, no adverse effects of concern to either infants or children are anticipated.

F. International Tolerances

There are no Codex maximum residue levels established for residues of amides, from acetic acid, C5-9 carboxylic acids and diethylenetriamine-ethyleneimine polymer in or on crops or commodities at this time.

[FR Doc. 04–27032 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7846–3]

Proposed CERCLA Section 122(h) Administrative Agreement for the Bayonne Barrel & Drum Site, Located in Newark, NJ

AGENCY: Environmental Protection Agency.

ACTION: Notice of Proposed Administrative Settlement and opportunity for public comment.

SUMMARY: The United States Environmental Protection Agency (EPA) is proposing to enter into an administrative settlement to resolve certain claims under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). Notice is being published to inform the public of the proposed settlement and of the opportunity to comment.

The settlement requires thirty-seven (37) Settling Parties to make three payments to resolve their liability for EPA's Past Response Costs, defined as those costs incurred through January 31, 2003. The first payment, $500,000, is due within 30 days of the Agreement's effective date. The second, $300,000, is due by January 31, 2005. The third and final payment is due within 540 days of the Agreement's effective date, and will consist of the balance of the Past Response Costs, equal to $2,186,500, except that the last payment will be subject to reduction pursuant to EPA's orphan share policy, based on the value of the work that the Settling Parties have performed and have committed to perform at the Site as of the due date of the final payment. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region II, 290 Broadway, New York, New York 10007–1866.

DATES: Comments must be submitted on or before January 10, 2005.

ADDRESSES: Comments should be addressed to Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866, and should reference: In the Matter of the Bayonne

Barrel & Drum Superfund Site, U.S. EPA Region II, CERCLA Docket No. 02–2004–2023. The proposed settlement is available for public inspection at EPA Region II offices at 290 Broadway, New York, New York 10007–1866. To request a copy, please contact the individual identified below.

FOR FURTHER INFORMATION CONTACT: Sarah Flanagan, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. Telephone: 212–637–3136.

Dated: November 23, 2004.

Kathleen C. Callahan,

Deputy Regional Administrator, Region 2.

[FR Doc. 04–27030 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7846–5]

Clean Water Act Section 303(d): Availability of Total Maximum Daily Loads. (TMDL)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability for comment of the administrative record files for 9 TMDLs and the calculations for these TMDLs prepared by EPA Region 6 for waters listed in the Atchafalaya River, Barataria, Calcasieu River, Lake Pontchartrain, Mermentau River, Vermilion-Teche River, Mississippi River, Sabine River, and Terrebonne Basins of Louisiana, under section 303(d) of the Clean Water Act (CWA). These TMDLs were completed in response to a court order in the lawsuit styled *Sierra Club, et al.* v. *Clifford, et al.*, No. 96–0527, (E.D. La.).

DATES: Comments must be submitted in writing to EPA on or before January 10, 2005.

ADDRESSES: Comments on the 9 TMDLs should be sent to Linda Adams, Environmental Scientist, Water Quality Protection Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, TX 75202–2733 or email: *adams.lindak@epa.gov.* For further information, contact Linda Adams at (214) 665–6546 or fax (214) 665–2191. The administrative record files for the 9 TMDLs are available for public inspection at this address as well. Documents from the administrative record files may be viewed at *www.epa.gov/region6/water/tmdl.htm*, or obtained by calling or writing Ms. Adams at the above address. Please contact Ms. Adams to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Linda Adams at (214) 665–6546.

SUPPLEMENTARY INFORMATION: In 1996, two Louisiana environmental groups, the Sierra Club and Louisiana Environmental Action Network (plaintiffs), filed a lawsuit in Federal Court against the EPA, styled *Sierra Club, et al.* v. *Clifford, et al.*, No. 96–0527, (E.D. La.). Among other claims, plaintiffs alleged that EPA failed to establish Louisiana TMDLs in a timely manner. EPA proposes these TMDLs pursuant to a consent decree entered in this lawsuit.

EPA Seeks Comment on 9 TMDLs

By this notice EPA is seeking comment on the following 9 TMDLs for waters located within Louisiana basins:

Subsegment	Waterbody Name	Pollutant
010901	Atchafalaya Bay and Delta and Gulf Waters to the State 3-mile Limit	Mercury.
021102	Barataria Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
031201	Calcasieu River Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
042209	Lake Pontchartrain Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
050901	Mermentau River Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
061201	Vermilion-Teche River Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
070601	Mississippi River Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
110701	Sabine River Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.
120806	Terrebonne Basin Coastal Bays and Gulf Waters to the State 3-mile Limit	Mercury.

EPA requests that the public provide to EPA any water quality related data and information that may be relevant to the calculations for the 9 TMDLs. EPA will review all data and information submitted during the public comment period and revise the TMDLs where appropriate. EPA will then forward the TMDLs to the Louisiana Department of Environmental Quality (LDEQ). The LDEQ will incorporate the TMDLs into its current water quality management plan.

Dated: December 2, 2004.

James R. Brown,

Acting Director, Water Quality Protection Division, Region 6.

[FR Doc. 04–27029 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

December 1, 2004.

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, Pub. L. 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 February 7, 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: 3060–0991.

Title: AM Measurement Data.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 1,900.

Estimated Time per Response: 0.25—25 hours.

Frequency of Response: On occasion reporting requirement; recordkeeping requirement; third party disclosure requirement.

Total Annual Burden: 29,180 hours.

Total Annual Cost: $72,500.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On March 14, 2002, the Commission released an *Order*, In the Matter of Establishment of the Media Bureau and Other Organizational Changes, DA No. 02–577, which amended 47 CFR Section 73.1125 (d) to reflect the reorganization of the existing Cable Services and Mass Media Bureaus into a new Media Bureau.

In order to control interference between stations and assure adequate community coverage, AM stations must conduct various engineering measurements to demonstrate that the antenna system operates as authorized. The data is used by station engineers to correct the operating parameters of an antenna. The data is also used by FCC staff in field operations to ensure that stations are in compliance with the technical requirements of the Commission's rules.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27052 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–10–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority

December 2, 2004.

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 February 7, 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: 3060–0649.

Title: 47 CFR Section 76.1601, Deletion or Repositions of Broadcast Signals; 47 CFR Section 76.1617, Initial Must Carry Notice; 47 CFR Sections 76.1607 and 76.1708, Principal Headend.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 8,250.

Estimated Time per Response: 0.5 to 1 hour.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 2,200 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR § 76.1601 requires that effective April 2, 1993, a cable operator shall provide written notice to any broadcast television station at least 30 days prior to either deleting from carriage or repositioning that station. Such notification shall also be provided to subscribers of the cable system. 47 CFR 1617(a) states that within 60 days of activation of a cable system, a cable operator must notify all qualified NCE stations of its principal headend by certified mail. 47 CFR 76.1607 states that cable operators shall provide written notice by certified mail to all stations carried on its system pursuant to the must-carry rules at least 60 days prior to any changes in the designation of its principal headend. 47 CFR 1708(a) states that the operator of every cable television system shall maintain for public inspection the designation and location of its principal headend. If an operator changes the designation of its principal headend, that new designation must be included in its public file.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27054 Filed 12–8–04; 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

December 1, 2004

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 January 10, 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 or copy 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: 3060–0647.

Title: Annual Survey of Cable Industry Prices.

Form Number: Not Applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; State, Local or Tribal Government.

Number of Respondents: 720.

Estimated Time per Response: 6.5 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 4,680 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Section 623(k) of the Cable Television Consumer Protection and Competition Act of 1992 requires the Commission to publish an annual statistical report on average rates for basic cable service, cable programming and equipment. The report must compare the prices charged by cable systems subject to effective competition and those not subject to effective competition. The annual Price Survey is used to collect the data needed to prepare this report.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27055 Filed 12–8–04; 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

December 1, 2004.

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, Pub. L. 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 January 10, 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 or copy 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: 3060–0316.

Title: Section 76.1700, Records To Be Maintained Locally by Cable System Operators for Public Inspection.

Form Number: Not Applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 4,000.

Estimated Time per Response: 26 hours.

Frequency of Response: Recordkeeping requirement.

Total Annual Burden: 104,000 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR Section 76.1700 of the Commission's rules requires cable television systems having 1,000 or more subscribers to maintain a public inspection file containing certain records. The records are used by FCC staff in field inspections/investigations, local public officials, and the public to access a cable television system's performance and to ensure that the system is in compliance with all of the Commission's applicable rules and regulations.

OMB Control Number: 3060–0332.

Title: Section 76.614, Cable Television System Regular Monitoring and Section 76.1706, Signal Leakage Logs and Repair Records.

Form Number: Not Applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 8,250.

Estimated Time per Response: 0.5 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement.

Total Annual Burden: 5,775 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The requirements under this OMB control number were previously contained in 47 CFR Section 76.614. The data is used by cable television systems and the Commission to prevent, locate and eliminate harmful

interference as it occurs, to help assure safe operation of aeronautical and marine radio services, and to minimize the possibility of interference to these safety-of-life services.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27056 Filed 12–8–04; 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

December 2, 2004.

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 February 7, 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 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.*

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.: 3060–0816.

Title: Local Telephone Competition and Broadband Reporting, WC Docket No. 04–141, FCC 04–266 (Report and Order).

Form No.: FCC Form 477.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, State, local or tribal government.

Number of Respondents: 1,400.

Estimated Time per Response: 22 hours (average).

Frequency of Response: Semi-annual reporting requirement.

Total Annual Burden: 61,295 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Needs and Uses: FCC Form 477 seeks to gather information on the development of local telephone competition and deployment of broadband service also known as advanced telecommunications services. The data are necessary to evaluate the status of developing competition in local exchange telecommunications markets and to evaluate the status of broadband deployment. The information is used by Commission staff to advise the Commission about the efficacy of Commission rules and policies adopted to implement the Telecommunications Act of 1996.

In the Report and Order, FCC 04–266, WC Docket No. 04–141, we adopted rules and a standardized form to improve our FCC Form 477, local telephone competition and broadband data-gathering program, including extending the program for five years beyond its currently designated sunset in March 2005, eliminating existing reporting thresholds, and gathering more granular data from service providers.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 04–27057 Filed 12–8–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission

DATE & TIME: *Tuesday, December 14, 2004 at 10 a.m.*

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, section 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE & TIME: *Thursday, December 16, 2004 at 10 a.m.*

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Merit and Service Awards.

Election of Officers.

Draft Advisory Opinion 2004–41: CUNA Mutual Insurance Society, by counsel Cleta Mitchell.

Draft Advisory Opinion 2004–42: Pharmavite LLC, by counsel Robert K. Kelner.

Draft Advisory Opinion 2004–43: Missouri Broadcasters Association, by counsel Gregg P. Skall.

Draft Notice of Proposed Rulemaking on Overnight Mail.

Draft Notice of Proposed Rulemaking on Payroll Deductions.

Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Robert Biersack, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 04–27184 Filed 12–7–04; 3:12 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 10 a.m.—December 14, 2004.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. Docket No 04–12—*Non-Vessel-Operating Common Carrier Service Arrangements*

FOR FURTHER INFORMATION CONTACT: Bryant L. VanBrakle, Secretary, (202) 523–5725.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 04–27131 Filed 12–7–04; 11:00 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Board of Governors of the Federal Reserve System

SUMMARY: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act, as per 5 CFR 1320.16, to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320 Appendix A.1. Board–approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83–Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Request for comment on information collection proposal

The following information collections, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collections, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. whether the proposed collections of information are necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. the accuracy of the Federal Reserve's estimate of the burden of the proposed information collections, including the validity of the methodology and assumptions used;

c. ways to enhance the quality, utility, and clarity of the information to be collected; and

d. ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before February 7, 2005.

ADDRESSES: You may submit comments, identified by FR G–1, FR G–2, FR G–3, FR G–4, FR T–4, and FR U–1, by any of the following methods:

- Agency Web Site: http://www.federalreserve.gov. Follow the instructions for submitting comments at http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.
- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- E–mail: regs.comments@federalreserve.gov. Include docket number in the subject line of the message.
- FAX: 202/452–3819 or 202/452–3102.
- Mail: Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, DC 20551.

All public comments are available from the Board's web site at www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm as submitted, except as necessary for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, N.W.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed form and instructions, the Paperwork Reduction Act Submission (OMB 83–I), supporting statement, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below.

Cindy Ayouch, Federal Reserve Board Clearance Officer (202–452–3829), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202–263–4869), Board of Governors of the Federal Reserve System, Washington, DC 20551.

Proposal to approve under OMB delegated authority the extension for three years, without revision, of the following reports:

Report titles: Registration Statement for Persons Who Extend Credit Secured by Margin Stock (Other Than Banks, Brokers, or Dealers); Deregistration Statement for Persons Registered Pursuant to Regulation U; Statement of Purpose for an Extension of Credit Secured by Margin Stock by a Person Subject to Registration Under Regulation U; Annual Report; Statement of Purpose for an Extension of Credit by a Creditor; and Statement of Purpose for an Extension of Credit Secured by Margin Stock

Agency form numbers: FR G–1, FR G–2, FR G–3, FR G–4, FR T–4, FR U–1

OMB control numbers: 7100–0011: FR G–1, FR G–2, FR G–4; 7100–0018: FR G–3; 7100–0019: FR T–4; and 7100–0115: FR U–1

Frequency: FR G–1, FR G–2, FR G–3, FR T–4, and FR U–1: on occasion; FR G–4: annual

Reporters: Individuals and business

Annual reporting hours: 1,506 reporting; 155,147 recordkeeping

Estimated average hours per response: FR G–1: 2.5 hours; FR G–2: 15 minutes; FR G–3: 10 minutes; FR G–4: 2.0 hours; FR T–4: 10 minutes; and FR U–1: 10 minutes

Number of respondents: FR G–1: 39; FR G–2: 103; FR G–3: 278; FR G–4: 691; FR T–4: 138; and FR U–1: 4,278

General description of report: These information collections are mandatory (15 U.S.C. §§ 78g). The information in the FR G–1 and FR G–4 is given confidential treatment under the Freedom of Information Act (5 U.S.C. §§ 552(b)(4)). The FR G–2 does not contain confidential information. The FR G–3, FR T–4, and FR U–1 are not submitted to the Federal Reserve and, as such, no issue of confidentiality arises.

Abstract: The Securities Exchange Act of 1934 ('34 Act) authorizes the Board to regulate securities credit issued by banks, brokers and dealers, and other lenders. The purpose statements, FR U–1, FR T–4, and FR G–3, are recordkeeping requirements for banks, brokers and dealers, and other lenders, respectively, to document the purpose of their loans secured by margin stock. Other lenders also must register and deregister with the Federal Reserve using the FR G–1 and FR G–2, respectively, and must file an annual report (FR G–4). The Federal Reserve uses the data to identify lenders subject to Regulation U, to verify compliance with Regulations T, U, and X, and to monitor margin credit.

Board of Governors of the Federal Reserve System, December 3, 2004.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 04–27010 Filed 12–8–04; 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 January 3, 2005.

Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

Main Street Trust, Inc., Champaign, Illinois; to acquire 100 percent of the voting shares of Citizens First Financial Corp., Bloomington, Illinois, and thereby indirectly acquire Citizens Savings Bank, Bloomington, Illinois.

Board of Governors of the Federal Reserve System, December 3, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–27011 Filed 12–8–04; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the General Counsel; Privacy Act of 1974: Revision to Existing System of Records

AGENCY: Office of the General Counsel (OGC), Office of the Secretary, HHS.

ACTION: Notice of revision to an existing system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Department of Health and Human Services (HHS) is publishing a notice of the minor revision of an existing system of records, 09–90–0062, Administrative Claims. The revised system makes some minor changes due to the records that will be part of the Early Offers Pilot, which HHS announced in the **Federal Register** on September 24, 2004 (67 FR 57294).

DATES: The revision does not add routine uses to this system. This amendment will be effective without further notice on the day of its publication.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Davis, Acting Associate General Counsel, General Law Division, Office of the General Counsel, U.S. Department of Health and Human Services, Room 4760, 330 Independence Ave., SW., Washington, DC 20201. The telephone number is 202–690–0153.

SUPPLEMENTARY INFORMATION: The revised system adds a new location in the Appendix for a small subset of information contained in this system pertinent to HHS's Early Offers Pilot, which was announced in the **Federal Register** on September 24, 2004 (67 FR 57294). The new location is for the contractor who maintains the Early Offers Pilot records. The revised system clarifies that the existing categories of records in the system cover Early Offers Pilot records because those records are pertinent to the particular claim asserted and are relevant to the final determinations made on claims. The revised system adds the Early Offers Pilot contractor to the ''Safeguards'' section of the system notice. The revised system limits the existing routine uses that the agency may use for information that is gathered under the Early Offers Pilot. The revised system corrects typographical errors in the previous system notice, updates the ''Retrievability'' section, and updates addresses in the Appendix of the system. The revised notice also updates the notification procedures. Finally, this revised system removes the references in the ''Safeguards'' section and the Appendix of the system notice to the Social Security Administration (SSA) because the SSA became an independent agency in 1995 and, therefore, is no longer part of HHS. The notice is published below in its entirety, as amended.

09–90–0062

SYSTEM NAME:

Administrative Claims, HHS/OS/OGC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

See Appendix.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

HHS employees, recipients of Federal assistance under HHS funded programs, and members of the public who have a claim against HHS or against whom HHS has a claim—Federal Torts Claims Act, Military Personnel and Civilian Employees Claims Act, Federal Claims Collection Act, Federal Medical Care Recovery Act, Act for Waiver of Overpayment of Pay.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information that is pertinent to the particular claim being asserted, including accident reports, hospital records, charges for medical services, certifications of overpayment, certifications of indebtedness, audits of payroll accounts during periods of overpayments, earning and leave statements, claims officers memoranda, final determinations made on claims (including Early Offers Pilot records), identify of debtors and information pertaining to how debts arose.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Tort Claims Act, 28 U.S.C. 261–2680, 1346(b); Waiver of Overpayment of Pay Act, 5 U.S.C. 5584; Military Personnel and Civilian Employees Claims Act, 31 U.S.C. 240–243; Federal Claims Collection Act, 31 U.S.C. 951–953; Federal Medical Care Recovery Act, 42 U.S.C. 2651–2653.

PURPOSE(S):

To adjudicate claims asserted by or against the Department.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records maintained for the Early Offers Pilot may be disclosed only for Routine Use Nos. 1 (to the extent the disclosure is to the HHS contractor who maintains the records for the Early Offers Pilot), 3 (in the event of Freedom of Information Act litigation), 5, and 13 below.

Records from this system may be disclosed as follows:

1. Federal, State, and local government agencies, private individuals, private and public hospitals, allegedly negligent parties, private attorneys, insurance companies, individual law enforcement officers, tribal officials, and other persons with relevant information for the purpose of investigating, settling, or adjudicating claims and subsequent litigation action.

2. To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provide such disclosure is compatible with the purpose for which the records were collected.

4. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statue, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether local, state, federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

5. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

6. To a federal, state or local agency maintaining civil, criminal or other pertinent records, such as current licenses, if necessary to obtain a record relevant to a DHHS decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

7. To a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

8. To the Department of Justice or other appropriate federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

9. A record from this system may be disclosed to the following entities in order to help collect a debt owed the United States.

a. To another Federal agency so that agency can effect a salary offset;

b. To another Federal agency so that agency can effect an administrative offset under common law or under 31 U.S.C. 3716 (withholding from money payable to, or held on behalf of, the individual);

c. To the Treasury Department to request his/her mailing address under I.R.C. 6103(m)(2) in order to locate him/her or in order to have a credit report prepared;

d. To agents of the Department and to other third parties to help locate him/her in order to help collect or compromise a debt;

e. To debt collection agents under 31 U.S.C. 3718 or under common law to help collect a debt; and

f. To the Justice Department for litigation or further administrative action. Disclosure under part (d) of this use is limited to the individual's name, address, Social Security Number, and other information necessary to identify him/her. Disclosure under parts (a)–(c) and (e) is limited to those items; the amount, status, and history of the claim; and the agency or program under which the claim arose. An address obtained from IRS may be disclosed to a credit reporting agency under part (d) only for purposes of preparing a commercial credit report on the individual. Part (a) applies to claims or debts arising under or payable under the Social Security Act if and only if the employee consents in writing to the offset.

10. A record from this system may be disclosed to another federal agency that has asked the Department to effect an administrative offset, under common law or under 31 U.S.C. 3716, to help collect a debt owed the United States. Disclosure under this routine use is limited to: Name, address, Social Security Number, and other information necessary to identify the individual; information about the money payable to or held for the individual; and other information concerning the administrative offset.

11. Disclosures with regard to claims or debts arising under or payable under the Social Security Act may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). However, this disclosure will not be made with regard to debts from overpayments to beneficiaries under Title II (Old-Age, Survivors, and Disability Insurance) and Title XVI (Supplemental Security Income) of this Act. The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal Government. Disclosure of records is limited to the individual's name, address, Social Security number, and other information necessary to establish the individual's identity; the amount, status, and history of the claim; and the agency or program under which the claim arose.

12. When a debt becomes legally or administratively uncollectible in whole or in part, a record may be disclosed to the Internal Revenue Service to report the written-off part as income.

13. Records may be disclosed to student volunteers, individuals working under a personal services contract, and other individuals performing functions for the Department but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12): Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) or the Federal Claims Collections Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of this disclosure is to aid in the collection

of outstanding debts owed to the Federal Government, typically, to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. Disclosure of records is limited to the individual's name, address, Social Security number, and other information necessary to establish the individual's identity; the amount, status, and history of the claim; and the agency or program under which the claim arose. This disclosure will be made only after the procedural requirements of 31 U.S.C. 3711(f) have been followed.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Legal size files in filing cabinets.

RETRIEVABILITY:

These records are manually retrieved by name of the non-Government party, whether claimant, plaintiff, or alleged debtor. In some instances, these records are retrievable by computer using name of the party involved.

SAFEGUARDS:

Office buildings in which files are kept are locked after the close of the business day. These files are only accessible to General Counsel staff, to designated claims program specialists in the Public Health Service, and with respect to the Early Offers Pilot records, to HHS's contractor.

RETENTION AND DISPOSAL:

The records are maintained for an indefinite duration.

SYSTEM MANAGER(S) AND ADDRESS:

The agency official responsible for the system policies and practices outlined above is: The General Counsel, Department of Health and Human Services, Office of the General Counsel, Room 713F, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION:

Any inquiries regarding this system of records should be addressed to the System Manager.

(These notification and access procedures are in accordance with Department Regulations (45 CFR 5b.5).)

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. (These access procedures are in accordance with Department Regulations (45 CFR 5b.5(a)(2)), **Federal Register**, October 8, 1975, page 47410.)

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under System Manager(s) Address above, and reasonably identify the record, specify the information to be contested, and specify the corrective action sought, with supporting justification (i.e., how it is inaccurate, irrelevant, not timely, or incomplete). (These procedures are in accordance with Department Regulations (45 CFR 5b.7), **Federal Register**, October 8, 1975, page 47411.)

RECORD SOURCE CATEGORIES:

The information in this system comes from a number of sources including private individuals, private and public hospitals, doctors, law enforcement agencies and officials, private attorneys, accident reports, third parties, claimants or beneficiaries and their relatives, other Federal agencies, State and local governments, agencies and instrumentalities.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix

Office of the General Counsel—Headquarters Offices, Department of Health and Human Services, Humphrey Building, Room 713F, 200 Independence Avenue, SW., Washington, DC 20201.

Office of the General Counsel, Regional Attorney—Region I, Department of Health and Human Services, John F. Kennedy Federal Building, Room 2250, Government Center, Boston, Massachusetts 02203.

Office of the General Counsel, Regional Attorney—Region II, Department of Health and Human Services, Jacob K. Javitz Federal Building, Room 3908, 26 Federal Plaza, New York, New York 10278.

Office of the General Counsel, Regional Attorney—Region III, Department of Health and Human Services, The Public Ledger Building, Suite 418, 150 S. Independence Mall West, Philadelphia, Pennsylvania 19106–3499.

Office of the General Counsel, Regional Attorney—Region IV, Department of Health and Human Services, Suite 5M60, 61 Forsyth Street, Atlanta, Georgia 30303.

Office of the General Counsel, Regional Attorney—Region V, Department of Health and Human Services, Suite 700, 233 North Michigan Avenue, Chicago, Illinois 60601–5519.

Office of the General Counsel, Regional Attorney—Region VI, Department of Health and Human Services, Room 1138, 1301 Young Street, Dallas, Texas 75202.

Office of the General Counsel, Regional Attorney—Region VII, Department of Health and Human Services, Room 1711, 601 East 12th Street, Kansas City, Missouri 64106.

Office of the General Counsel, Regional Attorney—Region VIII, Department of Health and Human Services, Room 300, 1961 Stout Street, Denver, Colorado 80294.

Office of the General Counsel, Regional Attorney—Region IX, Department of Health and Human Services, Room 420, 50 United Nations Plaza, San Francisco, California 94102–4912.

Office of the General Counsel, Regional Attorney—Region X, Department of Health and Human Services, Blanchard Plaza, Suite 702, 2201 Sixth Avenue, Seattle, Washington 98121–1833.

Director, Division of Public Health Service Claims, Room 17A–17, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

For records related to the Early Offers Pilot, Professor David A. Hyman, University of Illinois College of Law, 504 East Pennsylvania Avenue, Champaign, Illinois 61820–6909.

Dated: December 3, 2004.

Alex M. Azar II,

General Counsel,

[FR Doc. 04–27008 Filed 12–8–04; 8:45 am]

BILLING CODE 4190–26–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Nominations of Topics for Evidence-based Practice Centers

AGENCY: Agency for Healthcare Research and Quality (AHRQ), DHHS.

ACTION: Nominations of topics for evidence reports and technology assessments.

SUMMARY: AHRQ invites nominations of topics for evidence reports and technology assessments relating to the prevention, diagnosis, treatment and management of common diseases and clinical conditions, as well as topics relating to the organization and financing of health care. Previous evidence reports can be found at *http://www.ahrq.gov/clinic.epcix.htm.*

DATES: Topic nominations should be submitted by January 31, 2005, in order to be considered for fiscal year 2005. In addition to timely responses to this request for nominations, AHRQ also accepts topic nominations on an ongoing basis for consideration for future years. AHRQ will not reply to individual responses, but will consider all nominations during the selection process. Those who submitted topics that were selected will be notified by AHRQ.

ADDRESSES: Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850.

Electronic submissions to *epc@ahrq.gov.* are preferred.

FOR FURTHER INFORMATION CONTACT: Kenneth Fink, MD, MGA, MPH, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850; Phone: (301) 427–1617; Fax: (301 427–1640; E-mail: *kfink@ahrq.gov.*

Arrangement for Public Inspection: All nominations will be available for public inspections at the Center for Outcomes and Evidence, telephone (301) 427–1600, weekdays between 8:30 a.m. and 5 p.m. (eastern time).

SUPPLEMENTARY INFORMATION:

Background

Under Title IX of the Public Heath Service Act (42 U.S.C. 299–299c–7) as amended by Public Law 106–129 (1999), AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and through the promotion of improvements in clinical practice and health systems practices, including the prevention of diseases and other health conditions.

2. Purpose and Overview

The purpose of this notice is to solicit topic nominations for evidence reports and technology assessments. Professional societies, health systems, employers, insurers, providers, and consumer groups are encouraged to nominate topics and then collaborate with AHRQ, *e.g.*, with suggestions for, and comments, on, draft assessments, as it carries out its mission to promote the practice of evidence-based health care. In this endeavor, AHRQ serves as a science partner with private-sector and public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care delivery in the United States, and to expedite the translation of evidence-based research findings into improved health care services. To undertake scientific analyses and evidence syntheses on topics of high-priority to its public and private health care partners and the health care community generally, AHRQ awards task order contracts to its Evidence-based Practice Centers (EPCs).

The EPCs produce science syntheses—evidence reports and technology assessments—that provide to public and private organizations the foundation for developing and implementing their own practice guidelines, performance measures, educational programs, and other strategies to improve the quality of health care and decisionmaking related to the effectiveness and appropriateness of specific health care technologies and services. The evidence reports and technology assessments also may be used to inform coverage and reimbursement policies. As the body of scientific studies related to organization and financing of health care grows, systematic review and analysis of these studies, in addition to clinical and behavioral research, can provide health system organizations with a scientific foundation for developing or improving system-wide policies and practices.

Each year, the AHRQ supports approximately nine evidence reports in collaboration with non-Federal partners, including national associations, medical societies, health plans, and others. Nominations of topics from non-Federal partners are solicited annually through a notice in the **Federal Register**. However, topic nominations are accepted on an ongoing basis. All nominations received in the previous year as well as topics that were previously submitted but not selected are considered for the upcoming year.

Reports and assessments usually require about 12 months for completion. AHRQ widely disseminates the EPC evidence reports and technology assessments, both electronically and in print. The EPC evidence reports and technology assessments do not make clinical recommendations or recommendations regarding reimbursement and coverage policies.

3. Role/Responsibilities of Partners

Nominators of topics selected for development of an EPC evidence report or technology assessment assume the role of partners of AHRQ and the EPCs. Partners have defined roles and responsibilities. AHRQ places high value on these cooperative relationships, and takes into consideration a partner organization's past performance of these responsibilities, when considering whether to accept additional topics nominated by that organization in subsequent years. Specifically, partners are expected to serve as resources to EPCs as they develop the evidence reports and technology assessments related to the nominated topic; serve as external peer reviewers of relevant draft evidence reports and assessments; and commit to timely translation of the EPC reports and assessments into their own quality improvement tools (*e.g.*, clinical practice guidelines, performance measures), educational programs, and reimbursement policies; and dissemination of these derivative products to their membership as appropriate. AHRQ also is interested in members' use of these derivative products and the products' impact on enhanced health care. AHRQ looks to its partners to provide the use and impact data on products that are based on EPC evidence reports and technology assessments.

4. Topics for Reports

The EPCs prepare evidence reports and technology assessments on topics for which there is significant demand for information by health care providers, insurers, purchasers, health-related societies, and patient advocacy organizations. Such topics may include the prevention, diagnosis and/or treatment of particular clinical and behavioral conditions, use of alternative or complementary therapies, and appropriate use of commonly provided services, procedures, or technologies. Topics also may include issues related to the organization and financing of care such as risk adjustment methodologies, market performance measures, provider payment mechanisms, and insurance purchasing tools, as well as measurement or evaluation of provider integration of new scientific findings regarding health care and delivery innovations. Previous evidence reports can be found at *http://www.ahrq.gov/clinic/epcix.htm.*

AHRQ is very interested in receiving topic nominations from professional societies and organizations comprised of members of minority populations, as well as topic nominations that have significant impact on AHRQ priority populations including low income groups, minority groups, women, children, the elderly, and individuals with special health care needs, such as those with disabilities, those who need chronic care or end-of-life health care, or those who live in inner-city and rural areas.

5. Topic Nomination

Nominations of topics for AHRQ evidence reports and technology assessments should focus on specific aspects of prevention, diagnosis, treatment and/or management of a particular condition; an individual procedure, treatment, or technology; or a specific health care organizational or financial strategy. The processes that AHRQ employs to select clinical and behavioral topics as well as organization and financing topics nominated by the EPCs is described below. For each topic, the nominating organization must provide the following information:

A. Rationale and supporting evidence on the relevance and importance of the topic;

B. Three to five focused questions on the topic to be addressed;

C. Plans for rapid translation of the evidence reports and technology assessments into clinical guidelines, performance measures, educational programs, or other strategies for strengthening the quality of health care services, or plans to inform development of reimbursement or coverage policies;

D. Plans for use and/or dissemination of these derivative products, *e.g.,* to membership if appropriate; and,

E. Process by which the nominating organization will measure the use of these products and impact of such use.

6. Topic Selection

Factors that will be considered in the selection of topics for AHRQ evidence report and technology assessment topics include:

A. Burden of disease including severity, incidence and/or prevalence or relevance of organizational/financial topic to the general population and/or AHRQ's priority populations;

B. Controvery or uncertainty about the topic and availability of scientific data to support the systematic review and analysis of the topic;

C. Total costs associated with a condition, procedure, treatment, technology, or organization/financial topic taking into account the number of people needing such care, the unit cost of care, and related or indirect costs;

D. Potential for achieving clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition; or in changing the use of a procedure or technology; informing and improving patient and/or provider decisionmaking; improving health outcomes; and/or reducing costs;

E. Relevance to the needs of the Medicare, Medicaid and other Federal health care programs; and,

F. Nominating organization's plan to disseminate derivative products, measure use and impact of these products on outcomes, or otherwise incorporate the report into its managerial or policy decisionmaking.

7. Submission of Nominations

Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850. Electronic submissions to *epc@ahrq.gov* are preferred.

Dated: November 30, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–27058 Filed12–8–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0519]

Cottage Cheese Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Wells' Dairy, Inc., to market test cottage cheese that deviates from the U.S. standard of identity for cottage cheese. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than March 9, 2005.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Wells' Dairy, Inc., 1 Blue Bunny Dr., P.O. Box 1310, Le Mars, IA 51031.

The permit covers limited interstate marketing tests of these products:

1. Blue Bunny Brand
   - ''Cottage cheese, 4% milkfat, homestyle, large curd'' 24 ounces (oz);
   - ''Cottage cheese, 4% milkfat, original, small curd'' 32 oz;
   - ''Cottage cheese, 4% milkfat, original, small curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, original, small curd'' 12 oz;
   - ''Cottage cheese, 2% milkfat, reduced fat'' 24 oz;
   - ''Cottage cheese, 2% milkfat, reduced fat'' 12 oz;
   - ''Cottage cheese, 1% milkfat, lowfat'' 24 oz;
   - ''Cottage cheese, 1% milkfat, lowfat'' 12 oz; and
   - ''Cottage cheese, Health Smart, fat free'' 24 oz.

2. Great Value Brand
   - ''Cottage cheese, 4% milkfat, large curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, large curd'' 16 oz;
   - ''Cottage cheese, 4% milkfat, small curd'' 24 oz;
   - ''Cottage cheese, 4% milkfat, small curd'' 16 oz;
   - ''Cottage cheese, 1% milkfat, lowfat, small curd'' 24 oz;
   - ''Cottage cheese, 1% milkfat, lowfat, small curd'' 16 oz; and
   - ''Cottage cheese, fat free, small curd'' 24 oz.

3. ShurFresh Brand
   - ''Cottage cheese, 4% milkfat, small curd'' 24 oz.

These cottage cheese products may deviate from the U.S. standard of identity for cottage cheese (21 CFR 133.128) in that the products are formulated using fluid ultrafiltered (UF) skim milk. Fluid UF skim milk is obtained by subjecting skim milk to a physical separation process called ultrafiltration using a membrane with a pore size of 10,000 Daltons molecular weight cutoff, resulting in the partial loss of lactose, minerals, water-soluble vitamins, and water present in skim milk. The casein-to-whey protein ratio of skim milk is not altered during the ultrafiltration process. The moisture content of fluid UF skim milk so obtained is about 80 percent. Fluid UF skim milk is added to skim milk at a level needed to increase the total solids of the cheese milk by 5 to 25 percent. The physical, chemical, and sensory properties characteristic of cottage cheese are not altered in the test product. The fluid UF skim milk will be declared in the ingredient statement of the finished cottage cheese as ''ultrafiltered skim milk.'' The test product meets all the requirements of the standard with the exception of the use of fluid UF skim milk. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of a total of 15 million pounds (6.8 million kilograms) of the test product. The test products will be manufactured by Wells' Dairy,

Inc., at 12th and Lincoln Sts. SW., Le Mars, IA 51031. The test products will be distributed by Wells' Dairy, Inc., throughout the States of Iowa, Minnesota, Wisconsin, Missouri, Nebraska, Oklahoma, Kansas, South Dakota, North Dakota, Arkansas, and Colorado. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of part 101 (21 CFR part 101). The information panel of the labels will bear nutrition labeling in accordance with § 101.9. This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the product into interstate commerce, but not later than March 9, 2005.

Dated: November 29, 2004.

Barbara Schneeman,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–26996 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices 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: Circulatory System Devices Panel of the Medical Devices 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 January 13, 2005, from 9 a.m. to 5 p.m.

Location: Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative. The committee will also discuss, make recommendations, and vote on a premarket approval application for a thoracic endoprosthesis intended for endovascular repair of the descending thoracic aorta.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

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 January 5, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 5, 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 AnnMarie Williams, at 301–594–1283, ext. 113, 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: December 1, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–26994 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee (NDAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC).

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 13, 2005, from 8 a.m. to 5 p.m., and January 14, 2005, from 8 a.m. to 3 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Cathy A. Groupe, or Hilda F. Scharen, 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, e-mail *GroupeC@cder.fda.gov* or *scharenh@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512541 and 3014512536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committees will consider the safety and efficacy of new drug application (NDA) 21–213, proposing over-the-counter (OTC) use of MEVACOR (lovastatin), 20 milligrams a day, Merck & Co., Inc., to help lower LDL ''bad'' cholesterol, which may prevent a first heart attack. The background material will become available no later than the day before the meeting and will be posted under the NDAC or the EMDAC Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* (click on the year 2005 and scroll down to NDAC or EMDAC).

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 January 6, 2005. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:30 a.m. on January 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 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 LaNise Giles 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: December 1, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–26995 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0327]

Draft Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand the new over-the-counter (OTC) labeling requirements and to prepare new labeling within the prescribed implementation compliance dates.

DATES: Submit written or electronic comments on the draft compliance guidance by February 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft compliance guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft compliance guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft compliance guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format regulations for the labeling of OTC drug products. This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The new format will require revision of all existing labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). To reduce the economic impact on small business entities, the new regulations provide an additional 1-year period to comply with § 201.66 (21 CFR 201.66) for OTC drug products with sales of less than $25,000 per year. You can find a copy of § 201.66 at the Division of Dockets Management Web site at *http://www.fda.gov/cder/otc/label/label-fr-reg.htm*.

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the new standardized content and format requirements. This draft guidance summarizes the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance also describes how to list those inactive ingredients that are different when a finished OTC drug product is obtained from multiple suppliers.

This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft compliance guidance, when finalized, will represent the agency's current thinking on how OTC drug monograph labeling finalized prior to or after the new requirements can be converted to the new OTC ''Drug Facts'' format labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft compliance guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft compliance guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: December 1, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26993 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4903–N–98]

Notice of Submission of Proposed Information Collection to OMB; Resident Services and Satisfaction Survey

AGENCY: Office of the Chief Information Officer.

ACTION: Notice.

SUMMARY: The proposed 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. The Department is soliciting public comments on the subject proposal.

This is a request for continued approval to collect the information related to a survey of residents of assisted housing and insured housing. HUD conducts this to measure resident satisfaction with living conditions. Public housing agencies are required to implement the survey.

DATES: Comments Due Date: January 10, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2507–0001) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* or Lillian Deitzer at *Lillian_L_Deitzer@HUD.gov* or telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms. Deitzer and at HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: This Notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB a request for approval of the information collection described below. This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Resident Service and Satisfaction Survey.

OMB Approval Number: 2507–0001.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: HUD conducts a resident survey of assisted and insured housing residents to measure resident satisfaction with living conditions. Public housing agencies are required to implement the survey.

Frequency of Submission: Annually.

	Potential respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting Burden	595,797	216,979		0.3		64,021

The total potential respondents include public housing agencies, multifamily housing owners, and residents.

Total Estimated Burden Hours: 64,021.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: December 2, 2004.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. E4–3560 Filed 12–8–04; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4837–D–54]

Delegation of Authority Under Section 42(d)(5)(C) of the Internal Revenue Code

AGENCY: Office of the Secretary, HUD.

ACTION: Notice.

SUMMARY: In this notice, the Secretary delegates to the Assistant Secretary for Policy Development and Research concurrent authority to carry out the duties and responsibilities authorized to the Secretary of HUD by Section 42(d)(5)(C) of the Internal Revenue Code.

DATES: *Effective Date:* January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Kurt G. Usowski, Associate Deputy Assistant Secretary for Economic Affairs, Office of Policy Development and Research, Room 8204, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–6000, telephone (202) 708–2770 (this is not a toll-free number), or email *Kurt_G._Usowski@hud.gov.* Persons with speech or hearing impairments may access this number through TTY by calling the Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Section 42(d)(5)(C) of the Internal Revenue Code of 1986 (26 U.S.C. 42(d)(5)(C)) authorizes the Secretary of HUD to designate qualified census tracts and difficult development areas for the low-income housing tax credit. Section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)) authorizes the Secretary to delegate this authority, and the Secretary delegates the authority as follows:

Section A. Authority Delegated

The Secretary delegates to the Assistant Secretary for Policy Development and Research, concurrent with the Secretary's authority, the authority to designate qualified census tracts and difficult development areas for the low-income housing tax credit as authorized by Section 42(d)(5)(C) of the Internal Revenue Code of 1986 (26 U.S.C. 42(d)(5)(C)), as well as such other statutory authority, duties, and responsibilities related to the designation of these tracts and areas.

Section B. Redelegation

The authority delegated to the Assistant Secretary for Policy Development and Research in Section A may not be redelegated.

Authority: Section 42(d)(5)(C) of the Internal Revenue Code of 1986 (26 U.S.C. 42(d)(5)(C)), and Section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: October 25, 2004.

Alphonso Jackson,

Secretary.

[FR Doc. E4–3593 Filed 12–8–04; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Decision and Availability of the Record of Decision for the Final Comprehensive Conservation Plan and Environmental Impact Statement for Nisqually National Wildlife Refuge, Thurston and Pierce Counties, Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of decision and availability of the record of decision.

SUMMARY: This is a notice of decision and availability of the Record of Decision (ROD) for the Nisqually National Wildlife Refuge Final Comprehensive Conservation Plan and Environmental Impact Statement (Final CCP/EIS). The Refuge is located in Thurston and Pierce Counties, Washington. A thorough analysis of the environmental, social, and economic considerations was completed and presented in the Final CCP/EIS. The Final CCP/EIS was released to the public and a Notice of Availability was published in the **Federal Register** on August 31, 2004 (69 FR 53084). The ROD documents the selection of Alternative D, the Preferred Alternative in the Final CCP/EIS, as the CCP for Nisqually Refuge. The ROD was signed by the Regional Director, U.S. Fish and Wildlife Service, Pacific Region, on November 1, 2004.

ADDRESSES: A copy of the ROD or Final CCP/EIS may be obtained from the Refuge Manager, Nisqually National Wildlife Refuge Complex, 100 Brown Farm Road, Olympia, Washington 98516, Phone (360) 753–9467, or from the following Web site: *http://pacific.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Contact the Refuge Manager, Nisqually National Wildlife Refuge Complex, 100 Brown Farm Road, Olympia, Washington 98516, Phone (360) 753–9467.

SUPPLEMENTARY INFORMATION: The Nisqually Refuge's CCP will provide management guidance for conservation of Refuge resources and public use activities during the next 15 years. The following is a summary of the Nisqually Refuge's Final CCP/EIS ROD.

The Service has selected Alternative D, the Preferred Alternative, as the CCP for Nisqually Refuge. Alternative D addresses the key issues and conflicts identified during the planning process and will best achieve the purposes and goals of the Refuge as well as the mission of the National Wildlife Refuge System. This decision includes adoption of stipulations and mitigation measures identified in Alternative D, Appendix G Compatibility Determinations, and Appendix I Goals, Objectives and Strategies, of the Final CCP/EIS. Implementation of the CCP will occur over the next 15 years, depending on future staffing levels, funding, and willing sellers.

Factors Considered in Making the Decision

The decision was based on a thorough analysis of the environmental, social, and economic considerations presented in the Final CCP/EIS. During the decision making phase of the CCP process, the Service reviewed and considered: the impacts identified in Chapter 4 of the Draft and Final CCP/EIS; the results of various studies and surveys conducted in conjunction with the Draft and Final CCP/EIS; relevant issues, concerns, and opportunities; comments on the Draft and Final CCP/EIS; and other relevant factors, including the purposes for which the Refuge was established, and statutory and regulatory guidance. Alternative D incorporates several components addressing a variety of needs including fish and wildlife sanctuary, habitat restoration and protection, Refuge expansion, and the National Wildlife Refuge System's six priority public uses. It is, however, the unique combination of these components that contributes the most to achieving the Refuge's purposes and goals. Alternative D strengthens the monitoring of fish, wildlife, habitat, and public uses on the Refuge which will provide the means to better respond to rapidly changing conditions within the surrounding, growing urban environment. Alternative D was selected for implementation because it provides the greatest number of opportunities for the Refuge to contribute to the fish, wildlife, and habitat needs of the Nisqually River watershed and the greater Puget Sound region.

David J. Wesley,

Acting Regional Director, Region 1, Portland, Oregon.

[FR Doc. 04–27023 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Proposed Low Effect Habitat Conservation Plan for Shaw Mira Loma LLC, Riverside County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Shaw Mira Loma LLC (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for a 1-year incidental take permit for one covered species pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The application addresses the potential for ''take'' of the endangered Delhi Sands flower-loving fly *(Rhaphiomidas terminatus abdominalis)* associated with construction of commercial and industrial facilities within a 5.02-acre parcel located in the unincorporated City of Mira Loma, Riverside County, California. A conservation program to mitigate for the project activities would be implemented as described in the proposed Shaw Mira Loma LLC Low Effect Habitat Conservation Plan (proposed Plan), which would be implemented by the Applicant.

We are requesting comments on the permit application and on the preliminary determination that the proposed Plan qualifies as a ''Low-effect'' Habitat Conservation Plan, eligible for a categorical exclusion under the National Environmental Policy Act (NEPA) of 1969, as amended. The basis for this determination is discussed in the Environmental Action Statement (EAS) and the associated Low Effect

Screening Form, which are also available for public review.

DATES: Written comments should be received on or before January 10, 2005.

ADDRESSES: Comments should be addressed to the Field Supervisor, Fish and Wildlife Service, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Carlsbad, California 92008. Written comments may be sent by facsimile to (760) 918–0638.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Goebel, Assistant Field Supervisor, Carlsbad Fish and Wildlife Office (*see* **ADDRESSES**); telephone: (760) 431–9440.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Individuals wishing copies of the application, proposed Plan, and EAS should immediately contact the Service by telephone at (760) 431–9440 or by letter to the Carlsbad Fish and Wildlife Office (*see* **ADDRESSES**). Copies of the proposed Plan and EAS also are available for public inspection during regular business hours at the Carlsbad Fish and Wildlife Office (*see* **ADDRESSES**).

Background

Section 9 of the Act and its implementing Federal regulations prohibit the take of animal species listed as endangered or threatened. The definition of take under the Act includes the following activities: to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect listed animal species, or attempt to engage in such conduct (16 U.S.C. 1538). However, under section 10(a) of the Act, the Service may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the Act as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species, respectively, are found in the Code of Federal Regulations at 50 CFR 17.22 and 50 CFR 17.32

The Applicant is seeking a permit for take of the Delhi Sands flower-loving fly during the life of the permit. The project encompasses construction of commercial and industrial facilities within the 5.02-acre project site. The Delhi Sands flower-loving fly has been observed on the proposed project site; however, the Service believes that the site has limited long-term conservation value for the fly because the site is surrounded on all sides by development, which effectively isolates the site from other locations of the species. Construction of the proposed project would result in the death or injury of any Delhi Sands flower-loving flies that may remain on the site. The project site does not contain any other rare, threatened, or endangered species or habitat. No critical habitat for any listed species occurs on the project site.

The Applicant proposes to mitigate the effects to the Delhi Sands flower-loving fly associated with the covered activities by fully implementing the Plan. The purpose of the proposed Plan's conservation program is to promote the biological conservation of the Delhi Sands flower-loving fly. The Applicant proposes to mitigate the impacts of the taking of the Delhi Sands flower-loving fly by purchasing two credits of occupied, high quality habitat at a Service-approved conservation bank.

The Proposed Action consists of the issuance of an incidental take permit and implementation of the proposed Plan, which includes measures to mitigate impacts of the project on the Delhi Sands flower-loving fly. Three alternatives to the taking of the listed species under the Proposed Action are considered in the proposed Plan. Under the No Action Alternative, no permit would be issued, and no construction would occur. Under the Reduced Project Alternative, incidental take of the Delhi Sands flower-loving fly would be authorized, but the applicant would reduce the area of impact and maintain a small Delhi Sands flower-loving fly preserve on site. Under the Western Riverside Multiple Species Habitat Conservation Plan (MSHCP) Alternative, incidental take would be authorized under the permit issued for this regional plan, and Delhi Sands flower-loving fly conservation would be consistent with the MSHCP.

The Service has made a preliminary determination that approval of the proposed Plan qualifies as a categorical exclusion under NEPA, as provided by the Department of the Interior Manual (516 DM 2, Appendix 1 and 516 DM 6, Appendix 1) and as a ''low-effect'' plan as defined by the Habitat Conservation Planning Handbook (November 1996). Determination of Low-effect Habitat Conservation Plans is based on the following three criteria: (1) Implementation of the proposed Plan would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) implementation of the proposed Plan would result in minor or negligible effects on other environmental values or resources; and (3) impacts of the proposed Plan, considered together with the impacts of other past, present and reasonably foreseeable similarly situated projects would not result, over time, in cumulative effects to environmental values or resources which would be considered significant.

Based upon this preliminary determination, we do not intend to prepare further NEPA documentation. We will consider public comments in making the final determination on whether to prepare such additional documentation.

This notice is provided pursuant to section 10(c) of the Act. We will evaluate the permit application, the proposed Plan, and comments submitted thereon to determine whether the application meets the requirements of section 10 (a) of the Act. If the requirements are met, we will issue a permit to Shaw Mira Loma LLC for the incidental take of the Delhi Sands flower-loving fly from development of the Applicant's parcel on Philadelphia Avenue in Riverside County, California.

Pursuant to an order issued on June 10, 2004, by the District Court for the District of Columbia in *Spirit of the Sage Council* v. *Norton* Civil Action No. 98–1873 (D. D.C.), the Service is enjoined from issuing new section 10(a)(1)(B) permits or related documents containing ''No Surprises'' assurances, as defined by the Service's ''No Surprises'' rule published at 63 FR 8859 (February 23, 1998), until such time as the Service adopts new permit revocation rules specifically applicable to section 10(a)(1)(B) permits in compliance with the public notice and comment requirements of the Administrative Procedures Act. This notice concerns a step in the review and processing of a section 10(a)(1)(B) permit and any subsequent permit issuance will be in accordance with the Court's order. Until such time as the June 10, 2004, order has been rescinded or the Service's authority to issue permits with ''No Surprises'' assurances has been otherwise reinstated, the Service will not approve any incidental take permits or related documents that contain ''No Surprises'' assurances.

Dated: December 2, 2004.

Ken McDermond,

Deputy Manager, California/Nevada Operations Office, Sacramento, California.

[FR Doc. 04–27021 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

San Luis Unit Long-Term Contract Renewals

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of the draft environmental impact statement (EIS).

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (as amended) and the California Environmental Quality Act, the Bureau of Reclamation has made available for public review and comment a Draft EIS for the renewal of long-term water service contracts for the San Luis Unit of the Central Valley Project (CVP). The Draft EIS describes and presents the environmental effects of three alternatives, including no action, for implementing the renewal of the long-term water service contracts. A 45-day public comment period will be allowed to receive comments from individuals and organizations on the Draft EIS.

DATES: Written comments on the Draft EIS will be accepted on or before January 24, 2005.

ADDRESSES: Send comments on the Draft EIS to Joe Thomson, Bureau of Reclamation, Mid-Pacific Region, 1243 ''N'' Street, Fresno, CA 93644.

Copies of the Draft EIS may be requested from Ms. Sammie Cervantes, Bureau of Reclamation, 2800 Cottage Way, Sacramento, CA 95825 or by calling 916–978–5104, TDD 916–978–5608. See Supplementary Information section for locations where copies of the Draft EIS are available for public inspection.

FOR FURTHER INFORMATION CONTACT: Joe Thompson, Environmental Specialist, Bureau of Reclamation, at 559–487–5179.

SUPPLEMENTARY INFORMATION: The Draft EIS will address impacts related to the renewal of long-term water service contracts between Reclamation and the contractors in the San Luis Unit. The alternatives present a range of water service agreement provisions that could be implemented for long-term contract renewals. The first alternative, the No-Action Alternative, consists of renewing water service contracts as described by the preferred alternative of the Programmatic EIS for the Central Valley Project Improvement Act. A proposal by Reclamation was submitted to the contractors in 1999 with an alternative contract being submitted by the contractors in 2000. Reclamation and the contractors have continued to negotiate the CVP-wide terms and conditions with these proposals serving as the basis for analysis of such ''bookends.'' The EIS also evaluates the proposals against the No-Action Alternative as bookends to be considered for the environmental documentation that evaluates the impacts and benefits of renewing the long-term water service contracts.

Copies of the Draft EIS are available for public inspection and review at the following locations:

- Bureau of Reclamation, Denver Office Library, Building 67, Room 167, Denver Federal Center, 6th and Kipling, Denver, CO 80225; telephone: 303–445–2072.
- Bureau of Reclamation, Office of Public Affairs, 2800 Cottage Way, Sacramento, CA 95825–1898; telephone: 916–978–5100.
- Bureau of Reclamation, South Central California Area Office, 1243 ''N'' Street, Fresno, CA 93721.
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW., Main Interior Building, Washington, DC 20240–0001.

Public Libraries:

- Fresno County Public Library, 2420 Mariposa Street, Fresno, CA 93721.
- Los Banos Public Library, 1312 S. 7th Street, Los Banos, CA 93635.

Oral and written comments, including names and home addresses of respondents will be available for public review. Individual respondents may request that we withhold their home address from public disclosure, which will be honored to the extent allowable by law. There may be circumstances in which respondent's identity may also be withheld from public disclosure, as allowable by law. If you wish to have your name and/or address withheld, you must state this prominently at the beginning of your comment. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Dated: September 28, 2004.

John F. Davis,

Deputy Regional Director, Mid-Pacific Region.

[FR Doc. 04–27005 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Mendota Pool Ten-Year Exchange Agreements, Proposed Annual Water Exchange, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of the final environmental impact statement (EIS).

SUMMARY: The Department of the Interior, Bureau of Reclamation (Reclamation), has prepared a final EIS, pursuant to the National Environmental Policy Act (NEPA), to evaluate the proposed annual water exchange agreements of up to 25,000 acre-feet of water per year for up to a 10-year period with the Mendota Pool Group.

The purpose of the proposed project is to provide water to irrigable lands on Mendota Pool Group properties in Westlands Water District and San Luis Water District to offset substantial reductions in contract water supplies attributable to the Central Valley Project Improvement Act (CVPIA), the Endangered Species Act listings and regulations, and new Bay-Delta water quality rules. This water would thereby enable the Mendota Pool Group farmers to maintain production on historically irrigated lands. The project is not intended to increase the amount of water for farming activities, but would replace some of the contract water lost because of increased environmental regulations that restrict water deliveries south of the export pumps at Tracy, California.

DATES: Reclamation will not make a decision on the proposed action until at least 30 days after release of the Final EIS/EIR. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

ADDRESSES: The final EIS may be obtained by contacting Mr. David Young at the Bureau of Reclamation, South-Central California Area Office, 1243 N Street, Fresno, CA 93721–1813; by telephone at 559–487–5127; (TDD 559–487–5933); by e-mail at *dkyoung@mp.usbr.gov;* or by fax at 559–487–5397. The final EIS is also available via the Internet at *http://www.usbr.gov/mp/sccao/index.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Young, Environmental Specialist, at the above address or by telephone at 559–487–5127 (TDD 559–487–5933).

SUPPLEMENTARY INFORMATION: The Delta export service area of the Central Valley

Project (CVP) has total contractual obligations and delivery losses of approximately 3.45 million acre-feet per year. The theoretical maximum pumping capability of CVP facilities serving this area is approximately 3.09 million acre-feet per year. Available supplies are apportioned under a hierarchy of allocation in which agricultural water service contracts, totaling about 1.85 million acre-feet per year, are provided water only after all other obligations are met. Implementation of the CVPIA (1992), Endangered Species Act (1993–1995), and revised Bay-Delta water quality standards have further reduced pumping capabilities and water supplies available to agricultural contractors. Currently agricultural contractors can expect to receive a long-term average supply of about 50 to 55 percent of contract water as compared to a pre-1992 average of 88 to 92 percent.

Alternatives identified and evaluated, based on criteria adopted to maintain environmental quality, provide for continued agricultural production and include the proposed project, construction of new wells, and fallowing of farmland. The project proponents propose to pump up to 269,600 acre-feet of groundwater over the 10-year period from non-CVP wells located adjacent to the Mendota Pool into the Mendota Pool to make up for a portion of the annual shortfall in the contract water to be delivered via the CVP. The actual quantity of water to be pumped would depend on whether the year is classified as wet (0 acre-feet per year), normal (maximum of 31,600 acre-feet per year), or dry (maximum of 40,000 acre-feet per year). As part of this program, a maximum of 12,000 acre-feet per year of groundwater would be pumped from deep wells (*i.e.*, screened interval greater than 130 feet deep), with the remainder coming from shallow wells (*i.e.*, screened interval less than 130 feet deep). The proposed project will comply with the terms specified in the *Settlement Agreement for Mendota Pool Transfer Pumping Program,* effective January 1, 2001.

The Federal action contemplated in the EIS is the exchange with Reclamation of a maximum of 25,000 acre-feet of the total quantity pumped each year. This water would be made available to Reclamation in the Mendota Pool to offset their existing water contract obligations. In exchange, Reclamation would make an equivalent amount of CVP water available to the members of the Mendota Pool Group for irrigation purposes at Check 13 of the Delta-Mendota Canal. Any quantity of water pumped by the Mendota Pool Group beyond the 25,000 acre-feet exchanged is not part of the Federal action, but is evaluated in the EIS. The water pumped in excess of the 25,000 acre-feet exchanged with Reclamation would be delivered directly to other lands that are presently under irrigation around the Pool.

The primary environmental resource issues that are evaluated in the EIS include groundwater levels, groundwater quality, subsidence, surface water quality, and biological resources. Other resource areas evaluated include cost of water, CVP operations, archaeological and cultural resources, Indian Trust assets, environmental justice, socioeconomic resources, land use, transportation, air quality, and noise.

There are no known Indian Trust Assets or environmental justice issues associated with the proposed action.

Reclamation published the notice of availability of the draft EIS in the **Federal Register** on Tuesday, July 29, 2003 (68 FR 44542). The 60-day written comment period ended on September 29, 2003. Reclamation obtained public input on the scope of the project and potential alternatives through solicitation of comment letters and a public scoping meeting. Ten comment letters were received. The final EIS addresses the comments received on the draft EIS both as revisions to the text, and in an appendix that provides specific responses to each comment.

It is Reclamation's practice to publicly disclose respondents' comments, including names and addresses. Respondents may request that their address be withheld from disclosure; this will be honored to the extent allowable by law. There may also be circumstances in which a respondent's identity may be withheld from disclosure; again, this will be honored to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. All submissions from organizations or businesses will be publicly disclosed in their entirety.

Dated: November 29, 2004.

Kirk C. Rodgers,

Regional Director, Mid-Pacfic Region.

[FR Doc. 04–27006 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Change in Discount Rate for Water Resources Planning

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of change.

SUMMARY: The Water Resources Planning Act of 1965 and the Water Resources Development Act of 1974 require an annual determination of a discount rate for Federal water resources planning. The discount rate for Federal water resources planning for fiscal year 2005 is 5.375 percent. Discounting is to be used to convert future monetary values to present values.

DATES: This discount rate is to be used for the period October 1, 2004, through and including September 30, 2005.

FOR FURTHER INFORMATION CONTACT: Sandra L. Simons, Manager, Contract Services Office, Denver, Colorado, 80225; telephone: 303–445–2902.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the interest rate to be used by Federal agencies in the formulation and evaluation of plans for water and related land resources is 5.375 percent for fiscal year 2005.

This rate has been computed in accordance with Section 80(a), Pub. L. 93–251 (88.Stat 34) and 18 CFR 704.39, which: (1) Specify that the rate shall be based upon the average yield during the preceding fiscal year on interest-bearing marketable securities of the United States which, at the time the computation is made, have terms of 15 years or more remaining to maturity (average yield is rounded to nearest one-eighth percent); and (2) provide that the rate shall not be raised or lowered more than one-quarter of 1 percent for any year. The Treasury Department calculated the specified average to be 5.088 percent. Rounding this average yield to the nearest one-eighth percent is 5.125 percent, which exceeds the permissible one-quarter of 1 percent change from fiscal year 2004 to 2005. Therefore, the change is limited to one-quarter of 1 percent.

The rate of 5.375 percent shall be used by all Federal agencies in the formulation and evaluation of water and related land resources plans for the purpose of discounting future benefits and computing costs or otherwise converting benefits and costs to a common time basis.

Dated: November 13, 2004.

Roseann Gonzales,

Director, Office of Program and Policy Services.

[FR Doc. 04–27024 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 1, 2004.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor (DOL). To obtain documentation, contact Ira Mills on (202) 693–4122 (this is not a toll-free number) or e-mail: *mills.ira@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register.**

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: New collection.

Title: Unemployment Insurance Facilitation of Claimant Reemployment.

OMB Number: 1205–0NEW.

Frequency: Quarterly.

Affected Public: State, Local, or Tribal Government; Federal Government.

Number of Respondents: 53.

Number of Annual Responses: 212.

Total Burden Hours: 2,120.

Estimated Time Per Response: 10 Hours.

Total annualized capital/startup costs: $145,750.

Total annual costs (operating/maintaining systems or purchasing services): $79,500.

Description: The Department of Labor requests approval to establish a system to collect data at the state level on the percentage of individuals who become reemployed in the calendar quarter subsequent to the quarter in which they received their first Unemployment Insurance (UI) payment. This data will be used to measure performance for the Department's Government Performance and Results Act of 1993 goal of facilitating the reemployment of UI claimants.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 04–27012 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

December 2, 2004.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Bureau of Labor Statistics (BLS), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Bureau of Labor Statistics.

Type of Review: Extension of a currently approved collection.

Title: Census of Fatal Occupational Injuries.

OMB Number: 1220–0133.

Form Number: BLS CFOI–1.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: State, Local, or Tribal Government; individuals or households; business or other for-profit; not-for-profit institutions; farms; and Federal Government.

Number of Respondents: 1,345.

Number of Annual Responses: 27,750.

Estimated Time Per Response: 10 minutes to compile source documents and 20 minutes to complete the Form BLS CFOI–1.

Total Burden Hours: 4,813.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: The Census of Fatal Occupational Injuries provides policymakers and the public with comprehensive, verifiable, and timely measures of fatal work injuries. Data are compiled from various Federal, State, and local sources and include information on how the incident occurred as well as various characteristics of the employer and the deceased worker. The information is used for surveillance of fatal work injuries and for developing prevention strategies.

Agency: Bureau of Labor Statistics.

Type of Review: Reinstatement, without change, of a previously approved collection.

Title: Contingent Work Supplement to the CPS.

OMB Number: 1220–0153.

Form Number: None.

Frequency: One time.

Type of Response: Reporting.

Affected Public: Individuals or households.

Number of Respondents: 43,500.

Number of Annual Responses: 43,500.

Estimated Time Per Response: 8 minutes.

Total Burden Hours: 5,800.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: Since the mid-1980s, there has been a growing belief among labor market researchers that employers require greater flexibility in their use of labor. As a result, many workers find themselves in ''contingent jobs'' that are structured to last for only limited duration or in alternative employment arrangements such as independent contracting, on-call work, working through a contract company, or through a temporary help firm. It is feared that workers with such employment may have little job security, low pay, and no employee benefits. This CPS supplement provides objective information about ''contingent work.''

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 04–27013 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,843]

Ancon Tool and Die, a Subsidiary of H.E. Services, Saginaw, MI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on October 21, 2004 in response to a petition filed by a state agency representative on behalf of workers at Ancon Tool and Die, a subsidiary of H.E. Services, Saginaw, Michigan.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 23rd day of November, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3582 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,832]

Davlyn Manufacturing Company, Inc., Spring City; PA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on October 20, 2004, in response to a petition filed by the company on behalf of workers at Davlyn Manufacturing Company, Inc., Spring City, Pennsylvania.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 22nd day of November, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3581 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,991]

Fruit of the Loom, Jamestown, KY; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 15, 2004 in response to a petition filed by a company official on behalf of workers at Fruit of the Loom, Jamestown, Kentucky.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 24th day of November, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3585 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,982]

Hewlett Packard, Corvallis, OR, Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 12, 2004 in response to a petition filed on behalf of workers at Hewlett Packard, Corvallis, Oregon.

The petition has been deemed invalid. There were not three petitioners from the same firm requesting certification to apply for trade adjustment assistance benefits.

Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 19th day of November, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3584 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, (19 U.S.C. 2273), the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the periods of November 2004.

In order for an affirmative determination to be made and a certification of eligibility to apply for directly-impacted (primary) worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance as an adversely affected secondary group to be issued, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

TA–W–55,745; Interstate Brands Corp., Grand Rapids, MI
TA–W–55,773; Dorado Sock, Inc., Gibsonville, NC
TA–W–55,703; Otsego Tool and Engineering, Inc., Albertville, MN
TA–W–55,803; Collins and Aikman, Plastics Div., Manchester, MI
TA–W–55,730; B&J Knits, Inc., Statesville, NC
TA–W–55,742; Rock-Tenn Co., Otsego, MI
TA–W–55,741; Jefferson Smurfit Corp., Corrugated Container Div., a subsidiary of Smurfit Stone Container Corp., Milford, CT
TA–W–55,485; American Italian Pasta Co., Excelsior Springs, MO
TA–W–55,658; General Dynamics Land Systems, California Technical Center, including on-site workers from CDI Professional Services, Goleta, CA
TA–W–55,704; Quantegy, Inc., Opelika, AL
TA–W–55,839; Lindsay Claire Designs, Ltd, Niagara Falls, NY
TA–W–55,705; Mid-South Waste, a subsidiary of Hi-Rise Recycling Companies, Inc., New Albany, MS
TA–W–55,863; Dorby Frocks, New York, NY
TA–W–55,690; Tower Automotive, Michigan Limited Partnership, Greenville, MI
TA–W–55,775; American Fibrit, Automotive Group, a wholly owned subsidiary of Johnson Controls, Inc., Battle Creek, MI, engaged in employment related to the production of Saturn instrument panels and Mercedes door panels are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–55,650; Nokia, Inc., subsidiary of Nokia Corp., Customer Care Repair Services, Fort Worth, TX
TA–W–55,767; Lenox, Inc., Oxford, NC
TA–W–55,813; Nuvo Corp., subsidiary of Nuvo Network Management, Inc., Minnetonka, MN
TA–W–55,663; Hewlett-Packard Co., Mobile Computing Group, Boise, ID
TA–W–55,755; GE IT Solutions, Inc., Erlandger Help Desk, Erlanger, KY
TA–W–55,732; John Crane, Inc., McAllen Warehouse, McAllen, TX
TA–W–55,739; Zenith Electronics Corp., a subsidiary of LG Electronics, Inc., Lincolnshire, IL
TA–W–55,692; Falcon Garments, Dallas, TX
TA–W–55,867; Blue River Consulting, Inc., Denver, CO
TA–W–55,777; Language Line Services, a div. of Language Line, LLC, Monterey, CA
TA–W–55,807; Wilbur-Ellis Co., Umatilla, OR
TA–W–55,840; Sun Microsystems, Inc., Restoration Services, Burlington, MA
TA–W–55,855; Van de Wiele-IRO, Inc., Charlotte, NC
TA–W–55,826; Dendrite International, Stroudsburg, PA

The investigation revealed that criterion (a)(2)(A)(I.A) and (a)(2)(B)(II.A) (no employment decline) has not been met.

TA–W–55,780; GE Security, Tualatin Div., a subsidiary of General Electric, Tualatin, OR
TA–W–55,849; Eaton Corp., Three Rivers, MI
TA–W–55,764; DeVlieg Bullard II, Inc., Services Group, Machesney Park, IL
TA–W–55,757; Bernhardt Furniture Co., Bernhardt Central Warehouse, Lenoir, NC, A; Bernhardt Central Services, Lenoir, NC, B; Corporate Office, Lenoir, NC, D; Plant 1B, Lenoir, NC, F; Plant 3, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, G; Plant 4, including on-site leased workers of People Connection Staffing, Lenoir, NC, H; Plant 5, including on-site leased workers of Able Body Labor, Lenoir, NC, I; Plant 6, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, J; Plant 7, Lenoir, NC, K; Plant 9, including on-site leased workers of Accuforce Staffing Forces and PSU, Shelby, NC, L; Plant 11, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, M; Plant 14, including on-site leased workers of USA Staffing, Cherryville, NC

The investigation revealed that criterion (a)(2)(A)(I.B) (Sales or

production, or both, did not decline) and (a)(2)(B)(II.B) (has shifted production to a county not under the free trade agreement with U.S.) have not been met.

TA–W–55,594; Bosch-Rexroth Corp., Mobile Hydraulics Div., Wooster, OH

TA–W–55,689; Alpha Circuit Technology LLC, Rogers, MN

TA–W–55,715; Merix Corp., including leased workers of Express Personnel and Xenium, Forest Grove, OR

TA–W–55,796; Volunteer Knit Apparel, Inc., New Tazewell, TN

TA–W–55,760; C&D Lumber Co., Riddle, OR

TA–W–55,874 & A; Evansville Veneer, Div. of Kimball, Inc., Chandler, IN and Sales Office, Div. of Kimball, Inc., High Point, NC

TA–W–55,794; Schneider Electric, Oxford Manufacturing Plant, Oxford, OH

The investigation revealed that criteria (a)(2)(A) (I.C) increased imports and (II.C) (has shifted production to a foreign country) have not been met.

TA–W–55,748; Liz Claiborne, Inc., North Bergen, NJ

The investigation revealed that criteria (2) has not been met. The workers firm (or subdivision) is not a supplier or downstream producer to trade-affected companies.

TA–W–55,821; Lear Corp., Seating Systems Div., Hazelwood, MO

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of (a)(2)(A) (increased imports) of Section 222 have been met.

TA–W–55,707; Iris Apparel, Inc., including on-site leased workers from Skilstaf, Clarkrange, TN: September 20, 2003.

TA–W–55,770; Tie Assembly, Inc., New York, NY: September 22, 2003.

TA–W–55,758; Technical Associates, leased workers at Brown & Williamson Tobacco Corp., Macon, GA: March 18, 2003.

TA–W–55,717; General Chemical, Marcus Hook Plant, a Div. of Gentek, Inc., Claymont, DE: September 14, 2003.

TA–W–55,656 & A; Bombardier Transportation, a subsidiary of Bombardier, Inc., Propulsion Div., Pittsburgh, PA and Total Transit Systems (TTS) Div., Pittsburgh, PA: September 8, 2003.

TA–W–55,723; Rising Tide Ltd, Kindred Spirit Div., Florence, MA: September 15, 2003.

TA–W–55,713; Techform Advanced Casting Technology, LLC, a subsidiary of Techform, Inc., including on-site leased workers from Employment Trends, Milwaukie, OR: September 27, 2003.

TA–W–55,761; Technicon Engineering, leased workers at Brown & Williamson Tobacco Corp., Macon, GA: September 24, 2003.

TA–W–55,714; Interface Fabrics, Customer Service Department, Elkin, NC: October 1, 2003.

TA–W–55,774; Capitol Records, Inc., Customer Fulfillment Operations, a subsidiary of EMI Music, including on-site leased workers of Adecco, Jacksonville, IL: September 29, 2003.

TA–W–55,878; Jumpking, Trampoline Div., a subsidiary of Icon Health & Fitness, including leased workers of Gonzales Labor Staffing and PDQ Staffing, Mesquite, TX: October 20, 2003.

TA–W–55,908; Boericke and Tafel, a subsidiary of Nature's Way Products Holding Company, including leased workers of Remedy Intelligence Staffing, Santa Rosa, CA: October 21, 2003.

TA–W–55,941; Gerity-Schultz Corp., Toledo, OH: October 4, 2003.

TA–W–55,710; MPR Associates, subsidiary of Distinct Marketing Designs, Inc., High Point, NC: September 27, 2003.

TA–W–55,816; Tek Industries, Accu, Cut Division, Fremont, NE: October 6, 2003.

TA–W–55,687; Lace Lastics, Inc., Oxford, NC: September 24, 2003.

TA–W–55,697; MacDonald Tube Products, Inc., Madison Heights, MI: September 19, 2003.

TA–W–55,811; Goza Manufacturing, Fort Payne, AL: October 15, 2003.

TA–W–55,654; ELCA Fashion, Inc., including on-site leased workers from CMD Management Corp., El Monte, CA: September 20, 2003.

TA–W–55,861; Northwest Pipe Co., Portland, OR: October 19, 2003.

TA–W–55,828; Ross Mould, Inc., Washington, PA: October 12, 2003.

TA–W–55,852; Guide Corp., Monroe, LA: October 22, 2003.

TA–W–55,754 & A; Dan River, Inc., 111 W 40th St., Sales & Styling Div., New York, NY and 1325 Ave. of The Americas, New York, NY: October 8, 2003.

TA–W–55,830; Modine Manufacturing, Emporia, KS: October 18, 2003.

TA–W–55,860; United States Ceramic Tile Co., East Sparta, OH: November 30, 2003.

TA–W–55,844; Stauffer Glove and Safety Co., Employees Working at Techneglas, Inc., Pittston, PA: September 28, 2003.

TA–W–55,752; Grand Traverse Engineering, Inc., Williamsburg, MI: September 29, 2003.

TA–W–55,746 &A; Westpoint Stevens, Alamance Plant and Distribution Center, Bed Products Div., Burlington, NC and Clemson Fabrication Plant and Distribution Center, Bed Products Div., Clemson, SC: October 4, 2003.

TA–W–55,670; Hartford Technologies Co., Subsidiary of Virginia Industries, Inc., Rocky Hill, CT: September 22, 2003.

TA–W–55,751; Seams, Inc., White Mills, PA: October 6, 2003.

TA–W–55,888; Trimtex Co., Inc., Williamsport, PA: October 29, 2003.

TA–W–55,672; American Umbrella Co., Inc., Ridgewood, NY: August 27, 2003.

TA–W–55,743; Dawson Furniture Co., Inc., Webb City, MO: November 8, 2004.

TA–W–55,934; Bogner of America, Newport, VT: November 2, 2003.

TA–W–55,801 & A; Atwood Mobile Products, a subsidiary of Dura Automotive Systems, Hiawatha Plant, Rockford, IL and Fabrication Center, Rockford, IL: October 14, 2003.

TA–W–55,762; Seton Company, Newark, NJ: October 7, 2003.

TA–W–55,797; Hedstrom Corp., Backyard and Fun Div., including on-site leased workers from Spherion Corp., and Thomas Staffing Services, Bedford, PA: October 13, 2003.

TA–W–55,776; Whitewood Industries, Inc., Pocahontas Div., Pocahontas, AR: October 7, 2003.

TA–W–55,711; San Francisco Sewing Association, Daly City, CA: September 29, 2003.

TA–W–55,737; F.S. Childers and Sons Lumber Co., Inc., Taylorsville, NC: October 4, 2003.

TA–W–55,870; Philadelphia Binding & Trimming Corp., Philadelphia, PA: October 20, 2003.

TA–W–55,615 & A; Innovative Leather Technologies, Livonia, MI and Canton, MI: September 13, 2003.

TA–W–55,725; Tupperware U.S., Inc., including on-site leased workers from The Holland Group, Hemingway, SC: August 28, 2003.

TA–W–55,721; NCH Sewing, Inc., (formerly located in San Francisco,

CA), Daly City, CA: September 20, 2003.

TA–W–55,673; Magi, Inc., Okanogan, WA: September 21, 2003.

TA–W–55,667; Dynamic Machining & Plastics, Henry, TN: September 23, 2003.

TA–W–55,757C & TA–W–55,757E; Bernhardt Furniture Co, Plant 1A, including on-site leased workers of People Connection Staffing, Lenoir, North Carolina and Plant 2, including on-site leased workers of People Connection Staffing, Lenoir, NC: September 26, 2004.

The following certifications have been issued. The requirements of (a) (2) (B) (shift in production) of Section 222 have been met.

TA–W–55,768; Japlar Group, Inc., Cincinnati, OH: October 1, 2003.

TA–W–55,858; Orion Sewing Co., San Francisco, CA: September 29, 2003.

TA–W–55,926; Emerson Heating Products, Vernon, AL: November 3, 2003.

TA–W–55,963; Square D Company, Standard Products Div., Lincoln, NE: November 5, 2003.

TA–W–55,932; Leon-Ferenbach, Inc., Johnson City, TN: October 13, 2003.

TA–W–55,795; Emerson Network Power, Energy Systems, North America, Lorain, OH: November 7, 2004.

TA–W–55,882; Federal-Mogul Corp., Sealing Systems Div., Frankfort, IN: October 21, 2003.

TA–W–55,869; Teleplan International, Norcross, GA: October 1, 2003.

TA–W–55,766; Aerotek, Inc., Employees Working at Solectron USA, Inc., Charlotte, NC: October 8, 2003.

TA–W–55,775; American Fibrit, Automotive Group, a wholly owned subsidiary of Johnson Controls, Inc., Battle Creek, MI, engaged in employment related to the production of GM Grand Prix door panels who became totally or partially separated on or after October 7, 2003.

TA–W–55,856; Teepak, LLC, including leased workers of Westaff, Alternative Staffing, Snelling Personnel and TPC Staffing Agency, Wienie Pak Div., Summerville, SC: October 20, 2003.

TA–W–55,784; Conso International Corp., Outside Sales, Murrieta, CA: August 23, 2003.

TA–W–55,729; Jervis B. Webb Company, Mt. Vernon, OH: September 22, 2003.

TA–W–55,814; United Receptacle, Inc., Pottsville, PA: October 13, 2003.

TA–W–55,930; Trivirix, Salt Lake City, UT: October 26, 2003.

TA–W–55,916; Furnlite, Inc., Fallston, NC: October 26, 2003.

TA–W–55,788; TI Group Automotive Systems, Ashley, IN: October 4, 2003.

TA–W–55,834; Dreamtime, Inc., Santa Cruz, CA: October 12, 2003.

TA–W–55,872; Renfro Corp., Riverside Plant, Mt. Airy, NC: October 21, 2003.

TA–W–55,853; Avery Dennison, Summit Plant, formerly known as L&E Pack, including on-site leased workers of Adecco, Greensboro, NC: October 22, 2003.

TA–W–55,825 & A; Jockey International, Inc., Carlisle, KY and Mt. Sterling, KY: October 18, 2003.

TA–W–55,818; Vishay Intertechnology, Dale Electronics Div., Norfolk, NE: October 18, 2003.

TA–W–55,520 & A; Galey & Lord Industries, Inc., New York, NY and Greensboro Corporate Office, Greensboro, NC: August 24, 2003.

TA–W–55,902; Lion Ribbon Company, Inc., a subsidiary of Berwick Offray, LLC, Anniston, AL: November 1, 2003.

TA–W–55,804; South East Printing and Embroidery, including leased workers of Staffing Concepts National, Miami, FL: October 14, 2003.

TA–W–55,824; Naturally Knits, Inc., Gastonia, NC: October 12, 2003.

TA–W–55,901; Raltron Electronics Corp., Miami, FL: November 1, 2003.

TA–W–55,910; Temoinsa Corp., a wholly owned subsidiary of Temoinsa, Plattsburgh, NY: October 27, 2003.

TA–W–55,909; Turbon International, Inc., including on-site leased workers of Performance Personnel, York, PA: November 3, 2003.

TA–W–55,954; Standard Register Co., a wholly owned subsidiary of Standard Register, Radcliff, KY: November 5, 2003.

TA–W–55,790; St. John Knits, Inc., Jewelry Department, Santa Ana, CA: October 4, 2003.

TA–W–55,759A; Chroma Systems, a subsidiary of Collins & Aikman/ Tandus Co. and The Dixie Group, Santa Ana, CA: September 13, 2003.

TA–W–55,791; Mid-West Metal Products Co., Inc., Cowan Road Plant and Warehouse One, Muncie, IN: September 30, 2003.

TA–W–55,759; Monterey Carpets, a subsidiary of Collins & Aikman/ Tandus Co., Santa Ana, CA: September 13, 2003.

TA–W–55,868; MT Picture Display Corporation of America (Ohio), a subsidiary of Matsushita Toshiba Picture Display Co., Ltd, Troy, OH: October 26, 2003.

TA–W–55,744 & A; Hendry Telephone Products, including leased workers of Volt Temporary Services, Goleta, CA and including leased workers of Adecco, Apply One, Chase, Dicker, Express Personnel, Grove, Kestone, Manpower, PDQ Temporaries, Pomerantz, Sterling, Sunbelt and Verion, Plano, TX: October 5, 2003.

TA–W–55,639; Maxine Swim Group, Inc., Los Angeles, CA: September 15, 2003.

TA–W–55,823; Haldex Brake Products Corp., Braking Controls Div., Iola, KS: October 18, 2003.

TA–W–55,802; Techneglas, Inc., Perrysburg, OH: October 7, 2003.

TA–W–55,895; Rosemount Analytical, Inc., Process Analytic Division, Orrville, OH: September 17, 2004.

TA–W–55,881; Landis + Gyr, Inc., a div. of Bayard Americas, Inc., Lafayette, In: October 27, 2003.

TA–W–55,740; American Slate & Marble of Hickory, Inc., Hickory, NC: September 28, 2003.

TA–W–55,753; VF Imagewear, Sparta, TN: September 28, 2003.

TA–W–55,693; Acuity Lighting Group, Inc., Acuity Brands Lighting Supply Chain Div., Cochran, GA: September 20, 2003.

TA–W–55,728; Medex, Inc., including leased workers of Adecco, Dublin, OH: September 28, 2003.

Negative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issued a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have not been met for the reasons specified.

The Department as determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–55,697; MacDonald Tube Products, Inc., Madison Heights, MI

TA–W–55,687; Lace Lastics, Inc., Oxford, NC

TA–W–55,788; TI Group Automotive Systems, Ashley, IN

TA–W–55,816; Tek Industries, Accu Cut Div., Fremont, NE

TA–W–55,710; MPR Associates, subsidiary of Distinct Marketing Designs, Inc., High Point, NC

TA–W–55,941; Gerity-Schultz Corp., Toledo, OH

TA–W–55,916; Furnlite, Inc., Fallston, NC

TA–W–55,930; Trivirix, Salt Lake City, UT

TA–W–55,908; Boericke and Tafel, a subsidiary of Nature's Way Products Holding Co., including leased workers of Remedy Intelligence Staffing, Santa Rosa, CA

TA–W–55,878; Jumpking, Trampoline Div., a subsidiary of Icon Health & Fitness, including leased workers of Gonzales Labor Staffing and PDQ Staffing, Mesquite, TX

TA–W–55,814; United Receptacle, Inc., Pottsville, PA

TA–W–55,729; Jervis B. Webb Company, Mt. Vernon, OH

TA–W–55,784; Conso International Corp., Outside Sales, Murrieta, CA

TA–W–55,815; Philips Consumer Electronics, Service Publications Department, Knoxville, TN

TA–W–55,856; Teepak, LLC, including leased workers of Westaff, Alternative Staffing, Snelling Personnel and TPC Staffing Agency, Wienie Pak Div., Summerville, SC

TA–W–55,766; Aerotek, Inc., Employees Working at Solectron USA, Inc., Charlotte, NC

TA–W–55,774; Capitol Records, Inc., Customer Fulfillment Operations, a subsidiary of EMI Music, including on-site leased workers of Adecco, Jacksonville, IL

TA–W–55,714; Interface Fabrics, Customer Service Department, Elkin, NC

TA–W–55,775; American Fibrit, Automotive Group, a wholly owned subsidiary of Johnson Controls, Inc., Battle Creek, MI engaged in employment related to the production of GM Grand Prix door panels.

The Department as determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

TA–W–55,834; Dreamtime, Inc., Santa Cruz, CA

TA–W–55,654; ELCA Fashion, Inc., including on-site leased workers from CMD Management Corp., El Monte, CA

TA–W–55,811; Goza Manufacturing, Fort Payne, AL

Since the workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

TA–W–55,689; Alpha Circuit Technology LLC, Rogers, MN

TA–W–55,715; Merix Corp., including leased workers of Express Personnel and Xenium, Forest Grove, OR

TA–W–55,730; B&J Knits, Inc., Stateville, NC

TA–W–55,742; Rock-Tenn Co., Otsego, MI

TA–W–55,741; Jefferson Smurfit Corp., Corrugated Container Div., a subsidiary of Smurfit Stone Container Corp., Milford, CT

TA–W–55,485; American Italian Pasta Co., Excelsior Springs, MO

TA–W–55,658; General Dynamics Land Systems, California Technical Center, including on-site Workers from CDI Professional Services, Goleta, CA

TA–W–55,704; Quantegy, Inc., Opelika, AL

TA–W–55,839; Lindsay Claire Designs, Ltd, Niagara Falls, NY

TA–W–55,705; Mid-South Waste, a subsidiary of Hi-Rise Recycling Co., Inc., New Albany, MS

TA–W–55,863; Dorby Frocks, New York, NY

TA–W–55,690; Tower Automotive, Michigan Limited Partnership, Greenville, MI

TA–W–55,732; John Crane, Inc., McAllen Warehouse, McAllen, TX

TA–W–55,739; Zenith Electronics Corp., a subsidiary of LG Electronics, Inc., Lincolnshire, IL

TA–W–55,692; Falcon Garments, Dallas, TX

TA–W–55,867; Blue River Consulting, Inc., Denver, CO

TA–W–55,807; Wilbur-Ellis Co., Umatilla, OR

TA–W–55,849; Eaton Corp., Three Rivers, MI

TA–W–55,777; Language Line Services, a div. of Language Line, LLC, Monterey, CA

TA–W–55,840; Sun Microsystems, Inc., Restoration Services, Burlington, MA

TA–W–55,855; Van de Wiele-IRO, Inc., Charlotte, NC

TA–W–55,826; Dendrite International, Stroudsburg, PA

TA–W–55,780; GE Security, Tualatin Div., a subsidiary of General Electric, Tualatin, OR

TA–W–55,760; C&D Lumber Co., Riddle, OR

TA–W–55,764; DeVlieg Bullard II, Inc., currently known as Bourn and Dock, Inc., Services Group, Machesney Park, IL

TA–W–55,796; Volunteer Knit Apparel, Inc., New Tazewell, TN

TA–W–55,874 &A; Evansville Veneer, div. of Kimball, Inc., Chandler, IN and Sales Office, Div. of Kimball, Inc., High Point, NC

TA–W–55,794; Schneider Electric, Oxford Manufacturing Plant, Oxford, OH

TA–W–55,748; Liz Claiborne, Inc., North Bergen, NJ

TA–W–55,821; Lear Corp., Seating Systems Div., Hazelwood, MO

TA–W–55,775; American Fibrit, Automotive Group, a wholly owned subsidiary of Johnson Controls, Inc., Battle Creek, MI, engaged in employment related to the production of Saturn instrument panels and Mercedes door panels.

TA–W–55,757; Bernhardt Furniture Co., Bernhardt Central Warehouse, Lenoir, NC, A; Bernhardt Central Services, Lenoir, NC, B; Corporate Office, Lenoir, NC, D; Plant 1B, Lenoir, NC, F; Plant 3, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, G; Plant 4, including on-site leased workers of People Connection Staffing, Lenoir, NC, H; Plant 5, including on-site leased workers of Able Body Labor, Lenoir, NC, I; Plant 6, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, J; Plant 7, Lenoir, NC, K; Plant 9, including on-site leased workers of Accuforce Staffing Forces and PSU, Shelby, NC, L; Plant 11, including on-site leased workers of Accuforce Staffing Forces, Lenoir, NC, M; Plant 14, including on-site leased workers of USA Staffing, Cherryville, NC

Affirmative Determinations for Alternative Trade Ajdustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determinations.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have been met.

I. Whether a significant number of workers in the workers' firm are 50 years of age or older.

II. Whether the workers in the workers' firm possess skills that are not easily transferable.

III. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

TA–W–55,728; Medex, Inc., including leased workers of Adecco, Dublin, OH: September 28, 2003.

TA–W–55,740; American Slate & Marble of Hickory, Inc., Hickory, NC: September 28, 2003.

TA–W–55,753; VF Imagewear, Sparta, TN: September 28, 2003.

TA–W–55,802; Techneglas, Inc., Perrysburg, OH: October 7, 2003.

TA–W–55,693; Acuity Lighting Group, Inc., Acuity Brands Lighting Supply Chain Div., Cochran, GA: September 20, 2003.

TA–W–55,667; Dynamic Machining & Plastics, Henry, TN: September 23, 2003.

TA–W–55,673; Magi, Inc., Okanogan, WA: September 21, 2003.

TA–W–55,721; NCH Sewing, Inc., (formerly located in San Francisco, CA), Daly City, CA: September 20, 2003.

TA–W–55,725; Tupperware U.S., Inc., including on-site leased workers from The Holland Group, Hemingway, SC: August 28, 2003.

TA–W–55,615 &A; Innovative Leather Technologies, Livonia, MI and Canton, MI: September 13, 2003.

TA–W–55,639; Maxine Swim Group, Inc., Los Angeles, CA: September 15, 2003.

TA–W–55,823; Haldex Brake Products Corp., Braking Controls Div., Iola, KS: October 18, 2003.

TA–W–55,895; Rosemount Analytical, Inc., Process Analytic Div., Orrville, OH: September 17, 2004.

TA–W–55,881; Landis + Gyr, Inc., a Div. of Bayard Americas, Inc., Lafayette, IN: October 27, 2003.

TA–W–55,870; Philadelphia Binding & Trimming Corp., Philadelphia, PA: October 20, 2003.

TA–W–55,868; MT Picture Display Corporation of America (Ohio), a subsidiary of Matsushita Toshiba Picture Display Co., Ltd, Troy, OH: October 26, 2003.

TA–W–55,711; San Francisco Sewing Association, Daly City, CA: September 29, 2003.

TA–W–55,762; Seton Co., Newark, NJ: October 7, 2003.

TA–W–55,737; F.S. Childers and Sons Lumber Co., Inc., Taylorsville, NC: October 4, 2003.

TA–W–55,759; Monterey Carpets, a subsidiary of Collins & Aikman/ Tandus Company, Santa Ana, CA: September 13, 2003.

TA–W–55,791; Mid-West Metal Products Co., Inc., Cowan Road Plant and Warehouse One, Muncie, IN: September 30, 2003.

TA–W–55,759A; Chroma Systems, a subsidiary of Collins & Aikman/ Tandus Co. and The Dixie Group, Santa Ana, CA: September 13, 2003.

TA–W–55,776; Whitewood Industries, Inc., Pocahontas Div., Pocahontas, AR: October 7, 2003.

TA–W–55,790; St. John Knits, Inc., Jewelry Department, Santa Ana, CA: October 4, 2003.

TA–W–55,797; Hedstrom Corp., Backyard and Fun Div., including on-site leased workers from Spherion Corporation and Thomas Staffing Services, Bedford, PA: October 13, 2003.

TA–W–55,801 &A; Atwood Mobile Products, a subsidiary of Dura Automotive Systems, Hiawatha Plant, Rockford, IL and Fabrication Center, Rockford, IL: October 14, 2003.

TA–W–55,934; Bogner of America, Newport, VT: November 2, 2003.

TA–W–55,954; Standard Register Co., a wholly owned subsidiary of Standard Register, Radcliff, KY: November 5, 2003.

TA–W–55,909; Turbon International, Inc., including on-site leased workers of Performance Personnel, York, PA: November 3, 2003.

TA–W–55,910; Temoinsa Corp., a wholly owned subsidiary of Temoinsa, Plattsburgh, NY: October 27, 2003.

TA–W–55,901; Raltron Electronics Corp., Miami, FL: November 1, 2003.

TA–W–55,888; Trimtex Co., Inc., Williamsport, PA: October 29, 2003.

TA–W–55,672; American Umbrella Co., Inc., Ridgewood, NY: August 27, 2003.

TA–W–55,743; Dawson Furniture Company, Inc., Webb City, MO: November 4, 2004.

TA–W–55,804; South East Printing and Embroidery, including leased workers of Staffing Concepts National, Miami, FL: October 14, 2003.

TA–W–55,824; Naturally Knits, Inc., Gastonia, NC: October 12, 2003.

TA–W–55,751; Seams, Inc., White Mills, PA: October 6, 2003.

TA–W–55,902; Lion Ribbon Co., Inc., a subsidiary of Berwick Offray, LLC, Anniston, AL: November 1, 2003.

TA–W–55,744 &A; Hendry Telephone Products, including leased workers of Volt Temporary Services, Goleta, CA and including leased workers of Adecco, Apple One, Chase, Dicker, Express Personnel, Grove, Keystone, Manpower, PDQ Temporaries, Pomerantz, Sterling, Plano, TX: October 5, 2003.

TA–W–55,670; Hartford Technologies Co., subsidiary of Virginia Industries, Inc., Rocky Hill, CT: September 22, 2003.

TA–W–55,746; Westpoint Stevens, Alamance Plant and Distribution Center, Bed Products Div., Burlington, NC and Clemson Fabrication Plant and Distribution Center, Bed Products Div., Clemson, SC: October 4, 2003.

TA–W–55,752; Grand Traverse Engineering, Inc., Williamsburg, MI: September 29, 2003.

TA–W–55,844; Stauffer Glove and Safety Co., Employees Working at Techneglas, Inc., Pittston, PA: September 28, 2003.

TA–W–55,860; United States Ceramic Tile Co., East Sparta, OH: November 30, 2003.

TA–W–55,830; Modine Manufacturing, Emporia, KS: October 18, 2003.

TA–W–55,754 & A; Dan River, Inc., 111 W 40th St, Sales & Styling Div., New York, NY and 1325 Avenue of The Americas, New York, NY: October 8, 2003.

TA–W–55,818; Vishay Intertechnology, Dale Electronics Div., Norfolk, NE: October 18, 2003.

TA–W–55,825 & A; Jockey International, Inc., Carlisle, KY and Mt, Sterling, KY: October 18, 2003.

TA–W–55,828; Ross Mould, Inc., Washington, PA: October 12, 2003.

TA–W–55,852; Guide Corporation, Monroe, LA: October 22, 2003.

TA–W–55,853; Avery Dennison, Summit Plant, Formerly Known as L&E Pack, Including On-Site Leased Workers of Adecco, Greensboro, NC: October 22, 2003.

TA–W–55,861; Northwest Pipe Company, Portland, OR: October 19, 2003.

TA–W–55,872; Renfro Corp., Riverside Plant, Mt. Airy, NC: October 21, 2003.

TA–W–55,757C and TA–W–55,757E; Bernhardt Furniture Co., Plant 1A, including on-site leased workers of People Connection Staffing, Lenoir, NC and Plant 2, including on-site leased workers of People Connection Staffing, Lenoir, NC: September 26, 2004.

I hereby certify that the aforementioned determinations were issued during the month of November 2004. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: November 30, 2004.

Timothy Sullivan,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E4–3587 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–56,037]

Specialty Electronics, Inc., Landrum, SC; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on November 19, 2004 in response to a worker petition which was filed by a company official on behalf of workers at Specialty Electronics, Inc., Landrum, South Carolina.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC this 22nd day of November, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3586 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–54,635]

Westside Stitching, Inc., West Wyoming, PA; Notice of Negative Determination on Remand

The United States Court of International Trade (USCIT) granted the Department of Labor's request for voluntary remand of the negative determination on reconsideration in *Former Employees of Westside Stitching, Inc.* v. *Secretary of Labor* (Court No. 04–00410).

The Department's denial of Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) for the workers of Westside Stitching, Inc., West Wyoming, Pennsylvania was issued on June 16, 2004 and was published in the **Federal Register** on July 7, 2004 (69 FR 40983). Workers produce motion furniture. The investigation revealed no shift of production or increased imports of motion furniture during the relevant period by the subject company or its customers.

By application of July 12, 2004, the company requested administrative reconsideration of the negative determination, alleging that the subject firm lost business due to its major customer importing lift mechanisms from China.

The Notice of Negative Determination Regarding Application for Reconsideration was issued on August 3, 2004 and was published in the **Federal Register** on August 11, 2004 (69 FR 48895). The request was denied because lift mechanisms are a component part of motion furniture and because the company's major declining customer did not import motion furniture.

On October 5, 2004, the USCIT granted a consent motion for voluntary remand and ordered the Department to conduct a further investigation and determine whether the petitioning workers are eligibility for trade adjustment assistance.

In response to Plaintiff's allegations regarding alleged increased imports of lift mechanisms, the Department contacted the company to ascertain whether the subject facility produced lift mechanisms. The investigation revealed that the subject company produces motion furniture and not lift mechanisms.

Pursuant to 29 CFR Section 90.2, ''[a]n imported article is directly competitive with a domestic article at an earlier or later stage of processing, and a domestic article is directly competitive with an imported article at an earlier or later stage of processing, if the importation of the article has an economic effect on producers of the domestic article comparable to the effect of importation of articles in the same stage of processing as the domestic article.''

The Department has consistently determined that the economic impact of imported component parts is not competitive with the economic impact of imported final products.

The determination that components of a product are not like or directly competitive with the final product is consistent with *Gropper* v. *Donovan,* 6 CIT 103, 104, 569 F.Supp. 883, 884 (1983) where the court held that ''a component, such as finished fabric, is not 'like or directly competitive' with an end product, such as knit fabric garments, within the meaning of section 222(3) [of the Trade Act].'' Because the subject company produced only the final product, increased imports of component parts, absent increased imports of the final product, cannot be the basis for TAA certification.

The Department also conducted another survey of the subject company's major declining customer regarding import purchases of articles produced at the subject facility during the relevant period, 2002, 2003, January through March 2003 and January through March 2004. The survey revealed that the customer did not import motion furniture during the relevant period.

Because no basis for TAA certification of the subject worker group was found, an investigation to determine ATAA certification was not conducted.

Conclusion

After reconsideration on remand, I affirm the original notice of negative determination of eligibility to apply for adjustment assistance for workers and former workers of Westside Stitching, Inc., West Wyoming, Pennsylvania.

Signed at Washington, DC, this 2nd day of December 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3579 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,887]

Woodbridge Corporation, Whitmore Lake, MI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on October 29, 2004 in response to a worker petition which was filed by a company official on behalf of workers at Woodbridge Corporation, Whitmore Lake, Michigan.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC this 24th day of November, 2004.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–3583 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–54,636]

Wyoming Wood Products, Inc., West Wyoming, PA; Notice of Negative Determination on Remand

The United States Court of International Trade (USCIT) granted the Department of Labor's request for voluntary remand of the negative determination on reconsideration in *Former Employees of Westside Stitching, Inc. and Wyoming Wood*

Products, Inc. v. *Secretary of Labor* (Court No. 04–00410).

The Department's denial of Trade Adjustment Assistance (TAA) and Alternate Trade Adjustment Assistance (TAA) for workers of Wyoming Wood Products, Inc., West Wyoming, Pennsylvania was issued on June 16, 2004 and was published in the **Federal Register** on July 7, 2004 (69 FR 40983). Petitioners had filed as an adversely affected secondary group. The workers produced wood frames used in the production of motion furniture. The investigation revealed that the company to which the subject company supplied component parts was not TAA certified.

A Dismissal of Application for Reconsideration was issued on August 4, 2004 and was published in the **Federal Register** on August 11, 2004 (69 FR 48895). The request was denied because the application contained no new substantial information.

On October 5, 2004, the USCIT granted a consent motion for voluntary remand and ordered the Department to conduct a further investigation and determine whether the petitioning workers are eligible for trade adjustment assistance.

Pursuant to 19 U.S.C. 2272(c)(4), a worker must be employed by a company that produces or supplies ''component parts for articles that were the basis for a certification of eligibility'' of a group of primarily trade-affected workers to be certified as a secondarily trade-affected worker, per the Trade Act.

The subject company supplied wood frames exclusively to Westside Stitching, Inc., West Wyoming, Pennsylvania, a company that the Department has determined not to be adversely import-impacted (TA–W–54,635).

Conclusion

After reconsideration on remand, I affirm the original notice of negative determination of eligibility to apply for adjustment assistance for workers and former workers of Wyoming Wood Products, Inc., West Wyoming, Pennsylvania.

Signed at Washington, DC this 2nd day of December 2004.

Elliott S. Kushner,

Certifying Officer, Division of of Trade Adjustment Assistance.

[FR Doc. E4–3580 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–30–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of existing safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Consolidation Coal Company

[Docket No. M–2004–048–C]

Consolidation Coal Company, 1800 Washington Road, Pittsburgh, Pennsylvania 15241–1421 has filed a petition to modify the application of 30 CFR 75.507 (Power connection points) to its Blacksville No. 2 Mine (MSHA I.D. No. 46–01968) located in Monongalia County, West Virginia. The petitioner proposes to use non-permissible submersible pumps in bleeder and return entries and sealed areas of the Blacksville No. 2 Mine under specific terms and conditions. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

2. Consolidation Coal Company

[Docket No. M–2004–049–C]

Consolidation Coal Company, 1800 Washington Road, Pittsburgh, Pennsylvania 15241–1421 has filed a petition to modify the application of 30 CFR 75.507 (Power connection points) to its Loveridge No. 22 Mine (MSHA I.D. No. 46–01433) located in Marion County, West Virginia. The petitioner proposes to use non-permissible submersible pumps in bleeder and return entries and sealed areas of the Loveridge No. 22 Mine under specific terms and conditions. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

Request for Comments

Persons interested in these petitions are encouraged to submit comments via Federal eRulemaking Portal: *http://www.regulations.gov*; e-mail: *Comments@MSHA.gov*; fax: (202) 693–9441; or Regular Mail/Hand Delivery/Courier: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. All comments must be postmarked or received in that office on or before January 10, 2005. Copies of these petitions are available for inspection at that address.

Dated at Arlington, Virginia this 3rd day of December 2004.

Marvin W. Nichols, Jr.,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 04–27035 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR 1218–0242(2005)]

Powered Industrial Trucks; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits public comment concerning its request for an extension of the information-collection requirements contained in the Powered Industrial Trucks Standard (29 CFR 1910.178).

DATES: Comments must be submitted by the following dates:

Hard copy: Your comments must be submitted (postmarked or received) by February 7, 2005.

Facsimile and electronic transmission: Your comments must be received by February 7, 2005.

ADDRESSES: You may submit comments, identified by OSHA Docket No. ICR–1218–0242(2005), by any of the following methods:

Regular mail, express delivery, hand delivery, and messenger service: Submit your comments and attachments to the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). OSHA Docket Office and Department of Labor hours are 8:15 a.m. to 4:45 p.m., e.t.

Facsimile: If your comments are 10 pages or fewer in length, including attachments, you may fax them to the OSHA Docket Office at (202) 693–1648.

Electronic: You may submit comments through the Internet at *http://ecomments.osha.gov.* Follow instructions on the OSHA Web page for submitting comments.

Docket: For access to the docket to read or download comments or background materials, such as the complete Information Collection Request (ICR) (containing the

Supporting Statement, OMB–83–I Form, and attachments), go to OSHA's Web page at *http://www.OSHA.gov.* In addition, comments, submissions and the ICR are available for inspection and copying at the OSHA Docket Office at the address above. You may also contact Theda Kenney at the address below to obtain a copy of the ICR. For additional information on submitting comments, please see the ''Public Participation'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Theda Kenney, Directorate of Standards and Guidance, OSHA, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Public Participation—Submission of Comments on this Notice and Internet Access to Comments and Submissions

You may submit comments and supporting materials in response to this notice by (1) hard copy, (2) FAX transmission (facsimile), or (3) electronically through the OSHA Web page. Because of security-related problems, there may be a significant delay in the receipt of comments by regular mail. Please contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about security procedures concerning the delivery of submissions by express delivery, hand delivery and courier service.

All comments, submissions and background documents are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions posted on OSHA's Web page are available at *http://www.OSHA.gov.* Contact the OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance using the Web page to locate docket submissions.

Electronic copies of this **Federal Register** notice as well as other relevant documents are available on OSHA's Web page. Since all submissions become public, private information such as social security numbers should not be submitted.

II. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information-collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657).

Paragraph (a)(4) of 1910.178 requires that employers obtain the manufacturer's written approval before modifying a powered industrial truck in a manner that affects its capacity and safe operation; if the manufacturer grants such approval, the employer must revise capacity, operation, and maintenance instruction plates, tags, and decals accordingly. For front-end attachments not installed by the manufacturer, paragraph (a)(5) mandates that employers provide a label (marking) on the truck that identifies the attachment, as well as the weight of both the truck and the attachment when the attachment is at maximum elevation with a laterally centered load. Paragraph (a)(6) specifies that employers must ensure that the markers required by paragraphs (a)(3) through (a)(5) remain affixed to the truck and are legible.

Paragraphs (l)(1) through (l)(6) of the Standard contain the paperwork requirements necessary to certify the training provided to powered industrial truck operators. Accordingly, these paragraphs specify the following requirements for employers:

- Paragraph (l)(1)—Ensure that trainees successfully complete the training and evaluation requirements of paragraph (1) prior to operating a truck without direct supervision.
- Paragraph (1)(2)—Allow trainees to operate a truck only under the direct supervision of an individual with the knowledge, training, and experience to train operators and to evaluate their performance, and under conditions that do not endanger other employees. The training program must consist of formal instruction, practical training, and evaluation of the trainee's performance in the workplace.
- Paragraph (1)(3)—Provide the trainees with initial training on each of 22 specified topics, except on topics that the employer demonstrates do not apply to the safe operation of the truck(s) in the employer's workplace.
- Paragraphs (1)(4)(i) and (1)(4)(ii)—Administer refresher training and evaluation on relevant topics to operators found by observation or formal evaluation to operate a truck unsafely, involved in an accident or near-miss incident, or assigned to operate another type of truck, or if the employer identifies a workplace condition that could affect safe truck operation.
- Paragraph (1)(4)(iii)—Evaluate each operator's performance at least once every three years.
- Paragraph (1)(5)—Train rehires only in specific topics that they performed unsuccessfully during an evaluation and that are appropriate to the employer's truck(s) and workplace conditions.
- Paragraph (1)(6)—Certify that each operator meets the training and evaluation requirements specified by paragraph (1). This certification must include the operator's name, the training date, the evaluation date, and the identity of the individual(s) who performed the training and evaluation.

Requiring markers notifies employees of the conditions under which they can safely operate powered industrial trucks, thereby preventing such hazards as fires and explosions caused by poorly designed electrical systems, rollovers/tipovers that result from exceeding a truck's stability characteristics, and falling loads that occur when loads exceed the lifting capacities of attachments. Certification of training and evaluation provides a means of informing employers that their employees received the training, and demonstrated the performance necessary to operate a truck within its capacity and control limitations. Therefore, by ensuring that employees operate only trucks that are in proper working order, and do so safely, employers prevent severe injury and death to truck operators and other employees who are in the vicinity of the trucks. Finally, these paperwork requirements are the most efficient means for an OSHA compliance officer to determine that an employer properly notified employees regarding the design and construction of, and modifications made to, the trucks they are operating, and that an employer provided them with the required training.

III. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information-collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;

• The accuracy of OSHA's estimate of the burden (time and costs) of the information-collection requirements, including the validity of the methodology and assumptions used;

• The quality, utility, and clarity of the information collected; and

• Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information-collection and -transmission techniques.

IV. Proposed Actions

OSHA proposes to extend the Office of Management and Budget's (OMB) approval of the collection of information (paperwork) requirements necessitated by the Powered Industrial Trucks Standard (29 CFR 1910.178). The Agency will include this summary in its request to OMB to extend the approval of these collection of information requirements.

Type of Review: Extension of currently approved information collection requirements.

Title: Powered Industrial Trucks.

OMB Number: 1218–0242.

Affected Public: Business or other for-profits; not-for-profit organizations, Federal government, State, local or tribal government.

Number of Respondents: 999,000.

Frequency: On occasion; annually; triennially.

Average Time Per Response: Ranges from two minutes (.03 hour) to mark an approved truck to 6.50 hours to train new truck operators.

Estimated Total Burden Hours: 773,145.

Estimated Cost (Operation and Maintenance): $209,790.

V. Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*), and Secretary of Labor's Order No. 5–2002 (67 FR 65008).

Signed in Washington, DC, on December 1, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 04–27014 Filed 12–8–04; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency proposes to request extension of a currently approved information collection, the Financial Disclosure Form, Standard Form 714, that is used to make personnel security determinations, including whether to grant a security clearance, to allow access to classified information, sensitive areas, and equipment; or to permit assignment to a sensitive national security position. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before February 7, 2005 to be assured of consideration.

ADDRESSES: Comments should be sent to: Paperwork Reduction Act Comments (NHP), Room 4400, National Archives and Records Administration, 8601 Adelphi Rd, College Park, MD 20740–6001; or faxed to 301–837–3213; or electronically mailed to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694, or fax number 301–837–3213.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA'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, including the use of information technology, to minimize the burden of the collection of information on all respondents; and (e) whether small businesses are affected by this collection. The comments that are submitted will be summarized and included in the NARA request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA is soliciting comments concerning the following information collection:

Title: Financial Disclosure Form.

OMB number: 3095–0058.

Agency form number: Standard Form 714.

Type of review: Regular.

Affected public: Business or other for-profit.

Estimated number of respondents: 25,897.

Estimated time per response: 2 hours.

Frequency of response: On occasion.

Estimated total annual burden hours: 51,794 hours.

Abstract: Executive Order 12958 as amended, ''Classified National Security Information'' authorizes the Information Security Oversight Office to develop standard forms that promote the implementation of the Government's security classification program. These forms promote consistency and uniformity in the protection of classified information.

The Financial Disclosure Form contains information that is used to make personnel security determinations, including whether to grant a security clearance; to allow access to classified information, sensitive areas, and equipment; or to permit assignment to sensitive national security positions. The data may later be used as a part of a review process to evaluate continued eligibility for access to classified information or as evidence in legal proceedings.

The Financial Disclosure Form helps law enforcement obtain pertinent information in the preliminary stages of potential espionage and counter terrorism cases.

Dated: December 2, 2004.

L. Reynolds Cahoon,

Assistant Archivist for Human Resources and Information Services.

[FR Doc. 04–26997 Filed 12–8–04; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

AGENCY HOLDING MEETING: National Science Foundation, National Science Board and its Subdivisions.

DATE AND TIME: December 15–16, 2004. December 15, 2004: 8 a.m.–5 p.m. Concurrent Sessions:

8 a.m.–8:45 a.m. (Open).

8:45 a.m.–9:15 a.m. (Open).

9:30 a.m.–12 noon (Open).

12 noon–12:30 p.m. (Closed).
1:30 p.m.–2 p.m. (Closed).
2 p.m.–4:30 p.m. (Open).
4:30 p.m.–4:45 p.m. (Open).
4:45 p.m.–5 p.m. (Closed).
December 16, 2004: 8 a.m.–3 p.m.
Concurrent Sessions:
8 a.m.–9 a.m. (Open).
9 a.m.–10 a.m. (Closed).
10 a.m.–10:45 a.m. (Open).
10:45 a.m.–11:30 a.m. (Closed).
11:30 a.m.–11:45 a.m. (Closed).
11:45 a.m.–12 noon (Closed).
1 p.m.–3 p.m. (Open).

PLACE: The National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, *www.nsf.gov/nsb.*

CONTACT FOR INFORMATION: NSF Information Center (703) 292–5111.

STATUS: Part of this meeting will be closed to the public. Part of this meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Wednesday, December 15, 2004

Open

Subcommittee on S&E Indicators (8 a.m.–8:45 a.m.) Room 1295

- Approval of minutes
- Discussion of NSB review process for Indicator Chapters and designation of chapter reviewers
- Suggestions for external reviewers
- Discussion of topics for Board Companion Piece
- Information item: Subcommittee approval of revised schedule

ad hoc Task Group on High Risk Research (8:45 a.m.–9:15 a.m.) Room 1295

- Summary of Discussion for October 2004
- Review of Charter for Task Force on Transformative Research

Committee on Audit & Oversight (9:30 a.m.–12 noon) Room 1235

- Approval of minutes
- Development of Board position on NAPA study recommendations
- 2004 Financial Statement Audit
- Chief Financial Officer's update
- Chief Information Officer's Update
- Overview of Investigative Process
- OIG Semi-Annual Report discussion
- Audit of Project Reporting on NSF Awards

Committee on Education and Human Resources (2 p.m.–4:30 p.m.) Room 1235

- Approval of minutes
- Reports and discussion items
- Presentation: Human Capital in a Global Knowledge Society
- Discussion of Industry Panel

Executive Committee (4:30 p.m.–4:45 p.m.) Room 1295

- Approval of minutes
- Updates or new business from Committee Members
- Update on 2005 NSB Retreat

Closed

Committee on Audit & Oversight (12 noon–12:30 p.m. Room 1235

- Pending Investigations

ad hoc Committee on Nominations—Class of 2006–2012 (1:30 p.m.–2 p.m.) Room 1295

- Review of candidates
- Final slate of candidates for Board approval

Executive Committee (4:45 p.m.–5 p.m.) Room 1295

- Director's Items

Thursday, December 16, 2004

Open

Committee on Programs and Plans (8 a.m.–9 a.m.) Room 1235

- Approval of Minutes
- Working Group reports
  - Task Group on Long-Lived Data Collections
  - High Risk Task Group
- Report on Major Research Facilities

Committee on Strategy and Budget (10 a.m.–10:45 a.m.) Room 1235

- Approval of minutes
- Status of FY 2005 budget request to Congress
- Discussion of budget impacts on NSB recommendations for future funding

Plenary Session of the Board (1 p.m.–3 p.m.) Room 1235

- Swear in new Board Members
- Approval of minutes
- Resolution to close portions of the February 2005 meeting
- Chairman's Report
- Director's Report
  - Congressional Update
- Committee Reports

Closed

Committee on Programs and Plans (9 a.m.–10 a.m.) Room 1235

- Action items

Committee on Strategy & Budget (10:45 a.m.–11:30 a.m.) Room 1235

- Discussion of FY 2006 NSF budget request to OMB

Executive Closed Plenary Session of the Board (11:30 a.m.–11:45 a.m.) Room 1235

- Approval of Executive Closed minutes
- Report from Nominations Committee

Closed Plenary Session ot the Board (11:45 a.m.–12 noon) Room 1235

- Approval of Closed minutes
- Awards and Agreements Resolutions
- Closed Committee reports

Michael P. Crosby,

Executive Officer, NSB.

[FR Doc. 04–27106 Filed 12–7–04; 8:44 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–336 and 50–423]

Dominion Nuclear Connecticut, Inc., Millstone Power Station, Units 2 and 3; Notice of Availability of the Draft Supplement 22 to the Generic Environmental Impact Statement and Public Meeting for the License Renewal of Millstone Power Station, Units 2 and 3

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC, the Commission) has published a draft plant-specific supplement to the Generic Environmental Impact Statement (GEIS), NUREG–1437, regarding the renewal of operating licenses DPR–65 and NPF–49 for the Millstone Power Station (MPS) Units 2 and 3, for an additional 20 years of operation. MPS is located in Waterford, Connecticut, on Millstone Point between the Niantic and Thames Rivers, approximately 40 miles to the southeast of Hartford, Connecticut. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources.

The draft Supplement to the GEIS is available for public inspection in the NRC Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, or from the Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html.* (**Note:** Public access to ADAMS has been temporarily suspended so that security reviews of publically available documents may be performed and potentially sensitive

information removed. Please check the NRC Web site for updates on the resumption of ADAMS access.) Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the PDR reference staff at 1–800–397–4209, (301) 415–4737, or by e-mail to *pdr@nrc.gov.* In addition, the Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut, and the Thames River Campus Library, 574 New London Turnpike, Norwich, Connecticut, have agreed to make the draft supplement to the GEIS available for public inspection.

Any interested party may submit comments on the draft supplement to the GEIS for consideration by the NRC staff. To be certain of consideration, comments on the draft supplement to the GEIS and the proposed action must be received by March 2, 2005. Comments received after the due date will be considered if it is practical to do so, but the NRC staff is able to assure consideration only for comments received on or before this date. Written comments on the draft supplement to the GEIS should be sent to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mailstop T–6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Comments may be hand-delivered to the NRC at 11545 Rockville Pike, Room T–6D59, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Electronic comments may be submitted to the NRC by e-mail at *MillstoneEIS@nrc.gov.* All comments received by the Commission, including those made by Federal, state, local agencies, Native American Tribes, or other interested persons, will be made available electronically at the Commission's PDR in Rockville, Maryland, and from the PARS component of ADAMS.

The NRC staff will hold a public meeting to present an overview of the draft plant-specific supplement to the GEIS and to accept public comments on the document. The public meeting will be held on January 11, 2005, at the Waterford Town Hall Auditorium, 15 Rope Ferry Road, Waterford, Connecticut. There will be two sessions to accommodate interested parties. The first session will commence at 1:30 p.m. and will continue until 4:30 p.m. The second session will commence at 7 p.m. and will continue until 10 p.m. Both meetings will be transcribed and will include: (1) A presentation of the contents of the draft plant-specific supplement to the GEIS, and (2) the opportunity for interested government agencies, organizations, and individuals to provide comments on the draft report. Additionally, the NRC staff will host informal discussions one hour prior to the start of each session at the same location. No comments on the draft supplement to the GEIS will be accepted during the informal discussions. To be considered, comments must be provided either at the transcribed public meeting or in writing, as discussed below. Persons may pre-register to attend or present oral comments at the meeting by contacting Mr. Richard L. Emch, Jr., by telephone at 1–800–368–5642, extension 1590, or by e-mail at *MillstoneEIS@nrc.gov* no later than January 6, 2005. Members of the public may also register to provide oral comments within 15 minutes of the start of each session. Individual, oral comments may be limited by the time available, depending on the number of persons who register. If special equipment or accommodations are needed to attend or present information at the public meeting, the need should be brought to Mr. Emch's attention no later than January 6, 2005, to provide the NRC staff adequate notice to determine whether the request can be accommodated.

For Further Information Contact: Mr. Richard L. Emch, Jr., License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Mr. Emch may be contacted at the aforementioned telephone number or e-mail address.

Dated in Rockville, Maryland, this 3rd day of December, 2004.

For the Nuclear Regulatory Commission.

Pao-Tsin Kuo,

Program Director, License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 04–27007 Filed 12–8–04; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 26686 ; 812–13062]

Man-Glenwood Lexington, LLC, et al., Notice of Application

December 2, 2004.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order under section 17(b) of the Investment Company Act of 1940 (the ''Act'') for an exemption from section 17(a) of the Act.

APPLICANTS: Man-Glenwood Lexington, LLC (''Lexington''), Man-Glenwood Lexington TEI, LLC (''TEI,'' together with Lexington, the ''Funds''), Man-Glenwood Lexington Associates Portfolio, LLC (''Portfolio Company''), Glenwood Capital Investments, L.L.C. (the ''Adviser''), and Man Investments Inc. (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order to permit a purchase and sale transaction as part of an exchange tender offer by a registered closed-end investment company.

FILING DATES: The application was filed on January 23, 2004, and amended on November 30, 2004.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 27, 2004, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants, 123 N. Wacker Drive, 28th Floor, Chicago, IL 60606.

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, (202) 942–0634 or Todd Kuehl, Branch Chief, (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. 202–942–8090).

Applicants' Representations

1. Lexington, TEI and the Portfolio Company, each a Delaware limited liability company, are non-diversified closed-end management investment companies registered under the Act. Lexington and TEI are each ''feeder'' funds in a master-feeder structure in which they invest all or substantially all of their assets in interests of the Portfolio Company (''Interests''), which

serves as the ''master'' fund.[1] The Portfolio Company is a ''fund of hedge funds.'' Lexington, TEI and the Portfolio Company have the same investment objectives and policies. TEI is designed for investment solely by tax-exempt and tax-deferred investors (''Tax-Exempt Investors''). Lexington was organized on August 5, 2002, and began offering its limited liability company interests (''Units'') to the public in February, 2003. TEI was organized on October 22, 2003, and began offering its Units to the public in April, 2004. Lexington's and TEI's Units are registered under the Securities Act of 1933.

2. The Adviser is an Illinois limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as the Portfolio Company's investment adviser and also provides certain administrative services to Lexington and TEI. The Distributor, a New York corporation, is a broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'') and serves as distributor for Units of Lexington and TEI.

3. Lexington and TEI continuously offer their Units at net asset value (''NAV''). Investors who purchase Units and are admitted to Lexington or TEI by their respective board of managers (the ''Board'')[2] become members of the respective Fund (''Members''). Members may not redeem Units and Units are not listed on any securities exchange. In order to provide a limited degree of liquidity to Members, Lexington and TEI may from time to time offer to repurchase Units at their NAV. Lexington's and TEI's repurchase offers for Units (and the Portfolio Company's repurchase offers for Interests) are conducted pursuant to section 23(c)(2) of the Act and rule 13e–4 under the Exchange Act.

4. Since the creation of TEI, Tax-Exempt Investors have principally invested in TEI rather than Lexington. Both taxable investors and Tax-Exempt Investors currently hold Units of Lexington. Applicants believe that Lexington's tax-exempt Unit holders (''Tax-Exempt Unit Holders'') may determine that they would be in a better position investing in the Portfolio Company through TEI. Applicants propose to conduct a tender offer in which all Unit holders of Lexington may choose to tender Units to Lexington in exchange for a cash payment of a dollar amount equal to the NAV of the Units on the tender offer valuation date (''Valuation Date''), and those Tax-Exempt Unit Holders eligible to invest in TEI may choose to tender instead any or all of their Lexington Units for an amount of full and fractional Units of TEI based on their respective NAV on the Valuation Date (the ''Transaction''). Applicants state that the intent of the Transaction is to enable Tax-Exempt Unit Holders of Lexington to move their investment to TEI without creating potential adverse consequences to themselves, the Portfolio Company, or the remaining taxable Unit holders of Lexington. The Transaction will involve a tender offer by Lexington and the Portfolio Company.[3]

5. On July 20, 2004, the Board, including a majority of managers who are not ''interested persons,'' as defined in section 2(a)(19) of the Act (''Independent Managers''), approved the Transaction on behalf of each Fund and the Portfolio Company subject to the Commission issuing an order pursuant to the application. In approving the Transaction, the Board concluded that: (a) The Transaction is consistent with the policies of each Fund and the Portfolio Company, as recited in their respective registration statements, (b) the terms of the Transaction, including the consideration to be received by each Fund and the Portfolio Company, are reasonable and fair and do not involve overreaching on the part of any person concerned, and (c) participation in the Transaction is in the best interests of each Fund and its respective Members and the Portfolio Company and its Interest holders and interests of existing Members of Lexington and TEI and the Portfolio Company's Interest holders will not be diluted as a result of the Transaction. The tender offer in connection with the Transaction is expected to begin on January 31, 2005, and expire on March 1, 2005 (''Expiration Date''). Each Fund's Units and the Portfolio Company's Interests will be valued as of the Valuation Date, anticipated to be March 31, 2005.

6. The Transaction will not be effected until the Commission has issued an order relating to the application. Applicants have agreed not to make any material changes to the Transaction without prior approval of the Commission or its staff. No repurchase fee, brokerage commissions, fees (except for customary transfer fees, if any) or other remuneration will be paid by Lexington, TEI, the Portfolio Company or any Unit holder or Interest holder in connection with the Transaction. Each of the Funds and the Portfolio Company will bear its own expenses of filing tender offer materials with the Commission.

Applicants' Legal Analysis

1. Section 17(a) of the Act prohibits any affiliated person of a registered investment company, or any affiliated person of that person (''second-tier affiliate''), acting as principal, from selling to or purchasing from the registered investment company, or any company controlled by the registered company, any security or other property. Section 2(a)(3) of the Act defines an ''affiliated person'' as, among other things, any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person; any person controlling, controlled by or under common control with, the other person; any officer, director, partner, copartner or employee of the other person; and, if the other person is an investment company, its investment adviser.

2. Applicants state that Lexington and TEI may be deemed to be affiliated persons, or second-tier affiliates, of each other. Although Lexington and TEI, as feeder funds, do not have an investment adviser, they may be deemed to be under the common control of their managers and executive officers, which are the same for each Fund. Lexington and TEI may each be deemed to be an affiliated person of the Portfolio Company and, therefore, each may also be deemed to be a second-tier affiliate of the other. In addition, to the extent that an eligible Lexington Unit holder requesting an exchange to TEI (an ''Exchanging Holder'') holds 5% or more of the outstanding voting securities of Lexington, the Exchanging Holder could be an affiliated person of Lexington and if Lexington and TEI are deemed to be affiliated persons of each other, the Exchanging Holder may be deemed to be a second-tier affiliate of TEI. Thus applicants state that the Transaction may be prohibited under section 17(a).

3. Rule 17a–7 provides in pertinent part that a purchase or sale transaction between registered investment companies which are affiliated persons, or affiliated persons of affiliated persons, of each other, is exempt from section 17(a) provided that certain conditions are met. Applicants state that they can not rely on rule 17a–7, however, because the Transaction would not meet the terms of rule 17a–7 (a) and (b) because it would involve

[1] TEI invests indirectly in the Portfolio Company. See Man-Glenwood Lexington TEI, LLC and Man-Glenwood Lexington TEI, LDC (pub. avail. April 30, 2004).

[2] Lexington, TEI and the Portfolio Company have a common Board.

[3] TEI simultaneously will conduct a cash tender offer.

a purchase and sale for consideration other than cash (Lexington would purchase Units of TEI with its Portfolio Company Interests rather than with cash; and TEI would sell its Units for Portfolio Company Interests rather than for cash) and the Transaction would be effected at the NAV of the Portfolio Company's Interests rather than at an independent current market price.

4. Section 17(b) of the Act authorizes the Commission to exempt a transaction from the provisions of section 17(a) if the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned and the proposed transaction is consistent with the policy of each registered investment company concerned and the general purposes of the Act.

5. Applicants submit that the Transaction meets the requirements of section 17(b) of the Act. Applicants state that the Transaction will be effected at the Funds' and the Portfolio Company's NAVs, calculated in accordance with their respective policies and procedures as set forth in their registration statements under the Act. Applicants state that the valuation policies and procedures are identical for the Funds and the Portfolio Company. Applicants further state that the Transaction is consistent with the policies of the Funds and the Portfolio Company and does not involve overreaching on the part of any person concerned.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The Transaction will be effected at the NAV of the Portfolio Company's Interests determined in accordance with the Portfolio Company's registration statement under the Act. The NAV of the Units of each Fund for purposes of the Transaction will be determined in accordance with each Fund's registration statement under the Act.

2. The Transaction will comply with the terms of rule 17a–7(c), (d) and (f) under the Act.

3. At its next regular meeting following the Transaction, the Board of each Fund and the Portfolio Company, including a majority of the Independent Managers, will determine: (a) Whether the Units and Interests were valued in accordance with condition 1 and (b) whether the Transaction was consistent with the policies of each Fund and the Portfolio Company as reflected in its registration statement and reports filed under the Act.

4. The Funds and the Portfolio Company will maintain and preserve for a period of not less than six years from the end of the fiscal year in which the Transaction occurs, the first two years in an easily accessible place, a written record of the Transaction setting forth a description of each security transferred, the terms of the Transaction, and the information or materials upon which the determinations required by condition 3 were made.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–3570 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50785; File No. SR–OPRA–2004–06]

Options Price Reporting Authority; Notice of Filing of Proposed Amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information To Amend Guideline 2 of the Capacity Guidelines Adopted in Accordance With the Plan

December 2, 2004.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 11Aa3–2 thereunder,[2] notice is hereby given that on October 19, 2004, the Options Price Reporting Authority (''OPRA'')[3] submitted to the Securities and Exchange Commission (''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''Plan''). The proposed amendment would amend Guideline 2 of the Capacity Guidelines (''Guideline 2'') adopted in accordance with the Plan. The Commission is publishing this notice to solicit comments from interested persons on the proposed Plan amendment.

I. Description and Purpose of the Amendment

OPRA states that there are two purposes to the proposed amendment to Guideline 2. Guideline 2 describes the process to be followed by the Independent System Capacity Advisor (''ISCA'') under the Plan in soliciting and considering capacity projections and requests from the parties to the Plan. Among other things, Guideline 2 requires the ISCA to repeat this process on a quarterly cycle. The first purpose of the proposed amendment to Guideline 2 is to reduce the frequency of the capacity review cycle to no less frequently than semi-annually. OPRA states that, based on the experience of the ISCA and the parties to the Plan with this process, it is now apparent that, by requiring the solicitation and review of capacity projections on a quarterly cycle, Guideline 2 fails to take into account that it takes more than 3 months for the complete cycle of solicitation, discussion, revision, and review of these projections to be completed.[4] For this reason, the ISCA suggested, and the parties to the Plan agreed, that a six-month cycle for the capacity projection and review process would be more realistic. In the view of the ISCA and the parties to the Plan, a six-month cycle for this process would provide the ISCA with sufficiently current capacity projections to assure that the OPRA System would be able to meet the capacity needs of the parties as they may change from time to time.

The second purpose of the proposed amendment concerns the provision of Guideline 2 that requires the ISCA, once it has received capacity projections and requests from all of the parties and has estimated the cost of any modifications to the OPRA System necessary to accommodate these projections and requests, to furnish its cost estimates to each party requesting additional

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 240.11Aa3–2.

[3] OPRA is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 11Aa3–2 thereunder. *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981).

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The six participants to the OPRA Plan are the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Board Options Exchange, Inc., the International Securities Exchange, Inc., the Pacific Exchange, Inc., and the Philadelphia Stock Exchange, Inc.

[4] The ISCA's initial solicitation and review of capacity projections commenced in January 2004. Under the quarterly cycle required by Guideline 2, the second solicitation and review would have had to commence in April 2004. OPRA states that, when OPRA's Policy Committee met on March 1, 2004, it was plain that the January review would not be completed by April. Accordingly, OPRA waived the April 2004 solicitation and review and agreed that the next solicitation would call for projections to be furnished to the ISCA no later than July 1, 2004, which was done. According to OPRA, the Commission's representative at the March 1, 2004 meeting agreed that a one-time waiver of the ISCA's quarterly capacity review would not require a formal amendment of the Capacity Guidelines. OPRA believes that this suggests that waivers of quarterly reviews on a regular basis would require such an amendment, as this filing proposes.

capacity. After receiving the estimate, the party is able to reduce the amount of additional capacity it requested in light of the estimated cost, or to withdraw its request altogether. Guideline 2, however, does not contemplate that a party would be able to increase the amount of additional capacity it is requesting at this stage of the process. The ISCA has recommended to OPRA, and OPRA has concurred, that Guideline 2 should be amended to permit a party either to reduce or increase the amount of additional capacity it is requesting once it has received the ISCA's initial cost estimates. OPRA believes that providing the parties to the Plan with this additional flexibility is justified not only because, by the time these estimates are received, there may be changes to a party's projection of the capacity it would need, but also because the ISCA's cost estimates may themselves be based on implementing changes to the system that would result in greater additional capacity being available than the aggregate amount of added capacity initially requested by the parties. In such an event, OPRA believes that the parties to the Plan should have an opportunity to adjust their requests upward if they so desire in order to receive an allocation of any additional capacity that may be available.[5]

The text of the proposed revised Capacity Guideline 2 is set forth below. Proposed new language is in *italics;* proposed deletions are in [brackets].

* * * * *

2. *Procedures and Timetable to be Followed by the ISCA; Reports to OPRA.* The OPRA Plan requires each of the parties, independently and from time to time, to project the amount of system capacity it will need, and to communicate to the ISCA, privately and in writing, requests for system capacity based on its projections in accordance with procedures developed by the ISCA. An applicant to become a party will likewise have to inform the ISCA, at least six months prior to the time it proposes to commence trading, concerning the initial amount of system capacity it will need. The costs of providing initial system capacity to an applicant in accordance with its request, as determined by the ISCA, will be included in the applicant's Participation Fee payable under Section 1(b) of the OPRA Plan. The ISCA will describe to the parties (and to applicants to become parties) the specific information that it wishes to receive from them for this purpose, the format in which the information is to be presented, and when the information is to be provided, provided that the ISCA shall solicit and consider capacity projections and requests from the parties no less frequently than semi-annually [quarterly]. The ISCA may also request additional information pertaining to System capacity from the parties at any time, subject to the confidentiality requirements described above.

As promptly as practicable after each due date for the receipt of capacity projections and requests from the parties, the ISCA will complete its review of the material furnished by the parties and any other information it deems relevant, and will present a written report to OPRA's Policy Committee concerning the extent and timing of any modifications to the OPRA System that it determines are necessary to meet the capacity needs of the parties in accordance with their requests. Whenever the ISCA believes it will not be able to meet this timetable for furnishing its report to OPRA, it will promptly notify the Executive Director of OPRA in writing, explaining why the timetable can not be met and providing a date when it believes the report will be available.

Before presenting any report to OPRA that includes proposed modifications to the OPRA System, the ISCA shall discuss the proposed modifications with the OPRA Processor and with representatives of the parties (which may include OPRA's Policy Committee and its Technical Committee) individually or collectively, and it may also discuss the proposed modifications with other persons (such as OPRA's administrative officers, vendors and subscribers) whose views the ISCA believes may be of assistance. Among other things, the ISCA will furnish to each party that has submitted a request for additional capacity an estimate of the cost to that party of obtaining the capacity it has requested, following receipt of which, the party will be afforded an opportunity to *increase* or reduce the amount of additional capacity it is requesting or to withdraw its request in its entirety. Applicants to become parties shall also have an opportunity to discuss their initial capacity requests with the ISCA, to receive cost estimates, and to modify their initial requests. Persons with whom the ISCA discusses OPRA System capacity matters shall be required to agree in writing not to disclose to any of the other parties any information pertaining to a party's individual capacity projections or capacity requests, except in the form of aggregate capacity projections or requests that do not identify the individual capacity projections or requests of any of the parties.

* * * * *

II. Implementation of Plan Amendment

The proposed amendment will be effective upon its approval by the Commission pursuant to Rule 11Aa3–2 of the Act.[6]

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment 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–OPRA–2004–06 on the subject line.

Paper comments:

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–OPRA–2004–06. 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 plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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

[5] OPRA states that, although Capacity Guideline 5(a) makes it clear that the ISCA is not authorized to implement system changes that would provide more capacity than has been requested by the parties unless the changes are approved by 75% of the parties, the ISCA may find it prudent for reasons of economy and efficiency to recommend modifying the system to provide more capacity than has been requested on the reasonable assumption that at least 75% of the parties would approve such a recommendation. Telephone conversation between Michael L. Meyer, Counsel to OPRA, Schiff Hardin LLP, and Karl Varner, Special Counsel, Division of Market Regulation (''Division''), Commission, and David Liu, Attorney, Division, Commission, on November 30, 2004.

[6] 17 CFR 240.11Aa3–2.

the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of OPRA. 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–OPRA–2004–06 and should be submitted on or before December 27, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E4–3576 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50789; File No. SR–OPRA–2004–05]

Options Price Reporting Authority; Notice of Filing and Immediate Effectiveness of Amendment to OPRA Plan To Revise Two Fees Charged by OPRA to Professional Subscribers to OPRA's Basic Service

December 3, 2004.

Pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 11Aa3–2 thereunder,[2] notice is hereby given that on October 14, 2004, the Options Price Reporting Authority (''OPRA'')[3] submitted to the Securities and Exchange Commission (''Commission'') an amendment to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan''). On December 1, 2004, OPRA submitted Amendment No. 1 to the proposal.[4] The proposed OPRA Plan amendment would revise two of the fees charged by OPRA to professional subscribers for OPRA's Basic Service. The Commission is publishing this notice to solicit comments from interested persons on the proposed OPRA Plan amendment.

I. Description and Purpose of the Amendment

OPRA states that one of the purposes of the proposed amendment is to offer a ''30-day free trial'' period to new professional subscribers to OPRA's Basic Service. The free trial would apply to those new professional subscribers that sign OPRA's Professional Subscriber Agreement, which obligates them to pay monthly access fees to OPRA on either a per-device basis or on the basis of OPRA's professional subscriber enterprise rate, and that indicate on such agreement that they wish to subscribe for a 30-day free trial period. Unless the subscriber provides written notice of cancellation to OPRA prior to the end of the 30-day trial period, the subscriber would be obligated to pay OPRA's device-based or enterprise rate access fees commencing with the 31st day after the initiation of service. The 30-day free trial would not apply to any other fees that may otherwise apply, including direct or indirect access fees, synthesized speech service fees or usage-based fees payable by vendors who furnish OPRA data to professional subscribers.

According to OPRA, the other purpose of the proposed amendment is to impose a cap on the monthly usage-based fees payable by vendors who provide OPRA data to professional subscribers pursuant to a Subscriber Agreement between the vendor and the subscriber, rather than pursuant to a Professional Subscriber Agreement between OPRA and the subscriber that imposes device-based fees or an enterprise rate fee.[5] OPRA states that, although vendor's usage-based fees are currently capped for OPRA data provided to nonprofessional subscribers, heretofore there has been no cap on usage-based fees payable by vendors on account of OPRA data provided to professional subscribers. OPRA proposes to cap the monthly fee payable by a vendor on account of a usage-based fee service provided to any one professional subscriber at the highest per-device fee applicable to a professional subscriber had such professional subscriber paid OPRA directly for such OPRA data (currently $32.25), multiplied by the number of the professional subscriber's authorized user IDs. OPRA believes that this would assure that the capped usage-based fee payable on account of any professional subscriber in any month does not exceed the highest per-device fee that would have applied if the professional subscriber had been subject to device-based fees.[6]

OPRA states that these proposed fee changes are intended to encourage professionals to become OPRA subscribers by expanding the fee choices available to them and to their vendors. The text of the proposed rule change is available at the principal office of OPRA, and at the Commission.

II. Implementation of the OPRA Plan Amendment

Pursuant to paragraph (c)(3)(i) of Rule 11Aa3–2 under the Act,[7] OPRA designates this amendment as establishing or changing a fee or other charge collected on behalf of all of the OPRA participants in connection with access to, or use of, OPRA facilities, thereby qualifying for effectiveness upon filing. The Commission may summarily abrogate the amendment within sixty days of its filing and require refiling and approval of the amendment by Commission order pursuant to Rule 11Aa3–2(c)(2) under the Act,[8] if it appears to the Commission that such action is necessary or appropriate in the public interest; for the protection of investors and the maintenance of fair and orderly markets; to remove impediments to, and perfect the mechanisms of, a national market system; or otherwise in furtherance of the purposes of the Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed OPRA Plan amendment 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

[7] 17 CFR 200.30–3(a)(29).

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 240.11Aa3–2.

[3] OPRA is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 11Aa3–2 thereunder. *See* Securities Exchange Act Release No. 17638 (March 18, 1981), 22 S.E.C. Docket 484 (March 31, 1981).

The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The six participants to the OPRA Plan are the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Board Options Exchange, Inc., the International Securities Exchange, Inc., the Pacific Exchange, Inc., and the Philadelphia Stock Exchange, Inc.

[4] *See* letter from Michael L. Meyer, Counsel to OPRA, Schiff Hardin LLP, to David Liu, Attorney, Division of Market Regulation, Commission, dated November 20, 2004. Amendment No. 1 made technical updates to the fee schedule contained in Exhibit II of the filing.

[5] OPRA states that professional subscribers who enter into Subscriber Agreements with vendors for which usage-based fees apply do not need to enter into Professional Subscriber Agreements with OPRA, and do not pay device-based or enterprise rate access fees to OPRA.

[6] Under OPRA's published policies, each authorized subscriber ID is treated as the equivalent of one device for purposes of applying the professional subscriber device-based fee.

[7] 17 CFR 240.11Aa3–2(c)(3)(i).

[8] 17 CFR 240.11Aa3–2(c)(2).

• Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–OPRA–2004–05 on the subject line.

Paper Comments

• Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–OPRA–2004–05. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan amendment that are filed with the Commission, and all written communications relating to the proposed plan amendment 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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of OPRA. 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–OPRA–2004–05 and should be submitted on or before December 27, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E4–3575 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

[9] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50794; File No. PCAOB–2004–08]

Public Company Accounting Oversight Board; Notice of Filing and Order Granting Accelerated Approval of Proposed Temporary Transitional Rule Relating to PCAOB Auditing Standard No. 2, ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements''

December 3, 2004.

Pursuant to Section 107(b) of the Sarbanes-Oxley Act of 2002 (the ''Act''), notice is hereby given that on December 1, 2004, the Public Company Accounting Oversight Board (the ''Board'' or the ''PCAOB'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule, described in Items I and II below, which items have been prepared by the Board. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons and is approving the proposal on an accelerated basis.

I.Board's Statement of the Terms of Substance of the Proposed Rule

On November 30, 2004, the Board adopted a temporary transitional provision for PCAOB Auditing Standard No. 2, ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements.'' (PCAOB Rule 3201T). The proposed rule text is set out below.

SECTION 3. PROFESSIONAL STANDARDS

* * * * *

Part 1—General Requirements

* * * * *

Rule 3201T. Temporary Transitional Provision for PCAOB Auditing Standard No. 2, ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements.''

(a) Notwithstanding Auditing Standard No. 2, in connection with the audit of an issuer that does not file *Management's annual report on internal control over financial reporting* in reliance on SEC Release No. 34–50754, Order Under Section 36 of the Securities Exchange Act of 1934 Granting an Exemption from Specified Provisions of Exchange Act Rules 13a–1 and 15d–1 (November 30, 2004), a registered public accounting firm and its associated persons need not:

(1) Date the auditor's report on management's assessment of the effectiveness of internal control over financial reporting with the same date as the auditor's report on the issuer's financial statements, provided that the date of the auditor's report on management's assessment of the effectiveness of internal control over financial reporting is later than the date of the auditor's report on the issuer's financial statements; or

(2) Add a paragraph to the auditor's separate report on the financial statements of an issuer that refers to a separate report on management's assessment of the effectiveness of internal control over financial reporting.

(b) This temporary rule will expire on July 15, 2005.

II. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule

In its filing with the Commission, the Board included statements concerning the purpose of, and basis for, the proposed rule.

A.Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule

(a) Purpose

The Board adopted the proposed rule in response to an exemptive order of the Commission (the Exemptive Order).[1] The Exemptive Order allows certain issuers an additional 45 days to file *Management's annual report on internal control over financial reporting*, required by Item 308(a) of Regulation S–K, and the related Attestation report of the *registered public accounting firm*, required by Item 308(b) of Regulation S–K. The proposed rule would temporarily relieve auditors, in connection with the audit of an issuer relying on the Exemptive Order, from certain provisions of PCAOB Auditing Standard No. 2, *An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements* (''Auditing Standard No. 2''). The proposed rule would permit eligible auditors to date a report on management's assessment of the effectiveness of internal control over financial reporting later than the date of the report on the same issuer's financial statements. The proposed rule would also permit these auditors to omit reference in the auditor's separate report on the issuer's financial statements to the auditor's report on management's

[1] Exchange Act Release No. 50754 (Nov. 30, 2004).

assessment of the effectiveness of internal control over financial reporting.

Specifically, Rule 3201T consists of two paragraphs. Paragraph (a) provides that the proposed rule would apply to registered public accounting firms and their associated persons in connection with the audit of an issuer relying on the Exemptive Order. Such auditors are temporarily relieved from certain provisions of Auditing Standard No. 2, described in subparagraphs (a)(1) and (a)(2). Subparagraph (a)(1) permits eligible auditors to date a report on management's assessment of the effectiveness of internal control over financial reporting later than the date of the report on the same issuer's financial statements. Subparagraph (a)(2) permits these auditors to omit reference in the auditor's separate report on the issuer's financial statements to the auditor's report on management's assessment of the effectiveness of internal control over financial reporting. Paragraph (b) provides that the rule expires on July 15, 2005.

(b) Statutory Basis

The statutory basis for the proposed rule is Title I of the Act.

B.Board's Statement on Burden on Competition

The Board does not believe that the proposed rule will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule would temporarily relieve auditors, in connection with the audit of an issuer relying on the Exemptive Order, from certain provisions of Auditing Standard No. 2.

C.Board's Statement on Comments on the Proposed Rule Received From Members, Participants or Others

The Board determined that public comment was not practicable in light of the timing of the Exemptive Order and the imminence of the filing requirements at issue.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule is consistent with the requirements of Title I of 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/pcaob.shtml*); or

• Send an E-mail to *rule-comments@sec.gov*. Please include File Number PCAOB–2004–08 on the subject line.

Paper Comments

• Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number PCAOB–2004–08. 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/pcaob.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule 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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of PCAOB. 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. All submissions should refer to File Number PCAOB–2004–08 and should be submitted on or before January 10, 2005.

IV. Commission's Finding and Order Granting Accelerated Approval of Proposed Rule

The PCAOB's proposed rule is intended to address auditing issues attendant to the separate Commission Exemptive Order dated November 30, 2004. Pursuant to Commission rules adopted under the Securities Exchange Act of 1934 (''Exchange Act''), an accelerated filer is generally required to submit an annual report on Form 10–K within 75 calendar days after the end of such issuer's fiscal year. Regulation S–K under the Exchange Act requires that an accelerated filer's Form 10–K include, among other things, a management assessment on internal control over financial reporting and an attestation report on that assessment by a registered public accounting firm.[2] The Commission's Exemptive Order granted an exemption from these requirements for a period of 45 days to accelerated filers with less than $700 million in common equity market value outstanding as of the end of the second quarter of 2004 whose fiscal years end on or between November 15, 2004 and February 28, 2005. The PCAOB's proposed rule would exempt registered public accounting firms from compliance with (i) the concurrent reporting date requirement of Auditing Standard No. 2 with respect to audits of issuers exempt under the Commission's Exemptive Order and (ii) the requirement to add a paragraph to the auditor's report on the financial statements that refers to the auditor's report on management's assessment of the effectiveness of internal control over financial reporting.

As noted in the Commission's Exemptive Order, the Commission had become increasingly concerned that many smaller accelerated filers may not be in a position to meet the Form 10–K deadline. Accordingly, to ensure that there is a continuing and orderly flow of annual report information to investors and the U.S. capital markets, and to ensure that certain annual report filers and their registered public accounting firms are able to file complete and accurate reports regarding the effectiveness of the filers' internal control over financial reporting, the Commission determined that the exemptions were necessary and appropriate in the public interest and consistent with the protection of investors. The PCAOB's proposed rule is consistent with the substance and purpose of the Commission's order exempting smaller accelerated filers from the Form 10–K report deadline and it will assist auditors of issuers seeking to rely on the Exemptive Order. The proposed rule is a temporary measure and does not modify the substance of Auditing Standard No. 2 as originally approved by the Commission.

On the basis of the foregoing, the Commission finds that the proposed rule is consistent with the requirements of Sections 103 and 107(b) of the Act and the securities laws and is necessary and appropriate in the public interest and for the protection of investors.

The Commission also finds good cause to approve the proposed rule on an accelerated basis.[3] The Commission

[2] Item 308(a) and 308(b), respectively, of Regulation S–K.

[3] Section 107(b)(4) of the Act states that paragraphs (1) through (3) of section 19(b) of the Exchange Act, with certain amendments, govern

believes that the proposed rule is an important component of the relief provided in the Exemptive Order, and that together the proposed rule and the Exemptive Order would benefit both smaller accelerated filers and registered public accounting firms by providing the additional time necessary to produce complete, thorough and accurate audits of the internal control structure and procedures of affected filers. The Commission believes that it is in the public interest to approve the proposed rule on an accelerated basis in order to achieve the goals set forth in the Commission's Exemptive Order and to avoid any confusion resulting from inconsistencies between Auditing Standard No. 2 and the Commission's Exemptive Order.

Accordingly, the Commission finds that there is good cause, consistent with sections 103 and 107 of the Act, and section 19(b) of the Exchange Act, to approve the rule on an accelerated basis.

V.Conclusion

It is therefore ordered, pursuant to Section 107 of the Act and Section 19(b)(2) of the Exchange Act that the proposed rule (File No. PCAOB–2004–08) be and hereby is approved on an accelerated basis.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–3568 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50795]

Order Pursuant to Section 11A of the Securities Exchange Act of 1934 and Rule 11Aa3–2(f) Thereunder Extending a de minimis Exemption for Transactions in Certain Exchange-Traded Funds from the Trade-Through Provisions of the Intermarket Trading System

December 3, 2004.

This order extends, for an additional nine-month period, a *de minimis* exemption to the provisions of the Intermarket Trading System Plan (''ITS Plan''),[1] a national market system plan,[2] governing intermarket trade-throughs. The *de minimis* exemption was originally issued by the Commission on August 28, 2002 [3] and extended on May 30, 2003 [4] and on March 3, 2004.[5]

The ITS Plan system is an order routing network designed to facilitate intermarket trading in exchange-listed securities among participating SROs based on current quotation information emanating from their markets. Quotations in exchange-listed securities are collected and disseminated by the Consolidated Quote System (''CQS''), which is governed by a national market system plan that the Commission has approved pursuant to Rule 11Aa3–2 under the Act.[6] Under the ITS Plan, a member of a participating SRO may access the best bid or offer displayed in CQS by another Participant by sending an order (a ''commitment to trade'') through ITS to that Participant. Exchange members participate in ITS through facilities provided by their respective exchanges. NASD members participate in ITS through a facility of the Nasdaq Stock Market (''Nasdaq'') known as the Computer Assisted Execution System (''CAES''). Market makers and electronic communications networks (''ECNs'') that are members of the NASD and seek to display their quotes in exchange-listed securities through Nasdaq must register with the NASD as ITS/CAES Market Makers.[7]

The March 2004 Order continued the *de minimis* exemption from compliance with Section 8(d)(i) of the ITS Plan with respect to three specific exchange-traded funds (''ETFs''), the Nasdaq-100 Index ETF (''QQQ''), the Dow Jones Industrial Average ETF (''DIA''), and the Standard & Poor's 500 Index ETF (''SPY'').[8] Section 8(d)(i) of the ITS Plan provides that participants should not purchase or sell any security that trades on the ITS Plan system at a price that is worse than the price at which that security is otherwise being offered on the ITS Plan system.[9] By its terms, the March 2004 Order continued the exemption from the trade-through provisions of the ITS Plan any transactions in the three ETFs that are effected at prices at or within three cents away from the best bid and offer quoted in the CQS for a period of nine months, which ends on December 4, 2004.

The three cent *de minimis* exemption allows ITS participants and their members to execute transactions, through automated execution or otherwise, without attempting to access the quotes of other participants when the expected price improvement would not be significant. In providing the three cent *de minimis* exemption, the Commission believed that, on balance, exempting the specified transactions from the ITS trade-through provisions would provide investors increased liquidity and expand the choice of execution venues, while limiting the possibility that investors would receive significantly inferior prices.[10]

Commission approval of the rules of the Board. Section 19(b)(2) of the Exchange Act provides for the Commission to approve rules on an accelerated basis if ''the Commission finds good cause for so doing and publishes its reasons for so finding.''

[1] The self-regulatory organizations (''SROs'') participating in the ITS Plan include the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Board Options Exchange, Inc., the Chicago Stock Exchange, Inc., the National Stock Exchange, Inc. (formerly the Cincinnati Stock Exchange, Inc.), the National Association of Securities Dealers, Inc. (''NASD''), the New York Stock Exchange, Inc., the Pacific Exchange, Inc., and the Philadelphia Stock Exchange, Inc. (collectively, the ''participants''). *See* Securities Exchange Act Release No. 19456 (January 27, 1983), 48 FR 4938 (February 3, 1983).

[2] Securities Exchange Act of 1934 (''Act'') Rule 11Aa3–2(d), 17 CFR 240.11Aa3–2(d), promulgated under Section 11A, 15 U.S.C. 78k–1, of the Act requires each SRO to comply with, and enforce compliance by its members and their associated persons with, the terms of any effective national market system plan of which it is a sponsor or participant. Rule 11Aa3–2(f), 17 CFR 240.11Aa3–2(f), under the Act authorizes the Commission to exempt, either unconditionally or on specified terms and conditions, any SRO, member of an SRO, or specified security from the requirement of the rule if the Commission determines that such exemption is consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system.

[3] *See* Securities Exchange Act Release No. 46428 (August 28, 2002), 67 FR 56607 (September 4, 2002) (the ''August 2002 Order''). The August 2002 Order granted relief through June 4, 2003.

[4] *See* Securities Exchange Act Release No. 47950 (May 30, 2003), 68 FR 33748 (June 5, 2003) (the ''May 2003 Order''). The May 2003 Order granted relief through March 4, 2004.

[5] See Securities Exchange Act Release No. 49356 (March 3, 2004), 69 FR 11057 (March 9, 2004) (the ''March 2004 Order''). The March 2004 Order granted relief through December 4, 2004.

[6] 17 CFR 240.11Aa3–2.

[7] *See* Securities Exchange Act Release No. 42536 (March 16, 2000), 65 FR 15401 (March 22, 2000). Market Makers and ECNs are required to provide their best-priced quotations and customer limit orders in certain exchange-listed and Nasdaq securities to an SRO for public display under Commission Rule 11Ac1–1 and Regulation ATS. 17 CFR 240.11Ac1–1 and 242.301(b)(3).

[8] The Commission limited the *de minimis* exemption to these three securities because they share certain characteristics that may make immediate execution of their shares highly desirable to certain investors. In particular, trading in the three ETFs is highly liquid and market participants may value an immediate execution at a displayed price more than the opportunity to obtain a slightly better price.

[9] Each ITS participant has adopted a trade-through rule substantially similar to the rule of the ITS Plan. *See* ITS Plan, Section 8(d)(ii); *See, e.g.*, NYSE Rule 15A, NASD Rule 5262.

[10] *See* August 2002 Order, *supra* note 3. The Commission's Office of Economic Analysis conducted an analysis of trading in the QQQs in 2002, comparing trading on a day before the *de*

Continued

In March 2004 and in May 2003, the Commission extended the three cent *de minimis* exemption for additional nine-month periods, in order to assess trading data associated with the *de minimis* exemption and to consider whether to adopt the *de minimis* exemption on a permanent basis, to adopt some other alternative solution, or to allow the exemption to expire. As a result of its review of trading data associated with the *de minimis* exemption, the Commission has proposed, as part of its market structure initiatives, Regulation NMS under the Act, which would include a new rule relating to trade-throughs.[11] Because the Commission has not yet taken action with respect to proposed Regulation NMS, the Commission believes it is appropriate to extend the *de minimis* exemption.

This extension of the *de minimis* exemption, however, applies only to the DIA and the SPY, and not the QQQ. On December 1, 2004, trading of the QQQ transferred from the American Stock Exchange to Nasdaq, and trades in the QQQ ceased to be subject to the trade-through provisions of the ITS Plan. Accordingly, an exemption for the QQQ is no longer necessary.

The Commission believes that an extension of the *de minimis* exemption for an additional nine-month period is consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system. Depending on the action the Commission takes on proposed Regulation NMS prior to September 4, 2005, the Commission may determine to modify, withdraw, or extend the *de minimis* exemption. The Commission emphasizes, as it did in the March 2004 Order, the May 2003 Order and the August 2002 Order, that the *de minimis* exemption does not relieve brokers and dealers of their best execution obligations under the federal securities laws and SRO rules.

Accordingly, it is ordered, pursuant to Section 11A of the Act and Rule 11Aa3–2(f) thereunder,[12] that participants of the ITS Plan and their members are hereby exempt from Section 8(d) of the ITS Plan during the period covered by this Order with respect to transactions in DIAs and SPYs that are executed at a price that is no more than three cents lower than the highest bid displayed in CQS and no more than three cents higher than the lowest offer displayed in CQS. This Order extends the *de minimis* exemption from December 4, 2004 through September 4, 2005.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–3569 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

minimis exemption was implemented, a day after the exemption was implemented before Island, an ECN, stopped displaying its orders to anyone, even its subscribers (going ''dark''), and a day after the exemption was implemented when Island was ''dark.'' The analysis showed that the percent of trades executed outside the national best bid and offer (''NBBO'') did not increase, and that less than 1% of total trades were executed more than three cents away from the NBBO, after the *de minimis* exemption was implemented. A copy of the analysis is available in File No. S7–10–04.

[11] On February 24, 2004, the Commission proposed Regulation NMS for public comment. Securities Exchange Act Release No. 49325 (February 26, 2004), 69 FR 11126 (March 9, 2004). On May 20, 2004, the Commission published a supplemental request for comment and extended the period for comment on proposed Regulation NMS. Securities Exchange Act Release No. 49749 (May 20, 2004), 69 FR 30142 (May 26, 2004). In part, proposed Rule 611 of Regulation NMS would require certain identified market centers to establish, maintain, and enforce policies and procedures reasonably designed to prevent trade-throughs. Extension of the *de minimis* pilot in no way prejudges or determines what actions the Commission may take with respect to any rule proposal.

[12] 17 CFR 240.11Aa3–2(f).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50792; File No. SR–Amex–2004–38]

Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change and Amendment Nos. 2, 3 and 4 Thereto by the American Stock Exchange LLC Relating to the Listing and Trading of the iShares(®) COMEX Gold Trust

December 3, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, as amended (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 24, 2004, the American Stock Exchange LLC (''Amex'' 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. On November 9, 2004, Amex amended its proposal; however, the Exchange withdrew this amendment on November 17, 2004. On November 10, 2004 the Exchange submitted a second amendment.[3] On November 16, 2004, the Exchange submitted a third amendment.[4] On December 1, 2004, the Exchange submitted a fourth amendment.[5] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Amendment No. 2, dated November 10, 2004 (''Amendment No. 2''). In Amendment No. 2, the Exchange revised the proposed rule text and corresponding description. Amendment No. 2 replaced Amex's original filing in its entirety.

[4] *See* Amendment No. 3, dated November 16, 2004 (''Amendment No. 3''). In Amendment No. 3, the Exchange proposed clarifying changes to certain aspects of Amendment No. 2 and modified the proposed rule text.

[5] *See* Amendment No. 4, dated December 1, 2004 (''Amendment No. 4''). In Amendment No. 4, the Exchange provided additional description of the creation and redemption process for the Gold Trust shares and made clarifying changes to the proposed rule text. Amendment No. 4 replaced Amex's amended proposal in its entirety.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade under new Amex Rules 1200A *et seq.* iShares(®) COMEX Gold Trust Shares (''Gold Shares''). The text of the proposed rule change, as amended, is set forth below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

Exchange Rules

Commodity-Based Trust Shares

Rule 1200A. (a) Applicability. The Rules in this Section are applicable only to Commodity-Based Trust Shares. In addition, except to the extent specific Rules in this Section govern or unless the context otherwise requires, the provisions of the Trust Issued Receipt rules and the Constitution and all other rules and policies of the Board of Governors shall be applicable to the trading on the Exchange of such securities. Pursuant to the provisions of Article I, Section 3(i) of the Constitution, Commodity-Based Trust Shares are included within the definition of ''security'' or ''securities'' as such terms are used in the Constitution and Rules of the Exchange.

(b) Definitions. The following terms as used in the Rules shall, unless the context otherwise requires, have the meanings herein specified:

(1) Commodity-Based Trust Shares. The term ''Commodity-Based Trust Shares'' means a security (a) that is issued by a trust (the ''Trust'') that holds a specified commodity deposited with the Trust; (b) that is issued by such Trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) that, when aggregated in the same specified minimum number, may

be redeemed at a holder's request by such Trust which will deliver to the redeeming holder the quantity of the underlying commodity.

(2) Commodity. The term ''commodity'' is defined in Section 1(a)(4) of the Commodity Exchange Act.

Commentary

.01 A Commodity-Based Trust Share is a Trust Issued Receipt that holds a specified commodity deposited with the Trust.

.02 The Exchange requires that members and member organizations provide to all purchasers of newly issued Commodity-Based Trust Shares a prospectus for the series of Commodity-based Trust Shares.

.03 Transactions in Commodity-Based Trust Shares will occur between 9:30 a.m. and either 4 p.m. or 4:15 p.m. for each series, as specified by the Exchange.

.04 (a) Limit Orders—Members and member organizations shall not enter orders into the Exchange's order routing system, as principal or agent, limit orders in the same Commodity-Based Trust, for the account or accounts of the same or related beneficial owner, in such a manner that the member or beneficial owner(s) effectively is operating as a market maker by holding itself out as willing to buy and sell such Commodity-Based Trust Shares on a regular or continuous basis. In determining whether a member or beneficial owner effectively is operating as a market maker, the Exchange will consider, among other things, the simultaneous or near-simultaneous entry of limit orders to buy and sell the same Commodity-Based Trust Shares; the multiple acquisition and liquidation of positions in the same Commodity-Based Trust Shares during the same day; and the entry of multiple limit orders at different prices in the same Commodity-Based Trust Shares.

(b) Members and member organizations may not enter, nor permit the entry of, orders into the Exchange's order routing system if those orders are (i) created and communicated electronically without manual input (i.e., order entry by public customers or associated persons of members must involve manual input such as entering the terms of an order into an order-entry screen or manually selecting a displayed order against which an off-setting order should be sent) and (ii) eligible for execution through the Exchange's automatic execution system for Commodity-Based Trust Shares. Nothing in this paragraph, however, prohibits members from electronically communicating to the Exchange orders manually entered by customers into front-end communication systems (e.g., Internet gateways, on-line networks, etc.).

Designation of an Underlying Commodity

Rule 1201A. The Exchange may list and trade Commodity-Based Trust Shares based on an underlying commodity. Each issue of a Commodity-Based Trust Share shall be designated as a separate series and shall be identified by a unique symbol.

Initial and Continued Listing

Rule 1202A. Commodity-Based Trust Shares will be listed and traded on the Exchange subject to application of the following criteria:

(a) Initial Listing—The Exchange will establish a minimum number of Commodity-Based Trust Shares required to be outstanding at the time of commencement of trading on the Exchange.

(b) Continued Listing—The Exchange will remove from listing Commodity-Based Trust Shares under any of the following circumstances:

(i) if following the initial twelve month period following the commencement of trading of the shares, (A) the Trust has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of Commodity-Based Trust Shares for 30 or more consecutive trading days; (B) if the Trust has fewer than 50,000 receipts issued and outstanding; or (C) if the market value of all receipts issued and outstanding is less than $1,000,000;

(ii) if the value of the underlying commodity is no longer calculated or available on at least a 15-second delayed basis from a source unaffiliated with the sponsor, Trust, custodian or the Exchange or the Exchange stops providing a hyperlink on its Web site to any such unaffiliated commodity value;

(iii) if the Indicative Trust Value is no longer made available on at least a 15-second delayed basis; or

(iv) if such other event shall occur or condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

Upon termination of a Trust, the Exchange requires that Commodity-Based Trust Shares issued in connection with such Trust be removed from Exchange listing. A Trust may terminate in accordance with the provisions of the Trust prospectus, which may provide for termination if the value of the Trust falls below a specified amount.

(c) Term—The stated term of the Trust shall be as stated in the Trust prospectus. However, a trust may be terminated under such earlier circumstances as may be specified in the Trust prospectus.

(d) Trustee—The following requirements apply:

1. The trustee of a Trust must be a trust company or banking institution having substantial capital and surplus and the experience and facilities for handling corporate trust business. In cases where, for any reason, an individual has been appointed as trustee, a qualified trust company or banking institution must be appointed co-trustee.

2. No change is to be made in the trustee of a listed issue without prior notice to and approval of the Exchange.

(e) Voting—Voting rights shall be as set forth in the applicable Trust prospectus.

Commentary

.01 The Exchange will file separate proposals under Section 19(b) of the Securities Exchange Act of 1934 before listing and trading Commodity-Based Trust Shares designated on different underlying commodities.

Specialist Prohibitions

Rule 1203A. Rule 175(c) shall be deemed to prohibit an equity specialist, his member organization, or any other member, limited partner, officer, or approved person thereof from acting as a market maker or functioning in any capacity involving market-making responsibilities in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives. However, an approved person of an equity specialist that has established and obtained Exchange approval of procedures restricting the flow of material, non-public market information between itself and the specialist member organization pursuant to Rule 193, and any member, officer, or employee associated therewith, may act in a market making capacity, other than as a specialist in the Commodity-Based Trust Shares on another market center, in the underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives.

Commentary

.01 In connection with Commodity-Based Trust Shares, Commentaries .01, .02 and .07 of Rule 170 shall not apply to the trading of Trust Shares for the purpose of bringing the price of the Trust Shares into parity with the value of the underlying commodity on which the Trust Shares are based, with the net asset value of the Trust comprising the

Shares or with a futures contract on the underlying commodity on which the Trust Shares are based. Such transactions must be effected in a manner that is consistent with the maintenance of a fair and orderly market and with the other requirements of this rule and the supplementary material herein.

Securities Accounts and Orders of Specialists

Rule 1204A. (a) The member organization acting as specialist in Commodity-Based Trust Shares is obligated to conduct all trading in the Shares in its specialist account, subject only to the ability to have one or more investment accounts, all of which must be reported to the Exchange (See Rule 170). In addition, the member organization acting as specialist in Commodity-Based Trust Shares must file, with the Exchange, in a manner prescribed by the Exchange, and keep current a list identifying all accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the member organization acting as specialist may have or over which it may exercise investment discretion. No member organization acting as specialist in Commodity-Based Trust Shares shall trade in the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a member organization acting as specialist, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule.

(b) In addition to the existing obligations under Exchange rules regarding the production of books and records (See, e.g. Rule 31), the member organization acting as a specialist in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or any member, member organization, limited partner, officer or approved person thereof, registered or non-registered employee affiliated with such entity for its or their own accounts in the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

(c) In connection with trading the underlying physical commodity, related commodity futures or options on commodity futures or any other related commodity derivative (including Commodity-Based Trust Shares), the specialist registered as such in Commodity-Based Trust Shares shall not use any material nonpublic information received from any person associated with a member, member organization or employee of such person regarding trading by such person or employee in the physical commodity, commodity futures or options on commodity futures, or any other related commodity derivatives.

Limitation of Exchange Liability

Rule 1205A. Neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; net asset value; or other information relating to the purchase, redemption or trading of Commodity-Based Trust Shares, resulting from any negligent act or omission by the Exchange or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange or its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity.

* * * * *

Amex Company Guide

Section 140. Original Listing Fees

Stock Issues—No Change.

Issues Listed Under Section 106 (Currency and Index Warrants) and Section 107 (other Securities)—No Change

Warrants—No Change.

Bonds—No Change.

Index Fund Shares, Trust Issued Receipts, *Commodity-Based Trust Shares and Closed-End Funds*—The original listing fee for Index Fund Shares listed under Rule 1000A, Trust Issued Receipts listed under Rule 1200, *Commodity-Based Trust Shares listed under Rule 1200A* and Closed-End Funds listed under Section 101 of the Company Guide is $5,000 for each series or Fund, with no application processing fee.

Special Shareholder Rights Plans—No Change.

Section 141. Annual Fees

Stock Issues; Issues Listed Under Sections 106 and 107; [and] Rules 1200 (Trust Issued Receipts) *and 1200A (Commodity-Based Trust Shares)*; and Closed-End Funds

Shares outstanding	Fees
5,000,000 shares or less	$15,000 (minimum)
5,000,001 to 10,000,000 shares	17,500
10,000,001 to 25,000,000 shares	20,000
25,000,001 to 50,000,000 shares	22,500
In excess of 50,000,000 shares	30,000 (maximum)

The Board of Governors or its designee may, in its discretion, defer, waive or rebate all or any part of the applicable annual listing fee specified above excluding the fees applicable to issues listed under Sections 106 and 107 and rule 1200 (Trust Issued Receipts); and Closed-End Funds.

Issues Listed Under Rule 1000A (Index Fund Shares)

Shares outstanding	Fees
1,000,000 shares or less	$6,500 (minimum)
1,000,001 to 2,000,000 shares	7,000
2,000,001 to 3,000,000 shares	7,500
3,000,001 to 4,000,000 shares	8,000

Shares outstanding	Fees
4,000,001 to 5,000,000 shares	8,500
5,000,001 to 6,000,000 shares	9,000
6,000,001 to 7,000,000 shares	9,500
7,000,001 to 8,000,000 shares	10,000
8,000,001 to 9,000,000 shares	10,500
9,000,001 to 10,000,000 shares	11,000
10,000,001 to 11,000,000 shares	11,500
11,000,001 to 12,000,000 shares	12,000
12,000,001 to 13,000,000 shares	12,500
13,000,001 to 14,000,000 shares	13,000
14,000,001 to 15,000,000 shares	13,500
15,000,001 to 16,000,000 shares	14,000
In excess of 16,000,000 shares	14,500 (maximum)

The annual fee is payable in January of each year and is based on the total number of all classes of shares (excluding treasury shares) and warrants according to information available on Exchange records as of December 31 of the preceding year. (The above fee schedule also applies to companies whose securities are admitted to unlisted trading privileges.)

In the calendar year in which a company first lists, the annual fee will be prorated to reflect only that portion of the year during which the security has been admitted to dealings and will be payable within 30 days of the date the company receives the invoice, based on the total number of outstanding shares of all classes of stock at the time of original listing.

The annual fee for issues listed under Rule 1000A (Index Fund Shares), [and] Rule 1200 (Trust Issued Receipts) *and Rule 1200A (Commodity-Based Trust Shares)* is based upon the number of shares of a series of Index Fund Shares, [or] Trust Issued Receipts *or Commodity-Based Trust Shares* outstanding at the end of each calendar year. For multiple series of Index Fund Shares issued by an open-end management investment company, or for multiple series of Trust Issued Receipts *and/or Commodity-Based Trust Shares*, the annual listing fee is based on the aggregate number of shares in all series outstanding at the end of each calendar year.

The annual fee for a Closed-End Fund listed under Section 101 of the Company Guide is based upon the number of shares outstanding of such Fund at the end of each calendar year. For multiple Closed-End Funds of the same sponsor, the annual listing fee is based on the aggregate number of shares outstanding of all such Funds at the end of each calendar year.

Bond Issues—No Change.

Late Fee—No Change.

Note: 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, Amex 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add new Section 1200A *et seq.* for the purpose of permitting the listing and trading of Trust Issued Receipts (*i.e.,* Trust Shares) [6] based on commodity interests. In particular, the Amex initially proposes to list iShares COMEX [7] Gold Trust (the ''Gold Trust'' or ''Trust'') Shares that represent beneficial ownership interests in the net assets of the Trust consisting primarily of gold. The trustee of the Trust will not actively manage the gold held by the Trust, and therefore, a holder of Gold Shares will not be hedged to protect against the price volatility of the underlying gold.[8]

Under Amex Rule 1201, the Exchange may approve for listing and trading TIRs based on one or more securities.[9] The Amex proposes to list for trading Gold Shares under proposed Rule 1200A *et seq.*

Introduction

In September 1999, the Exchange adopted rules for the listing and trading of TIRs.[10] TIRs are negotiable receipts issued by trusts that represent investors' discrete identifiable and undivided beneficial ownership interest in the securities deposited into the trust. Since that time the Exchange has listed seventeen (17) TIRs under the trade name of HOLDRS, representing a wide variety of industry sectors and the market as a whole.

To accommodate the listing of additional TIRs, the Exchange in September 2000 revised the existing listing criteria and trading rules to permit the listing and trading of TIRs pursuant to Rule 19b–4(e) under the Act (the ''Generic Listing Standards'').[11] Because of the structure of the Gold Trust, representing an interest in underlying gold, the current Generic Listing Standards cannot be used by the

[6] A Trust Issued Receipt or ''TIR'' is defined in Exchange Rule 1200(b) as a security (a) that is issued by a trust which holds specified securities deposited with the trust; (b) that, when aggregated in some specified minimum number, may be surrendered to the trust by the beneficial owner to receive the securities; and (c) that pays beneficial owners dividends and other distributions on the deposited securities, if any are declared and paid to the trustee by an issuer of the deposited securities.

[7] COMEX is a division of the New York Mercantile Exchange, Inc. (''NYMEX'') where gold futures contracts are traded.

[8] The Exchange submits that Gold Shares may be used as a price discovery mechanism for gold from 1:30 pm to 4:15 p.m. New York time. The open outcry trading hours of the COMEX gold futures contract is from 8:20 a.m. to 1:30 p.m. New York time Monday through Friday. NYMEX ACCESS®, an electronic trading system, is open for price discovery on COMEX gold futures contracts from 2 p.m. Monday afternoon until 8 a.m. Friday morning New York time; and from 7 p.m. Sunday night until Monday morning at 8 a.m. New York time.

[9] The Exchange defines a ''security'' or ''securities'' to include stocks, bonds, options, and other interests or instruments commonly known as securities. See Article I, Section 3(j) of the Amex Constitution.

[10] *See* Securities Exchange Act Release No. 41892 (September 21, 1999), 64 FR 52559 (September 29, 1999) (''TIR Approval Order'').

[11] 17 CFR 240.19b–4(e). Rule 19b–4(e), adopted by the Commission on December 8, 1998, permits the Exchange to list and trade new derivative securities products without a rule change provided the Exchange has in place trading rules, procedures, a surveillance program and listing standards that pertain to the class of securities covering the new product. *See* Securities Exchange Act Release No. 40761 (December 8, 1998), 63 FR 70952 (December 22, 1998).

Exchange to list this product. However, the Exchange submits that the Gold Shares may be listed for trading pursuant to proposed Rule 1200A *et seq.*, subject to Commission review and approval.

Under proposed Rule 1201A, the Exchange may list and trade trust shares based on an underlying commodity (the ''Commodity-Based Trust Shares''). For each separate and discrete commodity interest that may underlie a trust, the Exchange will submit a filing pursuant to Section 19(b) of the Act [12] subject to Commission review and approval.

The Gold Shares will conform to the initial and continued listing criteria under proposed Rule 1202A.[13] The Gold Trust will be formed under a depositary trust agreement, among Bank of New York (''BNY''), the Trustee, Barclays Global Investors, N.A. (''Barclays''), the Sponsor, all depositors, if any, and the holders of Gold Shares.[14]

The Exchange notes that the Commission has permitted the listing and trading of products linked to the performance of an underlying commodity or commodities.[15]

Description of the Gold Market

In its filing with the Commission, the Exchange made the following representations regarding the worldwide gold market. The gold market is a global marketplace consisting of both over-the-counter (''OTC'') transactions and exchange-traded products. The OTC market generally consists of transactions in spot, forwards, options and other derivatives, while exchange-traded transactions consist of futures and options. A description of each of the OTC and exchange-traded markets for gold as well as the regulation is set forth below.

(a) *The OTC Market*

The OTC market trades on a 24-hour continuous basis and accounts for the substantial portion of global gold trading. Liquidity in the OTC market can vary from time to time during the course of the 24-hour trading day. Fluctuations in liquidity are reflected in adjustments to dealing spreads—the differential between a dealer's buy and sell prices. The period of greatest liquidity in the gold market is typically that time of day when trading in the European time zone overlaps with trading in the United States. This occurs when the OTC market trading in London, New York and other centers coincides with futures and options trading on the COMEX. This period lasts for approximately four (4) hours each New York business day morning.

The OTC market has no formal structure and no open-outcry meeting place. The main centers of the OTC market are London, New York and Zurich. Bullion dealers have offices around the world, and most of the world's major bullion dealers are either members or associate members of the London Bullion Market Association (''LBMA''), a trade association of participants in the London Bullion market.

There are no authoritative published figures for overall worldwide volume in gold trading. There are published sources that do suggest the significant size of the overall market. The LBMA publishes statistics compiled from the five (5) members offering clearing services.[16] The monthly average daily volume figures published by the LBMA for 2003 range from a high of 19 million to a low of 13.6 million troy ounces per day. Through September 2004, the monthly average daily volume has ranged from a high of 17 million to a low of 12.4 million. The COMEX also publishes price and volume statistics for transactions in contracts for the future delivery of gold. COMEX figures for 2003 indicate that the average daily volume for gold futures and options contracts was 4.89 million (48,943 contracts) and 1.7 million (17,241 contracts) troy ounces per day, respectively. Through October 2004, the average daily volume for gold futures and options was 6.08 million (60,817 contracts) and 2.01 million (20,173 contracts), respectively.[17]

(b) *Futures Exchanges*

The most significant gold futures exchanges are the COMEX division of the NYMEX and the Tokyo Commodity Exchange (''TOCOM'').[18] Trading on these exchanges is based on fixed delivery dates and transaction sizes for the futures and options contracts traded. Trading costs are negotiable. As a matter of practice, only a small percentage of the future market turnover ever comes to physical delivery of the gold represented by the contracts traded. Both exchanges permit trading on margin. COMEX operates through a central clearance system. TOCOM has a similar clearance system. In each case, the exchange acts as counterparty for each member for clearing purposes.

(c) *Gold Market Regulation*

There is no direct regulation of the global OTC market in gold. However, indirect regulation of some of the overseas participants does occur. In the United Kingdom, responsibility for the regulation of financial market participants, including the major participating members of the LBMA, falls under the authority of the Financial Services Authority (''FSA'') as provided by the Financial Services and Market Act of 2000 (''FSM Act''). Under the FSM Act, all UK-based banks, together with other investment firms, are subject to a range of requirements, including fitness and properness, capital adequacy, liquidity, and systems and controls. The FSA is responsible for regulating investment products, including derivatives, and those who deal in investment products. Regulation of spot, commercial forwards and deposits of gold and silver not covered by the FSM Act is provided for by The London Code of Conduct for Non-

[12] 15 U.S.C. 78s(b).

[13] Proposed Rule 1202A for Commodity-Based Trust Shares tracks but is not identical to current Rule 1202 relating to TIRs. The initial listing standards set forth in Rule 1202(a) provide that the Exchange establish a minimum number of TIRs required to be outstanding at the time of the commencement of trading on the Exchange. As set forth in the section ''Criteria for Initial and Continued Listing,'' the Exchange expects the minimum number of Gold Shares required to be outstanding at the time of trading to be 150,000. This section, *infra*, specifically details the initial and continued listing standards for Commodity-Based Trusts such as the Gold Trust.

[14] The trust is not an investment company as defined in Section 3(a) of the Investment Company Act of 1940 (the ''1940 Act'').

[15] *See* Securities Exchange Act Release Nos. 39402 (December 4, 1997), 62 FR 65459 (December 12, 1997) (approving the listing and trading of commodity index preferred or debt securities (ComPS) on various agricultural futures contracts and commodities indexes); 36885 (February 26, 1996), 61 FR 8315 (March 4, 1996) (approving the listing and trading of ComPS linked to the value of single commodity); 35518 (March 21, 1995), 60 FR 15804 (March 27, 1995) (approving the listing and trading of commodity indexed notes or COINS); and 43427 (October 10, 2000), 65 FR 62783 (October 19, 2000) (approving the listing and trading of inflation indexed securities). *See also* Central Fund of Canada (Registration No. 033–15180) (closed-end fund listed and traded on the Amex that invests in gold) and Salmon Phibro Oil Trust (Registration No. 033–33823) (trust units listed and traded on the Amex that held the right to a forward contract for the delivery of crude oil).

[16] Information regarding clearing volume estimates by the LBMA can be found at *http://www.lbma.org.uk/clearing_table.htm.* The three measures published by the LBMA are: volume, the amount of metal transferred on average each day measured in millions of troy ounces; value, measured in U.S. dollars, using the monthly average London PM fixing price; and the number of transfers, which is the average number recorded each day. The statistics exclude allocated and unallocated balance transfers where the sole purpose is for overnight credit and physical movements arranged by clearing members in locations other than London.

[17] Information regarding average daily volume estimates by the COMEX can be found at *http://www.nymex.com/jsp/markets.md_annual_volume6.jsp#2.* The statistics are based on gold futures contracts, each of which relates to 100 troy ounces of gold.

[18] There are other gold exchange markets, such as the Instanbul Gold Exchange, the Shanghai Gold Exchange and the Hong Kong Chinese Gold & Silver Exchange Society.

Investment Products, which was established by market participants in conjunction with the Bank of England, and is a voluntary code of conduct among market participants.

Participants in the U.S. OTC market for gold are generally regulated by their institutional supervisors, which regulate their activities in the other markets in which they operate. For example, participating banks are regulated by the banking authorities. In the U.S., the CFTC, an independent governmental agency with the mandate to regulate commodity futures and options markets in the U.S., regulates market participants and has established rules designed to prevent market manipulation, abusive trade practices and fraud.

TOCOM has authority to perform financial and operational surveillance on its members' trading activities, scrutinize positions held by members and large-scale customers, and monitor price movements of futures markets by comparing them with cash and other derivative markets' prices.

Product Description

Issuances of Gold Shares will be made only in baskets of 50,000 shares or multiples thereof (the ''Basket Aggregation'' or ''Basket''). The Trust will issue and redeem the Gold Shares on a continuous basis, by or through participants that have entered into participant agreements (each, an ''Authorized Participant'')[19] with the Sponsor, Barclays and the Trustee, BNY, at the net asset value (''NAV'') per share next determined after an order to purchase Gold Shares in a Basket Aggregation is received in proper form. Following issuance, Gold Shares will be traded on the Exchange similar to other equity securities.

Basket Aggregations will be issued in exchange for a corresponding amount of gold. The basket amount of gold, measured in fine ounces (the ''Basket Gold Amount''), will be determined on each business day by the Trustee, BNY. Authorized Participants that wish to purchase a Basket must transfer the Basket Gold Amount to the Trust in exchange for a Basket. Authorized Participants that wish to redeem a Basket will receive the Basket Gold Amount in exchange for each Basket surrendered. The Bank of Nova Scotia (''BNS'') will be the custodian for the Trust and responsible for safekeeping the gold.[20] Gold deposited with BNS must either (a) meet the requirements to be delivered in settlement of a COMEX gold futures contract pursuant to the rules adopted by the COMEX or (b) meet the specifications for weight, dimensions, fineness (or purity), identifying marks and appearance of gold bars as set forth in ''The Good Delivery Rules for Gold and Silver Bars'' published by the LBMA. Initially, creation of a Basket will require delivery of 5,000 fine ounces of gold. This Basket Gold Amount will decrease over the life of the Trust due to the payment or accrual of fees and other expenses payable by the Trust.

On each business day, BNY will make available immediately prior to the opening of trading on the Amex, the Basket Gold Amount for the creation of a Basket. BNY will adjust the quantity of gold included in the Basket Gold Amount to reflect sales of gold to cover expenses and any loss of deposited gold that may occur. The Amex will disseminate every 15 seconds throughout the trading day, via the facilities of the Consolidated Tape Association (''CTA''), an amount representing on a per share basis, the current value of the Basket Gold Amount. It is anticipated that the deposit of gold in exchange for Gold Shares will be made primarily by institutional investors, arbitrageurs, and the Exchange specialist. Baskets are then separable upon issuance into identical shares that will be listed and traded on the Amex.[21] Gold Shares are expected to be traded on the Exchange by professionals as well as institutional and retail investors. Gold Shares may be acquired in two (2) ways: (1) Through a deposit of the Basket Gold Amount with the BNY during normal business hours by Authorized Participants, or (2) through a purchase on the Exchange by investors.

Shortly after 4 p.m. each business day, the BNY will determine the NAV for the Trust, utilizing the 1:30 p.m. daily settlement value for the spot month COMEX gold futures contract. At or about 4 p.m. each business day, the BNY will determine the Basket Gold Amount for orders placed by Authorized Participants received before 4 p.m. that day. The BNY will also at the same time determine an ''Indicative Basket Gold Amount'' that Authorized Participants can use as an indicative amount of gold to be deposited for issuance of the Gold Shares on the next business day. Thus, although Authorized Participants place orders to purchase Gold Shares throughout the trading day, the actual Basket Gold Amount is determined at 4 p.m. or shortly thereafter.

Shortly after 4 p.m. each business day, the BNY, Amex and

Barclays (Sponsor) will disseminate the NAV for the Gold Shares, the Basket Gold Amount (for orders placed during the day), and the Indicative Basket Gold Amount (the indicative amount of gold for use by Authorized Participants on the next business day). The Basket Gold Amount, the Indicative Basket Gold Amount, and the NAV are communicated by the BNY to all Authorized Participants via facsimile or electronic mail message and will be available on the Trust's Web site at *http://www.ishares.com.* The Amex will also disclose the NAV and Basket Gold Amount on its Web site.

The Basket Gold Amount necessary for the creation of a Basket will change from day to day. The initial Basket Gold Amount is 5,000 fine ounces of gold. On each day that the Amex is open for regular trading, the BNY will adjust the quantity of gold constituting the Basket Gold Amount as appropriate to reflect sales of gold, any loss of gold that may occur, and accrued expenses. The BNY will determine the Basket Gold Amount for a given business day by multiplying the NAV for each Gold Share by the number of Gold Shares in each Basket (50,000) and dividing the resulting product by that day's COMEX settlement price for the spot month gold futures contract. The NAV is calculated by multiplying the fine ounces of gold held by the Trust (after gold has been sold for that day to pay that day's fees and expenses) by the daily settlement value of the COMEX spot month gold futures contract.

The Trust's expense ratio, in the absence of any extraordinary expenses and liabilities, is established at 0.40% of the net assets of the Trust. As a result, the amount of gold by which the Basket Gold Amount will decrease each day will be predictable (*i.e.* 1/365th of the net asset value of the Trust multiplied by 0.40%). As provided for above, the BNY will disclose and disseminate the Indicative Basket Gold Amount for the next business day. Authorized Participants may use the Indicative Basket Gold Amount as guidance regarding the amount of gold expected

[19] An ''Authorized Participant'' is a person, who at the time of submitting to the trustee an order to create or redeem one or more Baskets, (i) is a registered broker-dealer, (ii) is a Depository Trust Company (''DTC'') Participant or an Indirect Participant and (iii) has in effect a valid Authorized Participant Agreement.

[20] If the total value of the Trust's gold held by the custodian exceeds $2 billion, then the custodian will be under no obligation to accept additional gold deliveries. In such a case, the trustee will retain an additional custodian.

[21] Gold Shares are separate and distinct from the underlying gold comprising the portfolio of the Gold Trust. The Exchange expects that the number of outstanding Gold Shares will increase and decrease as a result of in-kind deposits and withdrawals of the underlying gold.

to deposit with the custodian, BNS, in connection with the issuance of Gold Shares on such next business day.

As a result, the amount of gold required for the Basket Gold Amount is not disseminated during the trading day to correspond to changes in the value of gold as identified by the COMEX gold futures contract.[22] All purchase orders received by the BNY prior to 4 p.m. will be settled by depositing with the custodian, BNS, the Basket Gold Amount disseminated by the BNY shortly after 4 p.m. Given the predictability of the daily decline in the Basket Gold Amount, BNY and Barclays will announce the Indicative Basket Gold Amount for the next business day, shortly after 4 p.m.

Thus, the BNY will disseminate shortly after 4 p.m. the amount of gold to be deposited for each Basket (50,000 shares) order properly submitted by Authorized Participants prior to 4 p.m. that business day. Before 4 p.m., the Authorized Participants may use the Indicative Basket Gold Amount published by Barclays and BNY the day before as guidance in respect of the amount of gold that they may expect to be required to deposit. But if the Indicative Basket Gold Amount published by Barclays and BNY turns out to be incorrect (for example, because the Trust incurred an extraordinary expense such as legal fees in excess of the amount assumed by Barclays), the amount actually determined by BNY will control.

The creation/redemption process in connection with the Gold Shares does not contemplate the existence of cash. Because the process is based entirely on the physical delivery of gold, the actual number of fine ounces required for the Basket Gold Amount will not change even though the value of the Basket Gold Amount may change based on the market price of gold. Therefore, because Authorized Participants will only know the amount of gold to be deposited after the close of trading of the COMEX gold futures contract, the intra-day price fluctuations on the COMEX will not result in the making of gold deposits that are more or less than the amount required for the Basket Gold Amount.

The Exchange believes that Gold Shares will not trade at a material discount or premium to the underlying gold held by the Trust based on potential arbitrage opportunities. Due to the fact that Gold Shares can be created and redeemed only in Basket Aggregations at NAV, the Exchange submits that arbitrage opportunities should provide a mechanism to mitigate the effect of any premiums or discounts that may exist from time to time.

Gold Shares will not be individually redeemable but will only be redeemable in Basket Aggregations. To redeem, an Authorized Participant will be required to accumulate enough Gold Shares to constitute a Basket Aggregation (*i.e.*, 50,000 shares). An Authorized Participant redeeming a Basket Aggregation will receive the physical gold amount of the Basket announced by the Trustee. Upon the surrender of the Gold Shares and payment of the applicable Trustee's fee and any expenses, taxes or charges, the BNY will deliver to the redeeming Authorized Participant the amount of gold corresponding to the redeemed Baskets. Unless otherwise requested by the Authorized Participants, gold will then be delivered to the redeeming Authorized Participants in the form of physical bars only.[23]

When calculating NAV, the BNY will value the gold held by the Trust on the basis of the day's announced COMEX settlement price for the spot month gold futures contract.[24] At any point in time, the spot month contract is the futures contract then closest to maturity. If a COMEX settlement price for a spot month gold futures contract is not announced, the Trustee will use the most recently announced spot month COMEX settlement price, unless the Trustee (BNY), in consultation with the Sponsor (Barclays), determines that such price is inappropriate. Once the value of the gold is determined, the BNY will then subtract all accrued fees (other than the fees to be computed by reference to the value of the Trust or its assets), expenses and other liabilities of the Trust from the total value of gold and all other assets of the Trust. This adjusted NAV is then used to compute all fees (including the Trustee and Sponsor fees) that are calculated from the value of Trust assets. To determine the NAV, the BNY will subtract from the adjusted NAV the amount of accrued fees from the value of Trust assets. The BNY will calculate the NAV per share by dividing the NAV by the number of Gold Shares outstanding.

Gold Shares will be registered in book entry form through DTC. Trading in Gold Shares on the Exchange will be effected until 4:15 p.m. New York Time each business day. The minimum trading increment for such shares will be $.01.

COMEX Gold Futures Contracts

The price of gold is volatile with fluctuations expected to affect the value of the Gold Shares. The price movement of gold may be influenced by a variety of factors, including announcements from Central Banks regarding reserve gold holdings, agreements among Central Banks, political uncertainties, and economic concerns. The price of gold during the period January 1994 through October 29, 2004 ranged from a high of $431.05 per ounce in April 2004 to a low of $251.95 in August 1999. As of October 29, 2004, the spot price per ounce for gold as provided by that day's spot COMEX gold futures contract was $428.50.

The NYMEX is the world's largest physical commodity futures exchange and the dominant market for the trading of energy and precious metals. The COMEX Division of the NYMEX commenced the trading of gold futures contracts on December 31, 1974. The NYMEX and the COMEX Division are subject to the regulation and oversight of the Commodity Futures Trading Commission (''CFTC''). The Amex states that the CFTC administers the Commodity Exchange Act (''CEA''), which requires commodity futures exchanges, such as the NYMEX, to have rules and procedures to prevent market

[22] However, the Amex will disseminate an ''Indicative Trust Value'' at least every 15 seconds through the facilities of the CTA during the trading day that represents an indicative value for the Gold Shares based on the most last reported trade price in the most actively-traded COMEX gold futures contract.

[23] If the amount of gold corresponding to the Basket Gold Amount results in an amount that is less than a full gold bar denomination, the Authorized Participant has the ability to take and/or deliver fractional gold bar amounts. Telephone conversation between Jeffrey Burns, Associate General Counsel, Amex, and Florence Harmon, Senior Special Counsel, Division of Market Regulation, Commission, on December 3, 2004.

[24] The COMEX daily settlement price for each gold futures contract is established by a subcommittee of COMEX members shortly after the close of trading in New York. The daily settlement price for each contract (delivery month) is derived from the daily settlement price for the most active futures contract month that is not necessarily the spot month. This settlement price is the average of the highest and lowest priced trades reported during the last one (1) minute of trading during regular trading hours. For all other gold futures contract months (which may include the spot month), the settlement prices are determined by COMEX based upon differentials reflected in spread trades between adjacent months, such differentials being directly or indirectly related to the most active month. These differentials are the average of the highest and lowest spread trades (trades based upon the differential between the prices for two contract months) reported during the last fifteen (15) minutes of trading during regular trading hours. In the case that there were no such spread trades, the average of the bids and offers for spread transactions during that last fifteen (15) minute period are used. In the case where there are no bids and offers during that time, the contracts are settled at prices consistent with the differentials for other contract months that were settled by the first or second method. If the third method is used, the subcommittee of the COMEX members establishing those settlement prices provides a record of the differentials from other contract months that formed the basis for those settlements.

manipulation, abusive trade practices and fraud. The CFTC conducts regular review and inspection of the NYMEX's enforcement programs.

The trading unit of COMEX gold futures contracts is 100 troy ounces. Gold bars tendered for delivery can be cast in the form of either one bar or three one-kilogram bars. In either form, the gross weight of the bar or bars tendered for each contract must be within a five percent tolerance of the 100 ounce contract, and the bars must assay at not less than 995 fineness, *i.e.*, 99.5% pure gold.

Dissemination of COMEX Gold Futures Information

The daily settlement price for COMEX gold futures contracts is publicly available on the NYMEX Web site at *http://nymex.com.*[25] The Exchange on its Web site at *http://www.amex.com* will include a hyperlink to the NYMEX Web site for the purpose of disclosing gold futures contract pricing. In addition, the Exchange represents that COMEX gold futures prices, options on futures quotes, and last sale information is widely disseminated through a variety of market data vendors worldwide, including Bloomberg and Reuters. In addition, the Exchange further represents that complete real-time data for COMEX gold futures and options is available by subscription from Reuters and Bloomberg. The NYMEX also provides delayed futures and options information on current and past trading sessions and market news free of charge on its Web site at *http://www.nymex.com.* The contract specifications for COMEX gold futures contracts are also available from the NYMEX at its Web site at *http://nymex.com* as well as other financial informational sources.

Availability of Information Regarding Gold Shares

The Web site for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The prior business day's NAV and the reported closing price; (b) the mid-point of the bid-ask price [26] in relation to the NAV as of the time the NAV is calculated (the ''Bid-Ask Price''); (c) calculation of the premium or discount of such price against such NAV; (e) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four (4) previous calendar quarters; (f) the Prospectus; and (g) other applicable quantitative information.

As described above, the NAV for the Trust will be calculated and disseminated daily. The Amex also intends to disseminate for the Trust on a daily basis by means of CTA/CQ High Speed Lines information with respect to the Indicative Trust Value (as discussed below), recent NAV and shares outstanding. The Exchange will also make available on its Web site daily trading volume, closing prices, and the NAV. The closing price and settlement prices of the COMEX gold futures contracts are also readily available from the NYMEX at *http://www.nymex.com,* automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. In addition, the Exchange will provide a hyperlink on its Web site at *http://www.amex.com* to the Trust's Web site at *http://www.ishares.com.*

Dissemination of Indicative Trust Value

As noted above, the BNY calculates the NAV of the Gold Trust once each trading day. In addition, the BNY causes to be made available on a daily basis the required amount of gold to be deposited in connection with the issuance of Gold Shares in Basket Aggregations. In addition, other investors can request such information directly from the BNY.

In order to provide updated information relating to the Trust for use by investors, professionals and persons wishing to create or redeem Gold Shares, the Exchange will disseminate through the facilities of CTA an updated Indicative Trust Value (the ''Indicative Trust Value''). The Indicative Trust Value will be disseminated on a per Gold Share basis every 15 seconds during regular Amex trading hours of 9:30 a.m. to 4:15 p.m. New York time through the facilities of the CTA. The Indicative Trust Value will be calculated based on the amount of gold required for creations and redemptions and a price of gold derived from the most recently reported trade price in the active gold futures contract. The prices reported for the active contract month will be adjusted based on the prior day's spread differential between settlement values for that contract and the spot month contract. In the event that the spot month contract is also the active contract, the last sale price for the active contract will not be adjusted.

The Indicative Trust Value will not reflect changes to the price of gold between the close of trading at the COMEX, typically 1:30 p.m. New York time, and the open of trading on the NYMEX ACCESS market at 2 p.m. New York time. While the market for the gold futures is open for trading, the Indicative Trust Value can be expected to closely approximate the value per share of the Basket Gold Amount. The Indicative Trust Value on a per Gold Share basis disseminated during Amex trading hours should not be viewed as a real time update of the NAV, which is calculated only once a day.

The Exchange believes that dissemination of the Indicative Trust Value based on the amount of gold required for a Basket Aggregation provides additional information that is not otherwise available to the public and is useful to professionals and investors in connection with Gold Shares trading on the Exchange or the creation or redemption of Gold Shares. In addition, the Trust's Web site at *http//www.ishares.com* will also provide continuously updated bids and offers indicative of the spot price of gold in the OTC market for the purpose of disclosing to investors on a real-time basis the underlying or spot price of gold.

Termination Events

The Trust will be terminated if any of the following circumstances occur: (1) The Gold Shares are delisted from the Amex and are not listed for trading on another national securities exchange within five business days from the date the Gold Shares are delisted; (2) holders of at least 75% of the outstanding Gold Shares notify the Trustee that they elect to terminate the Trust; (3) the Trustee resigns and no successor trustee is appointed within 60 days from the date the Trustee provides notice to Barclays of its intent to resign; (4) the SEC finds that the Trust should be registered as an investment company under the 1940

[25] As previously stated, the COMEX daily settlement price for each gold futures contract is established by a subcommittee of COMEX members shortly after the close of trading of regular trading on the COMEX. NYMEX Rule 3.43 sets forth the composition of the subcommittee requiring that it consist of three (3) members that represent the gold market. Specifically, the Rule calls for the subcommittee to include a floor broker, a floor trader and one who represents the trade. Rule 3.02 provides restrictions on Committee members and others who possess material, non-public information. A Committee Member is prohibited from disclosing for any purpose other than the performance of official duties relating to the Committee, material, non-public information obtained as a result of such person's participation on the Committee. In addition, no person may trade for his own account or for or on behalf of any other account, in any commodity interest on the basis of any material, non-public information that such person knows was obtained from such Committee member in violation of Rule 3.02. Telephone conversation between Jeffrey Burns, Associate General Counsel, Amex, and Florence Harmon, Senior Special Counsel, Division of Market Regulation, Commission, on December 3, 2004.

[26] The bid-ask price of Shares is determined using the highest bid and lowest offer as of the time of calculation of the NAV.

Act, and the Trustee has actual knowledge of the SEC finding; (5) the aggregate market capitalization of the Trust, based upon the closing price for the Gold Trust, was less than $350 million on each of five (5) consecutive trading days and the Trustee receives, within six (6) months from the last of those trading days, notice that the Sponsor has decided to terminate the Trust; (6) the CFTC determines that the Trust is a commodity pool under the Commodity Exchange Act and the Trustee has actual knowledge of that determination: or (7) the Trust fails to qualify for treatment, or ceases to be treated, as a grantor trust for U.S. federal income tax purposes and the Trustee receives notice that the Sponsor has determined that the termination of the Trust is advisable.

If not terminated earlier by the Trustee, the Trust will terminate in 2044 on a date to be determined once the Trust is established. Upon termination of the Trust, holders of the Gold Shares will surrender their shares and receive from the Trustee their portion of the underlying gold.

Criteria for Initial and Continued Listing

The Trust will be subject to the criteria in proposed Rules 1201A and 1202A for initial and continued listing of Gold Shares. The proposed continued listing criteria provides for the delisting or removal from listing of the Gold Shares under any of the following circumstances:

- Following the initial twelve month period from the date of commencement of trading of the Gold Shares: (i) If the Trust has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of the Gold Shares for 30 or more consecutive trading days; (ii) if the Trust has fewer than 50,000 Gold Shares issued and outstanding; or (iii) if the market value of all Gold Shares is less than $1,000,000.
- If the value of the underlying gold is no longer calculated or available on at least a 15-second delayed basis from a source unaffiliated with the sponsor, Trust, custodian or the Exchange or the Exchange stops providing a hyperlink on its website to any such unaffiliated gold value.
- The Indicative Trust Value is no longer made available on at least a 15-second delayed basis.
- If such other event shall occur or condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

It is anticipated that a minimum of 150,000 Gold Shares will be required to be outstanding at the start of trading. The minimum number of shares required to be outstanding at the start of trading is comparable to requirements that have been applied to previously listed series of trust issues receipts, Portfolio Depository Receipts and Index Fund Shares. It is anticipated that the initial price of a Gold Share will be approximately $40 per share. The Exchange believes that the anticipated minimum number of Gold Shares outstanding at the start of trading is sufficient to provide adequate market liquidity and to further the Trust's objective to seek to provide a simple and cost effective means of making an investment similar to an investment in gold. The Exchange represents that it prohibits the initial and/or continued listing of any security that is not in compliance with Rule 10A–3 under the Act.[27]

Original and Annual Listing Fees

The Amex original listing fee applicable to the listing of the Gold Trust is $5,000. In addition, the annual listing fee applicable under Section 141 of the Amex *Company Guide* will be based upon the year-end aggregate number of shares in all series of Gold Trusts outstanding at the end of each calendar year.

Information Circular

The Amex will distribute an information circular (''Information Circular'') to its members in connection with the trading of Gold Shares. The Information Circular will discuss the special characteristics and risks of trading this type of security. Specifically, the Information Circular, among other things, will discuss what the Gold Shares are, how a basket is created and redeemed, the requirement that members and member firms deliver a prospectus to investors purchasing the Gold Shares prior to or concurrently with the confirmation of a transaction, applicable Amex rules, dissemination information regarding the per share Indicative Trust Value, trading information and applicable suitability rules. The Information Circular will also explain that the Gold Trust is subject to various fees and expenses described in the Registration Statement, and that the number of ounces of gold required to create a basket or to be delivered upon a redemption of a basket will gradually decrease over time because the Gold Shares comprising a basket will represent a decreasing amount of gold due to the sale of the Gold Trust's gold to pay Trust expenses. The Information Circular will also reference the fact that there is no regulated source of last sale information regarding physical gold, that the Commission has no jurisdiction over the trading of gold as a physical commodity, and that the Commodity Futures Trading Commission (''CFTC'') has regulatory jurisdiction over the trading of gold futures contracts and options on gold futures contracts.

The Information Circular will also notify members and member organizations about the procedures for purchases and redemptions of Gold Shares in baskets, and that Gold Shares are not individually redeemable but are redeemable only in basket-size aggregations or multiples thereof. The Information Circular will advise members of their suitability obligations with respect to recommended transactions to customers in the Gold Shares. The Information Circular will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

The Information Circular will disclose that the net asset value (''NAV'') for Gold Shares will be disseminated shortly after 4:00 p.m. each trading day based on the COMEX daily settlement value, which is disseminated shortly after 1:30 p.m. New York time each trading day.

Disclosure

The Information Circular provided to Exchange members and member organizations will inform members and member organizations, prior to commencement of trading, of the prospectus delivery requirements applicable to the Trust. The Exchange notes that investors purchasing Gold Shares directly from the Trust (by delivery of the Basket Gold Amount) will receive a prospectus. Amex members purchasing Gold Shares from the Trust for resale to investors will deliver a prospectus to such investors.

Purchase and Redemptions in Basket Aggregations

In the Information Circular referenced above, members and member organizations will be informed that procedures for purchases and redemptions of Gold Shares in Basket Aggregations are described in the Prospectus and that Gold Shares are not individually redeemable but are redeemable only in Basket Aggregations or multiples thereof.

Trading Rules

Gold Shares are equity securities subject to Amex Rules governing the trading of equity securities, including, among others, rules governing priority, parity and precedence of orders,

[27] *See* 17 CFR 240.10A–3(c)(7).

specialist responsibilities and account opening and customer suitability (Amex Rule 411). Initial equity margin requirements of 50% will apply to transactions in Gold Shares. Gold Shares will trade on the Amex until 4:15 p.m. New York time each business day and will trade in a minimum price variation of $0.01 pursuant to Amex Rule 127. Trading rules pertaining to odd-lot trading in Amex equities (Amex Rule 205) will also apply.

Amex Rule 154, Commentary .04(c) provides that stop and stop limit orders to buy or sell a security (other than an option, which is covered by Rule 950(f) and Commentary thereto) the price of which is derivatively priced based upon another security or index of securities, may with the prior approval of a Floor Official, be elected by a quotation, as set forth in Commentary .04(c) (i–v). The Exchange has designated Gold Shares as eligible for this treatment.[28]

Gold Shares will be deemed ''Eligible Securities'', as defined in Amex Rule 230, for purposes of the Intermarket Trading System Plan and therefore will be subject to the trade through provisions of Amex Rule 236 which require that Amex members avoid initiating trade-throughs for ITS securities.

Specialist transactions of Gold Shares made in connection with the creation and redemption of Gold Shares will not be subject to the prohibitions of Amex Rule 190.[29] Unless exemptive or no-action relief is available, Gold Shares will be subject to the short sale rule, Rule 10a–1 under the Act.[30] If exemptive or no-action relief is provided, the Exchange will issue a notice detailing the terms of the exemption or relief.

The Exchange represents that the Gold Shares will generally be subject to the Exchange's stabilization rule, Amex Rule 170, except that specialists may buy on ''plus ticks'' and sell on ''minus ticks,'' in order to bring the Gold Shares into parity with the underlying gold and/or futures price. Proposed Commentary .01 to proposed Rule 1203A sets forth this limited exception to Amex Rule 170.

The Exchange's surveillance procedures for Gold Shares will be similar to those used for other trust issued receipts and exchange-traded funds (''ETFs'') and will incorporate and rely upon existing Amex surveillance procedures governing options and equities.

Amex states that the adoption of Rule 1203A relating to certain specialist prohibitions will address potential conflicts of interest in connection with acting as a specialist in the Gold Shares. Specifically, Rule 1203A provides that the prohibitions in Rule 175(c) apply to a specialist in the Gold Shares so that the specialist or affiliated person may not act or function as a market maker in the underlying gold, related gold futures contract or option or any other related gold derivative. An affiliated person of the specialist consistent with Amex Rule 193 (Affiliated Persons of Specialists) may be afforded an exemption to act in a market making capacity, other than as a specialist in the Gold Shares on another market center, in the underlying gold, related gold futures or options or any other related gold derivative. In particular, proposed Rule 1203A provides that an approved person of an equity specialist that has established and obtained Exchange approval for procedures restricting the flow of material, non-public market information between itself and the specialist member organization, and any member, officer, or employee associated therewith, may act in a market making capacity, other than as a specialist in the Gold Shares on another market center, in the underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives.

Also, the Exchange states that adoption of Rule 1204A will ensure that specialists handling the Gold Shares provide the Exchange with all the necessary information relating to their trading in physical gold, related gold futures contracts and options thereon or any other gold derivative. As a general matter, the Exchange has regulatory jurisdiction over its members, member organizations, and approved persons of a member organization. The Exchange also has regulatory jurisdiction over any person or entity controlling a member organization as well as a subsidiary or affiliate of a member organization that is in the securities business. A subsidiary or affiliate of a member organization that does business only in commodities would not be subject to Exchange jurisdiction, but the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

Trading Halts

The Information Circular issued to Amex members will inform them of, among other things, Exchange policies regarding trading halts in Gold Shares. First, the Information Circular will advise that trading will be halted in the event the market volatility trading halt parameters set forth in Amex Rule 117 have been reached. Second, the Information Circular will advise that, in addition to the parameters set forth in Rule 117, the Exchange will halt trading in Gold Shares if trading in the underlying COMEX gold futures contract is halted or suspended. Third, with respect to a halt in trading that is not specified above, the Exchange may also consider other relevant factors and the existence of unusual conditions or circumstances that may be detrimental to the maintenance of a fair and orderly market.

Suitability

The Information Circular referenced above will inform members and member organizations of the characteristics of the Gold Trust and of applicable Exchange rules, as well as of the requirements of Amex Rule 411 (Duty to Know and Approve Customers).

The Exchange notes that pursuant to Rule 411, members and member organizations are required in connection with recommending transactions in the Gold Shares to have a reasonable basis to believe that a customer is suitable for the particular investment given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such member.

Surveillance

Amex represents that its surveillance procedures applicable to trading in the proposed Gold Shares will be similar to those applicable to Trust Issued Receipts, Portfolio Depository Receipts and Index Fund Shares currently trading on the Exchange. The Exchange currently has in place an Information Sharing Agreement with the NYMEX for the purpose of providing information in connection with trading in or related to COMEX gold futures contracts. In addition, the Exchange is also in the process of negotiating an Information Sharing Agreement with the NYMEX for

[28] *See* Securities Exchange Act Release No. 29063 (April 10, 1991), 56 FR 15652 (April 17, 1991) at note 9, regarding the Exchange's designation of equity derivative securities as eligible for such treatment under Amex Rule 154, Commentary .04(c).

[29] *See* Commentary .05 to Amex Rule 190.

[30] The Gold Trust has requested relief in connection with the trading of Gold Shares from the operation of the short sale rule, Rule 10a–1 under the Act. *See* 17 CFR 240.10a–1. The requested relief is currently pending with the Commission staff in the Division of Market Regulation. If granted, Gold Shares would be exempt from Rule 10a–1 permitting sales without regard to the ''tick'' requirements of Rule 10a–1. Rule 10a–1(a)(1)(i) provides that a short sale of an exchange-traded security may not be effected (i) below the last regular-way sale price (an ''uptick'') or (ii) at such price unless such price is above the next preceding different price at which a sale was reported (a ''zero-plus tick'').

the sharing of information related to any financial instrument based, in whole or in part, upon an interest in or performance of gold.

1. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act [31] in general and furthers the objectives of Section 6(b)(5) [32] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the 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 will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange did not receive any written comments on the proposed rule change.

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, 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–Amex–2004–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–Amex–2004–38. 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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Amex. 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–Amex–2004–38 and should be submitted on or before December 30, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[33]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 04–27018 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

[31] 15 U.S.C. 78f(b).

[32] 15 U.S.C. 78f(b)(5).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50791; File No. SR–CBOE–2003–18]

Self-Regulatory Organizations; Notice of Withdrawal of Proposed Rule Change by the Chicago Board Options Exchange, Incorporated to Amend CBOE Rule 6.24 Relating to Systematizing Orders

December 3, 2004.

On May 5, 2003, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] to amend CBOE Rule 6.24 relating to the systematization of orders to comply with the requirement to implement a consolidated options audit trail system (''COATS''). On July 29, 2003, the Exchange submitted Amendment No. 1 to the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on August 7, 2003.[3] No comment letters were received. On November 24, 2004, the Exchange withdrew the proposed rule change.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E4–3578 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50790; File No. SR–FICC–2004–16]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Granting Approval of a Proposed Rule Change Relating to Establishment of a Cross-Margining Agreement With The Clearing Corporation

December 3, 2004.

I. Introduction

On August 12, 2004, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change File No. SR–FICC–2004–16

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 48267 (July 31, 2003), 68 FR 47116.

[4] 17 CFR 200.30–3(a)(12).

pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] Notice of the proposed rule change was published in the **Federal Register** on November 1, 2004.[2] No comment letters were received. For the reasons discussed below, the Commission is now granting approval of the proposed rule change.

II. Description

The proposed rule change establishes a cross-margining arrangement between FICC's Government Securities Division (''GSD'') and The Clearing Corporation (''TCC'').

(1) Background

The Government Securities Division of FICC is entering into a new cross-margining agreement with TCC. FICC had a cross-margining arrangement in place with the Board of Trade Clearing Corporation (''BOTCC''), TCC's predecessor, through which certain Chicago Board of Trade (''CBOT'') products were cross-margined with certain FICC products.[3] The BOTCC arrangement was terminated on January 2, 2004, the date on which BOTCC ceased being the clearing organization for the CBOT products that were the subject of the arrangement.[4] On January 2, 2004, the Chicago Mercantile Exchange (''CME'') became the clearing organization for the CBOT products that are now included in the cross-margining arrangement that FICC has with the CME.[5]

TCC recently became the clearing organization for EurexUS and has approached FICC regarding cross-margining certain U.S. Treasury and Agency futures and options on futures products traded on the EurexUS futures exchange and cleared by TCC with certain FICC products.[6]

FICC is entering into a new cross-margining agreement with TCC (''FICC–TCC Agreement'') to cover the EurexUS traded products cleared by TCC. Under the FICC–TCC Agreement, the FICC products that will be eligible for cross-margining will be Treasury securities that fall into the GSD's offset classes A through G, and GCF Repo Treasury securities with equivalent remaining maturities, non-mortgage-backed Agency securities that fall into the GSD's offset classes e and f, and GCF Repo non-mortgage-backed Agency securities with equivalent remaining maturities. The TCC products that will be eligible for cross-margining will be the EurexUS products, which are Two-Year Treasury Note Futures contracts and options thereon, Five-Year Treasury Note Futures contracts and options thereon, Ten-Year Treasury Note Futures contracts and options thereon, Thirty-Year Treasury Bond Futures contracts and options thereon, Five-Year Agency Note Futures contracts and options thereon, and Ten-Year Agency Note Futures contracts and options thereon, cleared or to be cleared by TCC.[7]

(2) FICC's Cross-Margining Program in General

In general, cross-margining allows members to optimize their capital usage by permitting their clearing organizations to view their positions across clearing organizations as a combined portfolio and to reduce margin requirements accordingly.[8] Margin based on the net combined risk of correlated positions is based on the cross margining arrangement under which FICC and each Participating CO agree to accept the correlated positions in lieu of supporting collateral.[9] All eligible positions maintained by a cross-margining participant in its account at FICC and in its (or its affiliate's) proprietary account at a Participating CO are eligible for cross-margining.[10]

Under the arrangement, FICC and each Participating CO holds and manages its own positions and collateral and independently determines the amount of margin that it will make available for cross-margining, which is referred to as the ''residual margin amount.'' FICC computes the amount by which the cross-margining participant's margin requirement can be reduced at each clearing organization (*i.e.*, the ''cross-margining reduction'') by comparing the participant's positions and the related margin requirements at FICC against those at each Participating CO.[11] FICC offsets each cross-margining participant's residual margin amount at FICC against the offsetting residual margin amounts of the participant (or its affiliate) at each Participating CO.

If the margin that FICC has available for a participant is greater than the combined margin submitted by the Participating COs, FICC will allocate a portion of its margin equal to the combined margin at the Participating COs. If the combined margin submitted by the Participating COs is greater than the margin that FICC has available for that participant, FICC will first allocate its margin to the Participating CO with the most highly correlated positions. If the positions are equally correlated, FICC will allocate on a pro rata basis based upon the residual margin amount available at each Participating CO. FICC and each Participating CO may then reduce the amount of collateral that they collect to reflect the offsets between the cross-margining participant's positions at FICC and its (or its affiliate's) positions at the Participating CO.[12]

FICC and each Participating CO will guarantee the cross-margining participant's (or its affiliate's) performance to each other up to a

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 50594 (October 26, 2004), 69 FR 63421.

[3] Securities Exchange Act Release No. 45335 (January 25, 2002), 67 FR 4768 [File No. SR–GSCC–2001–03].

[4] Securities Exchange Act Release No. 49142 (January 28, 2004), 69 FR 5623 [File No. SR–FICC–2004–02].

[5] Securities Exchange Act Release No. 49003 (December 29, 2003), 69 FR 712 [File No. SR–FICC–2003–10].

[6] The products traded on the EurexUS futures exchange and cleared by TCC are substantially similar to the CBOT products originally cleared by BOTCC.

[7] TCC is not currently clearing the Agency futures products. However, because it expects to clear Agency futures products in the future, FICC has included these products in the proposed rule change and the draft agreement. These Agency products are also covered by the current cross-margining agreement between FICC and the CME.

[8] Cross-margining is available to any FICC GSD netting member (with the exception of inter-dealer broker netting members) that is or that has an affiliate that is a member of a participating clearing organization (''Participating CO''). The FICC member (and its affiliate, if applicable) sign an agreement under which it (or they) agree to be bound by the cross-margining agreement between FICC and the Participating CO and which allows FICC or the Participating CO to apply the member's (or its affiliate's) margin collateral to satisfy any obligation of FICC to the Participating CO (or vice versa) that results from a default of the member (or its affiliate). Ownership of 50 percent or more of the common stock of an entity indicates control of the entity for purposes of the definition of ''affiliate.''

[9] FICC employs the ''hub-and-spoke'' method of cross-margining whereby FICC cross-margins on a multilateral basis (*i.e.*, with more than one Participating CO) with FICC as the ''hub.'' Each Participating CO enters into a separate cross-margining agreement between itself and FICC. No preference is given by FICC to any one Participating CO over another.

[10] Upon implementation of the new arrangement between FICC and TCC, the arrangement will not apply to positions in a customer account at TCC that would be subject to the segregation requirements of the Commodity Exchange Act. This is also the case under the cross-margining arrangement that FICC has in place with the CME.

[11] FICC and the Participating COs currently use different margin rates to establish margin requirements for their respective products. Margin reductions in the cross-margining arrangement are always computed based on the lower of the applicable margin rates. This methodology results in a potentially lesser benefit to the participant but ensures a more conservative result (*i.e.*, more collateral held at the clearing organization) for the Participating CO and FICC.

[12] FICC and each Participating CO unilaterally have the right not to reduce a participant's margin requirement by the cross-margining reduction or to reduce it by less than the cross-margining reduction. However, the clearing organizations may not reduce a participant's margin requirement by more than the cross-margining reduction.

specified maximum amount that relates back to the cross-margining reduction and the results of liquidating the member's positions and ultimately its collateral. The guaranty represents a contractual commitment that each clearing organization has to the other.

A default by a cross-margining participant will trigger the loss sharing provisions of the cross-margining agreement. The loss-sharing provisions determine the guaranty payments, if any, that will flow between the clearing organizations if the default of the participant results in a loss. It should be noted that a declaration of default of a cross-margining participant by one of the clearing organizations in and of itself will provide grounds for the other clearing organization to declare the participant (or its affiliate) in default as well. If the guaranty is triggered, the cross-margining participant becomes obligated to reimburse the guarantor clearing organization for the amount of the guaranty payment, which is called the ''Reimbursement Obligation.''

The cross-margining agreement also provides for the sharing of remaining resources beyond the cross-margining arrangement through a ''cross-guaranty'' provision. This provision reflects the view that excess collateral of a defaulting member should remain with the clearing organizations, if needed, to cover their losses. Specifically, if after guaranty payments, if any, one of the clearing organizations has a remaining surplus, and the other has a remaining loss, the agreement provides a mechanism for the distribution of that surplus to the clearing organization that still has a remaining loss.

(3) Key Changes to the Former Agreement Between FICC and TCC

(a) The minimum margin factor under the former FICC–BOTCC cross-margining agreement was 50 percent. FICC and TCC have agreed to a minimum margin factor of 25 percent. This is the same minimum margin factor used in the current cross-margining arrangement with the CME.[13]

(b) The FICC–TCC Agreement provides for inter-offset class cross-margining whereas the former BOTCC arrangement was limited to intra-offset class cross-margining. The new agreement is consistent with the approach in the existing arrangement between FICC and the CME.

(c) Appendix B of the FICC–TCC Agreement will include more FICC products than did the former BOTCC arrangement. The former BOTCC agreement covered FICC offset classes C, E, F, G and f, and offset classes E, F, and f were defined more narrowly for purposes of the arrangement than they were defined in the GSD's rules. The FICC–TCC Agreement includes the GSD's offset classes A through G, GCF Repo Treasury securities with equivalent remaining maturities, non-mortgage-backed Agency securities that fall into the GSD's offset classes e and f, and GCF Repo non-mortgage-backed Agency securities with equivalent remaining maturities. These offset classes are as broad as they are defined in the GSD's rules.

(d) Appendix B of the FICC–TCC Agreement will also include FICC's GCF Repo Treasury and non-mortgage-backed Agency products. FICC is now able to margin its GCF Repo Treasury and non-mortgage-backed Agency products based upon the specific underlying collateral as opposed to the former system of margining these products based upon the longest maturity of eligible underlying collateral.[14] Therefore, these GCF Repo products can now be included in the cross-margining arrangement because they are being margined at a specific rate based on the actual underlying Treasury and Agency collateral. These products are also included in the current cross-margining agreement between FICC and the CME.

(e) The FICC–TCC Agreement provides that the parties will agree from time to time in a separate writing on the disallowance factors that will be used in the program. Prior to the implementation date of the FICC–TCC cross-margining program, the disallowance factors will be tested and agreed to by FICC and TCC in writing.

(f) The current agreement between FICC and CME provides that in order to determine the gain or loss from the liquidation (resulting from a default) of the positions that were cross-margined, only the proceeds from the side of the market that was offset pursuant to the agreement at the last margin cycle will be considered. This approach will also be used in the FICC–TCC program to provide consistency in the liquidation methods.

(g) The former FICC–BOTCC agreement provided for a ''Maximization Payment'' whereby a clearing organization with a remaining surplus after all guaranty payments in relation to cross-margining were made (''Aggregate Net Surplus'') to distribute funds to one or more cross-margining partners with remaining losses. The FICC–TCC Agreement makes clear that: (i) the Maximization Payment is also a guaranty payment (albeit outside of cross-margining) and (ii) the defaulting member would have a reimbursement obligation with respect to such payment (''Maximization Reimbursement Obligation''). Should a clearing organization become obligated to pay the Maximization Payment, it may rely on the defaulting member's collateral to do so.[15]

(h) A provision has been added to take into account that a regulator or other entity having supervisory authority over FICC or TCC may direct the clearing organization not to liquidate a defaulting member or to partially liquidate such member. In order to prevent the affected clearing organization from being penalized under the agreement for failing to liquidate or partially liquidating the member in this type of situation, the FICC–TCC Agreement provides that the affected clearing organization would be deemed to have a cross-margin gain equal to the base amount of the guaranty (*i.e.*, cross-margining reduction) or a pro rated amount of the base amount of the guaranty in a partial liquidation scenario.

(i) The FICC–TCC Agreement makes clear that the clearing organizations have security interests in the ''Aggregate Net Surplus,'' a large component of which would be the collateral and proceeds of positions of a defaulting member, as security for any reimbursement obligation, including any maximization reimbursement obligation, that arises on the part of a defaulting member.

(j) The FICC–TCC Cross Margining Participant Agreement contains

[13] The minimum margin factor is the contractually agreed upon cap on the amount of the margin reduction that the clearing organizations will allow. Should FICC decide to change the minimum margin factor, it will submit a proposed rule filing under Section 19(b) of the Act.

[14] Because of a previous inability to obtain timely data on the actual instruments posted in support of GCF Repo positions, up until recently the GSD calculated affected members' clearing fund requirements based upon the assumption that collateral providers have assigned to each generic CUSIP the most volatile (*i.e.*, the longest maturity) collateral eligible. The GSD recently developed improvements to its margining methodology and is now able to identify the specific CUSIP posted.

[15] The guaranty provisions with respect to the Maximization Payment Guaranty are identical to the ones in the current cross-margining agreement between FICC and CME. In order to protect the clearing organizations in the event that a court determines that any amount of a Maximization Reimbursement Obligation may not be recovered by the clearing organization that made a Maximization Payment pursuant to a Maximization Payment Guaranty, a provision has been added to the FICC–TCC Agreement that provides that the payee clearing organization will be expected to return that amount. This protective provision is also in the FICC–CME cross-margining agreement.

language to further protect the clearing organizations by making clear that the clearing organizations have a security interest in the Aggregate Net Surplus and that a participant will have a reimbursement obligation in the event that a clearing organization becomes obligated to make a maximization payment. Members that wish to participate in the FICC–TCC cross-margining program will be required to execute the participant agreement to make them subject to the provisions of the FICC–TCC Agreement.

(4) Amendment 1 to the FICC–CME Cross-Margining Agreement

FICC is proposing to amend Appendix A of the cross-margining agreement with the CME to add a reference to the FICC–TCC Agreement. In Appendix A, the parties set forth the other cross-margining or similar arrangements that they have in place and indicate whether such other agreements take priority over the FICC–CME Cross-Margining Agreement. As stated above, no preference is given by FICC to one Participating CO over another.

III. Discussion

Section 17A(b)(3)(F) of the Act requires among other things that the rules of a clearing agency be designed to assure the safeguarding of securities and funds in its custody or control or for which it is responsible.[16] The Commission finds that FICC's proposed rule change is consistent with this requirement because by continuing its cross-margin program to include products cleared by TCC, FICC will provide its members with the benefits of cross-margining, including greater liquidity and more efficient use of collateral, in a manner that is consistent with FICC's overall risk management process.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[17] that the proposed rule change (File No. SR–FICC–2004–16) be and hereby is approved.

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 15 U.S.C. 78s(b)(2).

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–3567 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50787; File No. SR–NASD–2004–170]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment No. 1 Thereto by the National Association of Securities Dealers, Inc. To Establish Combined Nasdaq Market Center and Brut Pricing for Non-NASD Members

December 2, 2004.

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 November 2, 2004, 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 and II below, which Items have been prepared by Nasdaq. On November 9, 2004, Nasdaq submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons, and at the same time is granting accelerated approval of the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to establish a pricing and rebate schedule for non-NASD members that covers activity both on the Nasdaq Market Center (''NMC'') and Nasdaq's Brut Facility (''Brut''). Nasdaq seeks accelerated approval of the proposal and a retroactive effectiveness date of November 1, 2004. The text of the proposed rule change is available at the Office of the Secretary, Nasdaq, and at the Commission.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Edward S. Knight, Executive Vice President and General Counsel, Nasdaq, to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated November 9, 2004 (''Amendment No. 1''). Amendment No. 1 made technical corrections to the proposed rule text of the originally filed proposed rule 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 III below. Nasdaq has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On November 16, 2004, the Commission published notice of the immediate effectiveness of a proposed rule change submitted by Nasdaq, establishing a new pricing and rebate schedule (effective November 1, 2004) for NASD members for Nasdaq-listed securities that covers activity both on the NMC and Brut.[4] Nasdaq states that this proposed rule change seeks to impose the same fee and rebate structure on non-NASD members. Nasdaq is seeking accelerated approval of the non-member fee and rebate structure, as well as a retroactive effective date of November 1, 2004. Nasdaq represents that, as set forth in SR–NASD–2004–167, Nasdaq's new fee and rebate structure is based on multiple volume-based usage tiers that take into account the combined NMC and Brut volume of a non-NASD member. Nasdaq states that, like members, a non-NASD member will pay varying fees for having orders routed away from the systems or when accessing liquidity (''take-outs''), based upon the non-NASD member's combined volume activity in the NMC and Brut. Nasdaq also states that, likewise, rebates for non-NASD members providing liquidity will be based on the combined total of liquidity provided to both systems. Nasdaq believes that this pricing structure will encourage activity on both the NMC and Brut and will not provide financial incentives to use one system versus the other. In addition, Nasdaq states that the proposal will ensure that both NASD members and non-NASD members will pay equivalent fees and receive equivalent rebates based on their trading

[4] *See* Securities Exchange Act Release No. 50670 (November 16, 2004), 69 FR 67979 (November 22, 2004) (SR–NASD–2004–167).

activity and that the imposition of those fees will begin on the same November 1, 2004 start date. The combined NMC/Brut fee structure for Nasdaq-listed securities is provided below:

REBATE SCHEDULE FOR EXECUTIONS IN NASDAQ MARKET CENTER AND BRUT

Average daily shares of liquidity provided on NASDAQ and/or BRUT	Liquidity provider rebate per share executed
Greater than 20 million	$0.0025
Between 1–20 million	0.0022
Less than or equal to 1 million	0.0020

FEE SCHEDULE FOR TAKE-OUT AND ROUTING

Average daily shares of liquidity provided on NASDAQ and/or BRUT	Fee to take liquidity/Brut routing fee (per share)
Greater than 10 million	$0.0027
Greater than 500,000 but less than or equal to 10 million	0.0028
Less than or equal to 500,000	0.0030

Nasdaq represents that, as with members, Nasdaq will continue to charge non-NASD members a $0.001 per share NMC order delivery charge on NMC orders delivered to fee-charging ECNs participating in NMC. Nasdaq states that this charge is currently capped at $10,000 per month for firms providing more than 500,000 shares per day, on average, over the course of the month. Nasdaq also states that, as noted in SR–NASD–2004–167, in conjunction with the adoption of this pricing structure, Brut ceased charging an access fee on orders delivered to it from the NMC and that Nasdaq ended its practice of not charging a fee when a firm executes against its own quote or order. Nasdaq states that these changes will be applicable to non-NASD members as well.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,[5] in general and with Section 15A(b)(5) of the Act,[6] in particular, in that proposed rule change provides for the equitable allocation or reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which the association operates or controls.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Nasdaq states that written comments were neither solicited nor received.

III. 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–NASD–2004–170 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NASD–2004–170. 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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the 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 Number SR–NASD–2004–170 and should be submitted on or before December 30, 2004.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a self-regulatory organization.[7] Specifically, the Commission believes the proposed rule change is consistent with Section 15A(b)(5) of the Act,[8] which requires that the rules of the self-regulatory organization provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any

[5] 15 U.S.C. 78*o*–3.

[6] 15 U.S.C. 78*o*–3(b)(5).

[7] The Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78*o*–3(b)(5).

facilities or system which it operates or controls.

The Commission notes that this proposal, which permits the retroactive application of the pricing and rebate schedule for non-NASD members that covers activity both on the NMC and Brut and is effective as of November 1, 2004, would permit the schedule for non-NASD members to mirror the schedule applicable to NASD members that was effective as of November 1, 2004 pursuant to SR–NASD–2004–167. The Commission believes that the fees are scaled according to objective criteria applied across-the-board to all categories of users, *i.e.*, the pricing and rebate schedule will now apply equally to non-members as well as members, and is based on the volume of business they conduct on the NMS and Brut.

The Commission finds good cause for approving the proposed rule change prior to the 30th day of the date of publication of notice of filing thereof in the **Federal Register**. The Commission notes that the proposed pricing and rebate schedule for non-NASD members are identical to those in SR–NASD–2004–167, which implemented a new pricing and rebate schedule for NASD members and which was immediately effective upon filing. The Commission notes that this change will promote consistency in Nasdaq's fee schedule by applying the same pricing and rebate schedule for both NASD members and non-NASD members. Therefore, the Commission finds that there is good cause, consistent with Section 19(b)(2) of the Act,[9] to approve the proposed rule change on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (File No. SR–NASD–2004–170) be approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E4–3577 Filed 12–8–04; 8:45 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #P077]

State of Alaska (Amendment #1)

In accordance with a notice received from the Department of Homeland Security—Federal Emergency Management Agency, effective November 30, 2004, the above numbered Public Assistance declaration is hereby amended to include the Kashunamiut (Chevak) Regional Educational Attendance Area (REAA), the Lower Kuskokwim REAA, the Lower Yukon REAA, and the Pribilof Island REAA in the State of Alaska as disaster areas due to damages caused by a severe winter storm, tidal surges and flooding occurring on October 18 through 20, 2004. All other information remains the same, *i.e.*, the deadline for filing applications for physical damage is January 14, 2005.

(Catalog of Federal Domestic Assistance Program Nos. 59008).

Dated: December 2, 2004.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 04–27086 Filed 12–8–04; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4921]

Bureau of Educational and Cultural Affairs (ECA) Request for Grant Proposals: Fulbright Senior Scholar Program

Announcement Type: New Cooperative Agreement.

Funding Opportunity Number: ECA/A/E–06–01.

Catalog of Federal Domestic Assistance Number: 19.401.

Key Dates: *Application Deadline:* February 25, 2005.

Executive Summary: The Office of Academic Programs, Bureau of Educational and Cultural Affairs (ECA), U.S. Department of State announces an open competition for a cooperative agreement to assist in the administration of the worldwide Fulbright Senior Scholar Program. The Fulbright Senior Scholar Program is a major component of the overall Fulbright Program, which also includes the Fulbright Student Program.

For more than 55 years, the Fulbright Senior Scholar Program has offered grants for college and university faculty, as well as for non-academic professionals (such as lawyers and journalists) and independent scholars, to lecture and conduct research abroad. Tens of thousands of U.S. and non-U.S. scholars and professionals have participated in these exchanges since the Fulbright Program's inception in 1946.

The Fulbright Senior Scholar Program will send approximately 1,300 qualified U.S. scholars and professionals abroad to lecture, conduct research, and provide academic consulting at overseas institutions in FY 2006. Conversely, the program will bring approximately 920 visiting (non-U.S.) grantees from over 140 countries to the United States for similar activities.

Responsibility for the management of the Fulbright Senior Scholar Program is shared among the U.S. Department of State in Washington DC, 51 bilateral Fulbright commissions and 99 U.S. embassies overseas, and a private sector, cooperating agency in the United States. Overall policy guidelines for the Fulbright Senior Scholar Program are determined by the Presidentially-appointed J. William Fulbright Foreign Scholarship Board (FSB).

The organization that is awarded the cooperative agreement under this competition will be responsible for recruitment, selection, placement, enhancement activities for grantees, program promotion, and record keeping for both the U.S. and Visiting Fulbright Senior Scholar Programs. This work will be supervised by the Bureau of Educational and Cultural Affairs of the Department of State.

I. Funding Opportunity Description

Authority

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries* * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations* * *and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through legislation. The Fulbright Program also receives significant annual funding and other support from partner governments and private donors worldwide.

The Bureau of Educational and Cultural Affairs, as sponsor and manager of the Fulbright Senior Scholar Program, plays a significant role in the planning and implementation of all program initiatives, publicity, promotion and enhancement activities,

[9] 15 U.S.C. 78s(b)(2).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

and liaison with overseas field partners. The Bureau should also be consulted on participant selection procedures, development of selection panels, and stipend and benefit issues. Regular, ongoing contacts with Bureau managers will be required throughout the program year. Through this Request For Grant Proposal (RFGP), the Department seeks new ideas to develop effective responses to changing recruitment conditions, to improve the outreach of the program in the U.S. and overseas and to take advantage of opportunities to expand the program, as they appear.

Purpose

The Department of State will provide funding to the successful applicant organization to assist in the administration of both the U.S. and Visiting Fulbright Senior Scholar Program.

The Fulbright Program was created by the U.S. Congress at the end of World War II to provide the opportunity for future leaders to observe and better comprehend the political, economic, and cultural institutions and societies of other countries and people. In the intervening years, the Fulbright Program has evolved into the premier educational exchange program sponsored by the people of the United States through their federal government, and thus an important element in the conduct of U.S. foreign affairs. The Fulbright Program, which now extends to more than 150 foreign countries and involves approximately 5,000 participants per year, has helped to form and inform tens of thousands of the world's leaders in every academic and professional field.

The Senior Scholar portion of the Fulbright Program will engage approximately 2,220 scholars and professionals in FY 2006.

The hallmark of the Fulbright Program is binationalism. The United States Government and foreign governments, educational institutions and other public and private entities are all partners in this enterprise. In many countries of the world, financial contributions from governments or public/private sources match or exceed those of the United States. Because of its binational nature, the profile of the Fulbright Program worldwide reflects a range of objectives and interests.

Under the auspices of the J. William Fulbright Foreign Scholarship Board, approximately 850 U.S. citizens are awarded traditional, one or two semester Fulbright Senior Scholar grants each year through a merit-based, competitive process, to teach undergraduate or graduate courses, collaborate with foreign colleagues on projects, pursue individual research, conduct seminars, consult with government ministries and educational institutions, advise on curriculum development, and guest lecture at universities other than host institutions. The majority of grants under the Fulbright Senior Scholar Program are for individual awards for lecturing and/or research for an academic semester or academic year abroad. All grant opportunities are determined overseas by binational Fulbright commissions and U.S. embassies in coordination with the Department of State's Bureau of Educational and Cultural Affairs in Washington, DC. The cooperative organization administering the Fulbright Senior Scholar Program is responsible for advertising and recruiting applicants in the U.S. and for managing an academic peer review process to nominate candidates for participation in the program.

Similarly, foreign scholars and professionals receive grants each year for research, teaching, guest lecturing and academic consulting in the United States. These grantees are chosen through open, merit-based competitions in each country, which are conducted by a bilateral Fulbright commission or, in the absence of a commission, by a U.S. embassy.

In recent years, the Fulbright Senior Scholar Program has embarked on a range of new activities in response to changing conditions and requirements within the U.S. academic community and varying circumstances and emerging needs in overseas academic environments. While maintaining its traditional core long-term activities, the program now includes shorter-term grant opportunities for both American and foreign scholars, new opportunities for collaborative research and support for follow-on activities to build lasting links between U.S. and foreign academic institutions. These recent initiatives have made the Senior Scholar Program more responsive to academic environments and more relevant in supporting U.S. national interests. The Department continues to seek new program models that respond to changing recruitment and placement circumstances in the U.S. and overseas. The following are the major, recent initiatives under the Fulbright Senior Scholar Program.

In FY 2006, the Bureau of Educational and Cultural Affairs will continue to seek to strengthen exchanges with the Islamic World. It therefore seeks innovative recruitment approaches and creative strategies for the U.S. Senior Fulbright Scholar Program in countries where a significant portion of the population practices Islam. The Bureau is also looking to expand opportunities for visiting scholars from the Islamic World to engage U.S. audiences.

The Fulbright Senior Specialists Program provides short-term (two to six weeks) opportunities for approximately 450 American academic specialists annually to work with overseas, post-secondary institutions on projects ranging from lecturing and participation in teaching seminars to collaboration on curriculum and course design.

The Bureau also brings visiting scholars and professionals from abroad to the U.S. for two to six weeks to lecture at U.S. universities. This pilot initiative is currently limited to scholars from Muslim countries who address U.S. audiences about issues related to Islamic society and culture.

Through the Scholar-in-Residence component of the program, the Bureau brings scholars and professionals for an academic semester or academic year to U.S. campuses that do not often host foreign scholars. These campuses are selected through a competition managed by the cooperating agency.

The Bureau sponsors an annual collaborative research program, the Fulbright New Century Scholars Program, on a topic of worldwide significance involving 30 U.S. and foreign scholars. This program requires close collaboration between the Bureau, the cooperating agency in the United States, and Fulbright commissions and U.S. embassies overseas. The grantee organization is responsible for seeking private sector to supplement government funds based upon the program's direct relevance to current world issues.

The cooperating agency will also be responsible for the development and management of the Fulbright Alumni Initiative Awards Program that will provide small grants to alumni of the Fulbright Scholar and Senior Specialists Programs to expand upon their experience by building institutional ties between their home and host institutions.

The cooperating agency will also be responsible for other specials projects as directed by the Office of Academic Exchange Programs, Bureau of Educational and Cultural Affairs of the Department of State.

The Bureau welcomes proposals from applicant organizations for other scholarly activities consistent with Fulbright principles that are relevant to changing circumstances in the global academic community.

II. Award Information

Type of Award: Cooperative Agreement. The Bureau of Educational and Cultural Affairs' (ECA) level of involvement in this program is listed under number 1 above.

Fiscal Year Funds: 2006.

Approximate Total Funding: $6,560,000.

Approximate Number of Awards: One.

Approximate Average Award: $6,560,000.

Floor of Award Range: $6,560,000.

Ceiling of Award Range: $6,560,000.

Anticipated Award Date: Pending availability of funds, October 1, 2005.

Anticipated Project Completion Date: September 28, 2008.

Additional Information: Pending successful implementation of this program and the availability of funds in subsequent fiscal years, it is the Bureau's intent to renew this grant for at least four additional fiscal years, before openly competing it again.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

III.2. Cost Sharing or Matching Funds

There is no required minimum or maximum percentage for this competition. However, the Bureau encourages applicants to provide the maximum level of cost sharing and funding in support of its programs. When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved grant agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, the cooperating agency must maintain written records to support all costs that are claimed as your contribution, as well as costs to be paid by the Department of State. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event that the cooperating agency does not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

III.3. Other Eligibility Requirements

(a) Grants awarded to eligible organizations with less than four years of experience in conducting international exchange programs will be limited to $60,000. ECA anticipates awarding one grant, in an amount up to $6,560,000 to support program and administrative costs required to implement this exchange program. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

(b) Technical Eligibility: All proposals must comply with the technical eligibility requirements specified in the Proposal Submission Instructions (PSI) and the Project Objectives, Goals, and Implementation (POGI). Failure to do so will result in proposals being declared technically ineligible and given no further consideration in the review process.

IV. Application and Submission Information

Note: Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

IV.1. Contact Information To Request an Application Package

Please contact the Office of Academic Exchange Programs (ECA/A/E), Room 234, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, telephone (202) 619–4360, fax (202) 401–5914, e-mail *academic@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number (ECA/A/E–06–01) located at the top of this announcement when making your request.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document, which consists of required application forms and standard guidelines for proposal preparation.

It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Ms. Susan Borja and refer to the Funding Opportunity Number (ECA/A/E–06–01) located at the top of this announcement on all other inquiries and correspondence.

IV.2. To Download a Solicitation Package via the Internet

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/rfgps/menu.htm.* Please read all information before downloading.

IV.3. Content and Form of Submission

Applicants must follow all instructions in the Solicitation Package. The original and 10 copies of the application should be sent per the instructions under IV.3e. ''Submission Dates and Times section'' below.

IV.3a. Applicants are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF–424 which is part of the formal application package.

IV.3b. All proposals must contain an executive summary, proposal narrative and budget.

Please refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

IV.3c. You must have nonprofit status with the IRS at the time of application. If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

IV.3d. Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1. Adherence to All Regulations Governing the J Visa

The Bureau of Educational and Cultural Affairs is placing renewed emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantees and sponsors to all regulations governing the J visa. Therefore, proposals should demonstrate the

applicant's capacity to meet all requirements governing the administration of the Exchange Visitor Programs as set forth in 22 CFR 62, including the oversight of Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, recordkeeping, reporting and other requirements. The grantee will be responsible for issuing DS–2019 forms for all non-U.S. participants in the Fulbright Senior Scholar Program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, telephone: (202) 401–9810, fax: (202) 401–9809.

Please refer to Solicitation Package for further information.

IV.3d.2. Diversity, Freedom and Democracy Guidelines

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. ''Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the ''Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that ''in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy,'' the Bureau ''shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.'' Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. Program Monitoring and Evaluation

Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the grantee will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are ''smart'' (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes. Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. Participant satisfaction with the program and exchange experience.

2. Participant learning, such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.

3. Participant behavior, concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.

4. Institutional changes, such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

Please note: Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) Specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (*i.e.*, surveys, interviews, or focus groups). (Please note that evaluation plans that deal only with the first level of outcomes [satisfaction] will be deemed less competitive under the present evaluation criteria.)

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

IV.3d.4. Describe your plans for: *i.e.,* sustainability, overall program management, staffing, coordination with ECA, Fulbright commissions, and U.S. embassies' Public Affairs Sections or any other requirements etc.

IV.3e. Please take the following information into consideration when preparing your budget:

IV.3e.1. Applicants must submit a comprehensive budget for the entire program. Depending on the availability of funds, up to $6,560,000 in U.S. Government funding will be available to support the administration of the Fulbright Senior Scholar Program worldwide in FY 2006. In addition, a program budget totaling approximately $45,000,000 for the global Fulbright Senior Scholar Program will be transferred to the grantee organization at

regular intervals to cover the cost of individual participant grants.

IV.3e.2. Allowable costs for the program include the following: Staff salaries and benefits, rent, furniture and equipment, travel, communications, printing/publishing, and other fees associated with the normal administration of exchange programs.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

IV.3f. Submission Dates and Times

Application Deadline Date: February 25, 2005.

Explanation of Deadlines

In light of recent events and heightened security measures, proposal submissions must be sent via a nationally recognized overnight delivery service (*i.e.*, DHL, Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.) and be shipped no later than the above deadline. The delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. ECA will not notify you upon receipt of application. Delivery of proposal packages may not be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered. Applications may not be submitted electronically at this time.

Applicants must follow all instructions in the Solicitation Package.

Important note: When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to ''ECA/EX/PM''.

The original and 10 hard copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/A/E 06–01, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

Along with the Project Title, all applicants must enter the above Reference Number (ECA/A/E 06–01) in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3g. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

V. Application Review Information

V.1. Review Process

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Affairs Section at U.S. embassies overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards (cooperative agreements) resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. Program Planning: Proposals should respond to the planning requirements outlined in the RFGP. Planning should demonstrate substantive and rigorous preparation. A detailed agenda and work plan, including a timeline, should demonstrate feasibility and the applicant's logistical capacity to implement the program.

2. Ability to Achieve Program Objectives: Proposals should clearly demonstrate how the applicant will fulfill the program's objectives and implement plans, while demonstrating innovation and a commitment to academic excellence. Proposals should demonstrate a capacity for flexibility in the management of the program.

3. Multiplier Effect/Impact: Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term institutional and individual linkages.

4. Support of Diversity: Proposals should demonstrate substantive support of the Bureau's policy on diversity (included in Solicitation Packet). Achievable and relevant features should be cited in both program administration (selection of participants, program venues and program evaluation) and program content (orientations, program meetings, resource materials and follow-up activities). Individual grant awards as well as institutional participation should reflect the Fulbright Program's historic commitment to diversity.

5. Institutional Capacity: Proposed personnel and institutional resources should be adequate and appropriate to achieve Fulbright Senior Scholar Program goals in all respects. Applicants should demonstrate well-established links to the scholarly and professional community in the U.S. and knowledge of other educational environments, particularly an awareness of conditions in societies and educational institutions outside of the United States as they apply to academic and professional exchange programs. Applicants should demonstrate their capacity to provide information management compatible with ECA's systems as described in section VI.4. ''Additional Program Data Requirements'' in the RFGP.

6. Institution's Record/Ability: Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by Bureau Grants Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

7. Follow-on Activities: Proposals should provide a plan for continued follow-on activity (without Bureau support) ensuring that Bureau supported programs are not isolated events.

8. Project Evaluation: Proposals should include a plan to evaluate the success of the Fulbright Senior Scholar Program in all its components, both as program activities unfold and at the end of the individual grant cycles. Applicants should anticipate working closely with ECA on these evaluation activities.

9. Cost Effectiveness: The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

10. Cost Sharing: The proposal should maximize cost sharing through U.S. private sector support as well as institutional direct funding contributions. Preference will be given to proposal that demonstrate innovative approaches to the leveraging of funds, fundraising, and other sharing of costs. *Note:* The Fulbright Senior Scholar Program has historically enjoyed significant financial and other support from the U.S. and foreign academic communities and it is important that such support continues and be expanded wherever possible.

VI. Award Administration Information

VI.1. Award Notices

Final awards cannot be made until funds have been appropriated by Congress, allocated, and committed through internal Bureau procedures. Successful applicants will receive an Assistance Award Document (AAD) from the Bureau's Grants Office. The AAD and the original grant proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The AAD will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

VI.2. Administrative and National Policy Requirements

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, ''Cost Principles for Nonprofit Organizations.''

Office of Management and Budget Circular A–21, ''Cost Principles for Educational Institutions.''

OMB Circular A–87, ''Cost Principles for State, Local and Indian Governments''.

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations

Please reference the following Web sites for additional information:

http://www.whitehouse.gov/omb/grants.

http://exchanges.state.gov/education/grantsdiv/terms.htm#articleI

VI.3. Reporting Requirements

You must provide ECA with a hard copy original plus two copies of the following reports:

(1) A final program and financial report no more than 90 days after the expiration of the first year of the cooperative agreement;

(2) Quarterly program and financial reports.

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV. Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.)

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

VI.4. Additional Program Data Requirements

The grantee awarded this cooperative agreement will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau on demand. As a minimum, the data must include the following: Full name of applicant, home country address and contact information, host country affiliation, academic or professional discipline and biographical information (for example, but not limited to, date of birth, gender, country of birth, country of citizenship) for all participants awarded funding under the auspices of the Fulbright Senior Scholar Program. This includes the traditional Fulbright Senior Scholar Program and the recently developed New Century Scholars Program, Fulbright Senior Specialists Program, and the Direct Access to the Muslim World Visiting Specialist Program for scholars from the Islamic World. Applicant must consult with ECA/A/E to determine the requirements of the Bureau's Academic Exchanges Information System (AEIS) database.

VII. Department Contacts

For questions about this announcement, contact: Ms. Susan Borja, Office of Academic Exchange Programs (ECA/A/E), Room 234, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, Telephone (202) 619–4360, Fax (202) 401–5914, e-mail *academic@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the above title and number: ECA/A/E–06–01.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

VIII. Other Information

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: December 2, 2004.

C. Miller Crouch,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 04–27036 Filed 12–8–04; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Trade Policy Staff Committee: Public Comments Regarding the WTO Doha Development Agenda (DDA) and the WTO Dispute Settlement Understanding (DSU) Negotiations

AGENCY: Office of the United States Trade Representative.

ACTION: Notice and request for comments.

SUMMARY: The Trade Policy Staff Committee (TPSC) is requesting written public comments on general U.S. negotiating objectives as well as country-, product-, and service-specific priorities for the multilateral negotiations and work program in the Doha Development Agenda (DDA) negotiations conducted under the auspices of the World Trade

Organization. The TPSC is seeking to supplement and refine positions in the light of progress to date in the negotiations, notably, the Decision Adopted by the WTO General Council on 1 August 2004 on the Doha Work Program. The TPSC is also seeking comments on proposals advanced in the WTO review of the Dispute Settlement Understanding.

DATES: Public comments are due by January 31, 2005.

ADDRESSES: *Submissions by electronic mail: FR0514@USTR.EOP.GOV. Submissions by facsimile:* Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395–6143. The public is strongly encouraged to submit documents electronically rather than by facsimile. (See requirements for submissions below.)

FOR FURTHER INFORMATION CONTACT: General inquiries should be made to the USTR Office of WTO and Multilateral Affairs at (202) 395–6843; calls on individual subjects will be transferred as appropriate. Procedural inquiries concerning the public comment process should be directed to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the U.S. Trade Representative (USTR), (202) 395–3475. Further information on the WTO, including the declarations, decisions referred to in this notice or proposals tabled, can be obtained via the internet at the WTO Web site, *http://www.wto.org,* and/or the USTR Web site, *http://www.ustr.gov.* The 2004 President's Annual Report on the Trade Agreements Program, which is available on the USTR website, contains extensive information on the WTO, the Fifth WTO Ministerial Meeting in Cancún, Mexico, and the status of work in the WTO.

SUPPLEMENTARY INFORMATION: *Doha Development Agenda:* The next meeting of the WTO at the ministerial-level will be in December 2005. Work in 2005 is expected to focus on the technical issues necessary to move the agenda forward, particularly in the light of the WTO General Council's Decision of 1 August 2004, which contained frameworks for the agriculture and non-agricultural market access negotiations, further directions for a number of areas in the negotiation including services, and the launch of negotiations on trade facilitation. Accordingly, the TPSC seeks to provide a new opportunity for public comment to help guide U.S. participation in the on-going negotiations.

This request for comment supplements earlier requests for comments, and there is no need to resubmit comments previously provided to the TPSC. Submissions were received in response to notices seeking: (1) Public Comments Regarding the Doha Multilateral Trade Negotiations and Agenda in the World Trade Organization, published in 67 FR No. 53, March 19, 2002; (2) Public Comments on Preparations for the Fourth Ministerial Meeting of the World Trade Organization, November 9–13, 2001 in Doha, Qatar, published in 66 FR 18142, April 5, 2001; (3) Public Comments for Mandated Multilateral Trade Negotiations on Agriculture and Services in the WTO and Priorities for Future Market Access Negotiations on Non-Agricultural Products, published in 65 FR 16450, March 28, 2000; and, (4) Public Comments on Institutional Improvements to the World Trade Organization (WTO), Particularly with Respect to the Transparency of its Operations and Outreach to Civil Society, which included a solicitation of comments regarding the dispute settlement operations of the WTO and was published in 65 FR 36501, June 8, 2000. New or updated submissions are welcome. The TPSC will review supplemental or new comments, in conjunction with earlier submissions, in developing positions.

The U.S. International Trade Commission has provided to the TPSC the public comments received on agricultural and non-agricultural products as part of its investigation No. 332–440, Probable Economic Effects on Reduction or Elimination of U.S. Tariffs, August 9, 2002 (Confidential Report). Hence, these comments need not be resubmitted.

Comments are invited with as much specificity as possible on such subjects as:

(1) General, commodity or service-specific negotiating objectives;

(2) Country, service or product-specific export interests;

(3) Specific tariff or non-tariff barriers the respondent is facing in key export markets;

(4) Experience with particular foreign measures that impede U.S. market access; and,

(5) The methods to be used in negotiating market access improvements.

Information should be as detailed as possible, including specific tariff numbers for products under the Harmonized System (HS) wherever possible, product or service descriptions, current tariff levels faced in key export markets, and the target tariff rate the respondent is requesting. Specific recommendations or suggestions on the type of tariff-cutting mechanism to be used in the negotiations are also welcome. To assure a thorough and orderly review, the TPSC has identified the following headings under which comments may be submitted. Submissions should identify the relevant subject area or areas to which comments apply. These include:

(A) Agriculture—The framework for the agriculture negotiations is contained in Annex A of the 1 August WTO General Council Decision.

(B) Non-agricultural or Industrial Market Access (NAMA)—The framework for the NAMA negotiations is contained in Annex B of the 1 August WTO General Council Decision.

(C) Services—Recommendations for the negotiations in services are contained in Annex C of the 1 August WTO General Council Decision.

(D) Trade Facilitation—The 1 August 2004 Decision by the WTO General Council launched multilateral negotiations on Trade Facilitation, in accordance with modalities set forth in Annex D to the Decision.

The 1 August 2004 Decision by the WTO General Council also addressed certain development elements of the Doha Work Program (*e.g.*, special and differential treatment, trade-related technical assistance and implementation-related issues) and the work of other negotiating bodies (Rules, Trade and the Environment and Trade-Related Intellectual Property Rights). The TPSC welcomes comments on U.S. negotiating objectives on these elements of the Doha Work Program as well.

Dispute Settlement—The TPSC also calls attention to the progress to date in the negotiations to clarify and improve the Dispute Settlement Understanding. Proposals related to the DSU can be found at *http://www.wto.org* in the document series ''TN/DS/W''. The two proposals of the United States, for example, are found in documents TN/DS/W/46 (providing for public access to dispute settlement proceedings) and TN/DS/W/52 (a joint proposal with Chile on ensuring sufficient flexibility and Member control in the procedures to facilitate resolving disputes).

In document TN/DS/W/52, the United States proposed, as item (f) of that proposal, ''providing some form of additional guidance to WTO adjudicative bodies concerning (i) the nature and scope of the task presented to them (for example when the exercise of judicial economy is most useful) and (ii) rules of interpretation of the WTO agreements.'' The TPSC would welcome comments on areas in which to provide such guidance and the form such guidance should take.

In addition, proposals have spanned a broad range of topics from a wide spectrum of Members, both those that are frequent users of the dispute settlement system and those who have less experience with it. Proposals have been submitted on almost every phase of the dispute settlement process. For example, in addition to the U.S. proposals, a number of proposals have been made to require that a compliance panel must first review any measures taken to comply before a complaining party could request authorization to suspend equivalent concessions. Proposals have also been made to provide for a remand from the Appellate Body to a panel where there were insufficient factual findings to allow the Appellate Body to make a legal finding on a claim. Some of the proposals would result in a significant lengthening of the dispute settlement process. Proposals have also included ways in which to use time in the process more efficiently. The TPSC would welcome comments on any of the proposals made.

Written Submissions: Comments should state clearly the objective(s) and should contain detailed information supporting the objective(s). Submissions should clearly indicate the general topic (*e.g.*, agriculture, services, non-agricultural market access, etc.). As noted in the sections on services, agriculture and industrial market access, the provision of supplemental technical information would be helpful. This information should be provided in an attachment containing a spreadsheet or table in Microsoft Word, Word Perfect, Excel, Quatro Pro or MS Access.

Persons submitting comments may either send one copy by fax to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395–6143 or transmit a copy electronically to *FR0514@USTR.EOP.GOV,* with ''Doha Work Program'' in the subject line. For documents sent by fax, USTR requests that the submitter provide a confirmation copy electronically. The public is strongly encouraged to submit documents electronically rather than by facsimile. USTR encourages the use of Adobe PDF format to submit attachments to an electronic mail. Interested persons who make submissions by electronic mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. Similarly, to the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Comments should be submitted electronically no later than January 31, 2005.

Business confidential information will be subject to the requirements of 15 CFR 2003.6. Any business confidential material must be clearly marked as such and must be accompanied by a non-confidential summary thereof. A justification as to why the information contained in the submission should be treated confidentially should also be contained in the submission. In addition, any submissions containing business confidential information must clearly be marked ''Business Confidential'' at the top and bottom of the cover page (or letter) and each succeeding page of the submission. The version that does not contain business confidential information should also be clearly marked at the top and bottom of each page, ''Public Version'' or ''Non-Confidential.''

Written comments submitted in connection with this request, except for information granted ''business confidential'' status pursuant to 15 CFR 2003.6 will be available for public inspection in the USTR Reading Room, Office of the United States Trade Representative. An appointment to review the file can be made by calling (202) 395–6186. The Reading Room is open to the public from 10 a.m. to 12 noon and from 1 p.m. to 4 p.m. Monday through Friday.

Carmen Suro-Bredie,

Chairman, Trade Policy Staff Committee.

[FR Doc. 04–27037 Filed 12–8–04; 8:45 am]

BILLING CODE 3190–W5–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Ex Parte No. 333]

Sunshine Act Meeting

TIME AND DATE: 10 a..m., December 13, 2004.

PLACE: The Board's Hearing Room, Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423.

STATUS: The Board will meet to discuss among themselves the following agenda items. Although the conference is open for public observation, no public participation is permitted.

MATTERS TO BE CONSIDERED:

STB Docket No. AB–556 (Sub-No. 2X), *Railroad Ventures, Inc.—Abandonment Exemption—Between Youngstown, OH, and Darlington, PA, in Mahoning and Columbiana Counties, OH, and Beaver County, PA.*

Docket No. 41185, *Arizona Public Service Company & PacifiCorp* v. *The Burlington Northern and Santa Fe Railway Company.*

STB Docket No. 42057, *Public Service Company of Colorado D/b/a Xcel Energy* v. *The Burlington Northern and Santa Fe Railway Company.*

STB Docket No. 42071, *Otter Tail Power Company* v. *The Burlington Northern and Santa Fe Railway Company.*

STB Docket No. WCC–105, *DHX Inc.,* v. *Matson Navigation Company and Sea-Land Service, Inc.*

STB Ex Parte No. 656, *Motor Carrier Bureaus—Periodic Review Proceeding.*

STB Ex Parte No. 558 (Sub-No. 8), *Railroad Cost of Capital—2004.*

FOR FURTHER INFORMATION CONTACT: A. Dennis Watson, Office of Congressional and Public Services, Telephone: (202) 565–1596; FIRS: 1–800–877–8339.

Dated: December 6, 2004.

Vernon A. Williams,

Secretary.

[FR Doc. 04–27140 Filed 12–7–04; 11:26 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34619]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company

The Burlington Northern and Santa Fe Railway Company (BNSF) has agreed to grant temporary overhead trackage rights to Union Pacific Railroad Company (UP) over BNSF's rail line between BNSF milepost 2.1 near St. Louis, MO (Grand Avenue), and BNSF milepost 34.1 near Pacific, MO, a distance of 32.0 miles.

The transaction was scheduled to be consummated on December 1, 2004, and the temporary trackage rights are intended to expire on or about February 15, 2005. The purpose of the temporary rights is to facilitate maintenance work on UP lines.

As a condition to this exemption, any employee affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate,* 360 I.C.C. 653 (1980), and, any employee affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line*

R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it 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. 34619, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Robert T. Opal, 1400 Douglas Street, STOP 1580, Omaha, NE 68179.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: December 6, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–27039 Filed 12–8–04; 8:45 am]

BILLING CODE 4910–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34609]

State of Washington, Department of Transportation—Acquisition Exemption—Palouse River and Coulee City Railroad, Inc.

The State of Washington, Department of Transportation (WSDOT), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Palouse River and Coulee City Railroad, Inc. (PRCC) certain physical assets of seven rail lines and the underlying rights-of-way, totaling approximately 188 miles in the State of Washington. The rail lines are as follows: (1) The Hooper Jct.-Winona line, between milepost 26.6 at Hooper Junction and milepost 52.3 at Winona; (2) the Thornton-Winona line, between milepost 0.0 at Winona and milepost 31.7 at Thornton; (3) the Winona-Endicott line, between milepost 52.3 at Winona and milepost 57.9 at Endicott; (4) the Endicott-Colfax line, between milepost 57.9 at Endicott and milepost 77.7 at Colfax; (5) the Colfax-Moscow line (a) between milepost 0.0 at Colfax and milepost 18.7 at Pullman, and (b) between milepost 75.9 at Pullman and milepost 84.05 at the Washington-Idaho State line; (6) the WIM line, between milepost 0.0 at Palouse and milepost 3.85 at the Washington-Idaho State line; and (7) the P&L line, between milepost 1.0 at Marshall and milepost 75.9 at Pullman.

At the time of filing of the verified notice, WSDOT and PRCC were in the process of finalizing a purchase and sale agreement whereby: (1) WSDOT will acquire PRCC's right, title and interest in certain tracks, track materials and the underlying rights-of-way of seven rail lines; and (2) PRCC will retain a permanent, exclusive rail freight easement to provide rail freight service over the lines. WSDOT states that it will not be providing rail freight service over the lines.

The transaction was expected to be consummated on or shortly after November 5, 2004.

If the notice contains false or misleading information, the exemption is void *ab initio.*[1] Petitions to reopen the proceeding 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. 34609, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Jeanne A. Cushman, Assistant Attorney General, 905 Plum Street SE., Building 3, P.O. Box 40113, Olympia, WA 98504.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: December 3, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–27038 Filed 12–8–04; 8:45 am]

BILLING CODE 4915–01–P

[1] WSDOT states that it will be filing a motion to dismiss the notice of exemption in this proceeding. When the motion is filed, it will be addressed in a subsequent Board decision.

DEPARTMENT OF THE TREASURY

Executive Office for Asset Forfeiture; Proposed Collection; Comment Request

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 Executive Office for Asset Forfeiture within the Department of the Treasury is soliciting comments concerning the ''Request for Transfer of Property Seized/Forfeited by a Treasury Agency'', TD F 92–22.46.

DATES: Written comments should be received on or before December 31, 2004 to be assured of consideration.

ADDRESSES: Direct all written comments to the Executive Office for Asset Forfeiture, Attn: Jackie A. Jackson, Suite 700, 740–15th Street, NW., Washington, DC 20220. Telephone: (202) 622–2755. E-Mail Address: *Jackie.Jackson@TEOAF.Treas.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to the Executive Office for Asset Forfeiture, Attn: Jackie A. Jackson, Suite 700, 740–15th Street, NW., Washington, DC 20220. Telephone: (202) 622–2755. E-Mail Address: *Jackie.Jackson@TEOAF.Treas.gov*.

SUPPLEMENTARY INFORMATION:

Title: Request for Transfer of Property Seized/Forfeited by a Treasury Agency, TD F 92–22.46

OMB Number: 1505–0152.

Form Number: TD F 92–22.46

Abstract: The form was developed to capture the minimum amount of data necessary to process the application for equitable sharing benefits. Only one form is required per seizure. If a law enforcement agency does not make this one time application for benefits under the equitable sharing process, the agency will not benefit from the forfeiture process.

Current Actions: This is a notice for the continued use of the established form. There are several changes to the form or instructions. Type of Review: Extension (with changes).

Proposed Changes: On the entire form change wording: Treasury Agency to Treasury Forfeiture Fund Particpating Agency. Line III. Change wording—Asset Requested to Asset Seized Under Request Type: add a percentage sign.

Affected Public: Federal, State and local law enforcement agencies participating in the Treasury asset sharing program.

Estimated Number of Respondents: 5,000.

Estimated Time Per Respondent: 30 Minutes.

Estimated Total Annual Burden Hours: 2,500.

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.

Eric E. Hampl,

Acting Director, Executive Office for Asset Forfeiture.

[FR Doc. 04–27015 Filed 12–8–04; 8:45 am]

BILLING CODE 4811–15–P

Federal Register

Thursday,
December 9, 2004

Part II

Environmental Protection Agency

40 CFR Part 60

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Other Solid Waste Incineration Units; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[OAR–2003–0156; FRL–7845–4]

RIN 2060–AG31

Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Other Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rules.

SUMMARY: The EPA is proposing new source performance standards (NSPS) and emission guidelines for new and existing ''other'' solid waste incinerators (OSWI) units. The proposed rules fulfill the requirements of sections 111 and 129 of the Clean Air Act (CAA), which require EPA to promulgate NSPS and emission guidelines for solid waste incineration units. These requirements are based on the Administrator's determination that these waste incinerators cause, or contribute significantly to, air pollution that may reasonably be anticipated to endanger public health or welfare. The proposed rules, which address only nonhazardous solid wastes, would protect public health by reducing exposure to air pollution.

DATES: Comments must be received on or before February 7, 2005.

Public Hearing. If anyone contacts EPA by December 29, 2004, requesting to speak at a public hearing, EPA will hold a public hearing on January 10, 2005. If you are interested in attending the public hearing, contact Ms. Kelly Hayes at (919) 541–5578 to verify that a hearing will be held.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2003–0156, 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.epa.gov/edocket. EDOCKET, 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: Send your comments via electronic mail to *a-and-r-docket@epa.gov*, Attention Docket ID No. OAR–2003–0156.

Facsimile: Fax your comments to (202) 566–1741, Attention Docket ID No. OAR–2003–0156.

Mail: Send your comments to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OAR–2003–0156. Please include a total of two copies. The EPA requests a separate copy also be sent to either of the contact persons identified below (*see* **FOR FURTHER INFORMATION CONTACT**). In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

Hand Delivery: Deliver your comments to: EPA Docket Center (EPA/DC), EPA West Building, Room B108, 1301 Constitution Ave., NW., Washington, DC, 20460, Attention Docket ID No. OAR–2003–0156. Such deliveries are accepted only during the normal hours of operation (8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays), and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OAR–2003–0156. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket*, 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 EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites 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 EDOCKET 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.

Public Hearing: If a public hearing is held, it will be held at EPA's Campus located at 109 T.W. Alexander Drive in Research Triangle Park, NC, or an alternate site nearby.

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 EPA Docket Center (EPA/DC), EPA West Building, 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 EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Johnson or Mr. Fred Porter, Combustion Group, Emission Standards Division (C439–01), U.S. EPA, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5025 or (919) 541–5251; e-mail address: *johnson.mary@epa.gov* or *porter.fred@epa.gov.*

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply To Me?

Regulated Entities. Categories and entities potentially regulated by the proposed rules are very small municipal waste combustion (VSMWC) units and institutional waste incineration (IWI) units. The OSWI emission guidelines and NSPS would affect the following categories of sources:

Category	NAICS code	SIC code	Examples of potentially regulated entities
Any State, local, or Tribal government using a VSMWC unit as defined in the regulation.	562213, 92411	4953, 9511	Solid waste combustion units burning municipal waste collected from the general public and from residential, commercial, institutional, and industrial sources.
Institutions using an IWI unit as defined in the regulations.	922, 6111, 623, 7121	9223, 8211, 7999	Correctional institutions, primary and secondary schools, camps and national parks.
Any Federal government agency using an OSWI unit as defined in the regulations.	928	9711	Department of Defense (labs, military bases, munition facilities).
Any college or university using an OSWI unit as defined in the regulations.	6113, 6112	8221, 8222	Universities, colleges and community colleges.
Any church or convent using an OSWI unit as defined in the regulations.	8661	8131	Churches and convents.
Any civic or religious organization using an OSWI unit as defined in the regulations.	8641	8134	Civic associations and fraternal associations.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the proposed rules. To determine whether your facility would be regulated by the proposed rules, you should examine the applicability criteria in 40 CFR 60.2885 through 60.2888 of subpart EEEE, and 40 CFR 60.2991 through 60.2994 of subpart FFFF. If you have any questions regarding the applicability of the proposed rules to a particular entity, contact either of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

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

1. *Submitting CBI.* Do not submit information that you consider to be CBI electronically through EDOCKET, regulations.gov, or e-mail. Send or deliver information identified as CBI to only the following address: Ms. Mary Johnson, c/o OAQPS Document Control Officer (Room C404–02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. OAR–2003–0156. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

If you have any questions about CBI or the procedures for claiming CBI, please consult either of the persons identified in the **FOR FURTHER INFORMATION CONTACT** section.

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

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

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

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

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

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

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

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

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

Docket. The docket number for the proposed NSPS (40 CFR part 60, subpart EEEE) and emission guidelines (40 CFR part 60, subpart FFFF) is Docket ID No. OAR–2003–0156.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of the proposed rules is available on the WWW through the

Technology Transfer Network Web site (TTN Web). Following signature, EPA will post a copy of the proposed rules on the TTN's policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If you need more information regarding the TTN, call the TTN Help line at (919) 541–5384.

II. Background Information

A. What Is the Statutory Authority for the Proposed Rules?

Section 129 of the CAA, entitled ''Solid Waste Combustion,'' requires EPA to develop and adopt NSPS and emission guidelines for solid waste incineration units pursuant to CAA section 111. Section 111(b) of the CAA requires EPA to establish NSPS for new sources, and CAA section 111(d) requires EPA to establish procedures for States to submit plans for implementing emission guidelines for existing sources. Under CAA section 111, NSPS and emission guidelines must be developed for new and existing stationary sources that cause or contribute significantly to air pollution that may reasonably be anticipated to endanger public health or welfare.

Congress specifically added section 129 to the CAA to address concerns about emissions from solid waste combustion units. Section 129 of the CAA requires EPA to promulgate emissions standards and other requirements for ''each category of solid waste incineration unit.'' Section 129(a)(1) of the CAA identifies five categories of solid waste incineration units:

(1) Units with a capacity of greater than 250 tons per day (tpd) combusting municipal waste;

(2) Units with a capacity equal to or less than 250 tpd combusting municipal waste;

(3) Units combusting hospital, medical and infectious waste;

(4) Units combusting commercial or industrial waste; and

(5) Unspecified ''other categories of solid waste incineration units.''

Section 129(g)(1) of the CAA identifies several types of units that are not solid waste incineration units, including units required to have a permit under section 3005 of the Solid Waste Disposal Act (SWDA); materials recovery facilities; certain qualifying small power production facilities or qualifying cogeneration facilities which burn homogeneous waste; and certain air curtain incinerators that meet opacity limitations established by EPA.

For each category of incineration unit identified under CAA section 129, EPA must establish numerical emission limits for at least nine specified pollutants (particulate matter (PM), sulfur dioxide (SO_2), hydrogen chloride (HCl), nitrogen oxides (NO_X), carbon monoxide (CO), lead (Pb), cadmium (Cd), mercury (Hg), and dioxins and dibenzofurans), and for opacity as appropriate. Section 129 of the CAA provides EPA with the discretion to establish emission limitations for other pollutants as well. (*See* CAA section 129(a)(4).)

Under CAA section 129, the NSPS and emission guidelines adopted for solid waste combustion units must reflect the maximum achievable control technology (MACT). Accordingly, EPA's standards under CAA section 129 must ''* * * reflect the maximum degree of reduction in emissions of [the listed] air pollutants * * * that the Administrator, taking into consideration the cost of achieving such emissions reductions, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category * * *.'' (*See* CAA section 129(a)(2).) However, the standards for new units must not be less stringent than the emissions control that is achieved in practice by the best controlled similar unit, and the standards for existing sources must not be less stringent than the average emissions limitations achieved by the best performing 12 percent of units in the category.

Regulations have been developed for each of the listed categories of solid waste incineration unit except for the ''other categories of solid waste incineration units.'' Today's notice proposes regulations for these ''other'' (or OSWI) units. Three previous notices have been published regarding OSWI regulatory development (58 FR 31358, June 2, 1993; 58 FR 58498, November 2, 1993; 65 FR 67367, November 9, 2000). In the November 9, 2000 notice, EPA revised the OSWI regulatory schedule to promulgate regulations by November 2005. This was subsequently incorporated into a consent decree, requiring that EPA propose regulations for the OSWI source category by November 30, 2004, and promulgate by November 30, 2005.

B. What Are New Source Performance Standards?

The NSPS for solid waste incineration units are developed according to CAA sections 111 and 129. An NSPS applies to new stationary sources of emissions, that is, sources for which construction begins after a standard is proposed or sources that are modified on or after a specified date. The key elements in an NSPS are generally defined as follows:

1. *Source category to be regulated* means the industries or types of processes that are regulated. Section 129 of the CAA requires EPA to regulate several categories of incinerators specifically listed in CAA section 129 and to regulate ''other categories of solid waste incineration units'' (known as OSWI). The proposed NSPS applies to the OSWI category, which is VSMWC units and IWI units.

2. *Affected facility* means a solid waste incineration unit that will be subject to the NSPS. The proposed NSPS would affect each individual OSWI unit.

3. *Pollutants to be regulated* means the particular substances emitted by the affected facility that the NSPS regulates. Section 129 of the CAA specifies nine pollutants: Cd, CO, dioxins/furans, PM, HCl, Pb, Hg, NO_X, and SO_2. Opacity standards may also be required as appropriate. The CAA section 129 pollutants represent the minimum requirements; EPA can add other pollutants, if appropriate, but has determined that doing so in regulating the OSWI category is unnecessary because other potentially relevant pollutants are adequately addressed by control of the pollutants to be regulated.

4. *Maximum achievable control technology* means the technology on which the emission standards will be based. Section 129(a)(2) of the CAA specifies that standards be based on ''* * * the maximum degree of reduction in emissions * * * that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable * * *.'' (Note that solid waste incineration standards under CAA section 129 are different from typical NSPS under CAA section 111, which are based on ''best demonstrated technology'' rather than MACT.)

5. *Format for the standards* means the form in which the standards are expressed; for example, as pollutant concentration emission limits, as a percent reduction in emissions, or as equipment or work practice standards. Section 129 of the CAA also directs EPA to establish siting requirements for new incineration units and operator certification and training requirements for all units.

6. *Emission limits* generally means limits based on the level of reduction that the MACT can achieve. Only in unusual cases do standards require that

a specific technology be used. In general, the source owner or operator may select any method for complying with the limits.

7. *Other considerations in addition to emission limits for NSPS* usually include: Standards for visible emissions, modification and reconstruction provisions, monitoring requirements, performance test methods and compliance procedures, and reporting and recordkeeping requirements.

C. What Are Emission Guidelines?

Emission guidelines are similar to NSPS, except that they apply to existing sources. That is, they apply to sources for which construction began on or before the date a standard is proposed or that are modified before a specified date. Unlike NSPS, the emission guidelines are not enforceable until EPA approves a State plan or adopts a Federal plan for implementing and enforcing them, and the State or Federal plan becomes effective.

D. How Are the Emission Guidelines Implemented?

When standards of performance for solid waste incineration units are promulgated under CAA sections 111 and 129, the CAA requires States under CAA sections 111(d) and 129(b) to submit plans that: (1) Establish emission standards for existing sources, and (2) provide for implementation and enforcement of the emission standards.

States are required to adopt and submit to the Administrator a State plan implementing the emission guidelines within 1 year after the promulgation of the guidelines (CAA section 129(b)(2)). The State plan carries out and provides for enforcing the emission guidelines. Section 129 of the CAA provides that the State plan for existing incineration units must be at least as protective as the emission guidelines and must provide for compliance by affected facilities no later than 3 years after the effective date of State plan approval, but no later than 5 years after EPA promulgates the guidelines. Section 111(d) of the CAA further requires that the procedures for submitting a State plan must be similar to the procedures for submitting State implementation plans under CAA section 110. (The EPA has established specific procedures in 40 CFR part 60, subpart B.) Sections 111(d) and 129(b) of the CAA also require EPA to develop, implement, and enforce a Federal plan if a State fails to submit a satisfactory State plan.

III. Summary of the Proposed Rules

A. Do the Proposed Rules Apply to Me?

The proposed rules apply to you if you own or operate either of the following:

(1) An incineration unit burning municipal solid waste (MSW) (as defined in CAA section 129, 40 CFR 60.2977 of subpart EEEE, and 40 CFR 60.3078 of subpart FFFF) with a capacity less than 35 tpd, or

(2) An incineration unit located at an institutional facility burning institutional waste (as defined in 40 CFR 60.2977 of subpart EEEE and 40 CFR 60.3078 of subpart FFFF) generated at that facility.

If your incineration unit is currently meeting emission limitations and other requirements of another CAA section 129 regulation (*i.e.*, small or large municipal waste combustion (MWC) units; hospital, medical, infectious waste incineration units (HMIWI units); or commercial and industrial solid waste incineration units (CISWI units)), the proposed rules do not apply to you. Likewise, if your institutional combustion unit is covered under the CAA section 112 National Emission Standards for Hazardous Air Pollutants (NESHAP) for industrial, commercial, and institutional boilers and process heaters (boilers NESHAP), it would not be subject to the proposed rules. Certain types of combustion units listed in 40 CFR 60.2887 of subpart EEEE and 40 CFR 60.2993 of subpart FFFF are also excluded from the proposed rules.

If you began construction of your OSWI unit on or before December 9, 2004, it is considered an existing OSWI unit and would be subject to the proposed emission guidelines. If you began construction of your OSWI unit after December 9, 2004, it is considered a new OSWI unit and would be subject to the proposed NSPS.

If you began reconstruction or modification of your OSWI unit prior to [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], it is considered an existing unit and would be subject to the emission guidelines. Likewise, if you began reconstruction or modification of your OSWI unit on or after [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], it is considered a new OSWI unit and would be subject to the NSPS.

B. What Emission Limits Must I Meet?

As the owner or operator of a new or existing OSWI unit, you would be required to meet the emission limits specified in Table 1 of this preamble. You would be required to conduct a performance test to show compliance within 60 days after a new OSWI unit reaches the charge rate at which it will operate, but no later than 180 days after the unit's initial startup.

As the owner or operator of an existing OSWI unit, you would be required to meet the emission limits specified in Table 1 of this preamble within 3 years after the effective date of State plan approval or when EPA promulgates a Federal plan, but no later than 5 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

TABLE 1.—EMISSION LIMITS FOR NEW AND EXISTING OSWI UNITS

For these pollutants	You must meet these emission limits [a]	And determine compliance using these methods [b, c]
Cd	18 micrograms per dry standard cubic meter (μg/dscm).	EPA Method 29
CO	5.0 parts per million dry volume (ppmdv)	EPA Methods 10, 10A or 10B
Dioxins/Furans (total mass basis)	33 nanograms per dry standard cubic meter (ng/dscm).	EPA Method 23
HCl	3.7 ppmdv	EPA Method 26A
Pb	226 μg/dscm	EPA Method 29
Hg	74 μg/dscm	EPA Method 29
Opacity	10%	EPA Method 9
NO_X	103 ppmdv	EPA Methods 7, 7A, 7C, 7D, or 7E [d]
PM	0.013 grains per dry standard cubic foot (gr/dscf)	EPA Method 5 or 29
SO_2	3.1 ppmdv	EPA Method 6 or 6C [e]

[a] All emission limits (except opacity) are measured at 7 percent oxygen, dry basis at standard conditions.
[b] These methods are in 40 CFR part 60, appendix A.

[c] Compliance with the CO emission limit is determined on a 3-hour rolling average basis using continuous emission monitoring system data. Compliance for the other pollutants' emission limits is determined by stack testing.
[d] ASME PTC 19–10–1981—Part 10 is an acceptable alternative to only Methods 7 and 7C.
[e] ASME PTC 19–10–1981—Part 10 is an acceptable alternative to Method 6 only.

C. What Operating Limits Must I Meet?

If you use a wet scrubber to comply with the emission limits, you would be required to establish the maximum and minimum site-specific operating limits indicated in Table 2 of this preamble. You would then be required to operate the OSWI unit so that the charge rate does not exceed the established maximum charge rate. You would be required to operate the wet scrubber so that the pressure drop or amperage, scrubber liquor flow rate, and scrubber liquor pH do not fall below the minimum established operating limits.

TABLE 2.—OPERATING LIMITS FOR NEW AND EXISTING OSWI UNITS USING WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitor continuously using these recording times
Charge rate	Maximum charge rate	Every hour
Pressure drop across the wet scrubber, or amperage to the wet scrubber.	Minimum pressure drop or amperage	Every 15 minutes
Scrubber liquor flow rate	Minimum flow rate	Every 15 minutes
Scrubber liquor pH	Minimum pH	Every 15 minutes

NOTE: Compliance is determined on a 3-hour rolling average basis, except charge rate for batch incinerators, which is determined on a 24-hour basis.

If you use an air pollution control device other than a wet scrubber to comply with the emission limits, you would be required to petition the Administrator for other site-specific operating limits to be established during the initial performance test and continuously monitored thereafter. The information you must include in your petition is described in 40 CFR 60.2917 of subpart EEEE and 40 CFR 60.3024 of subpart FFFF.

D. What Are the Other Requirements?

As the owner or operator of a new or existing OSWI unit, you would be required to meet the following additional requirements.

Siting Analysis (new units only):

- Submit a report that evaluates site-specific air pollution control alternatives that minimize potential risks to public health or the environment, considering costs, energy impacts, nonair environmental impacts, or any other factors related to the practicability of the alternatives.

Waste Management Plan:

- Submit a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream to reduce or eliminate toxic emissions from incinerated waste.

Operator Training and Qualification Requirements:

- Qualify operators or their supervisors (at least one per facility) by ensuring that they complete an operator training course and annual review or refresher course.

Testing Requirements:

- Conduct initial performance tests for Cd, CO, dioxins/furans, HCl, Pb, Hg, NO_X, opacity, PM, and SO_2 and establish operating limits (*i.e.*, maximum or minimum values for operating parameters).
- Conduct annual performance tests for all nine pollutants and opacity. (An owner or operator may conduct less frequent testing if the facility demonstrates that it is in compliance with the emission limits for three consecutive performance tests.)

Monitoring Requirements:

- Continuously monitor CO emissions.
- If using a wet scrubber to comply with the emission limits, continuously monitor the following operating parameters: charge rate, pressure drop across the wet scrubber (or amperage), and scrubber liquid flow rate and pH.
- If something other than a wet scrubber is used to comply with the emission limits, monitor other operating parameters, as approved by the Administrator.

Recordkeeping and Reporting Requirements:

- Maintain for 5 years records of the initial performance tests and all subsequent performance tests, operating parameters, any maintenance, the siting analysis (for new units only), and operator training and qualification. Each record must be kept on site for at least 2 years. The records may be kept off site for the remaining 3 years.
- Submit the results of the initial performance tests and all subsequent performance tests and values for the operating parameters.
- Submit annual compliance reports and semiannual reports of any deviations from the emission limits, operating limits, or other requirements.
- Apply for and obtain a title V operating permit.

E. What Are the Requirements for Air Curtain Incinerators?

The proposed rules establish opacity limitations for air curtain OSWI units burning:

- 100 percent wood wastes,
- 100 percent clean lumber,
- 100 percent yard waste, or
- 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

The opacity limit is 10 percent. However, 35 percent opacity is allowed during startup periods that are within the first 30 minutes of operation. Air curtain incinerators burning only these materials would be required to meet the opacity limits and apply for and obtain a title V operating permit, but would be exempt from the other requirements of the proposed rules.

Air curtain incinerators burning other institutional waste or municipal waste would be required to meet the proposed rules including all emission limits in Table 1 of this preamble and the associated testing, permitting, monitoring, recordkeeping, and reporting requirements.

F. What Title V Permit Requirements Must I Meet?

All new and existing OSWI units would be required to apply for and obtain a title V permit. These title V operating permits would assure compliance with all applicable requirements for OSWI units, including all applicable CAA section 129 requirements. (*See* 40 CFR 70.6(a)(1), 70.2, 71.6(a)(1) and 71.2.)

When a CAA section 129 source is required to apply for a title V permit depends on when the source first becomes subject to the relevant title V

permits program. If an OSWI unit is a new unit and is not subject to an earlier permit application deadline, a complete title V permit application must be submitted on or before one of the following dates:

1. For an OSWI unit that commenced operation as a new source as of the promulgation date of 40 CFR part 60, subpart EEEE, then a complete title V permit application must be submitted not later than 12 months after the promulgation date of 40 CFR part 60, subpart EEEE.

2. For an OSWI unit that does not commence operation as a new source until after the promulgation of 40 CFR part 60, subpart EEEE, then a complete title V permit application must be submitted not later than 12 months after the date the OSWI unit commences operation as a new source. (*See* CAA section 503(c) and 40 CFR 70.5(a)(1)(i) and 71.5(a)(1)(i).)

If your OSWI unit is an existing unit and is not subject to an earlier permit application deadline, a complete title V permit application must be submitted by the earlier of the following dates:

1. Twelve months after the effective date of any applicable EPA-approved CAA section 111(d)/129 plan (*i.e.*, an approved State or Tribal plan that implements the OSWI emission guidelines).

2. Twelve months after the effective date of any applicable Federal plan.

3. Thirty-six months after promulgation of 40 CFR part 60, subpart FFFF.

For any existing OSWI unit not subject to an earlier permit application deadline, the application deadline of 36 months after the promulgation of 40 CFR part 60, subpart FFFF, applies regardless of whether or when any applicable Federal plan is effective, or whether or when any applicable CAA section 111(d)/129 plan is approved by EPA and becomes effective. (*See* CAA sections 129(e), 503(c), 503(d), and 502(a) and 40 CFR 70.5(a)(1)(i) and 71.5(a)(1)(i).)

If your OSWI unit is subject to title V as a result of some triggering requirement(s) other than those mentioned above (for example, an OSWI unit may be a major source or part of a major source), then your unit may be required to apply for a title V permit prior to the deadlines specified above. If more than one requirement triggers a source's obligation to apply for a title V permit, the 12-month time frame for filing a title V permit application is triggered by the requirement that first causes the source to be subject to title V. (*See* CAA section 503(c) and 40 CFR 70.3(a) and (b), 70.5(a)(1)(i), 71.3(a) and (b), and 71.5(a)(1)(i).)

For additional background information on the interface between CAA section 129 and title V, including EPA's interpretation of section 129(e), information on updating existing title V permit applications and reopening existing title V permits, see the final Federal Plan for Commercial and Industrial Solid Waste Incinerators, October 3, 2003 (68 FR 57518, 57532).

IV. Rationale for the Proposed Rules

A. How Did EPA Determine Which Pollution Sources Would Be Regulated Under the Proposed Rules?

Section 129(a) of the CAA requires the promulgation of standards for several categories of solid waste combustion units, including units combusting municipal waste; units combusting hospital, medical and infectious waste; units combusting commercial or industrial waste; and unspecified ''other categories of solid waste incineration units.'' The subject of the proposed rules is the unspecified other categories of solid waste incineration units.

One important part of EPA's rulemaking process is determining what universe of sources will be subject to regulation. With regard to OSWI units, the statutory provisions of CAA sections 129(a), (g) and (h) make it clear that EPA must determine, as a part of the regulatory process, (1) where to draw the line between combustion units potentially subject to regulation under CAA section 129 and combustion units potentially subject to regulation under other statutory authority (such as CAA section 112(d)), and (2) to which categories of solid waste combustion units the standards for ''other categories of solid waste incineration units'' apply. For example, the reference in CAA section 129(g)(1) to a permit issued under section 3005 of the SWDA, refers to units burning hazardous solid waste. This effectively limits the scope of EPA's authority under CAA section 129 to the regulation of solid waste incineration units that burn nonhazardous solid waste. Similarly, the language of CAA section 129(h) makes clear the Congressional intent for CAA regulation under CAA section 129 or CAA section 112 to be mutually exclusive. Accordingly, sources subject to CAA section 112 standards do not constitute OSWI (the dividing line between boilers regulated under CAA section 112 and OSWI is discussed in detail below). Absence of regulation under CAA section 112, however, is not determinative of what constitutes an OSWI unit. Inherent in EPA's implementation of CAA section 129 is the discretion to reasonably define what constitutes the statutorily undefined other categories of solid waste incineration units and to determine which of these other units warrant regulation under CAA section 129.

In response to the requirement to publish a schedule for regulation of other categories of solid waste incineration units, a **Federal Register** notice (58 FR 31358, June 2, 1993) was published that proposed a regulatory schedule and a draft list of potential subcategories for consideration of regulation under OSWI standards. After receiving comments on the June 1993 notice, another **Federal Register** notice (58 FR 58498, November 2, 1993) was published to include comments received on the draft category list and proposed regulatory schedule. The November 1993 notice listed the following potential subcategories of OSWI:

(1) Very small municipal waste combustion units;
(2) Residential incinerators;
(3) Agricultural waste incinerators;
(4) Wood waste incinerators;
(5) Construction and demolition waste incinerators;
(6) Crematories; and
(7) Contaminated soil treatment facilities.

A third **Federal Register** notice (65 FR 67357, November 9, 2000) was published that revised the regulatory schedule. The third notice also noted that, as additional information is collected and assessed, EPA may add or delete subcategories within the OSWI category.

Since publication of the third **Federal Register** notice, EPA has gathered additional information and updated the inventory of possible OSWI units through review of multiple Federal and State databases, literature and permit searches, and contacts with State agencies, incinerator manufacturers, trade associations, and other stakeholders. The following discussion details EPA's current assessment of each of the seven potential subcategories previously identified as under consideration for regulation within the OSWI category. Eight additional subcategories EPA has considered for regulation within the OSWI category are also discussed.

EPA recognizes that there are some subclasses of incinerators that we considered for regulation within the OSWI category that should be handled differently due to unusual circumstances (*e.g.*, unique geographic or climatic factors, used only during emergencies) that would prevent those

incinerators from having the option of using an alternative waste disposal method that our assessment indicates would be lower in cost than complying with the proposed rule. We have attempted to address these subclasses of incinerators accordingly. It has come to our attention that there exists a subclass of IWI that burn national security documents and that this subclass should be considered for potential exclusion from regulation within the OSWI category. We specifically request comment on whether this is an appropriate subclass of incinerators for exclusion.

We also request comment on whether other such subclasses may exist and the precise nature of any special and/or extenuating circumstances. Therefore, in order to make such a determination, the specific information that we are requesting from commenters includes unit location; unit capacity; age of unit; type of waste burned (*e.g.*, paper waste, garbage, laboratory waste, etc.); amount of waste burned per week; frequency and hours of operation per week; unit design characteristics (*e.g.*, single chamber, multi-chamber, presence of afterburner or control technology); an outline of routine maintenance activities to ensure good combustion within the unit; availability and description of test data; availability and cost of local commercial waste collection services; and potential economic burden associated with the proposed rule. In particular, we are interested in this information for very small units (*e.g.*, IWI units with capacities less than 0.5 ton per day). Finally, we request specific information on the nature (*e.g.*, private or public elementary school, not-for-profit) and size (*e.g.*, number of students, members, employees) of the institutions that own affected units, as well as their sources of funding (*e.g.*, county, State, Federal, tuition fees), the size of their overall budget (or revenue for profit-making entities), and the current cost of waste disposal (including the operating, maintenance, and anticipated capital costs).

1. Very Small Municipal Waste Combustion Units

Section 129 of the CAA identifies and defines ''municipal waste'' as a distinct type of waste. The proposed rules adopt the CAA section 129 definition of municipal waste. Municipal waste, as defined in CAA section 129 and the proposed rules, is:

''refuse (and refuse-derived fuel) collected from the general public and from residential, commercial, institutional, and industrial sources consisting of paper, wood, yard wastes, food wastes, plastics, leather, rubber, and other combustible materials and non-combustible materials such as metal, glass and rock, provided that: (A) The term does not include industrial process wastes or medical wastes that are segregated from such other wastes; and (B) an incineration unit shall not be considered to be combusting municipal waste for purposes of this subpart if it combusts a fuel feed stream, 30 percent or less of the weight of which is comprised, in aggregate, of municipal waste * * *.''

Municipal waste, therefore, is waste that has been ''collected from'' various solid waste sources or generators.

Very small municipal waste combustion units are typically owned or operated by municipalities, such as towns, cities, or counties. The VSMWC units are units that are not covered by the other CAA section 129 MWC regulations for small (35 to 250 tpd) or large (greater than 250 tpd) MWC units already established (40 CFR part 60 subparts Cb, Ea, Eb, AAAA, and BBBB). The EPA's research indicates that, for the most part, VSMWC units are no longer economical and the majority of them have closed down. Vendors and State agencies have indicated that new purchases and installations of VSMWC units are extremely rare, and that no growth or negative growth is the expected trend for the future. However, the EPA was able to identify a small population of existing VSMWC units.

As mentioned earlier, the larger MWC units (*i.e.*, 35 tpd or greater) are already regulated. As a result, EPA is including VSMWC units as a subcategory of OSWI for regulation.

2. Residential Incinerators

The EPA's research indicates that burning of household trash by individual households does not occur in conventional ''incinerators,'' but, rather, in burn barrels. Burn barrels are typically modified fifty-five gallon steel drums. They have no provisions for regulating air supply to the waste being burned and have no pollution control devices. They are typically used in rural areas where burning household trash may be viewed as more convenient than taking it to a landfill or having a waste management service collect it.

If EPA were to regulate residential burn barrels as a subcategory of OSWI, the costs necessary to comply with the proposed rules would effectively rule out the use of burn barrels. Any regulation established under CAA section 129 requires that sources, at a minimum, undertake operator training, perform emissions testing, and complete permitting, monitoring, recordkeeping and reporting duties. The annual cost of these activities alone would add up to several thousands of dollars per year. As a result, regulation under section 129 would effectively eliminate the use of residential burn barrels as a legal method of trash disposal.

While this might, at first, seem a desirable outcome, in those rural areas where State and local governments have not provided appropriate alternatives, it could lead to even greater problems if residents turned to open burning, littering, or dumping. This could result because households that use burn barrels to dispose of waste may be located in areas where convenient waste disposal alternatives do not exist. As a result, if the use of burn barrels is effectively prohibited by Federal regulation, households could turn to disposing of trash along a roadside (littering), in a field or woodland, or resorting to open burning. Littering and dumping, besides being unsightly, pose significant other problems, such as potential contamination of streams or other water bodies, and attracting vermin and wild animals, which could contribute to disease transmission. Open burning presents the same air pollution problems as barrel burning and can lead to an increased likelihood of accidental fires. Therefore, Federal regulation of residential barrel burning could lead to a number of undesirable consequences where effective local alternatives do not exist.

The EPA believes that its overriding responsibility must be to promote the use of environmentally sound integrated waste management practices. Effective management of the burning of household waste in rural areas will require the development of suitable waste disposal alternatives as well as the development of a public education effort to inform people of the environmental impacts associated with barrel burning and open burning. It should be noted that regulating open burning is beyond the scope of CAA section 129, since open burning is not done in an incinerator. Most importantly, because uncontrolled burning of household waste occurs in millions of households across rural America, programs to reduce or eliminate this practice can only be effectively managed at the local level through the development of locally based solutions that combine public education, with the development of local infrastructure for waste disposal. In many areas it will also require establishing additional State and local ordinances, and locally managed compliance programs. Many of these concerns are well beyond the scope of the CAA.

Given the highly varied nature of local government, large differences in

existing waste management infrastructure and economic resources, differences in rural population density, and regional differences in practices and attitudes towards waste management, EPA has concluded that adoption of Federal regulations that would mandate use of a uniform set of waste management practices does not appear to be practical. The EPA has chosen, instead, to develop technical assistance to help states and localities design and develop waste management programs tailored to the unique needs and constraints individual communities face. As a result, EPA has decided not to include residential incinerators (*i.e.*, burn barrels) as a subcategory of OSWI for regulation.

To provide additional information about EPA's back yard burning activities, EPA has developed a back yard burning Web site, (*http://www.epa.gov/msw/backyard*), which includes background information, access to available publications, and links to related Web sites.

3. Agricultural Waste Incinerators

Agricultural residue combustion units are primarily those units that are burning rice hulls, bagasse (pressed sugar cane), and other types of biomass. The EPA's information collection efforts, however, indicate that, when burned, these agricultural residues are used as boiler fuel. As such, the boiler is regulated under the boilers NESHAP, a CAA section 112 regulation (69 FR 55218, September 13, 2004). Since sources regulated under CAA section 112 cannot be regulated by CAA section 129 also, these sources would not be subject to the proposed rules.

Manure and livestock bedding material are also considered a type of agricultural residue, and any combustion unit burning these materials could potentially be considered an agricultural residue combustion unit. However, EPA was unable to identify any such incinerators, and has encountered only anecdotal evidence and proposals for manure combustion units. In addition, these proposed units are planned as boilers for energy production and, if built, would likely be ''qualifying small power producing facilities,'' which are excluded from the definition of ''solid waste incineration unit'' in CAA section 129. Therefore, EPA is not including them as a subcategory of OSWI for regulation at this time.

4. Wood Waste Incinerators

As noted in a previous **Federal Register** notice (65 FR 67357, November 9, 2000), EPA did not anticipate the discovery of many wood residue combustion units that were not already covered by other rules. The EPA was unable to locate and identify any wood residue combustion units that are not covered by other regulations. Information collection efforts indicate that wood residue is combusted as a fuel in boilers or process heaters. In these situations, the boilers NESHAP under CAA section 112 will regulate these combustion units. To the extent that there are any incinerators that burn wood residue, they are located at sites considered to be commercial or industrial sites, and are properly covered by the CISWI NSPS and emission guidelines. Therefore, EPA is not including wood residue combustion units as a subcategory of OSWI for regulation at this time.

5. Construction and Demolition Waste Incinerators

Like some of the other potential OSWI subcategories, EPA was unable to locate and identify any construction or demolition materials combustion units. Construction and demolition materials contain cement, concrete, gypsum and other non-combustible items. As a result, construction and demolition materials are landfilled rather than burned. In addition to this, there appears to be a trend in minimizing construction site waste generation and recycling of construction and demolition materials for use in other products (*e.g.*, asphalt, mulch, soil amendment, etc.) or structures (*e.g.*, use of ''antique'' or ''restored'' woodwork or fixtures in newly constructed buildings or residences).

Since EPA has been unable to identify any construction and demolition materials combustion units and does not anticipate a future growth of these types of units, EPA is not including the construction and demolition materials combustion units as a subcategory of OSWI for regulation at this time.

6. Crematories

Crematories are used to incinerate either human or animal remains. For the purposes of this discussion, EPA differentiates between human and animal crematories.

a. Human Crematories. As mentioned previously, CAA section 129 regulations deal solely with solid waste combustion units. In considering the nature of human crematories since the previous OSWI **Federal Register** notices were published, EPA has come to the conclusion that the human body should not be labeled or considered ''solid waste.'' Therefore, human crematories are not solid waste combustion units, and are not a subcategory of OSWI for regulation. If EPA or States determine, in the future, that human crematories should be considered for regulation, they would be addressed under other authorities.

b. Animal Crematories. Animal crematories are those used to dispose of animal carcasses at places like veterinary clinics, animal control facilities, universities and research institutions, pet cremation services, and livestock farms such as poultry and swine farms. From the information EPA has gathered, the emissions from these units are very low when compared to other solid waste combustion units. The emissions levels from uncontrolled animal crematory units are, in fact, less than emissions after controls from other types of incinerators that are regulated, such as MWC units and HMIWI units. This is because operation of these units involves incineration of animal or pathological tissue, which consists primarily of water, with negligible or no other materials, such as plastic, wood, metals, etc. Furthermore, the units are typically very small and operated only a few hours a week.

In addition to the low emissions from these units, EPA is also concerned about biosecurity within the agricultural sector. Incineration of diseased animals is often necessary to prevent the spread of infectious diseases. Research within the agricultural community has shown that vehicles traveling among farms to collect dead animals for off-site disposal are significant disease transmission vectors. Thus, on-site incineration is often a preferred method of animal carcass disposal, since it carries no risk of disease transmission between farms. If EPA were to impose regulations that discouraged incineration relative to rendering (which, for economic reasons, requires that trucks travel between farms to pick up animal carcasses), there could be an increase in disease transmission and mortality along with the corresponding economic impacts on farmers.

In many areas there is also a lack of reasonable and economic alternatives (*e.g.*, rendering, composting, burial) to incineration. For example, burial is often prohibited due to water quality concerns and the potential for pathogen contamination. Therefore, any regulation that adds to the costs of operating an animal incinerator would mean additional costs to farmers in areas without disposal alternatives.

Taking these concerns into account, EPA has determined that the adverse impacts associated with regulation of animal crematories outweigh the benefits of regulation and these units are

not included as a subcategory of OSWI for regulation at this time.

7. Contaminated Soil Treatment Facilities

When looking into these types of units, EPA discovered a wide variety of treatment methods as well as a wide variety of facilities at which remediations were being carried out. The methods can be carried out either *in-situ* (*e.g.*, air-sparging) or *ex-situ* (*e.g.*, thermal desorption). Most treatment methods do not involve any type of combustion. Two methods involve some type of combustion device: (1) Incineration, where the soil is extracted and then burned to combust the contaminants; and (2) thermal desorption, where the contaminated soil is heated (not burned) to drive off contaminant vapors. Non-combustion treatments are far more popular, and incineration is very rarely used.

Typically, contaminants being removed from the soil are either hazardous wastes or petroleum products leaked from underground storage tanks (UST). Hazardous waste soil treatment units are covered under Resource Conservation and Recovery Act (RCRA) subtitle C programs. Petroleum products being removed from soil at small UST site remediations are subject to RCRA subtitle I. The few site remediation sites EPA had identified for possible regulation under OSWI were, as discovered through State contacts, regulated under RCRA subtitles C or I. If a unit is subject to RCRA subtitle C, it is treating hazardous waste. Hazardous waste incinerators are exempt from CAA section 129 regulation.

Subtitle I of RCRA, which covers petroleum products coming from UST, specifies stringent site-specific environmental safeguards. Since each site and the remediation thereof may require different treatment methods, subtitle I is designed to ensure a high degree of pollution control for a variety of possible treatment options and a high degree of local regulatory and citizen involvement in selecting the use of equipment and environmental safeguards. At major sources, any site remediation activity would be covered by the CAA section 112 NESHAP for site remediations. As mentioned before, any source regulated under CAA section 112 is not subject to CAA section 129.

Therefore, after assessing the information available on soil treatment facilities and units, EPA has determined that these units are regulated elsewhere. As a result, EPA is not including contaminated soil treatment facilities as a subcategory of OSWI for regulation.

8. Institutional Waste Incinerators

When reviewing the information gathered on potential subcategories of OSWI, EPA identified IWI as a type of unit that is not regulated under other rules and should be regulated under the proposed rules. The OSWI inventory shows over 350 incineration units located at institutions. However, EPA considers this a significant overestimate of the number of IWI units. The EPA's inventory information is several years old (in some cases, as much as 5–10 years old), and research indicates that the population of these types of units has been declining for years. As a result, EPA considers it likely that the actual population of IWI units actually operating today could be half, or possibly less, of what is shown by our inventory.

The inventory information shows that these IWI units are located at a variety of facilities, including schools, universities, prisons, military bases, government facilities, churches, and other institutions, and that they burn solid materials that are generated on site, such as paper, packaging, food waste, rubbish, and garbage. They are not part of the VSMWC category, because the definition of ''municipal waste'' in CAA section 129 is waste ''collected from'' establishments, whereas these IWI units burn only waste generated on site.

Moreover, these units are not covered under the CISWI rules, because CAA section 129 limits CISWI to commercial and industrial establishments, and does not include institutions. Therefore, EPA proposes to regulate IWI as a subcategory of OSWI.

Note that under the CAA section 129 definition of ''municipal waste,'' small incinerators that are located at commercial businesses (such as stores and restaurants) or industrial sites and that burn solid materials generated on site are not MWC units because they do not burn waste which has been ''collected from.'' As mentioned above, such units are properly covered under the CISWI rules, because of their location at commercial or industrial establishments.

As mentioned previously, one important part of EPA's rulemaking process is determining what universe of sources to subject to a regulation. The statutory provisions of CAA sections 129(a) and (h) make it clear that EPA must determine, as part of the regulatory process, where to draw the line between combustion units regulated under CAA section 129 and combustion units subject to regulation under other statutory authority, such as CAA section 112. The language of CAA section 129(h) makes clear the Congressional intent that nonhazardous combustion sources not be regulated under both CAA section 129 and CAA section 112. Thus, for the IWI subcategory of OSWI, EPA must determine which sources to include in the subcategory, and which sources to regulate under CAA section 112 (*e.g.*, boilers). For example, institutional boilers burning solid materials are already regulated under CAA section 112 by the boilers NESHAP (40 CFR part 63, subpart DDDDD).[1] Many of the combustion units at institutional facilities (*e.g.*, boilers or steam generating units, heaters, and incinerators) burn ''solid'' materials. If the solid materials in question are considered institutional waste, the units would be regulated as part of OSWI under CAA section 129. Conversely, if the materials are not considered institutional waste (*e.g.*, they are hazardous solid waste, fuel, solid materials burned for chemical or material recovery, *etc.*), the units would not be regulated under CAA section 129 but may be regulated under other statutory authority. Thus, collectively, in the process of developing the proposed rules, developing the boilers NESHAP (already promulgated), developing rules for area source boilers, promulgating requirements for electric utility steam generating units, and establishing rules applicable to other combustion sources, EPA will map the regulatory boundaries that identify which units are subject to which requirements.

The process of determining the regulatory applicability of different rules is not unique to the OSWI category. In fact, EPA is addressing similar issues in the CISWI category (*see* 69 FR 7390, February 17, 2004) and in connection with the boilers NESHAP. The identification of the scope of one rule does not necessarily define the scope of another, or preclude EPA from adjusting the regulatory division in a subsequent rule.

To define IWI units, the proposed rules include definitions of solid waste, institutional waste, and IWI units. The definition of solid waste, for the purposes of the proposed rules, is consistent with the SWDA definition and EPA's existing regulatory

[1] Other such units might be subject to regulation under any number of other EPA regulations, such as: Regulations promulgated pursuant to CAA section 112(k) to control emissions from industrial, commercial and institutional boilers that are area sources; and various other regulations developed under CAA section 112 which cover combustion units burning solid materials to recover their chemical or other material constituents.

definitions. It serves to define nonhazardous solid waste. The definition of ''institutional waste'' distinguishes between institutional waste and solid materials that should not be considered institutional waste, as well as between IWI units and non-IWI combustion units. This distinction is particularly difficult for institutional units.[2] For example, there is general agreement that the coal burned in a coal-fired boiler or steam generating unit is not a solid waste because coal is commonly thought of as a fuel. Coal is considered a fuel because it is customarily burned to recover energy (*i.e.*, heat) for some useful purpose such as to heat water or generate steam for space heating or other purposes. However, there is no such general agreement, for example, about a solid material such as paper generated on site at an institution when it is burned in a boiler at that institution to heat a building.

From EPA's point of view, the nature of a material that is burned in a unit at an institutional facility is less important than how the material is burned. In the example, paper is burned to generate the heat necessary to heat a building. If the paper were not burned to generate this heat, then the facility would instead burn another material such as coal. Like the coal, the paper is burned for a useful purpose—to heat the building. Therefore, it is reasonable to consider the paper in this second example, as the coal in the first example, to be a solid fuel and distinct from institutional waste. Thus, for purposes of distinguishing institutional waste from solid fuel, its status is determined by its use, as well as by its nature. Alternatively, if the paper were burned in a combustion unit without heat recovery, its combustion would serve no useful purpose other than to effectuate destruction or disposal of an unwanted material. The EPA would then consider it appropriate to identify the paper as institutional waste, and regulate the combustion unit as an IWI unit under the proposed rules. Similarly, if a material (that is not hazardous waste) is burned in a combustion unit at an institutional facility with heat recovery, for reasons that do not include the recovery of heat for useful purposes, that material would be institutional waste and the unit would be an IWI unit and would be regulated under the proposed rules. Thus, in general, if a solid material (which is not a hazardous solid waste) is burned with heat recovery at an institutional facility to generate heat for a useful purpose, it is appropriate to consider that material not to be institutional waste, and not to regulate the device as an OSWI unit under CAA section 129. See the recent CISWI notice (69 FR 7390, February 17, 2004) for additional rationale for EPA's discretion to develop definitions under CAA section 129 that distinguish between solid waste incineration units and other combustion units.

The EPA has determined that for purposes of the IWI subcategory of OSWI units, the critical consideration in determining whether the unit is burning institutional waste is the primary function of the combustion unit; and the primary indicator of function is whether or not a unit is designed and operated to recover heat for a useful purpose. That is, if the unit located at an institutional facility combusts material without heat recovery (functions primarily as an incineration unit), then the material burned in that unit is institutional waste. Similarly, if a material is burned in a unit at an institutional facility for reasons that do not include the recovery of heat for useful purposes, that material is institutional waste and the unit is an IWI unit. However, if the unit combusts material with heat recovery for a useful purpose, then the material burned is not institutional waste, and the combustion unit would not be subject to the proposed rules. By specifically defining IWI units to include only units that behave like incinerators, EPA can appropriately identify the scope of regulation of combustion units at institutional facilities under CAA section 129.

In addition to units that combust materials without heat recovery, the definition of institutional waste in the proposed rules also includes materials that are burned in a unit at an institutional facility that is followed by external waste heat recovery only (*i.e.*, no heat recovery in the combustion firebox). The boilers NESHAP covers combustion units at institutional facilities that burn solid materials and recover heat in the combustion firebox. Combustion units at institutional facilities that burn solid materials and do not recover heat in the combustion firebox, but do recover waste heat from the hot combustion gases following the combustion firebox, would not be covered by the boilers NESHAP. The EPA does not consider it appropriate to regulate such units as boilers.[3]

Incineration units are designed to discard materials by burning them at high temperatures and leaving as little residue as possible. Incineration units do not have heat recovery in the combustion firebox, but they may be followed by waste heat recovery units. Unlike a boiler (which is specifically designed to recover the maximum amount of heat from a material's combustion), waste heat recovery units are designed to cool the exhaust gas stream from an incineration unit, and/or to recover, indirectly, the useful heat remaining in the exhaust gas. The presence of a waste heat recovery unit on the exhaust gas does not change the fact that the unit combusting the material is primarily an incineration unit. Thus, a combustion unit with no heat recovery in the combustion firebox is still considered an incineration unit (*i.e.*, used primarily to dispose of solid waste), whether the incineration unit is followed by a waste heat recovery unit or not. Such incineration units just happen to have an external device (the waste heat recovery unit) that is recovering some of the waste heat from the incineration unit's exhaust gas. Therefore, IWI units are those units that combust materials with only waste heat recovery (*i.e.*, no heat recovery in the combustion firebox) or no heat recovery.

9. Rural Institutional Waste Incinerators

As discussed above, the OSWI inventory information shows slightly over 350 IWI. These units are located at a variety of institutions and burn solid waste materials generated on site, such as paper, packaging, food waste, rubbish, and garbage. About three-quarters of these IWI appear to be located at primary and secondary schools although, as mentioned, EPA considers this a significant overestimate of the number of IWI. While many IWI appear to be located in areas one would consider suburban or urban, a number appear to be located in areas one might consider rural.

In suburban and urban areas, commercial waste collection/transport/disposal services are widely available and, as a result, IWI in such areas have readily available alternatives to incineration (*i.e.*, commercial waste collection/transport/disposal services). In many rural areas, however, such

[2] In many cases, such as MWC units and HMIWI units, the identification of the relevant wastes and the relevant units is sufficiently clear that EPA need not address the issue at length in its rule. Indeed, CAA section 129 provides specific guidance for EPA's definitions of municipal waste and medical waste, as well as municipal waste incineration units. *See* CAA section 129(g)(5) and (6). In addition, there is broad and general agreement between EPA, the regulated community, and other stakeholders regarding what materials are municipal waste and hospital, medical and infectious waste, and which combustion units belong in the respective regulatory categories.

[3] These units are often referred to as incinerators with waste heat recovery units or incinerators with waste heat boilers.

services are often very limited and, in some cases, unavailable. Thus, EPA considers IWI located in rural areas (*i.e.*, rural IWI) a distinct class of OSWI due to the lack of readily available commercial waste collection/transport/disposal services.

Because of the limited availability or even lack of such services, the only alternative to incineration for a rural IWI may be to transport their waste to a suburban or urban area, where such services are available. This, of course, would significantly increase the costs and, as such, EPA believes rural IWI merit separate consideration.

Thus, EPA has assessed the increased costs for a rural IWI which may have no reasonable alternative to incineration other than to transport their waste to a suburban or urban area. Based on this assessment, EPA concludes that such costs become significant when transport distances exceed 50 miles.

As mentioned above, the class of rural IWI consist primarily of incinerators located at primary or secondary schools in rural communities. In such communities, the local tax base supporting the school system is limited. School budgets are often stretched to the breaking point and unable to provide more than the minimum and bare essentials. In such an environment, a significant increase in solid waste disposal costs would impose an additional economic burden, which EPA concludes is unreasonable. For this reason, EPA has decided to exclude rural IWI.

To achieve this end, EPA has defined a rural IWI as an IWI located more than 50 miles from the boundary of the nearest Metropolitan Statistical Area (MSA). The Office of Management and Budget identifies areas classified as MSA and these areas are considered by EPA as suburban or urban areas. Thus, defining a rural IWI as an IWI located more than 50 miles from the boundary of the nearest MSA serves the objective of identifying those IWI located in rural areas where commercial waste collection/transport/disposal services may not be readily available or available at all, as well as identifying the maximum reasonable transport distance for an IWI to transport their waste to areas where such services are readily available.

10. Air Curtain Incinerators

Air curtain technology covers a wide variety of combustion equipment designs. For example, all air curtain units contain a fan and ductwork necessary to develop the ''air curtain.'' However, some units are designed to carry out waste combustion within a partially enclosed firebox (e.g., floor and walls, but open on top), while other designs may not involve a ''firebox,'' per se. These other designs consist only of a fan and ductwork to provide the ''air curtain,'' but the combustion is carried out in an earthen trench. The former are referred to as ''firebox'' units, and the latter are referred to as ''trench burners.'' For the purposes of the proposed rules, EPA is defining ''air curtain incinerators'' to include both types of units; firebox units as well as trench burners. Since air curtain incinerators could potentially be used for long-term municipal or institutional waste disposal, it makes sense to regulate them as OSWI units subject to the emission limits, operating limits, and other requirements of the proposed rules. Therefore, air curtain incinerators that otherwise meet the definition of OSWI would be regulated as OSWI.

Note that, as required by CAA section 129(g)(1), the proposed rules contain separate opacity requirements for air curtain incinerators burning only yard waste, wood waste, and clean lumber, and those units would not have to meet emission limits for the other CAA section 129 pollutants or the associated monitoring, recordkeeping and recording requirements. Air curtain incinerators that burn institutional or municipal waste, however, would have to meet all requirements of the proposed rules. Since air pollution control devices are unavailable for air curtain incinerators, this has the net effect of precluding the use of air curtain incinerators for burning municipal solid waste or institutional waste.

11. Incinerators and Air Curtain Incinerators in Isolated Areas of Alaska

There are locations in Alaska where limited options exist for solid waste disposal. These areas face unique situations that are not encountered elsewhere in the United States, and incinerators located in these areas merit special consideration. These are sparsely populated areas where access to a large MSW landfill or any other solid waste disposal option outside of the community is not available for all or part of a year. Within these areas, there are many isolated villages with small populations that have no road access. The only surface transportation in and out of many of these communities is barge traffic during the summer months. Other areas have roads that are not passable for much of the winter due to snow. In other cases, roads can be used in the winter when the rivers or streams that the road must cross are frozen, but the road is not available in the summer when the top layer of permafrost melts, turning the road into a bog. Rivers and streams without bridges thaw and become impassable. In such situations, there is no practical means of transporting waste. As a result, local waste management is the only option available to these communities.

In addition to the unavailability of waste transportation options, climatic conditions can make effective local landfilling difficult or even technically infeasible. These areas experience extended subfreezing conditions for the duration of the winter. In the summer months, the top layer of permafrost melts, turning potential waste disposal areas into bogs. Operation of a conventional landfill is extremely difficult under both weather extremes. In addition, adequate landfill cover material is unavailable in many areas. If waste is simply placed outside in a dump with no or insufficient cover material, it can attract birds and wild animals (such as bears and foxes) that can threaten villagers or spread disease. Waste burning in these remote Alaskan locations has the added benefits of decontaminating the waste, making the waste less attractive to wild animals, reducing the problem of blowing litter, and minimizing the generation and impacts of leachate.

In some Alaskan villages, incineration is used in conjunction with landfilling. In these areas, land that is physically suitable for a landfill is extremely scarce, so waste volume reduction is important to the village to prolong the life of the landfill. Alaskan villages may utilize waste segregation and recycling programs to reduce waste streams, but burning the remaining waste is also important to further reduce the waste volume and prolong the useful life of the local landfill.

Under authority of the SWDA, Alaskan State codes define landfills serving small populations in isolated areas with no access to a regional waste management facility for 3 or more months per year as ''Class II'' or ''Class III'' depending on size and accessibility constraints. Disposal sites classified as Class II or III experience the solid waste disposal challenges outlined in the previous paragraphs and incineration is common at these facilities.

As the previous discussion details, the challenges to the use of environmentally sound waste management practices at these remote Alaskan communities make incineration an essential component to their waste management system. Any CAA section 129 regulation imposed on incineration units used at these Class II or Class III facilities in Alaska, however, would effectively preclude use of incinerators.

Even a minimal rule that did not require new air pollution controls would make the cost of incineration prohibitively expensive, because CAA section 129 rules must contain testing, permitting, monitoring, recordkeeping, and reporting requirements. These requirements would easily double or triple the cost of operating an incinerator. These small Alaskan villages would not have the economic resources to comply with a regulation and would likely cease operating incineration units in response to any regulation.

The potential implications of the cessation of incineration at these Class II and Class III facilities include the rapid exhaustion of available landfill capacity, increased transmission of disease, increased threats from wild animals, and an increase in open burning. Therefore, EPA considers it important to preserve incineration as a waste disposal option for Class II and III facilities in Alaska. The EPA's consideration of the solid waste disposal options available at Class II and III facilities in Alaska shows an adverse environmental result from any action that would preclude or build barriers to incineration within these areas.

For these reasons, EPA has decided to exclude incinerators and air curtain incinerators used at solid waste disposal sites in Alaska that are classified as Class II or Class III facilities.

12. Incinerators Located on Remote Islands

The EPA recognizes that certain islands, Guam, American Samoa, the Virgin islands, and the Commonwealth of the Northern Mariana Islands, may lack suitable alternative disposal methods and find the cost of having sources comply with the proposed rules prohibitive. The EPA is not proposing an exclusion or exemption for such sources, but draws the attention of these islands to CAA section 325, which permits EPA to grant an exemption from CAA section 129 requirements upon petition of the ''Governor'' of one of these islands. The EPA would respond favorably and promptly to any such properly supported petition.

13. Temporary-Use Incinerators Used in Disaster or Emergency Recovery Efforts

The EPA realizes that in certain catastrophic situations, an incinerator may be a very useful tool in the recovery process. Clean-up and recovery efforts after disasters such as floods, tornados, or hurricanes are examples of situations where an incinerator may be useful. In these situations, quick removal of debris is of utmost importance to maintain public health and safety. Likewise, bioterrorist activities may warrant the immediate destruction of contaminated materials, in which case an incinerator may be best suited to perform the task. In these situations, the incinerator is used at a site only long enough to complete the recovery tasks, and is not used as a long-term waste disposal device. Accordingly, EPA considers that regulations imposed on incinerators temporarily used to recover from an emergency or disaster could perhaps hinder the recovery efforts, and this impact would outweigh any benefits possible under regulation of the units. To address this, EPA has included an exclusion for temporary-use incinerators used in disaster or emergency recovery efforts from regulation under OSWI.

This exclusion applies to temporary-use incinerators used in recovery efforts at local, State and Federally-declared disasters or emergencies. If the incinerator is used for recovery efforts in an area declared by the State as a State of Emergency, or that the President has declared, under the authority of the Stafford Act, a major disaster or emergency, then it would be excluded from regulation under OSWI for as long as required by the recovery effort. However, if the disaster or emergency has not been declared a State of Emergency or a major disaster or emergency, then the exclusion would apply to temporary-use incinerators used in recovery efforts at one location for 8 weeks or less. If the disaster recovery efforts are expected to take longer, the owner/operator of the unit would be required to submit a notification to the Administrator requesting approval to continue operating for a longer period of time. The incinerator may then be used for an additional 8 weeks at the same location while the Administrator reviews the request. After that time period the incinerator must cease operations or comply with the proposed rules unless the Administrator approves the request to operate at the location for a longer period of time.

14. Units that Combust Contraband or Prohibited Goods

The EPA realizes that government agencies sometimes must resort to incineration to destroy illegal drugs and items that are prohibited in all or portions of the U.S. due to biosecurity reasons. For example, few options other than incineration exist for the destruction or disposal of marijuana and other drugs seized by the police. Landfill disposal is not adequate due to the risk of someone recovering the contraband after authorities have attempted to dispose of it. As another example, produce seized by customs agents at points of entry into the United States may be infected by pathogens or pests that could severely threaten the domestic agriculture industry. In these cases, complete destruction via incineration may be the preferred method of disposal of the contaminated produce.

In such situations, EPA does not want to hinder or deter the use of incinerators by the government agency if it is necessary to protect public health and safety. Therefore, EPA has chosen to exclude units operated by government agencies that combust only contraband or prohibited goods from the proposed rules. Note that if contraband or prohibited goods are combusted with other waste in a VSMWC unit or IWI unit, the unit would be covered by the proposed rules.

15. Units That Combust Municipal Waste or Institutional Waste With Other Materials

In the discussion above, EPA has assumed that units within a potential subcategory are burning only the material described (*e.g.*, MSW, wood residue, contraband, etc.). As EPA has discussed, units at institutions burning institutional waste generated at that institution (IWI units) and VSMWC units would be subject to the emission limits and other requirements of the proposed rules. Any VSMWC or IWI unit that is also combusting other materials, such as contraband, agricultural residue, etc., described in this section of this preamble would be subject to the emission limits and other requirements of the proposed rules. For example, a VSMWC unit that is burning contraband along with municipal waste would be regulated under OSWI and would not qualify for the exclusion for units burning contraband. An incinerator that is burning only contraband would be excluded from the proposed rules. Similarly, an incineration unit that originally is excluded from regulation under OSWI, but subsequently burns municipal waste or institutional waste, would be subject to the emission limits and other requirements of the proposed rules.

B. How Did EPA Select the Pollutants to be Regulated?

The EPA selected emission limits for nine pollutants, as well as an opacity standard, for the proposed rules. As required by CAA section 129, the proposed rules would establish numerical emission limits for Cd, CO, dioxins/furans, HCl, Pb, Hg, opacity, NO_X, PM, and SO_2.

Section 129 of the CAA authorizes, but does not require, EPA to set limits for additional pollutants. The EPA has concluded that emission limits for additional pollutants are not needed because the emission limits for the nine listed pollutants ensure control of the other pollutants emitted by OSWI units. This decision is consistent with other CAA section 129 NSPS and emission guidelines (those for MWC units, HMIWI units, and CISWI units). The pollutants emitted by OSWI units fall into three general classes: Metals, organics, and acid gases. The limits for the nine pollutants, in conjunction with the combustor and control device operating parameter limits established by the regulations, would result in good control of all three classes of pollutants.

The emission limits for PM, Cd, and Pb ensure that emissions of all non-volatile metals are controlled. Cadmium, Pb, and other non-volatile metals are emitted as PM, and are removed by the same control devices that control PM emissions. The Cd, Pb, and PM limits would ensure that a wet scrubber or other control device is installed and operated in a manner that reduces emissions of all non-volatile metals. Mercury is the most volatile of the metals found in emissions from waste combustion units. If emission control devices meet the Hg limits, they would also be controlling any other volatile metals that may be present. Setting emission limits for additional metals would increase testing costs without obtaining any additional emissions reductions.

The emission limits for CO and dioxins/furans ensure control of organic pollutant emissions. Carbon monoxide concentration is a good indicator of combustion efficiency and the destruction of organic compounds. Complete combustion, as indicated by low CO emission limits, results in low emissions of organic compounds. High levels of CO indicate poor combustion conditions that are likely to result in high levels of organic compound emissions. The combustion techniques employed to minimize CO emissions are the same as those that are used to minimize organic compound emissions. Therefore, the CO emission limit would ensure that organic compound emissions are reduced.

Combustor load is also related to organic compound emissions. At loads above 100 percent, PM carryover could increase, and incinerator residence times could decrease, contributing to increased emissions of organic compounds including dioxins/furans. The proposed rules include a maximum charge rate operating limit, which would help achieve good control of organic pollutants. Dioxins/furans are a type of organic pollutant that is of particular health concern, and they can form on fly ash in the presence of oxygen at temperatures in the range of 250° to 400 °C (480° to 750 °F). Rapid flue gas cooling, for example by a wet scrubber, avoids dioxins/furans formation by this method. The specific emission limits for dioxins/furans would ensure that dioxins/furans emissions are minimized and, along with the CO and operating limits, would also result in the incinerators and control devices being designed and operated in a way that reduces emissions of other organic pollutants.

The emission limits for SO_2 and HCl would result in control of acid gases. Sulfur dioxide and HCl constitute the majority of acid gas emissions from waste combustion units. The same control technologies that reduce emissions of SO_2 and HCl, such as wet scrubbing, also remove emissions of any other acid gases. The SO_2 and HCl emission limits would ensure that the devices that control these two pollutants and other acid gases are installed and operated in a manner that reduces emissions.

The proposed rules require continuous monitoring of selected operating parameters to ensure that the control devices are continuously operated in the manner intended and result in continuous emissions reductions of PM and metals, organic pollutants, and acid gases. In summary, emission limits for other pollutants are not necessary because the emission limits for the nine pollutants would result in control of the other pollutants emitted by OSWI units.

C. How Did EPA Select the Format for the Proposed Rules?

The EPA selected an outlet concentration format for each pollutant because outlet data are available for combustion units using the control technologies that are the basis of the MACT emission limits. All concentration limits are corrected to 7 percent oxygen to provide a common basis. Opacity requirements are proposed on a percentage basis. The individual limits for each pollutant reflect the achievable performance of units using the MACT controls. The units of measure for each of the pollutants are consistent with other CAA section 129 rules and with the available data.

For regulating Cd, Pb, and Hg, the proposed numerical concentration limits are in units of µg/dscm. For total PM, the proposed concentration limits are in units of gr/dscf. Dioxins/furans emission limits are in units of total ng/dscm (total mass basis), based on measuring emissions of each tetra- through octa-chlorinated dibenzo-p-dioxin and dibenzofuran and summing them. For CO, HC1, NO_X, and SO_2, the proposed rules are volume concentrations (ppmdv).

In addition to numerical emission limits, the proposed rules include siting requirements (for new sources only) and operator training and qualification provisions as required by CAA section 129. Owners or operators of OSWI units would also be required to prepare a waste management plan.

D. How Did EPA Determine the Proposed Emission Limits for New OSWI Units?

All standards established pursuant to CAA section 129 must reflect MACT, the maximum degree of reduction in emissions of air pollutants that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for each category. The CAA also specifies that the degree of reduction in emissions that is deemed achievable for new OSWI units must be at least as stringent as the emissions control that is achieved in practice by the best-controlled similar unit. This requirement constitutes the MACT ''floor'' for new OSWI units and EPA may not consider costs or other impacts in determining the MACT floor. The EPA may require a greater degree of reduction in emissions that is more stringent than the MACT floor (beyond-the-floor) if the Administrator considers the cost, environmental, and energy impacts to be reasonable.

Section 129(c) of the CAA specifies that standards ''shall be based on methods and technologies for removal or destruction of pollutants before, during, or after combustion.'' In determining the MACT floors and MACT, EPA considered source reduction and materials separation as potential methods of reducing pollutants before combustion. The EPA determined that the variable and heterogeneous nature of municipal solid waste and the site-specific and diverse nature of institutional waste make reliable quantification of emissions reductions associated with removal of various materials technically infeasible for the OSWI unit population. Each OSWI unit combusts a unique mixture of materials and, therefore, a single materials separation approach would not suffice for all OSWI units. Instead,

the EPA would require a site-specific waste management plan for each OSWI unit that identifies the feasibility and methods to reduce or separate components of solid waste from the waste stream to reduce toxic emissions from incineration of waste, as discussed later in this preamble.

In developing the MACT floors and MACT, EPA also considered methods for destruction of pollutants during combustion. The MACT floors and MACT are based on emission data for well-designed and well-operated combustion units, and the CO emission limits would assure proper operation of the combustor, which minimizes emissions of organic pollutants. Technologies for control of pollutants after combustion were also considered as described in the following discussions of the VSMWC and IWI unit MACT floors and beyond-the-floor alternatives.

For the proposed rules, we determined the new source MACT floors and MACT separately for the two subcategories of OSWI—the VSMWC subcategory and the IWI subcategory. Because there are similarities in unit size, design, and operation between the two subcategories, we request public comment on whether we should combine the two subcategories and determine a single new source MACT floor and a single set of new source MACT emission limits for the OSWI category as a whole. If the subcategories were combined, then we would use any available data for OSWI units (regardless of whether they are VSMWC or IWI units) to determine the MACT floor and MACT for the OSWI category.

1. How Did EPA Determine the MACT Floor for New OSWI Units?

To determine the MACT floor for new OSWI units, EPA must identify the ''best performing similar unit, as determined by the Administrator.'' The best performing ''similar source'' need not be in the category or subcategory subject to the MACT standard at issue. Rather, the source must be one that EPA, based on our evaluation of similarities and differences (*e.g.*, size, design, method of operation, purpose) has determined is sufficiently similar for us to base our regulations on. While EPA does not have emission test data for the units in the OSWI inventory, emissions information is available for other incineration units that EPA has concluded are ''similar.'' Accordingly, emission levels for the MACT floor level of control were determined by using actual emissions test data from similar units in other source categories.

New VSMWC MACT floor. The inventory of VSMWC units contains 14 units. All of the units for which MACT compliance control information is available report that they are ''afterburner/uncontrolled'' units (*i.e.*, two-chamber units consisting of a primary combustion chamber and an afterburner chamber, but no add-on control devices). However, all two-chamber incineration units use an ''afterburner'' in the second combustion chamber to ensure complete combustion burn-out. Thus, the use of an afterburner in the second combustion chamber is an integral part of the design and operation of these incinerators and does not represent an additional level of emission control beyond that which is inherent in the basic design and operation of VSMWC units. As a result, for the purposes of assessing the performance of these incineration units, EPA considers them ''uncontrolled.''

While all of the sources in the VSMWC subcategory are uncontrolled, EPA has data on emissions and controls for HMIWI units that are similar to VSMWC units in size, design, and operation. Based on EPA's review of this information, EPA has determined that the most representative similar source would be an HMIWI unit using a ''medium efficiency'' wet scrubber. Small and medium sized HMIWI units, which are similar in size and design to VSMWC units, have low or medium efficiency wet scrubbers as required by the HMIWI rules. Furthermore, there is one OSWI unit, an IWI unit, with a medium efficiency wet scrubber.

While EPA has no emissions data for the IWI unit, EPA has reviewed compliance test data for HMIWI units, which includes the type of units that EPA has determined constitute the best performing similar source. Using this data, EPA determined the performance level of a ''medium efficiency'' wet scrubber by calculating the average emissions rate for all of the wet scrubbers on HMIWI units. Table 3 of this preamble shows the emission limits associated with the MACT floor for new VSMWC units.

TABLE 3.—NEW VSMWC MACT FLOOR EMISSION LIMITS

Pollutant (concentration units @ 7% O_2)	Emission limit
PM (gr/dscf)	0.013
HCl (ppmdv)	3.7
SO_2 (ppmdv)	3.1
CO (ppmdv)	5.0
NO_X (ppmdv)	103
Dioxins/Furans, Total Mass Basis (ng/dscm)	33
Hg (μg/dscm)	74
Cd (μg/dscm)	18
Pb (μg/dscm)	226

New IWI MACT floor. The IWI inventory contains 358 units. These units are two-chamber incineration units with an afterburner in the second chamber. Of these, there is one unit controlled with a medium efficiency wet scrubber.

While EPA has no emissions data on IWI units, EPA has data for HMIWI units that are similar to IWI units in size, design, and operation. Based on EPA's review of this information, EPA has determined that the most representative similar source would be an HMIWI unit using a ''medium efficiency'' wet scrubber. Small and medium sized HMIWI units, which are similar in size and design to IWI units, have low or medium efficiency wet scrubbers as required by the HMIWI rules. The EPA reviewed compliance test data for HMIWI units, which includes the type of units that EPA has determined constitute the best performing similar source. Using this data, EPA determined the performance level of a ''medium efficiency'' wet scrubber by calculating the average emissions rate for all of the wet scrubbers on HMIWI units. Table 4 of this preamble shows the emission limits associated with the MACT floor for new IWI units.

TABLE 4.—NEW IWI MACT FLOOR EMISSION LIMITS

Pollutant (concentration units @ 7% O_2)	Emission limit
PM (gr/dscf)	0.013
HCl (ppmdv)	3.7
SO_2 (ppmdv)	3.1
CO (ppmdv)	5.0
NO_X (ppmdv)	103
Dioxins/Furans, Total Mass Basis (ng/dscm)	33
Hg (μg/dscm)	74
Cd (μg/dscm)	18
Pb (μg/dscm)	226

2. How Did EPA Determine Whether Options More Stringent Than the MACT Floor Were Appropriate for New OSWI Units?

In determining MACT, CAA section 129 directs EPA to ''* * * require the maximum degree of reduction in emissions * * * that the Administrator, taking into consideration the cost of achieving such emission reduction and any non-air quality health and

environmental impacts and energy requirements, determines is achievable. * * *'' However, MACT standards may be more stringent than the MACT floor.

The MACT floors for both the new VSMWC subcategory and the new IWI subcategory of OSWI are based on similar units with wet scrubbers, as described earlier in this preamble. The EPA did not identify any feasible regulatory options more stringent than the MACT floors for new VSMWC and IWI units. The EPA considered the possibility of dry sorbent injection systems with carbon injection and fabric filters, but available information indicated that the emissions reductions would be similar to wet scrubbing, and the costs to install and operate the controls would likely be much greater. Furthermore, analyses conducted for other CAA section 129 rules (*e.g.*, HMIWI) for incineration units of the same size and design have found that wet scrubbers are generally the emission control systems selected for very small incineration units.

The EPA does not expect any new VSMWC or IWI units to be built. However, a model plant analysis indicates that total emissions reductions for the nine regulated pollutants that would be achieved by requiring the floor level of control for a new VSMWC unit would range from 2.3 tpy to 67 tpy, depending on the model size and hours of operation. For a new IWI unit, the emissions reductions would range from 2.3 to 34 tpy, depending on the model size and hours of operation. The lower end of each range is based on a model batch unit with the capacity to burn 1 tpd of waste. The upper end of each range is based on an intermittently operated model unit with the capacity to burn 30 tpd for VSMWC units and 15 tpd for IWI units. The size ranges included in the model plant analysis represent the size ranges of units in each subcategory.

Because CAA section 129 requires EPA to establish regulations that are no less stringent than the MACT floor, EPA must require the MACT floor level of control for new VSMWC units and new IWI units regardless of cost. However, model plant cost analyses were conducted for informational purposes. The analyses showed that it is typically less expensive to send waste to a landfill than it is to construct and operate a new VSMWC unit or a new IWI unit. Available information indicates that no new VSMWC or IWI units are being built. The cost impacts of the MACT floor level of control are expected to be minimal, because municipalities and institutions would choose not to construct and operate new VSMWC or IWI units and would select an alternative waste disposal method.

Given that the MACT floors for both the new VSMWC subcategory and the new IWI subcategory of OSWI are based on wet scrubbers, the floor level of control achieves significant emissions reductions, and EPA has not identified any feasible beyond-the-floor alternatives that would achieve greater emissions reductions, EPA has chosen to base the NSPS for both the new VSMWC subcategory and the new IWI subcategory of OSWI on the use of wet scrubbers. The associated emission limits are shown in Tables 3 and 4 of this preamble.

E. How Did EPA Determine the Proposed Emission Limits for Existing OSWI Units?

All standards established pursuant to CAA section 129 must reflect MACT, the maximum degree of reduction in emissions of air pollutants that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for each category. The CAA also specifies that the degree of reduction in emissions that is deemed achievable for existing units must not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category. This requirement constitutes the MACT ''floor'' for existing OSWI units. However, EPA may not consider costs or other impacts in determining the MACT floor. The EPA may require a greater degree of reduction in emissions that is more stringent than the MACT floor (beyond-the-floor) if the Administrator considers the cost, environmental, and energy impacts to be reasonable.

As with new units, EPA considered methods and technologies for removal or destruction of pollutants before combustion. For the same reasons described for new OSWI units, EPA concluded that the MACT floor for existing OSWI units does not include specific source reduction or materials separation requirements. Instead, EPA would require a site-specific waste management plan for each OSWI unit that identifies the feasibility and methods to reduce or separate components of solid waste from the waste stream to reduce toxic emissions from incinerated waste. Waste management plan requirements are discussed in more detail later in this preamble.

In developing the MACT floors and MACT, EPA also considered methods for destruction of pollutants during combustion. The MACT floors and MACT are based on emissions data for well-designed and well-operated combustion units, and the CO emission limits would assure proper operation of the combustor, which minimizes emissions of organic pollutants. Technologies for control of pollutants after combustion were also considered as described in the following discussions of the VSMWC and IWI unit MACT floors and beyond-the-floor alternatives.

For the proposed rules, we determined the existing source MACT floors and MACT separately for two subcategories of OSWI—the VSMWC subcategory and the IWI subcategory. Because there are similarities in unit size, design, and operation between the two subcategories, we request public comment on whether we should combine the two subcategories and determine a single existing source MACT floor and a single set of existing source MACT emission limits for the OSWI category as a whole. If the subcategories were combined, then we would use any available data for OSWI units (regardless of whether they are VSMWC or IWI units) to determine the MACT floor and MACT for the OSWI category.

1. How Did EPA Determine the MACT Floor for Existing OSWI Units?

To determine the MACT floor for existing OSWI units EPA must identify the ''best performing units'' in the category or subcategory. The EPA does not have emissions test data for the units in the OSWI inventory. However, the inventory contains information on air pollution control devices installed on the units. Therefore, information on control devices was used to identify the best performing units in the VSMWC and IWI subcategories and establish the control technology basis of the MACT floors for each. The EPA then determined emissions levels achieved by the MACT floor level of control by using actual emissions test data from similarly controlled incineration units in other source categories, because of the lack of OSWI emissions test data.

Existing VSMWC MACT floor. The inventory of VSMWC units contains 14 units. All of the units for which MACT compliance control information is available report that they are ''afterburner/uncontrolled'' units (*i.e.*, two-chamber units consisting of a primary combustion chamber and an afterburner chamber, but no add-on control devices). However, all conventional two-chamber incineration units use an ''afterburner'' in the second

combustion chamber to ensure complete combustion burn-out. Thus, the use of an afterburner in the second combustion chamber is an integral part of the design and operation of these incinerators and does not represent an additional level of emission control beyond that which is inherent in the basic design and operation of VSMWC units. As a result, for the purposes of assessing the performance of these incineration units, EPA considers them ''uncontrolled.'' For existing VSMWC units, 12 percent of 14 units is two units. Therefore, the average of the best performing two units, or existing source MACT floor, is based on the emission limits achievable by a well-operated, uncontrolled (*i.e.*, afterburner), two-chamber incinerator.

Because there were not any emissions test data available for the actual OSWI units in our inventory, EPA looked to similar source categories for test data. The EPA found test data for small uncontrolled, modular/starved air MWC units that were collected during the MWC regulatory development process. These units are two-chamber units that are the same in design and waste burned as the units within the OSWI category. Therefore, these data were used to establish the MACT floor emission limits. Table 5 of this preamble shows the emission limits associated with the MACT floor for existing VSMWC units.

TABLE 5.—EXISTING VSMWC AND IWI MACT FLOOR EMISSION LIMITS

Pollutant (concentration units @ 7% O_2)	Emission limit
PM (gr/dscf)	0.1
HCl (ppmdv)	500
SO_2 (ppmdv)	200
CO (ppmdv)	50
NO_X (ppmdv)	215
Dioxins/Furans, Total Mass Basis (ng/dscm)	300
Hg (μg/dscm)	500
Cd (μg/dscm)	310
Pb (μg/dscm)	4,300

Existing IWI MACT floor. The IWI inventory contains 358 units. Of these, there is one unit controlled with a medium efficiency wet scrubber. The rest of the IWI units are ''afterburner/uncontrolled'' units (see VSMWC discussion above). Twelve percent of 358 units is 43 units. Therefore, the average of the best performing 12 percent, or MACT floor, is based on the emission limits achievable by a well-operated, uncontrolled, two-chamber incinerator. Because there were not any emissions test data available for the actual OSWI units in our inventory, EPA looked to similar source categories for test data. The EPA found test data for small uncontrolled, modular/starved air MWC units that were collected during the MWC regulatory development process. These units are two-chamber units that are the same in design and waste burned as the units within the OSWI category. Therefore, these data were used to establish the emission limits for uncontrolled units. Table 5 of this preamble shows the emission limits associated with the MACT floor for existing IWI units.

2. How Did EPA Determine Whether Options More Stringent Than the MACT Floor Were Appropriate for Existing OSWI Units?

In determining MACT, CAA section 129 directs EPA to ''* * * require the maximum degree of reduction in emissions * * * that the Administrator, taking into consideration the cost of achieving such emission reduction and any non-air quality health and environmental impacts and energy requirements, determines is achievable. * * *'' The MACT standards may be more stringent than the MACT floor. The MACT floors for both the existing VSMWC subcategory and the existing IWI subcategory of OSWI are based on the emission limits achievable by a well-operated, uncontrolled, two-chamber unit. For existing VSMWC and IWI units, EPA identified one regulatory option beyond the floor: Emission limits based on the use of a wet scrubber. One OSWI unit (an IWI unit) currently uses a wet scrubber, and this control technology could be applied to both IWI and VSMWC units and would substantially reduce emissions. After considering the emission reduction benefits, costs, and other impacts, EPA has decided to base the emission guidelines for the existing VSMWC subcategory and for the existing IWI subcategory of OSWI on the emission limits achievable through the use of a wet scrubber. These emission limits are significantly more stringent than the MACT floors for these subcategories. The EPA expects that the cost impacts of the emission guidelines for existing VSMWC and IWI units would be minimal for reasons described below.

Table 6 of this preamble shows the emission levels associated with the MACT floor for existing VSMWC and IWI units and the wet scrubber beyond-the-floor regulatory option. These emission levels were established from the data described earlier in this preamble. Because the MACT floors for existing VSMWC and IWI are based on units without controls, the emission reduction that would be achieved by requiring existing VSMWC and IWI units to meet the MACT floor is negligible. In contrast, the total emissions reductions for the nine regulated pollutants that would be achieved by requiring any existing units to meet the beyond-the-floor option would range from 2.3 tpy to 67 tpy for a VSMWC model unit and from 2.3 to 34 tpy for an IWI model unit, depending on the unit's capacity and hours of operation. The lower end of each range is based on a model batch unit with a capacity of 1 tpd, and the upper end is based on an intermittently operated model unit with a capacity of 30 tpd for VSMWC units and 15 tpd for IWI units. These represent the size ranges of existing units in each subcategory.

TABLE 6.—EMISSION LEVELS FOR MACT FLOOR AND BEYOND-THE-FLOOR REGULATORY OPTIONS FOR THE EXISTING VSMWC AND IWI SUBCATEGORIES OF OSWI

Pollutant (concentration units @ 7% O_2)	MACT floor emission limit	Emission limit based on wet scrubber
PM (gr/dscf)	0.1	0.013
HCl (ppmdv)	500	3.7
SO_2 (ppmdv)	200	3.1
CO (ppmdv)	50	5.0
NO_X (ppmdv)	215	103
Dioxins/Furans, Total Mass Basis (ng/dscm)	300	33
Hg (μg/dscm)	500	74
Cd (μg/dscm)	310	18
Pb (μg/dscm)	4,300	226

In comparing the cost impacts of the floor and the beyond-the-floor regulatory option, the cost impacts of both options are estimated to be minimal because facilities would elect to use a lower-cost alternative waste disposal method. The EPA analyzed the compliance costs for model existing VSMWC and IWI units for the floor regulatory option, the wet scrubbing regulatory option, and an alternative waste disposal method. The analysis indicates that, even though the floor option is based on units with no control, the cost of meeting emission guidelines based on the MACT floor would be significant, and municipalities and institutions would likely choose to shut down existing VSMWC or IWI units and would instead use alternative waste disposal options such as landfilling or sending their waste to a regional MWC unit that is already subject to the small or large MWC regulations.

The costs of complying with emission guidelines based on the MACT floor would be significant because all emission guidelines developed under

CAA section 129 must include operator training and qualification requirements as well as testing, permitting, monitoring, and reporting requirements. State and Federal plans developed to implement the emission guidelines must also contain these requirements. Even if an existing VSMWC or IWI unit did not need to install air pollution controls to meet the MACT floor emission levels, EPA estimates significant costs to meet all of these other requirements. For example, EPA estimates that operator training, testing, permitting, monitoring, recordkeeping, and reporting costs to comply with the MACT floor option would be over $116,000 per year for an existing VSMWC or IWI unit. This cost is significantly more than the annual cost of operating most VSMWC and IWI units. In fact, it could double, triple, or quadruple the annual costs of an existing VSMWC or IWI unit, depending on its size. The EPA estimates the annual costs of installing and operating a wet scrubber and meeting the training, testing, permitting, monitoring, recordkeeping, and reporting requirements of the emission guidelines would range from $162,000 to $253,000 per year for existing VSMWC units and from $162,000 to $207,000 for existing IWI units, depending on the unit's size and operating schedule. Therefore, the likely response to the emission guidelines (regardless of whether it is based on the floor or the beyond-the-floor option) would be for municipalities and institutions to examine and select alternative waste disposal options.

Information available on the response by existing sources to other CAA section 129 rulemakings indicates that many sources chose to close and rely on alternatives to incineration in managing their solid waste, rather than incur the costs of compliance with the regulation. The EPA anticipates a similar response would appeal to sources subject to OSWI emission guidelines. The model plant analysis indicates that, even in the absence of the emission guidelines, it typically would be less expensive to shut down an incinerator and send waste to a landfill than it would be to continue operating an existing VSMWC or IWI unit. The general findings of this analysis are reinforced by the trend of closure of many units over the past several years. However, EPA realizes that many site-specific factors influence both the cost of operating a specific existing waste combustion unit and the cost of sending the waste to a landfill or other alternative disposal method, and therefore, some facilities may experience a small increase over their current costs by switching to an alternative disposal method. Given the widespread availability of waste disposal alternatives such as landfilling, the trend toward closure of VSMWC and IWI units, the results of the model plant cost analysis, and the response of sources to other CAA section 129 regulations, EPA expects that the cost impacts of the beyond-the-floor option for existing VSMWC and IWI units would be minimal because most municipalities and institutions would choose to shut down their existing VSMWC and IWI units and would select an alternative waste disposal method. Use of an alternative disposal method would result in a negligible increase in costs, and may even result in cost savings for some units.

While EPA's objective is to adopt MACT emission guidelines that fulfill the requirements of CAA section 129 and not to cause the shutdown of most existing VSMWC and IWI units, EPA considers the replacement of poorly controlled incinerators with cost effective alternative disposal techniques that significantly reduce toxic emissions as an appropriate outcome. From a national perspective, emission guidelines for existing VSMWC and IWI units based on the use of wet scrubbing (and the switching to alternative waste disposal options that would result) would minimize emissions of PM, dioxin, acid gases, and metals from VSMWC and IWI units at a relatively low cost, due to the availability of alternative means of waste disposal. As a result, the proposed emission guidelines for both subcategories of OSWI are based on emission limits achievable through the use of wet scrubbers. These emission limits are substantially more stringent than the MACT floors for existing VSMWC and IWI units.

F. How did EPA Determine Testing and Monitoring Requirements for the Proposed Rules?

The EPA determined testing and monitoring requirements for the proposed rules that are consistent with the CAA. Section 129(c) of the CAA requires EPA to develop regulations that include monitoring and testing requirements. The purpose of these requirements is to allow EPA to determine whether a source is operating in compliance with the proposed rules. The proposed monitoring and testing requirements are discussed below.

1. Continuous Emission Monitoring Systems

The most direct means of ensuring compliance with emission limits is the use of continuous emission monitoring systems (CEMS). As a matter of policy, the first and foremost option considered by EPA is to require the use of CEMS to demonstrate continuous compliance with specific emission limits. The EPA considers other options only when CEMS are not available or when the impacts of including such requirements are considered unreasonable.

Continuous emissions monitoring of CO is feasible and is proposed to determine compliance with the CO emission limit and to indicate proper operation of the combustion unit. Monitoring emissions of CO on a continuous basis is the most effective way to ensure that the combustion unit is operating properly. Low CO emissions indicate good combustion, which, in turn, ensures destruction of other pollutants such as organics. In addition, good combustion helps to keep PM emissions lower.

Compliance with the CO emission limit would be determined on a 3-hour rolling average basis using CEMS data. The EPA would require CEMS for CO to ensure proper combustion performance. Data provided by CO CEMS assures EPA and the public that the combustion unit is operating properly.

Continuous emission monitors are not readily available for many of the other pollutants regulated under the proposed rules. For example, CEMS for metals and dioxins/furans are either very expensive or are still being developed. Thus, the proposed rules require monitoring of operating parameters to ensure proper operation of the air pollution control devices.

Although monitoring of operating parameters cannot provide a direct measurement of emissions, it is often a suitable substitute for CEMS. The information provided can be used to ensure that the air pollution control equipment is operating properly. This information reasonably assures EPA and the public that the reductions in acid gases, organic pollutants, metals, and PM envisioned by the regulations are being achieved. The proposed rules include requirements for initial and annual stack testing using EPA methods, coupled with monitoring of operating parameters. The owner or operator of each OSWI unit would use the initial stack test to calibrate the monitoring parameters.

Parameter monitoring is proposed to indicate proper operation of the wet scrubber. Parameter monitoring is

proposed on a rolling 3-hour basis to correspond to the approximate length of the required emission tests. The EPA selected parameters to monitor that indicate the proper operation of a wet scrubber and that can be monitored continuously at a reasonable expense. Maximum or minimum values for the operating parameters must be established during emission testing. For the OSWI unit, the maximum charge rate must be established as the average charge rate during the emission test. Likewise, for the wet scrubber, the minimum operating parameters (*i.e.,* pressure drop or amperage, scrubber liquor flow rate, and scrubber liquor pH) must be established as the average value during the emission test. An owner or operator of OSWI units that chooses to comply with the emission limits using controls other than wet scrubbers would be required to petition the Administrator for approval of alternative operating parameters.

2. Stack Testing

The proposed rules require the owner or operator of each new and existing OSWI unit to perform an initial stack test for emissions of the pollutants identified in CAA section 129 (Cd, CO, dioxins/furans, HCl, Pb, Hg, NO_X, PM, and SO_2), plus an initial opacity test. Additionally, the proposed rules require annual stack tests. The annual testing would ensure, on an ongoing basis, that the air pollution control device is operating properly and its performance has not deteriorated. An average of the results from three test runs would be required to determine compliance with the proposed regulations. The owner or operator would be allowed to skip two annual tests for a pollutant if all three previous annual stack tests show compliance with the emission limit for that pollutant. The EPA considers testing every 3 years sufficient to provide certainty about control device performance while reducing the overall costs of testing to the regulated source.

The emission tests upon which the proposed emission limits are based were conducted using approved EPA test methods. No applicable voluntary consensus standards were identified during the development of the proposed rules. Therefore, EPA proposes that the identified EPA test methods be followed when performing any emission testing required to determine compliance with the emission limits. This requirement would ensure that compliance testing follows the same procedures used to generate the emission data upon which the emission limits in the proposed rules are based.

G. How did EPA Determine Compliance Times for the Proposed Rules?

Section 129(f) of the CAA specifies the dates by which affected or designated facilities must comply with the NSPS or emission guidelines, respectively. New units must be in compliance with the NSPS within 6 months after the date of promulgation or 6 months after start-up, whichever is later. Existing units must be in compliance with the guidelines as expeditiously as practicable after approval of a State plan, but no later than 3 years after the effective date of State plan approval or 5 years after promulgation of the guidelines, whichever is earlier.

The EPA has chosen to include the full compliance time allowed by CAA section 129 in the emission guidelines for OSWI units. The OSWI units are small and are located at small municipalities and institutions that do not always have full-time environmental staff. They will need time to investigate the regulatory, technical, cost, financing, and economic implications of control techniques and alternative waste disposal options available to their facility. The EPA wants to allow sufficient time for owners and operators of OSWI units to investigate, plan, and carry out activities for compliance or, as expected in most cases, a closure of their waste combustion units and an orderly transition to the use of alternative waste disposal methods. State plans or the Federal plan developed to implement the emission guidelines will establish specific compliance schedules within these constraints.

H. How Did EPA Determine the Required Records and Reports for the Proposed Rules?

Section 129 of the CAA requires EPA to develop regulations that include requirements for reporting the results of testing and monitoring performed to determine compliance with the proposed rules. The requirements must specify the form and frequency of the reports demonstrating compliance. If there are no deviations, compliance reports are submitted annually. However, if there is a deviation from any emission limit, operating limit, or other requirement, reports showing the deviation must be submitted separately for review and potential enforcement action. Semiannual reporting of deviations allows both the facility and the enforcement agency to move more quickly to address and correct any possible noncompliance issues. This deviation report is due on August 1 if the deviation occurs during the first 6 months of the year, and February 1 of the next year if the deviation occurs during the second 6 months of the year. Other types of records are necessary to ensure that all provisions of the proposed rules are being met. Examples include siting analyses for new OSWI units and operator training and qualification records for new and existing OSWI units.

Copies of testing and monitoring results and other records must be maintained by the affected facility for 5 years. Records must be kept on site for the first 2 years, but can be maintained off site for the remaining 3 years. To reduce the storage burden, records can be maintained in hard copy or in electronic format.

I. How Did EPA Determine Operator Training and Qualification Requirements for the Proposed Rules?

The proposed rules include operator training and qualification requirements for OSWI unit operators, as required by CAA section 129(d). These requirements provide flexibility by allowing State-approved training and qualification programs. Where there are no State-approved programs, the proposed rules include minimum requirements for training and qualification. The minimum requirements include completion of a training course covering specified topics, plus annual review or a refresher course.

J. How Did EPA Determine the Waste Management Plan Requirements for the Proposed Rules?

The proposed rules require owners or operators of new or existing OSWI units to submit a waste management plan. Each facility is unique, and site-specific strategies are needed to achieve the most efficient results. Through the development of individual waste management programs, owners or operators of OSWI units may be able to reduce or eliminate certain materials in their waste streams, thereby reducing the amount of air pollution emissions associated with waste incineration.

The waste management plan would identify both the feasibility and the approach to reduce or separate certain materials from the waste stream to reduce the amount of toxic emissions from incinerated waste. The waste management plan may include the reduction or separation of waste stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan should identify any additional waste management measures that are practical and feasible, taking into account the

effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other associated environmental or energy impacts.

K. How Did EPA Determine the Siting Requirements for New Units for the Proposed Rules?

Section 129 of the CAA states that standards for new solid waste incineration units must incorporate siting requirements that minimize, on a site-specific basis and to the maximum extent practicable, potential risks to public health or the environment. In accordance with CAA section 129, EPA is proposing site selection criteria for OSWI units that commence construction after the date of proposal (*i.e.,* ''new'' units). The siting requirements would not apply to existing OSWI units.

The siting requirements would require you (the owner or operator of a new OSWI unit) to prepare an analysis of the impacts of the new unit. You must consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, you may consider costs, energy impacts, non-air environmental impacts, or any other factors related to the practicability of the alternatives. To avoid duplication, analyses of facility impacts prepared to comply with State, local, or other Federal regulatory requirements may be used to satisfy this requirement, provided they include the consideration of air pollution control alternatives specified above. Such State, local, or Federal requirements may include, but are not limited to, State-specific criteria or national criteria established by the National Environmental Policy Act or new source permitting requirements. You would be required to submit the siting information to EPA prior to commencing construction of the OSWI unit.

V. Impacts of the Proposed Rules for New Units

Information provided to EPA indicates that no or negative growth has been the trend for OSWI units for the past several years. The information indicates that this trend is expected to continue even in the absence of a regulation. Furthermore, as experience with other CAA section 129 regulations has shown, sources would likely respond to the proposed rules by choosing not to construct new waste incineration units and would utilize alternative waste disposal options rather than incur the costs of compliance.

Considering this information, EPA does not anticipate any new OSWI units, and therefore, no impacts of the proposed NSPS for new units. However, for the sake of demonstrating that emissions reductions would result from the NSPS in the unlikely event that a new unit is constructed, EPA has presented emissions reductions expected for each of the four OSWI model plants.

A. What Are the Air Impacts?

The EPA estimated emissions reductions for each of the model plants to demonstrate that the NSPS would, if a new unit were built, reduce emissions compared to an uncontrolled OSWI unit. Based on available information and past experience, EPA does not anticipate any new OSWI units to be constructed. Table 7 of this preamble presents the emissions reductions for the OSWI model plants. The same model plants are used to represent IWI units and VSMWC units. The first three model plants (with capacities of 1 tpd, 5 tpd, and 15 tpd) represent typical IWI units. All four models represent typical VSMWC units.

TABLE 7.—EMISSIONS REDUCTIONS ON A MODEL PLANT BASIS

Pollutant	Emission reduction for OSWI model plants (tpy)			
	1 tpd capacity	5 tpd 15 capacity	15 tpd capacity	30 tpd capacity
Cd	3.8×10^{-41}	1.9×10^{-31}	5.7×10^{-31}	1.1×10^{-21}
CO	9.0×10^{-21}	0.4	1.0	2.0
Dioxins/furans	3.6×10^{-71}	$1.7\text{x}10^{-61}$	5.2×10^{-61}	$1.0\text{x}10^{-51}$
HCl	1.0	4.9	15	29
Pb	9.7×10^{-31}	2.9×10^{-21}	7.6×10^{-21} 0.2	
Hg	4.0×10^{-41}	2.7×10^{-31}	8.2×10^{-31}	1.6×10^{-21}
NO_X	0.2	1.3	4.1	8.2
PM	0.3	1.3	3.8	7.7
SO_2	0.7	3.3	10	20
Total	2.3	11	34	67

B. What Are the Water and Solid Waste Impacts?

The EPA does not anticipate any new OSWI units to be constructed, and, therefore, does not expect there to be any water or solid waste impacts associated with the proposed NSPS.

C. What Are the Energy Impacts?

The EPA does not anticipate any new OSWI units to be constructed, and, therefore, does not expect there to be any energy impacts associated with the proposed NSPS.

D. What Are the Cost and Economic Impacts?

The EPA does not anticipate any new OSWI units to be constructed, and, therefore, does not expect there to be any cost and economic impacts associated with the proposed NSPS.

VI. Impacts of the Proposed Rules for Existing Units

Information provided to EPA indicates that many existing OSWI units have closed in recent years. The information indicates that this trend is expected to continue even in the absence of a regulation. Furthermore, as experience with other CAA section 129 regulations has shown, sources would likely respond to the proposed rules by choosing to shut down existing waste incineration units and Would utilize alternative waste disposal options rather than incur the costs of compliance.

The EPA's objective is not to encourage the use of alternatives or to discourage continued use of VSMWC units or IWI units; EPA's objective is to adopt emission guidelines for existing

OSWI units that fulfill the requirements of CAA section 129. In doing so the primary outcome associated with adoption of these emission guidelines is projected to be an increase in the use of alternative waste disposal and a decrease in the use of VSMWC units and IWI units. Consequently, EPA acknowledges and incorporates this outcome into the analyses of cost, environmental, and energy impacts associated with the emission guidelines.

A. What Are the Air Impacts?

The EPA estimated emissions reductions for each of the model plants to demonstrate that the emission guidelines reduce emissions compared to an uncontrolled OSWI unit. These emissions reductions are based on installation of a wet scrubber to meet the emission guidelines. Table 7 of this preamble presents the emissions reductions for the OSWI model plants used to represent typical VSMWC units and IWI units. Table 8 of this preamble presents estimated national emissions reductions for each pollutant if all VSMWC and IWI units in the OSWI inventory comply with the emission guidelines. As shown, total emissions reductions would be over 2,750 tpy. However, based on the information and past experience, EPA anticipates that most existing OSWI units would elect to shut down and utilize alternative waste disposal options (*e.g.,* send waste to a landfill or a large or small MWC unit). If OSWI units close and the waste is sent to a landfill, the emissions reductions of the nine pollutants would be slightly greater than shown on Tables 7 and 8 of this preamble. If all OSWI units close and the waste is landfilled, the estimated national emissions reductions would be approximately 428 tpy for VSMWC units and 2,680 tpy for IWI units, which totals over 3,100 tpy for all OSWI units.

TABLE 8.—NATIONAL EMISSIONS REDUCTIONS IF ALL EXISTING OSWI UNITS COMPLY WITH THE EMISSION GUIDELINES

Pollutant	Emission reduction (tpy)		
	VSMWC	IWI	Total
Cd	0.1	0.4	0.5
CO	11	71	83
Dioxins/furans,	5.8E–05	3.6E–04	4.2E–04
HCl	163	1,024	1,187
Pb	1	6	6
Hg	0.1	1	1
NO_X	46	292	338
PM	43	271	314
SO_2	114	714	828
Total	379	2,378	2,757

B. What Are the Water and Solid Waste Impacts?

The EPA anticipates that very few, if any existing OSWI facilities would elect to continue to operate their OSWI units, and that they would use an alternative waste disposal method. As a result, EPA does not anticipate significant water impacts due to increased use of wet scrubbers. In the cases where the OSWI facility elects to comply with the emission guidelines and installs and operates a wet scrubber, it would have an increase in water usage and waste water generation. However, due to the small size of these units (and that there will likely be very few of them continuing to operate), the water impacts would be negligible.

Because most, if not all, of the existing OSWI units would shut down and the waste would be disposed of in alternate ways, EPA anticipates that there could be solid waste impacts of the OSWI regulation. These impacts would be the result of institutional waste or municipal solid waste that otherwise would have been burned in an OSWI unit being diverted to a nearby landfill or to a small or large MWC unit. However, OSWI units are small units with small annual waste throughput. The EPA estimates that the national OSWI population is used to dispose of approximately 85,000 tpy of solid waste. Considering that over 100 million tpy of municipal waste is disposed of in landfills, the amount of additional waste that would be sent to landfills due to adoption of the emission guidelines is insignificant.

C. What Are the Energy Impacts?

The EPA anticipates that very few, if any existing OSWI facilities would elect to continue to operate their OSWI units, and that they would use an alternative waste disposal method. As a result, EPA does not anticipate significant energy impacts due to increased use of wet scrubbers. In the cases where the OSWI facility elects to comply with the emission guidelines and installs and operates a wet scrubber, it would have an increase in power consumption. However, due to the small size of these units (and that there will likely be very few of them continuing to operate), the energy impacts would be negligible.

D. What Are the Cost and Economic Impacts?

The EPA's analysis has shown that the national total costs for all existing OSWI units to comply with the emission guidelines (*i.e.,* installing controls, operator training, performance testing, monitoring, etc.) would be approximately $63 million a year.[4] However, the model plant analysis has also shown that alternative disposal options are readily available for institutional and municipal solid waste, and that most existing OSWI sources would incur no additional cost or perhaps a slight savings by shutting down their waste combustion unit and sending the waste to a landfill, or to a small or large MWC unit. However, EPA recognizes that there are many site-specific factors that affect the cost of operating a specific OSWI unit and the cost of alternative disposal methods. Therefore, some facilities may experience a small cost increase if they switch to an alternative disposal method. Nonetheless, as discussed previously, available information

[4] EPA believes that the actual cost of emissions reductions achieved under this rule will be substantially less than the costs associated with the MACT floor and beyond the floor regulatory options suggested by this analysis. This is a result of the finding of our analysis that regulated entities will use landfilling rather than incur the costs associated with rule compliance (*i.e.,* installing scrubbers). Assuming that all regulated entities switch to landfilling, and assuming, for purposes of this analysis only, no cost saving associated with abandonment of incineration, EPA estimates an actual cost of $1,380/ton of emission reduction.

indicates that the OSWI population has been steadily declining over the past several years, and this trend would likely continue in the absence of an OSWI regulation. This trend confirms EPA's analysis that it is often more economical to shut down OSWI units and use an alternative waste disposal method. Because most OSWI units would close and utilize an economical alternative waste disposal method, the cost impacts of the guidelines would be negligible, and some facilities may even experience a small cost savings.

VII. 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 review by OMB and the requirements of the Executive Order. The Executive 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 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.

Pursuant to the terms of Executive Order 12866, it has been determined that the proposed rules are a ''significant regulatory action'' because they raise novel legal or policy issues within the meaning of paragraph (4) above. Consequently, the proposed rules were submitted to OMB for review under Executive Order 12866. Any written comments from OMB and written EPA responses are available in the docket (see **ADDRESSES** section of this preamble).

B. Paperwork Reduction Act

The information collection requirements in the proposed rules have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) documents have been prepared by EPA (ICR No. 2163.01 for subpart EEEE and 2164.01 for subpart FFFF), and copies may be obtained from Susan Auby by mail at the Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460, by e-mail at *auby.susan@epa.gov,* or by calling (202) 566–1672. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.*

The proposed rules contain monitoring, reporting, and recordkeeping requirements. The information would be used by EPA to identify any new, modified, or reconstructed incineration units subject to the NSPS and to ensure that any new incineration units undergo a siting analysis and comply with the emission limits and other requirements. Similarly, the information specified in the emission guidelines would be used by States or EPA to identify existing units subject to the State or Federal plans that implement the emission guidelines, and to ensure that these units comply with their emission limits and other requirements. Records and reports would be necessary to enable EPA or States to identify waste incineration units that may not be in compliance with the requirements. Based on reported information, EPA would decide which units and what records or processes should be inspected.

These recordkeeping and reporting requirements are specifically authorized by CAA section 114 (42 U.S.C. 7414). All information submitted to EPA for which a claim of confidentiality is made will be safeguarded according to EPA policies in 40 CFR part 2, subpart B, Confidentiality of Business Information.

The EPA estimates that there is no burden for the first 3 years after promulgation of the NSPS for industry and the implementing agency. This is because EPA expects no new OSWI units to be constructed over this 3-year period.

The estimated average annual burden for the first 3 years after promulgation of the emission guidelines for industry and the implementing agency is outlined below.

Affected entity	Average annual hours	Labor costs	Capital costs	O&M costs	Total annual costs
Industry	5,704	$262,055	$0	$0	$262,055
Implementing agency	383	17,611	0	0	17,611

The EPA expects the emission guidelines to affect a maximum of 372 OSWI units over the first 3 years. There would be no capital, start-up, or operation and maintenance costs for existing units during the first 3 years, because compliance with the emission guidelines is not required until 5 years after promulgation of the emission guidelines (or 3 years after the effective date of approval of a State or Federal plan to implement the guidelines). Costs in the first 3 years include time to review the guidelines and the State or Federal plan. The implementing agency would not incur any capital or start-up costs.

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 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA

has established a public docket for this ICR under Docket ID No. OAR–2003–0156, which is available for public viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. (OAR–2003–0156) and OMB control number ( ) in any correspondence.

Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 9, 2004, a comment to OMB is best assured of having its full effect if OMB receives it by January 10, 2005. In the final rules, EPA will respond to any OMB or public comments on the information collection requirements contained in the proposed rules.

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of the proposed rules on small entities, small entity is defined as follows:

1. A small business that is an ultimate parent entity in the regulated industry that has a gross annual revenue less than $6.5 million (this varies by industry category, ranging up to $10.5 million for North American Industrial Classification System (NAICS) code 562213 (VSMWC)), based on Small Business Administration's size standards;

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; or

3. A small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of the proposed rules on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The economic impacts on small entities will not be significant because the costs of the proposed rules would be negligible or may actually be cost savings. Ten of the 14 entities that own VSMWC units likely to be affected by the proposed rules are small, and all of these may experience cost savings. It is uncertain how many affected IWI units that are OSWI units are owned by small entities, but it is expected that many of these may realize a cost savings under the likely response to the proposed rules that the EPA believes will occur. Alternative waste disposal methods, such as landfilling, are available. The annual cost of landfilling is typically less expensive than the annual cost of using an OSWI unit for waste disposal. Thus, the likely response to the proposed rules will be for small entities that own and operate OSWI units to close the units and use an alternative waste disposal method. Moreover, EPA believes that most small entities for which this might not be the case are covered by one of the exclusions we have provided and thus are not negatively impacted by the rule. We continue to be interested in the potential impacts of the proposed rules on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act (UMRA) 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 the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the proposed rules. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if EPA publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, EPA must develop a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA's regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that the proposed rules do not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any 1 year. Thus, the proposed rules are not subject to the requirements of section 202 and 205 of the UMRA. In addition, EPA has determined that the proposed rules contain no regulatory requirements that might significantly or uniquely affect small governments because the burden is small and the regulation does not unfairly apply to small governments. Therefore, the proposed rules are not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation 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. Also, EPA 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 proposed regulation.

The proposed rules do not have federalism implications. They will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The proposed rules will not impose substantial direct compliance costs on State or local governments, and will not preempt State law. Thus, Executive Order 13132 does not apply to the proposed rules.

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

Executive Order 13175, (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.'' ''Policies that have Tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

The proposed rules do not have Tribal implications, as specified in Executive Order 13175. They 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 the proposed rules.

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

Executive Order 13045 (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, EPA 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 EPA considered.

The 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 Executive Order has the potential to influence the regulation. The proposed rules are not subject to Executive Order 13045 because they are based on technology performance and not on health and safety risks. Also, the proposed rules are not ''economically significant.''

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution or Use

Executive Order 13211 (66 FR 28355, May 22, 2001) provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, OMB, a Statement of Energy Effects for certain actions identified as ''significant energy actions.'' Section 4(b) of Executive Order 13211 defines ''significant energy actions'' as ''* * * any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. * * *'' Although the proposed rules are considered to be a significant regulatory action under Executive Order 12866, they are not a ''significant energy action'' because they are not likely to have a significant adverse effect on the supply, distribution, or use of energy. The basis for the determination is as follows.

The EPA expects that few, if any, OSWI facilities would elect to continue to operate OSWI units, and that most facilities would respond to the proposed rules by closing existing OSWI units and utilizing alternative waste disposal techniques. This response is likely because the annual cost of landfilling, an alternative waste disposal method, is typically less expensive than the annual cost of using an OSWI unit for waste disposal. In the few cases where an OSWI facility elects to comply with the proposed rules by installing a wet scrubber, the operation of the scrubber would result in a small increase in power consumption. However, due to the small size of these units (and that there will likely be very few of them continuing to operate), the energy impacts would be negligible.

Given the negligible change in energy consumption resulting from the proposed rules, EPA does not expect any price increase for any energy type. The cost of energy distribution should not be affected by the proposed rules at all since the rules would not affect energy distribution facilities. We also expect that there would be no impact on the import of foreign energy supplies, and no other adverse outcomes are expected to occur with regards to energy supplies.

Therefore, EPA concludes that the proposed rules are not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Pub. L. 104–113; 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in their regulatory and procurement 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, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

The proposed rules involve technical standards. The EPA proposes to use EPA Methods 1, 2, 3A, 3B, 4, 5, 6 or 6C, 7 or 7A, 7C, 7D, or 7E, 9, 10, 10A or 10B, 23, 26A, and 29 of 40 CFR part 60, appendix A.

Consistent with the NTTAA, EPA conducted searches to identify voluntary consensus standards in addition to these EPA methods. No applicable voluntary consensus standards were identified for EPA Methods 7D, 9, and 10A. The search and review results have been documented and are placed in the docket for the proposed rules.

One voluntary consensus standard was identified as an acceptable alternative to EPA test methods for the purposes of the proposed rules. The voluntary consensus standard ASME PTC 19–10–1981–Part 10, ''Flue and Exhaust Gas Analyses,'' is cited in the proposed rules for its manual methods for measuring the nitrogen oxide, oxygen, and sulfur dioxide content of exhaust gas. These parts of ASME PTC 19–10–1981–Part 10 are acceptable alternatives to Methods 3B, 6, 7, and 7C.

The search for emissions measurement procedures identified 29 voluntary consensus standards applicable to the proposed rules. The EPA determined these 29 standards identified for measuring emissions of Cd, CO, dioxins/furans, HCl, Hg, Pb, PM, NO_X, and SO_2 subject to the emission limits were impractical alternatives to EPA test methods for the purposes of the proposed rules. Therefore, EPA does not intend to adopt the standards for this purpose. (*See* Docket ID No. OAR–2003–0156 for further information on the methods.)

Four of the 29 voluntary consensus standards identified in this search were not available at the time the review was conducted because they are under development by a voluntary consensus body: ASME/BSR MFC 13M, ''Flow Measurement by Velocity Traverse,'' for EPA Method 2 (and possibly 1); ASME/BSR MFC 12M, ''Flow in Closed Conduits Using Multiport Averaging Pitot Primary Flowmeters,'' for EPA Method 2; ISO/DIS 12039, ''Stationary Source Emissions-Determination of Carbon Monoxide, Carbon Dioxide, and Oxygen-Automated Methods' for EPA Method 3A; and ASTM Z6590Z, ''Manual Method for Both Speciated and Elemental Mercury'' for EPA Method 29 (portion for Hg only).

Tables 1 and 3 of subpart EEEE of 40 CFR part 60 and tables 2 and 4 of subpart FFFF of 40 CFR part 60 list the EPA testing methods included in the proposed rules. Under 40 CFR 60.8(b) and 60.13(i) of subpart A (General Provisions), a source may apply to EPA for permission to use alternative test methods or alternative monitoring requirements in place of any of the EPA testing methods, performance specifications, or procedures.

List of Subjects in 40 CFR Part 60

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

Dated: November 30, 2004.

Michael O. Leavitt,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 60—[AMENDED]

1. The authority citation for part 60 continues to read as follows:

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

Subpart A—[Amended]

2. Section 60.17 is amended by adding paragraph (h)(4) to read as follows:

§ 60.17 Incorporation by Reference.

* * * * *

(h) * * *

(4) ASME PTC 19–10–1981–Part 10, Flue and Exhaust Gas Analyses (manual methods for measuring nitrogen oxide, oxygen, and sulfur dioxide content only), IBR approved for Tables 1 and 3 of subpart EEEE, and Tables 2 and 4 of subpart FFFF of this part.

3. Part 60 is amended by adding subpart EEEE to read as follows:

Subpart EEEE—Standards of Performance for Other Solid Waste Incineration Units for Which Construction Is Commenced After December 9, 2004, or for Which Modification or Reconstruction Is Commenced on or After [Date 6 Months After Date Final Rule is Published in the *Federal Register*].

Introduction

Sec.

60.2880 What does this subpart do?

60.2881 When does this subpart become effective?

Applicability

60.2885 Does this subpart apply to my incineration unit?

60.2886 What is a new incineration unit?

60.2887 What combustion units are excluded from this subpart?

60.2888 Are air curtain incinerators regulated under this subpart?

60.2889 Who implements and enforces this subpart?

60.2890 How are these new source performance standards structured?

60.2891 Do all components of these new source performance standards apply at the same time?

Preconstruction Siting Analysis

60.2894 Who must prepare a siting analysis?

60.2895 What is a siting analysis?

Waste Management Plan

60.2899 What is a waste management plan?

60.2900 When must I submit my waste management plan?

60.2901 What should I include in my waste management plan?

Operator Training and Qualification

60.2905 What are the operator training and qualification requirements?

60.2906 When must the operator training course be completed?

60.2907 How do I obtain my operator qualification?

60.2908 How do I maintain my operator qualification?

60.2909 How do I renew my lapsed operator qualification?

60.2910 What site-specific documentation is required?

60.2911 What if all the qualified operators are temporarily not accessible?

Emission Limitations and Operating Limits

60.2915 What emission limitations must I meet and by when?

60.2916 What operating limits must I meet and by when?

60.2917 What if I do not use a wet scrubber to comply with the emission limitations?

60.2918 What happens during periods of startup, shutdown, and malfunction?

Performance Testing

60.2922 How do I conduct the initial and annual performance test?

60.2923 How are the performance test data used?

Initial Compliance Requirements

60.2927 How do I demonstrate initial compliance with the emission limitations and establish the operating limits?

60.2928 By what date must I conduct the initial performance test?

Continuous Compliance Requirements

60.2932 How do I demonstrate continuous compliance with the emission limitations and the operating limits?

60.2933 By what date must I conduct the annual performance test?

60.2934 May I conduct performance testing less often?

60.2935 May I conduct a repeat performance test to establish new operating limits?

Monitoring

60.2939 What continuous emission monitoring systems must I install?

60.2940 How do I make sure my continuous emission monitoring systems are operating correctly?

60.2941 What is my schedule for evaluating continuous emission monitoring systems?

60.2942 What is the minimum amount of monitoring data I must collect with my continuous emission monitoring

Introduction

§ 60.2880 What does this subpart do?

This subpart establishes new source performance standards for other solid waste incineration (OSWI) units. Other solid waste incineration units are very small municipal waste combustion units and institutional waste incineration units.

§ 60.2881 When does this subpart become effective?

This subpart takes effect 6 months after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**]. Some of the requirements in this subpart apply to planning the OSWI unit and must be completed even before construction is initiated on the OSWI unit (*i.e.*, the preconstruction requirements in §§ 60.2894 and 60.2895). Other requirements such as the emission limitations and operating limits apply when the OSWI unit begins operation.

Applicability

§ 60.2885 Does this subpart apply to my incineration unit?

Yes, if your incineration unit meets all the requirements specified in paragraphs (a) through (c) of this section.

(a) Your incineration unit is a new incineration unit as defined in § 60.2886.

(b) Your incineration unit is an OSWI unit as defined in § 60.2977. Other solid waste incineration units are very small municipal waste combustion units and institutional waste incineration units as defined in § 60.2977.

(c) Your incineration unit is not excluded under § 60.2887.

§ 60.2886 What is a new incineration unit?

(a) A new incineration unit is an incineration unit that meets either of the two criteria specified in paragraph (a)(1) or (2) of this section.

(1) Commenced construction after December 9, 2004.

(2) Commenced reconstruction or modification on or after [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(b) This subpart does not affect your incineration unit if you make physical or operational changes to your incineration unit primarily to comply with the emission guidelines in subpart FFFF of this part. Such changes do not qualify as reconstruction or modification under this subpart.

§ 60.2887 What combustion units are excluded from this subpart?

This subpart excludes the types of units described in paragraphs (a) through (p) of this section, as long as you meet the requirements of this section.

(a) *Cement kilns.* Your unit is excluded if it is regulated under subpart LLL of part 63 of this chapter (National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry).

(b) *Co-fired combustors.* Your unit, that would otherwise be considered a very small municipal waste combustion unit, is excluded if you meet four requirements:

(1) Your unit has a Federally enforceable permit limiting the combustion of municipal solid waste to 30 percent of the total fuel input by weight.

(2) You notify the Administrator that the unit qualifies for the exclusion.

(3) You provide the Administrator with a copy of the Federally enforceable permit.

(4) You record the weights, each calendar quarter, of municipal solid waste and of all other fuels combusted.

(c) *Cogeneration facilities.* Your unit is excluded if it meets the three requirements specified in paragraphs (c)(1) through (3) of this section.

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)).

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes.

(3) You notify the Administrator that the unit meets all of these criteria.

(d) *Commercial and industrial solid waste incineration units.* Your unit is excluded if it is regulated under subparts CCCC or DDDD of this part and is required to meet the emission limitations established in those subparts.

(e) *Hazardous waste combustion units.* Your unit is excluded if it meets either of the two criteria specified in paragraph (e)(1) or (2) of this section.

(1) You are required to get a permit for your unit under section 3005 of the Solid Waste Disposal Act.

(2) Your unit is regulated under 40 CFR part 63, subpart EEE (National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors).

(f) *Hospital/medical/infectious waste incinerators.* Your unit is excluded if it is regulated under subparts Ce or Ec of this part (New Source Performance Standards and Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators).

(g) *Incinerators and air curtain incinerators in isolated areas of Alaska.* Your incineration unit is excluded if it is used at a solid waste disposal site in Alaska that is classified as a Class II or Class III municipal solid waste landfill, as defined in § 60.2977.

(h) *Rural institutional waste incinerators.* Your incineration unit is excluded if it is an institutional waste incinerator, as defined in § 60.2977, and located more than 50 miles from the boundary of the nearest Metropolitan Statistical Area.

(i) *Institutional boilers and process heaters.* Your unit is excluded if it is regulated under 40 CFR part 63, subpart DDDDD (National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters).

(j) *Laboratory Analysis Units.* Your unit is excluded if it burns samples of materials only for the purpose of chemical or physical analysis.

(k) *Materials recovery units.* Your unit is excluded if it combusts waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(l) *Pathological waste incineration units.* Your institutional waste incineration unit or very small municipal waste combustion unit is excluded from this subpart if it burns 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.2977 and you notify the Administrator that the unit meets these criteria.

(m) *Small or large municipal waste combustion units.* Your unit is excluded if it is regulated under subparts AAAA, BBBB, Ea, Eb, or Cb, of this part and is required to meet the emission limitations established in those subparts.

(n) *Small power production facilities.* Your unit is excluded if it meets the three requirements specified in paragraphs (n)(1) through (3) of this section.

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)).

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity.

(3) You notify the Administrator that the unit meets all of these criteria.

(o) *Temporary-use incinerators used in disaster recovery.* Your incinerator is excluded if it is used on a temporary basis to combust debris from a disaster or emergency such as a tornado, hurricane, flood, or act of bioterrorism and you comply with the requirements in § 60.2969.

(p) *Units that combust contraband or prohibited goods.* Your unit is excluded if the unit is used by a government agency such as police, customs, agricultural inspection, or a similar agency to destroy only illegal or prohibited goods such as illegal drugs, or agricultural food products that can not be transported into the country or across state lines to prevent biocontamination.

§ 60.2888 Are air curtain incinerators regulated under this subpart?

(a) Air curtain incinerators that burn less than 35 tons per day of municipal solid waste or air curtain incinerators located at institutional facilities burning any amount of institutional waste generated at that facility are subject to all requirements of this subpart, including the emission limitations specified in Table 1 of this subpart.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (4) of this section must meet only the requirements in §§ 60.2970 through 60.2974 and the title V operating permit requirements of §§ 60.2966 and 60.2967, and are exempt from all other requirements of this subpart.

(1) 100 percent wood waste.

(2) 100 percent clean lumber.

(3) 100 percent yard waste.

(4) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2889 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by the U.S. Environmental Protection Agency (EPA), or a delegated authority such as your State, local, or tribal agency. If the EPA Administrator has delegated authority to your State, local, or tribal agency, then that agency (as well as EPA) has the authority to implement and enforce this subpart. You should contact your EPA Regional Office to find out if this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency, the authorities contained in paragraphs (b)(1) through (6) of this section are retained by the EPA Administrator and are not transferred to the State, local, or tribal agency.

(1) Approval of alternatives to the emission limitations in Table 1 of this subpart and operating limits established under § 60.2916 and Table 2 of this subpart.

(2) Approval of petitions for specific operating limits in § 60.2917.

(3) Approval of major alternatives to test methods.

(4) Approval of major alternatives to monitoring.

(5) Approval of major alternatives to recordkeeping and reporting.

(6) The status report requirements in § 60.2911(c)(2).

§ 60.2890 How are these new source performance standards structured?

These new source performance standards contain nine major components, as follows:

(a) Preconstruction siting analysis.

(b) Waste management plan.

(c) Operator training and qualification.

(d) Emission limitations and operating limits.

(e) Performance testing.

(f) Initial compliance requirements.

(g) Continuous compliance requirements.

(h) Monitoring.

(i) Recordkeeping and reporting.

§ 60.2891 Do all components of these new source performance standards apply at the same time?

No, you must meet the preconstruction siting analysis and waste management plan requirements before you commence construction of the OSWI unit. The operator training and qualification, emission limitations, operating limits, performance testing and compliance, monitoring, and most recordkeeping and reporting requirements are met after the OSWI unit begins operation.

Preconstruction Siting Analysis

§ 60.2894 Who must prepare a siting analysis?

(a) You must prepare a siting analysis if you commence construction of an

OSWI unit after [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(b) If you commence construction of your OSWI unit after December 9, 2004, but before [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], you are not required to prepare the siting analysis specified in this subpart.

(c) You must prepare a siting analysis if you are required to submit an initial application for a construction permit under 40 CFR part 51, subpart I, or 40 CFR part 52, as applicable, for the reconstruction or modification of your OSWI unit.

§ 60.2895 What is a siting analysis?

(a) The siting analysis must consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, you may consider costs, energy impacts, nonair environmental impacts, or any other factors related to the practicability of the alternatives.

(b) Analyses of your OSWI unit's impacts that are prepared to comply with State, local, or other Federal regulatory requirements may be used to satisfy the requirements of this section, provided they include the consideration of air pollution control alternatives specified in paragraph (a) of this section.

(c) You must complete and submit the siting requirements of this section as required under § 60.2952(c) prior to commencing construction.

Waste Management Plan

§ 60.2899 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.2900 When must I submit my waste management plan?

You must submit a waste management plan prior to commencing construction.

§ 60.2901 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures and implement those measures the source considers practical and feasible, considering the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Operator Training and Qualification

§ 60.2905 What are the operator training and qualification requirements?

(a) No OSWI unit can be operated unless a fully trained and qualified OSWI unit operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified OSWI unit operator may operate the OSWI unit directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified OSWI unit operators are temporarily not accessible, you must follow the procedures in § 60.2911.

(b) Operator training and qualification must be obtained through a State-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section.

(1) Training on the thirteen subjects listed in paragraphs (c)(1)(i) through (xiii) of this section.

(i) Environmental concerns, including types of emissions.

(ii) Basic combustion principles, including products of combustion.

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures.

(iv) Combustion controls and monitoring.

(v) Operation of air pollution control equipment and factors affecting performance (if applicable).

(vi) Inspection and maintenance of the incinerator and air pollution control devices.

(vii) Methods to monitor pollutants (including monitoring of incinerator and control device operating parameters) and monitoring equipment calibration procedures, where applicable.

(viii) Actions to correct malfunctions or conditions that may lead to malfunction.

(ix) Bottom and fly ash characteristics and handling procedures.

(x) Applicable Federal, State, and local regulations, including Occupational Safety and Health Administration workplace standards.

(xi) Pollution prevention.

(xii) Waste management practices.

(xiii) Recordkeeping requirements.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that may serve as reference material following completion of the course.

§ 60.2906 When must the operator training course be completed?

The operator training course must be completed by the latest of the three dates specified in paragraphs (a) through (c) of this section.

(a) Six months after your OSWI unit startup.

(b) One year after [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(c) The date before an employee assumes responsibility for operating the OSWI unit or assumes responsibility for supervising the operation of the OSWI unit.

§ 60.2907 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.2905(c).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.2905(c)(2).

§ 60.2908 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section.

(a) Update of regulations.

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling.

(c) Inspection and maintenance.

(d) Responses to malfunctions or conditions that may lead to malfunction.

(e) Discussion of operating problems encountered by attendees.

§ 60.2909 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section.

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.2908.

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.2907(a).

§ 60.2910 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all OSWI unit operators that addresses the nine topics described in paragraphs (a)(1) through (9) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request.

(1) Summary of the applicable standards under this subpart.

(2) Procedures for receiving, handling, and charging waste.

(3) Incinerator startup, shutdown, and malfunction procedures.

(4) Procedures for maintaining proper combustion air supply levels.

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart.

(6) Monitoring procedures for demonstrating compliance with the operating limits established under this subpart.

(7) Reporting and recordkeeping procedures.

(8) The waste management plan required under §§ 60.2899 through 60.2901.

(9) Procedures for handling ash.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator.

(1) The initial review of the information listed in paragraph (a) of this section must be conducted by [6 months after the effective date of this subpart] or prior to an employee's assumption of responsibilities for operation of the OSWI unit, whichever date is later.

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted not later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section.

(1) Records showing the names of OSWI unit operators who have completed review of the information in paragraph (a) of this section as required by paragraph (b) of this section, including the date of the initial review and all subsequent annual reviews.

(2) Records showing the names of the OSWI operators who have completed the operator training requirements under § 60.2905, met the criteria for qualification under § 60.2907, and maintained or renewed their qualification under § 60.2908 or § 60.2909. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.2911 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.*, not at the facility and not able to be at the facility within 1 hour), you must meet one of the three criteria specified in paragraphs (a) through (c) of this section, depending on the length of time that a qualified operator is not accessible.

(a) When all qualified operators are not accessible for 12 hours or less, the OSWI unit may be operated by other plant personnel familiar with the operation of the OSWI unit who have completed review of the information specified in § 60.2910(a) within the past 12 months. You do not need to notify the Administrator or include this as a deviation in your annual report.

(b) When all qualified operators are not accessible for more than 12 hours, but less than 2 weeks, the OSWI unit may be operated by other plant personnel familiar with the operation of the OSWI unit who have completed a review of the information specified in § 60.2910(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.2956.

(c) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (c)(1) and (2) of this section.

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible.

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the Administrator to continue operation of the OSWI unit. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (c)(1) of this section. If the Administrator notifies you that your request to continue operation of the OSWI unit is disapproved, the OSWI unit may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (c)(2)(i) and (ii) of this section.

(i) A qualified operator is accessible as required under § 60.2905(a).

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Emission Limitations and Operating Limits

§ 60.2915 What emission limitations must I meet and by when?

You must meet the emission limitations specified in Table 1 of this subpart 60 days after your OSWI unit reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

§ 60.2916 What operating limits must I meet and by when?

(a) If you use a wet scrubber to comply with the emission limitations, you must establish operating limits for four operating parameters (as specified in Table 2 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test.

(1) Maximum charge rate, calculated using one of the two different procedures in paragraphs (a)(1)(i) or (ii) of this section, as appropriate.

(i) For continuous and intermittent units, maximum charge rate is the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(ii) For batch units, maximum charge rate is the charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet scrubber, which is calculated as the average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(3) Minimum scrubber liquor flow rate, which is calculated as the average liquor flow rate at the inlet to the wet scrubber measured during the most recent performance test demonstrating

compliance with all applicable emission limitations.

(4) Minimum scrubber liquor pH, which is calculated as the average liquor pH at the inlet to the wet scrubber measured during the most recent performance test demonstrating compliance with the HCl and SO_2 emission limitation.

(b) You must meet the operating limits established during the initial performance test 60 days after your OSWI unit reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

§ 60.2917 What if I do not use a wet scrubber to comply with the emission limitations?

If you use an air pollution control device other than a wet scrubber or limit emissions in some other manner to comply with the emission limitations under § 60.2915, you must petition the Administrator for specific operating limits, the values of which are to be established during the initial performance test and then continuously monitored thereafter. You must not conduct the initial performance test until after the petition has been approved by the Administrator. Your petition must include the five items listed in paragraphs (a) through (e) of this section.

(a) Identification of the specific parameters you propose to use as operating limits.

(b) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters, and how limits on these parameters will serve to limit emissions of regulated pollutants.

(c) A discussion of how you will establish the upper and/or lower values for these parameters that will establish the operating limits on these parameters.

(d) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments.

(e) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

§ 60.2918 What happens during periods of startup, shutdown, and malfunction?

The emission limitations and operating limits apply at all times except during OSWI unit startups, shutdowns, or malfunctions.

Performance Testing

§ 60.2922 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) All performance tests must be conducted using the methods in Table 1 of this subpart.

(c) All performance tests must be conducted using the minimum run duration specified in Table 1 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method.

(f) Adjust all pollutant concentrations, except for opacity, to 7 percent oxygen using Equation 1 in § 60.2975.

§ 60.2923 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in Table 1 of this subpart.

Initial Compliance Requirements

§ 60.2927 How do I demonstrate initial compliance with the emission limitations and establish the operating limits?

You must conduct an initial performance test, as required under § 60.8, to determine compliance with the emission limitations in Table 1 of this subpart and to establish operating limits using the procedure in § 60.2916 or § 60.2917. The initial performance test must be conducted using the test methods listed in Table 1 of this subpart and the procedures in § 60.2922.

§ 60.2928 By what date must I conduct the initial performance test?

The initial performance test must be conducted within 60 days after your OSWI unit reaches the charge rate at which it will operate, but no later than 180 days after its initial startup.

Continuous Compliance Requirements

§ 60.2932 How do I demonstrate continuous compliance with the emission limitations and the operating limits?

(a) You must conduct an annual performance test for all of the pollutants in Table 1 of this subpart for each OSWI unit to determine compliance with the emission limitations. The annual performance test must be conducted using the test methods listed in Table 1 of this subpart and the procedures in § 60.2922.

(b) You must continuously monitor carbon monoxide emissions to determine compliance with the carbon monoxide emissions limitation. Three-hour rolling average values are used to determine compliance. Operation above the carbon monoxide emission limit in Table 1 constitutes a deviation from the emission limitation.

(c) You must continuously monitor the operating parameters specified in § 60.2916 or established under § 60.2917. Operation above the established maximum or below the established minimum operating limits constitutes a deviation from the established operating limits. Three-hour rolling average values are used to determine compliance unless a different averaging period is established under § 60.2917. Operating limits do not apply during performance tests.

§ 60.2933 By what date must I conduct the annual performance test?

You must conduct annual performance tests within 12 months following the initial performance test. Conduct subsequent annual performance tests within 12 months following the previous one.

§ 60.2934 May I conduct performance testing less often?

(a) You can test less often for a given pollutant if you have test data for at least three consecutive annual tests, and all performance tests for the pollutant over that period show that you comply with the emission limitation. In this case, you do not have to conduct a performance test for that pollutant for the next 2 years. You must conduct a performance test during the third year and no more than 36 months following the previous performance test.

(b) If your OSWI unit continues to meet the emission limitation for the pollutant, you may choose to conduct performance tests for that pollutant every third year, but each test must be within 36 months of the previous performance test.

(c) If a performance test shows a deviation from an emission limitation for any pollutant, you must conduct annual performance tests for that pollutant until three consecutive annual performance tests for that pollutant all show compliance.

§ 60.2935 May I conduct a repeat performance test to establish new operating limits?

Yes, you may conduct a repeat performance test at any time to establish new values for the operating limits. The

Administrator may request a repeat performance test at any time.

Monitoring

§ 60.2939 What continuous emission monitoring systems must I install?

(a) You must install, calibrate, maintain, and operate continuous emission monitoring systems for carbon monoxide and for oxygen. You must monitor the oxygen concentration at each location where you monitor carbon monoxide.

(b) You must install, evaluate, and operate each continuous emission monitoring system according to the ''Monitoring Requirements'' in § 60.13.

§ 60.2940 How do I make sure my continuous emission monitoring systems are operating correctly?

(a) Conduct initial, daily, quarterly, and annual evaluations of your continuous emission monitoring systems that measure carbon monoxide and oxygen.

(b) Complete your initial evaluation of the continuous emission monitoring systems within 60 days after your OSWI unit reaches the maximum load level at which it will operate, but no later than 180 days after its initial startup.

(c) For initial and annual evaluations, collect data concurrently (or within 30 to 60 minutes) using your carbon monoxide and oxygen continuous emission monitoring systems. To validate carbon monoxide concentration levels, use EPA Method 10, 10A, or 10B of appendix A of this part. Use EPA Method 3 or 3A to measure oxygen. Collect the data during each initial and annual evaluation of your continuous emission monitoring systems following the applicable performance specifications in appendix B of this part. Table 3 of this subpart shows the required span values and performance specifications that apply to each continuous emission monitoring system.

(d) Follow the quality assurance procedures in Procedure 1 of appendix F of this part for each continuous emission monitoring system. The procedures include daily calibration drift and quarterly accuracy determinations.

§ 60.2941 What is my schedule for evaluating continuous emission monitoring systems?

(a) Conduct annual evaluations of your continuous emission monitoring systems no more than 12 months after the previous evaluation was conducted.

(b) Evaluate your continuous emission monitoring systems daily and quarterly as specified in appendix F of this part.

§ 60.2942 What is the minimum amount of monitoring data I must collect with my continuous emission monitoring systems, and is the data collection requirement enforceable?

(a) Where continuous emission monitoring systems are required, obtain 1-hour arithmetic averages. Make sure the averages for carbon monoxide are in parts per million by dry volume at 7 percent oxygen. Use the 1-hour averages of oxygen data from your continuous emission monitoring system to determine the actual oxygen level and to calculate emissions at 7 percent oxygen.

(b) Obtain at least two data points per hour in order to calculate a valid 1-hour arithmetic average. Section 60.13(e)(2) requires your continuous emission monitoring systems to complete at least one cycle of operation (sampling, analyzing, and data recording) for each 15-minute period.

(c) Obtain valid 1-hour averages for at least 75 percent of the operating hours per day for at least 90 percent of the operating days per calendar quarter. An operating day is any day the unit combusts any municipal or institutional solid waste.

(d) If you do not obtain the minimum data required in paragraphs (a) through (c) of this section, you have deviated from the data collection requirement regardless of the emission level monitored.

(e) If you do not obtain the minimum data required in paragraphs (a) through (c) of this section, you must still use all valid data from the continuous emission monitoring systems in calculating emission concentrations.

(f) If continuous emission monitoring systems are temporarily unavailable to meet the data collection requirements, refer to Table 3 of this subpart. It shows alternate methods for collecting data when systems malfunction or when repairs, calibration checks, or zero and span checks keep you from collecting the minimum amount of data.

§ 60.2943 How do I convert my 1-hour arithmetic averages into the appropriate averaging times and units?

(a) Use Equation 1 in § 60.2975 to calculate emissions at 7 percent oxygen.

(b) Use Equation 2 in § 60.2975 to calculate the 3-hour rolling averages for concentrations of carbon monoxide.

§ 60.2944 What operating parameter monitoring equipment must I install, and what operating parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitations under § 60.2915, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in Table 2 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in Table 2 of this subpart at all times.

(b) You must install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of any stack that could be used to bypass the control device. The measurement must include the date, time, and duration of the use of the bypass stack.

(c) If you are using a method or air pollution control device other than a wet scrubber to comply with the emission limitations under § 60.2915, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.2917.

§ 60.2945 Is there a minimum amount of operating parameter monitoring data I must obtain?

(a) Except for monitor malfunctions, associated repairs, and required quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments of the monitoring system), you must conduct all monitoring at all times the OSWI unit is operating.

(b) You must obtain valid monitoring data for at least 75 percent of the operating hours per day for at least 90 percent of the operating days per calendar quarter. An operating day is any day the unit combusts any municipal or institutional solid waste.

(c) If you do not obtain the minimum data required in paragraphs (a) and (b) of this section, you have deviated from the data collection requirement regardless of the operating parameter level monitored.

(d) Do not use data recorded during monitor malfunctions, associated repairs, and required quality assurance or quality control activities for meeting the requirements of this subpart, including data averages and calculations. You must use all the data collected during all other periods in assessing compliance with the operating limits.

Recordkeeping and Reporting

§ 60.2949 What records must I keep?

You must maintain the 15 items (as applicable) as specified in paragraphs (a) through (o) of this section for a period of at least 5 years:

(a) Calendar date of each record.

(b) Records of the data described in paragraphs (b)(1) through (8) of this section:

(1) The OSWI unit charge dates, times, weights, and hourly charge rates.

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable.

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable.

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable.

(5) For affected OSWI units that establish operating limits for controls other than wet scrubbers under § 60.2917, you must maintain data collected for all operating parameters used to determine compliance with the operating limits.

(6) All 1-hour average concentrations of carbon monoxide emissions.

(7) All 3-hour rolling average values of carbon monoxide emissions and all 3-hour rolling average values of continuously monitored operating parameters.

(8) Records of the dates, times, and durations of any bypass of the control device.

(c) Identification of calendar dates and times for which continuous emission monitoring systems or monitoring systems used to monitor operating limits were inoperative, inactive, malfunctioning, or out of control (except for downtime associated with zero and span and other routine calibration checks). Identify the pollutant emissions or operating parameters not measured, the duration, reasons for not obtaining the data, and a description of corrective actions taken.

(d) Identification of calendar dates, times, and durations of malfunctions, and a description of the malfunction and the corrective action taken.

(e) Identification of calendar dates and times for which monitoring data show a deviation from the carbon monoxide emissions limit in Table 1 of this subpart or a deviation from the operating limits in Table 2 of this subpart or a deviation from other operating limits established under § 60.2917 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken.

(f) Calendar dates when continuous monitoring systems did not collect the minimum amount of data required under §§ 60.2942 and 60.2945.

(g) For carbon monoxide continuous emissions monitoring systems, document the results of your daily drift tests and quarterly accuracy determinations according to Procedure 1 of appendix F of this part.

(h) Records of the calibration of any monitoring devices required under § 60.2944.

(i) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations and a description of the types of waste burned during the test.

(j) All documentation produced as a result of the siting requirements of §§ 60.2894 and 60.2895.

(k) Records showing the names of OSWI unit operators who have completed review of the information in § 60.2910(a) as required by § 60.2910(b), including the date of the initial review and all subsequent annual reviews.

(l) Records showing the names of the OSWI operators who have completed the operator training requirements under § 60.2905, met the criteria for qualification under § 60.2907, and maintained or renewed their qualification under § 60.2908 or § 60.2909. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(m) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

(n) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment.

(o) The information listed in § 60.2910(a).

§ 60.2950 Where and in what format must I keep my records?

(a) You must keep each record on site for at least 2 years. You may keep the records off site for the remaining 3 years.

(b) All records must be available in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.2951 What reports must I submit?

See Table 4 of this subpart for a summary of the reporting requirements.

§ 60.2952 What must I submit prior to commencing construction?

You must submit a notification prior to commencing construction that includes the five items listed in paragraphs (a) through (e) of this section.

(a) A statement of intent to construct.

(b) The anticipated date of commencement of construction.

(c) All documentation produced as a result of the siting requirements of § 60.2895.

(d) The waste management plan as specified in §§ 60.2899 through 60.2901.

(e) Anticipated date of initial startup.

§ 60.2953 What information must I submit prior to initial startup?

You must submit the information specified in paragraphs (a) through (e) of this section prior to initial startup.

(a) The type(s) of waste to be burned.

(b) The maximum design waste burning capacity.

(c) The anticipated maximum charge rate.

(d) If applicable, the petition for site-specific operating limits under § 60.2917.

(e) The anticipated date of initial startup.

§ 60.2954 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a) and (b) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager.

(a) The complete test report for the initial performance test results obtained under § 60.2927, as applicable.

(b) The values for the site-specific operating limits established in § 60.2916 or § 60.2917.

§ 60.2955 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.2954. You must submit subsequent reports no more than 12 months following the previous report.

§ 60.2956 What information must I include in my annual report?

The annual report required under § 60.2955 must include the ten items listed in paragraphs (a) through (j) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.2957, 60.2958, and 60.2959.

(a) Company name and address.

(b) Statement by the owner or operator, with their name, title, and signature, certifying the truth, accuracy, and completeness of the report. Such certifications must also comply with the requirements of 40 CFR 70.5(d) or 71.5(d).

(c) Date of report and beginning and ending dates of the reporting period.

(d) The values for the operating limits established pursuant to § 60.2916 or § 60.2917.

(e) If no deviation from any emission limitation or operating limit that applies to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period, and that no monitoring system used to determine compliance with the emission limitations or operating limits was inoperative, inactive, malfunctioning or out of control.

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average, as applicable, for carbon monoxide emissions and for each operating parameter recorded for the calendar year being reported.

(g) Information recorded under § 60.2949(b)(6) and (c) through (e) for the calendar year being reported.

(h) If a performance test was conducted during the reporting period, the results of that test.

(i) If you met the requirements of § 60.2934(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.2934(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period.

(j) Documentation of periods when all qualified OSWI unit operators were unavailable for more than 12 hours, but less than 2 weeks.

§ 60.2957 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if any recorded 3-hour average carbon monoxide emission rate is above the emission limitation, if the control device was bypassed, or if a performance test was conducted that showed a deviation from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.2958 What must I include in the deviation report?

In each report required under § 60.2957, for any pollutant or operating parameter that deviated from the emission limitations or operating limits specified in this subpart, include the seven items described in paragraphs (a) through (g) of this section.

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements.

(b) The averaged and recorded data for those dates.

(c) Durations and causes of each deviation from the emission limitations or operating limits and your corrective actions.

(d) A copy of the operating limit monitoring data during each deviation and any test report that documents the emission levels.

(e) The dates, times, number, duration, and causes for monitor downtime incidents (other than downtime associated with zero, span, and other routine calibration checks).

(f) Whether each deviation occurred during a period of startup, shutdown, or malfunction, or during another period.

(g) The dates, times, and durations of any bypass of the control device.

§ 60.2959 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section.

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section.

(i) A statement of what caused the deviation.

(ii) A description of what you are doing to ensure that a qualified operator is accessible.

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section.

(i) A description of what you are doing to ensure that a qualified operator is accessible.

(ii) The date when you anticipate that a qualified operator will be accessible.

(iii) Request approval from the Administrator to continue operation of the OSWI unit.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.2911(c)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.2960 Are there any other notifications or reports that I must submit?

Yes, you must submit notifications as provided by § 60.7.

§ 60.2961 In what form can I submit my reports?

Submit initial, annual, and deviation reports electronically or in paper format, postmarked on or before the submittal due dates.

§ 60.2962 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Title V Operating Permits

§ 60.2966 Am I required to apply for and obtain a title V operating permit for my unit?

Yes, if you are subject to this subpart, you are required to apply for and obtain a title V operating permit unless you meet the relevant requirements for an exemption specified in § 60.2887.

§ 60.2967 When must I submit a title V permit application for my new OSWI unit?

(a) If your new OSWI unit is not subject to an earlier permit application deadline, a complete title V permit application must be submitted on or before one of the dates specified in paragraphs (a)(1) or (2) of this section. (*See* section 503(c) of the Clean Air Act and 40 CFR 70.5(a)(1)(i) and 71.5(a)(1)(i).)

(1) For an OSWI unit that commenced operation as a new source as of [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], then a complete title V permit application must be submitted not later than 12 months after [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(2) For an OSWI unit that does not commence operation as a new source until after [DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**], then a complete title V permit application must be submitted not later than 12 months after the date the OSWI unit commences operation as a new source.

(b) If your OSWI unit is subject to title V as a result of some triggering requirement(s) other than this subpart (for example, an OSWI unit may be a major source or part of a major source), then your unit may be required to apply for a title V permit prior to the deadlines specified in paragraph (a) of this section. If more than one requirement triggers a source's obligation to apply for a title V permit, the 12-month time

frame for filing a title V permit application is triggered by the requirement that first causes the source to be subject to title V. (*See* section 503(c) of the Clean Air Act and 40 CFR 70.3(a) and (b), 70.5(a)(1)(i), 71.3(a) and (b), and 71.5(a)(1)(i).)

(c) A ''complete'' title V permit application is one that has been determined or deemed complete by the relevant permitting authority under section 503(d) of the Clean Air Act and 40 CFR 70.5(a)(2) or 71.5(a)(2). You must submit a complete permit application by the relevant application deadline in order to operate after this date in compliance with Federal law. (*See* sections 503(d) and 502(a) of the Clean Air Act and 40 CFR 70.7(b) and 71.7(b).)

Temporary Use Incinerators Used in Disaster Recovery

§ 60.2969 What are the requirements for temporary use incinerators used in disaster recovery?

Your incinerator is excluded from the requirements of this subpart if it is used on a temporary basis to combust debris from a disaster or emergency such as a tornado, hurricane, flood, or act of bioterrorism, and you follow the requirements in paragraphs (a) or (b) of this section, depending on the extent of response necessary for disaster recovery.

(a) If the incinerator is used to combust debris in an area declared a State of Emergency by a State government, or the President, under the authority of the Stafford Act, has declared that an emergency or a major disaster exists in the area, then the incinerator is excluded from the requirements of this subpart.

(b) If the incinerator is used to combust debris in an area that is not declared a State of Emergency or major disaster, then you must meet the requirements of paragraphs (b)(1) through (b)(3) of this section, depending on the length of time the incinerator will be used at the same location.

(1) If the incinerator is used for less than 8 weeks at the same location, then it is excluded from the requirements of this subpart. You do not need to notify the Administrator of its use or meet the emission limits or other requirements of this subpart.

(2) If the incinerator will be used for 8 weeks or more at the same location, you must notify the Administrator that the temporary use incinerator will be used for 8 weeks or more and request permission to continue to operate the incinerator.

(i) The notification must be submitted in writing by the date 8 weeks after you start operation of the temporary use incinerator at its current location.

(ii) The notification must contain the date the incinerator started operation at its current location, identification of the disaster or emergency for which the incinerator is being used, a description of the types of materials being burned in the incinerator, a brief description of the size and design of the incinerator (for example, an air curtain incinerator or a modular starved-air incinerator), the reasons the incinerator must be operated for more than 8 weeks, and the amount of time for which you request permission to operate including the date you expect to cease operation of the incinerator.

(3) If you submitted the notification containing the information in paragraph (b)(2)(ii) by the date specified in paragraph (b)(2)(i), you may continue to operate the incinerator for 8 additional weeks, which is a total of 16 weeks from the date the incinerator started operation in its current location. You do not have to meet the emission limits or other requirements of this subpart during this period.

(i) At the end of 16 weeks from the date the incinerator started operation in its current location, you must cease operation of the incinerator or comply with all requirements of this subpart, unless the Administrator has approved in writing your request to continue operation.

(ii) If the Administrator has approved in writing your request to continue operation, then you may continue to operate the incinerator until the date specified in the approval, and you do not need to comply with any other requirements of this subpart during the approved time period.

Air Curtain Incinerators That Burn Only Wood Waste, Clean Lumber, and Yard Waste

§ 60.2970 What is an air curtain incinerator?

(a) An air curtain incinerator operates by forcefully projecting a curtain of air across an open, integrated combustion chamber (fire box) or open pit or trench (trench burner) in which combustion occurs. For the purpose of this subpart and subpart FFFF only, air curtain incinerators include both firebox and trench burner units.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (4) of this section are required to meet only the requirements in § 60.2970 through § 60.2973 and are exempt from all other requirements of this subpart.

(1) 100 percent wood waste.

(2) 100 percent clean lumber.

(3) 100 percent yard waste.

(4) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.2971 What are the emission limitations for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Within 60 days after your air curtain incinerator reaches the charge rate at which it will operate, but no later than 180 days after its initial startup, you must meet the two limitations specified in paragraphs (a)(1) and (2) of this section.

(1) The opacity limitation is 10 percent (6-minute average), except as described in paragraph (a)(2) of this section.

(2) The opacity limitation is 35 percent (6-minute average) during the startup period that is within the first 30 minutes of operation.

(b) The limitations in paragraph (a) of this section apply at all times except during malfunctions.

§ 60.2972 How must I monitor opacity for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.2973 What are the recordkeeping and reporting requirements for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Prior to commencing construction on your air curtain incinerator, submit the three items described in paragraphs (a)(1) through (3) of this section.

(1) Notification of your intent to construct the air curtain incinerators.

(2) Your planned initial startup date.

(3) Types of materials you plan to burn in your air curtain incinerator.

(b) Keep records of results of all initial and annual opacity tests in either paper copy or computer-readable format that can be printed upon request, unless the Administrator approves another format, for at least 5 years. You must keep each record on site for at least 2 years. You may keep the records off site for the remaining 3 years.

(c) Make all records available for submittal to the Administrator or for an inspector's review.

(d) You must submit the results (each 6-minute average) of the initial opacity tests no later than 60 days following the initial test. Submit annual opacity test

results within 12 months following the previous report.

(e) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date.

(f) Keep a copy of the initial and annual reports on site for a period of 5 years. You must keep each report on site for at least 2 years. You may keep the reports off site for the remaining 3 years.

§ 60.2974 Am I required to apply for and obtain a title V operating permit for my air curtain incinerator that burns only wood waste, clean lumber, and yard waste?

Yes, if your air curtain is subject to this subpart, you are required to apply for and obtain a title V operating permit as specified in §§ 60.2966 and 60.2967.

Equations

§ 60.2975 What equations must I use?

(a) *Percent oxygen.* Adjust all pollutant concentrations to 7 percent oxygen using Equation 1 of this section.

$$C_{adj} = C_{meas} * (20.9 - 7)/(20.9 - \%O_2) \qquad \text{(Eq. 1)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen

C_{meas} = pollutant concentration measured on a dry basis

(20.9 − 7) = 20.9 percent oxygen − 7 percent oxygen (defined oxygen correction basis)

20.9 = oxygen concentration in air, percent

$\%O_2$ = oxygen concentration measured on a dry basis, percent

(b) *Capacity of a very small municipal waste combustion unit.* For very small municipal waste combustion units that can operate continuously for 24-hour periods, calculate the unit capacity based on 24 hours of operation at the maximum charge rate. To determine the maximum charge rate, use one of two methods:

(1) For very small municipal waste combustion units with a design based on heat input capacity, calculate the maximum charging rate based on the maximum heat input capacity and one of two heating values:

(i) If your very small municipal waste combustion unit combusts refuse-derived fuel, use a heating value of 12,800 kilojoules per kilogram (5,500 British thermal units per pound).

(ii) If your very small municipal waste combustion unit combusts municipal solid waste, use a heating value of 10,500 kilojoules per kilogram (4,500 British thermal units per pound).

(2) For very small municipal waste combustion units with a design not based on heat input capacity, use the maximum design charging rate.

(c) *Capacity of a batch very small municipal waste combustion unit.* Calculate the capacity of a batch OSWI unit as the maximum design amount of municipal solid waste it can charge per batch multiplied by the maximum number of batches it can process in 24 hours. Calculate the maximum number of batches by dividing 24 by the number of hours needed to process one batch. Retain fractional batches in the calculation. For example, if one batch requires 16 hours, the OSWI unit can combust 24/16, or 1.5 batches, in 24 hours.

(d) *Carbon monoxide pollutant rate.* When hourly average pollutant rates (E_h) are obtained (*e.g.,* CEMS values), compute the rolling average carbon monoxide pollutant rate (E_a) for each 3-hour period using the following equation:

$$E_a = \frac{1}{3}\sum_{j=1}^{3} E_{hj} \qquad \text{(Eq. 2)}$$

Where:

E_a = Average carbon monoxide pollutant rate for the 3-hour period, ppm corrected to 7 percent O_2.

E_{hj} = Hourly arithmetic average pollutant rate for hour ''j,'' ppm corrected to 7 percent O_2.

Definitions

§ 60.2977 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subpart A (General Provisions) of this part.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Air curtain incinerator means an incineration unit operating by forcefully projecting a curtain of air across an open, integrated combustion chamber (fire box) or open pit or trench (trench burner) in which combustion occurs. For the purpose of this subpart and subpart FFFF only, air curtain incinerators include both firebox and trench burner units.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Batch OSWI unit means an OSWI unit that is designed such that neither waste charging nor ash removal can occur during combustion.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

Chemotherapeutic waste means waste material resulting from the production or use of anti-neoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Class II municipal solid waste landfill means a landfill that meets four criteria:

(1) Accepts, for incineration or disposal, less than 20 tons per day of municipal solid waste or other solid wastes based on an annual average;

(2) Is located on a site where there is no evidence of groundwater pollution caused or contributed to by the landfill;

(3) Is not connected by road to a Class I municipal solid waste landfill, as defined by Alaska regulatory code 18 AAC 60.300(c) or, if connected by road, is located more than 50 miles from a Class I municipal solid waste landfill; and

(4) Serves a community that meets one of two criteria:

(i) Experiences for at least three months each year, an interruption in access to surface transportation, preventing access to a Class I municipal solid waste landfill; or

(ii) Has no practicable waste management alternative, with a landfill located in an area that annually receives 25 inches or less of precipitation.

Class III municipal solid waste landfill is a landfill that is not connected by road to a Class I municipal solid waste landfill, as defined by Alaska regulatory code 18 AAC 60.300(c) or, if connected by road, is located more than 50 miles from a Class I municipal solid waste landfill, and that accepts, for disposal, either of the following two criteria:

(1) Ash from incinerated municipal waste in quantities less than one ton per day on an annual average, which ash must be free of food scraps that might attract animals; or

(2) Less than five tons per day of municipal solid waste, based on an annual average, and is not located in a place that meets either of the following criteria:

(i) Where public access is restricted, including restrictions on the right to move to the place and reside there; or

(ii) That is provided by an employer and that is populated totally by persons who are required to reside there as a condition of employment and who do not consider the place to be their permanent residence.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Collected from means the transfer of material from the site at which the material is generated to a separate site where the material is burned.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system or CEMS means a monitoring system for continuously measuring and recording the emissions of a pollutant from an affected OSWI unit.

Continuous OSWI unit means an OSWI unit that is designed to allow waste charging and ash removal during combustion.

Deviation means any instance in which an OSWI unit that meets the requirements in § 60.2885, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any OSWI unit that meets the requirements in § 60.2885 and is required to obtain such a permit; or

(3) Fails to meet any emission limitation, operating limit, or operator qualification and accessibility requirement in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is allowed by this subpart.

Dioxins/furans means tetra- through octachlorinated dibenzo-p-dioxins and dibenzofurans.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Institution means organizations having a governmental, educational, civic, or religious purpose such as schools, prisons, government facilities, churches, and other similar establishments or facilities.

Institutional waste means solid waste combusted for reasons that do not include the recovery of heat for a useful purpose, or combusted without heat recovery or with only waste heat recovery (*i.e.,* no heat recovery in the combustion firebox), in an enclosed unit using controlled flame combustion that is a distinct operating unit of the institutional facility. Institutional waste also includes solid waste combusted on site in an air curtain incinerator that is a distinct operating unit of the institutional facility that generated the waste.

Institutional waste incineration unit means any combustion unit that combusts institutional waste (as defined in this subpart), that is a distinct operating unit of the institutional facility that generated the waste. Institutional waste incineration units include field-erected, modular, and custom built incineration units operating with starved or excess air, and any air curtain incinerator that is a distinct operating unit of the institutional facility that generated the institutional waste (except those air curtain incinerators listed in § 60.2888(b)).

Intermittent OSWI unit means an OSWI unit that is designed to allow waste charging, but not ash removal, during combustion.

Low-level radioactive waste means waste material that contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable Federal or State standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or byproduct material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions.

Modification or modified OSWI unit means an OSWI unit you have changed on or after [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**] and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the OSWI unit (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the OSWI unit used to calculate these costs, see the definition of OSWI unit.

(2) Any physical change in the OSWI unit or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste means refuse (and refuse-derived fuel) collected from the general public and from residential, commercial, institutional, and industrial sources consisting of paper, wood, yard wastes, food wastes, plastics, leather, rubber, and other combustible materials and non-combustible materials such as metal, glass and rock, provided that:

(1) The term does not include industrial process wastes or medical wastes that are segregated from such other wastes; and

(2) An incineration unit shall not be considered to be combusting municipal waste for purposes of this subpart if it combusts a fuel feed stream, 30 percent or less of the weight of which is comprised, in aggregate, of municipal waste, as determined by § 60.2887(c).

Municipal waste combustion unit means, for the purpose of this subpart and subpart FFFF, any setting or equipment that combusts municipal solid waste (as defined in this subpart) including, but not limited to, field-erected, modular, and custom built incineration units (with or without heat recovery) operating with starved or excess air, boilers, furnaces, pyrolysis/combustion units, and air curtain incinerators (except those air curtain incinerators listed in § 60.2887(a)).

Other solid waste incineration (OSWI) unit means either a very small municipal waste combustion unit or an institutional waste incineration unit, as defined in this subpart. While not all OSWI units will include all of the following components, an OSWI unit includes, but is not limited to, the municipal or institutional solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The OSWI unit does not include air pollution control equipment or the stack. The OSWI unit boundary starts at the municipal or institutional waste hopper (if applicable) and extends through two areas:

(1) The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and

(2) the combustion unit bottom ash system, which ends at the truck loading station or similar equipment that

transfers the ash to final disposal. The OSWI unit includes all ash handling systems connected to the bottom ash handling system.

Particulate matter means total particulate matter emitted from OSWI units as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Reconstruction means rebuilding an OSWI unit and meeting two criteria:

(1) The reconstruction begins on or after [DATE 6 MONTHS AFTER DATE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the OSWI unit (not including land) updated to current costs (current dollars). To determine what systems are within the boundary of the OSWI unit used to calculate these costs, see the definition of OSWI unit.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel.

(2) Pelletized refuse-derived fuel.

Shutdown means the period of time after all waste has been combusted in the primary chamber. For continuous OSWI, shutdown shall commence no less than 2 hours after the last charge to the incinerator. For intermittent OSWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. For batch OSWI, shutdown shall commence no less than 5 hours after the high-air phase of combustion has been completed.

Solid waste means any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges that are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (33 U.S.C. 1342), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2014).

Standard conditions, when referring to units of measure, means a temperature of 68°F (20°C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means the period of time between the activation of the system and the first charge to the unit. For batch OSWI, startup means the period of time between activation of the system and ignition of the waste.

Very small municipal waste combustion unit means any municipal waste combustion unit that has the capacity to combust less than 35 tons per day of municipal solid waste or refuse-derived fuel, as determined by the calculations in § 60.2975.

Waste heat recovery means the process of recovering heat from the combustion flue gases by convective heat transfer only.

Wet scrubber means an add-on air pollution control device that utilizes an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands.

(2) Construction, renovation, or demolition wastes.

(3) Clean lumber.

Yard waste means grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs. Yard waste comes from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands. Yard waste does not include two items:

(1) Construction, renovation, and demolition wastes.

(2) Clean lumber.

Tables to Subpart EEEE of Part 60

As stated in § 60.2915, you must comply with the following:

TABLE 1 TO SUBPART EEEE OF PART 60.—EMISSION LIMITATIONS

For the air pollutant	You must meet this emission limitation [a]	Using this averaging time	And determining compliance using this method
1. Cadmium	18 micrograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Method 29 of appendix A of this part.
2. Carbon monoxide	5.0 parts per million by dry volume.	3-run average hour minimum sample time per run during performance test, and 3- hour rolling averages measured using continuous emissions monitoring system)[b].	Method 10, 10A, or 10B of appendix A of this part.
3. Dioxins/furans (total basis)	33 nanograms per dry standard cubic meter.	3-run average hour minimum sample time per run).	Method 23 of appendix A of this part.
4. Hydrogen chloride	3.7 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 26A of appendix A of this part.
5. Lead	226 micrograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Method 29 of appendix A of this part.
6. Mercury	74 micrograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Method 29 of appendix A of this part.
7. Opacity	10 percent	6-run average (1 hour minimum sample time per run).	Method 9 of appendix A of this part.

TABLE 1 TO SUBPART EEEE OF PART 60.—EMISSION LIMITATIONS—Continued

For the air pollutant	You must meet this emission limitation [a]	Using this averaging time	And determining compliance using this method
8. Oxides of nitrogen	103 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 7, 7A, 7C, 7D, or 7E of appendix A of this part. ASME PTC 19–10– 1981—Part 10 is an acceptable alternative to Methods 7 and 7C only (IBR, *see* § 60.17(h)).
9. Particulate matter	0.013 grains per dry standard cubic foot.	3-run average (1 hour minimum sample time per run).	Method 5 or 29 of appendix A of this part.
10. Sulfur dioxide	3.1 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 6 or 6c of appendix A of this part. ASME PTC 19–10–1981—Part 10 is an acceptable alternative to Method 6 only (IBR, *see* § 60.17(h)).

[a] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.
[b] Calculated each hour as the average of the previous 3 operating hours.

As stated in § 60.2916, you must comply with the following:

TABLE 2 TO SUBPART EEEE OF PART 60.—OPERATING LIMITS FOR INCINERATORS AND WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitoring using these minimum frequencies		
		Data measurement	Data recording	Averaging time
1. Charge rate	Maximum charge rate.	Continuous	Every hour	Daily for batch units. 3-hour rolling for continuous and intermittent units [a].
2. Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes	3-hour rolling [a].
3. Scrubber liquor flow rate	Minimum flow rate	Continuous	Every 15 minutes	3-hour rolling [a].
4. Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes	3-hour rolling [a].

[a] Calculated each hour as the average of the previous 3 operating hours.

As stated in § 60.2951, you must comply with the following:

TABLE 3 TO SUBPART EEEE OF PART 60.—REQUIREMENTS FOR CONTINUOUS EMISSION MONITORING SYSTEMS (CEMS)

For the following pollutants	Use the following span values for your CEMS	Use the following performance specifications (P.S.) in appendix B of this part for your CEMS	If needed to meet minimum data requirements, use the following alternate methods in appendix A of this part to collect data
1. Carbon Monoxide	125 percent of the maximum hourly potential carbon monoxide emissions of the waste combustion unit.	P.S.4A	Method 10.
2. Oxygen	25 percent oxygen	P.S.3	Method 3A or 3B. ASME PTC 19–10–1981—Part 10 is an acceptable alternative to Method 3B only (IBR, see § 60.17(h)).

As stated in § 60.2940, you must comply with the following:

TABLE 4 TO SUBPART EEEE OF PART 60—SUMMARY OF REPORTING REQUIREMENTS[a]

Report	Due date	Contents	Reference
1. Preconstruciton report	a. Prior to commencing construction.	i. Statement of intent to construct;	§ 60.2952.
		ii. Anticipated date of commencement of construction;	§ 60.2952.
	.....	iii. Documentation for siting requirements;	§ 60.2952.
		iv. Waste management plan; and	§ 60.2952.
		v. Anticipated date of initial startup	§ 60.2952.
2. Startup notification	a. Prior to initial startup	i. Types of waste to be burned;	§ 60.2953.
		ii. Maximum design waste burning capacity;	60.2953.
		iii. Anticipated maximum charge rate;	§ 60.2953.
		iv. If applicable, the petition for site-specific operating limits; and	§ 60.2953.
		v. Anticipated date of initial startup	§ 60.2953.
3. Initial test report	a. No later than 60 days following the initial performance test	i. Complete test report for the initial performance test; and	§ 60.2954.
		ii. The values for the site-specific operating limits	§ 60.2954.
4. Annual report	a. No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report.	i. Company Name and address;	§§ 60.2955 and 60.2956.
		ii. Statement and signature by the owner or operator;	§§ 60.2955 and 60.2956.
		iii. Date of report;	§§ 60.2955 and 60.2956.
		iv. Values for the operating limits;	§§ 60.2955 and 60.2956.
		v. If no deviations or malfunctions were reported, a statement that no deviations occurred during the reporting period;	§§ 60.2955 and 60.2956.
		vi. Highest recorded 3-hour average and the lowest 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported;	§§ 60.2955 and 60.2956.
	.....	vii. Information for deviations or malfunctions recorded under § 60.2949(b)(6) and (c) through (e);	§§ 60.2955 and 60.2956.
		viii. If a performance test was conducted during the reporting period, the results of the test;	§§ 60.2955 and 60.2956.
		ix. If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2934(a) or (b) were met; and	§§ 60.2955 and 60.2956.
		x. Documentation of periods when all qualified OSWI unit operators were unavailable for more than 12 hours but less than 2 weeks	§§ 60.2955 and 60.2956.
5. Emission limitation or operating limit deviation report.	a. By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	i. Dates and times of deviation;	§§ 60.2957 and 60.2958.
		ii. Averaged and recorded data for those dates;	§§ 60.2957 and 60.2958.
		iii. Duration and causes of each deviation and the corrective actions taken;	§§ 60.2957 and 60.2958.
		iv. Copy of operating limit monitoring data and any test reports;	§§ 60.2957 and 60.2958.
		v. Dates, times, and causes for monitor downtime incidents;	§§ 60.2957 and 60.2958.
		vi. Whether each deviation occurred during a period of startup, shutdown, or malfunction; and	§§ 60.2957 and 60.2958.
		vii. Dates, times, and durations of any bypass of the control device	§§ 60.2957 and 60.2958.
6. Qualified operator deviation notification.	a. Within 10 days of deviation.	i. Statement of cause of deviation	§ 60.2959(a)(1).
		ii. Description of efforts to have an accessible qualified operator; and	§ 60.2959(a)(1).
		iii. The date a qualified operator will be accessible	§ 60.2959(a)(1).
7. Qualified operation deviation status report.	a. Every 4 weeks following deviation.	i. Description of efforts to to have an accessible qualified operator;	§ 60.2959(a)(2).
		ii. The date a qualified operator will be accessible; and	§ 60.2959(a)(2).
		iii. Request to continue operation	§ 60.2959(a)(2).
8. Qualified operator deviation notification of resumed operation.	a. Prior to resuming operation.	i. Notification that you are resuming operation	§ 60.2959(b).

[a] This table is only a summary, see the referenced sections of the rule for the complete requirements.

4. Part 60 is amended by adding subpart FFFF to read as follows:

Subpart FFFF—Emission Guidelines and Compliance Times for Other Solid Waste Incineration Units That Commenced Construction On or Before December 9, 2004

Sec.

Introduction

Applicability of State Plans

Model Rule—Use of Model Rule

Model Rule—Compliance Schedule

Model Rule—Waste Management Plan

Model Rule—Operator Training and Qualification

Model Rule—Emission Limitations and Operating Limits

Model Rule—Performance Testing

Model Rule—Initial Compliance Requirements

Model Rule—Continuous Compliance Requirements

Model Rule—Monitoring

Model Rule—Recordkeep and Reporting

Model Rule—Title V Operating Permits

Model Rule—Temporary Use Incinerators Used in Disaster Recovery

Model Rule—Air Curtain Incinerators That Burn Only Wood Waste, Clean Lumber, and Yard Waste

Model Rule—Equations

Model Rule—Definitions

Tables to Subpart FFFF of Part 60

Introduction

§ 60.2980 What is the purpose of this subpart?

This subpart establishes emission guidelines and compliance schedules for the control of emissions from other solid waste incineration (OSWI) units. The pollutants addressed by these emission guidelines are listed in Table 2 of this subpart. These emission guidelines are developed in accordance with sections 111(d) and 129 of the Clean Air Act and subpart B of this part.

§ 60.2981 Am I affected by this subpart?

(a) If you are the Administrator of an air quality program in a State or United States protectorate with one or more existing OSWI units that commenced construction on or before December 9, 2004, you must submit a State plan to EPA that implements the emission guidelines contained in this subpart.

(b) You must submit the State plan to EPA within 1 year after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

§ 60.2982 Is a State plan required for all States?

No, you are not required to submit a State plan if there are no existing OSWI units in your State and you submit a negative declaration letter in place of the State plan.

§ 60.2983 What must I include in my State plan?

(a) You must include the following nine items in your State plan:

(1) Inventory of affected OSWI units, including those that have ceased operation but have not been dismantled.

(2) Inventory of emissions from affected OSWI units in your State.

(3) Compliance schedules for each affected OSWI unit.

(4) For each affected OSWI unit, emission limitations, operator training and qualification requirements, a waste management plan, and operating parameter requirements that are at least as protective as the emission guidelines contained in this subpart.

(5) Stack testing, recordkeeping, and reporting requirements.

(6) Transcript of the public hearing on the State plan.

(7) Provision for State progress reports to EPA.

(8) Identification of enforceable State mechanisms that you selected for implementing the emission guidelines of this subpart.

(9) Demonstration of your State's legal authority to carry out the sections 111(d) and 129 State plan.

(b) Your State plan may deviate from the format and content of the emission guidelines contained in this subpart. However, if your State plan does deviate, you must demonstrate that your State plan is at least as protective as the emission guidelines contained in this subpart. Your State plan must address regulatory applicability, compliance schedule, operator training and qualification, a waste management plan, emission limitations, stack testing, operating parameter requirements, monitoring, recordkeeping and reporting, and air curtain incinerator requirements.

(c) You must follow the requirements of subpart B of this part (Adoption and Submittal of State Plans for Designated Facilities) in your State plan.

§ 60.2984 Is there an approval process for my State plan?

Yes, the EPA will review your State plan according to § 60.27.

§ 60.2985 What if my State plan is not approvable?

If you do not submit an approvable State plan (or a negative declaration letter) within 2 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**], EPA will develop a Federal plan according to § 60.27 to implement the emission guidelines contained in this subpart. Owners and operators of OSWI units not covered by an approved State plan must comply with the Federal plan. The Federal plan is an interim action and applies to OSWI units until a State plan covering those units is approved and becomes effective.

§ 60.2986 Is there an approval process for a negative declaration letter?

No, the EPA has no formal review process for negative declaration letters. Once we receive your negative declaration letter, we will place a copy in the public docket and publish a notice in the **Federal Register**. If, at a later date, an existing OSWI unit is found in your State, the Federal plan implementing the emission guidelines contained in this subpart would automatically apply to that OSWI unit until your State plan is approved.

§ 60.2987 What compliance schedule must I include in my State plan?

Your State plan must include compliance schedules that require OSWI units to achieve final compliance as expeditiously as practicable after approval of the State plan but not later than the earlier of the following two dates:

(a) Five years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(b) Three years after the effective date of State plan approval.

§ 60.2988 Are there any State plan requirements for this subpart that apply instead of the requirements specified in subpart B?

Yes, subpart B establishes general requirements for developing and processing section 111(d) plans. This subpart applies instead of the requirements in subpart B of this part for the following:

(a) State plans developed to implement this subpart must be as protective as the emission guidelines contained in this subpart. State plans must require all OSWI units to comply within 5 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**] or 3 years after the effective date of State plan approval, whichever is sooner. This applies instead of the option for case-by-case less stringent emission standards and longer compliance schedules in § 60.24(f).

(b) State plans developed to implement this subpart are required to include only one increment of progress for the affected OSWI units. This increment is the final compliance date in § 60.21(h)(5). This applies instead of the requirement of § 60.24(e)(1).

§ 60.2989 Does this subpart directly affect OSWI unit owners and operators in my State?

(a) No, this subpart does not directly affect OSWI unit owners and operators in your State. However, OSWI unit owners and operators must comply with the State plan you develop to implement the emission guidelines contained in this subpart. Some States may choose to incorporate sections of the emission guidelines contained in this subpart into their State plans by direct incorporation by reference. Others may want to include components of the model rule text directly in their State plan.

(b) If you do not submit an approvable plan to implement and enforce the guidelines contained in this subpart within 2 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**], the EPA will implement and enforce a Federal plan, as provided in

§ 60.2985, to ensure that each unit within your State reaches compliance with all the provisions of this subpart within 5 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

Applicability of State Plans

§ 60.2991 What OSWI units must I address in my State plan?

Your State plan must address all OSWI units in your State that meet all the requirements specified in paragraphs (a) through (c) of this section.

(a) The incineration unit is an existing incineration unit as defined in § 60.2992.

(b) The incineration unit is an OSWI unit as defined in § 60.3078. OSWI units are very small municipal waste combustion units and institutional waste incineration units as defined in § 60.3078.

(c) The incineration unit is not excluded under § 60.2993.

§ 60.2992 What is an existing OSWI unit?

An existing OSWI unit is an OSWI unit that commenced construction on or before December 9, 2004, except as provided in paragraph (a) of this section.

(a) If the owner of operator of an OSWI unit makes changes that meet the definition of modification or reconstruction on or after [DATE 6 MONTHS AFTER DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**], the OSWI unit becomes subject to subpart EEEE of this part (New Source Performance Standards for Other Solid Waste Incineration Units) and the State plan no longer applies to that unit.

(b) If the owner or operator of an existing OSWI unit makes physical or operational changes to the unit primarily to comply with the State plan, then subpart EEEE of this part does not apply to that unit. Such changes do not qualify as modifications or reconstructions under subpart EEEE of this part.

§ 60.2993 Are any combustion units excluded from my State plan?

This subpart excludes the types of units described in paragraphs (a) through (p) of this section, as long as the owner/operator meets the requirements of this section.

(a) *Cement kilns.* The unit is excluded if it is regulated under subpart LLL of part 63 of this chapter (National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry).

(b) *Co-fired combustors.* The unit, that would otherwise be considered a very small municipal waste combustion unit, is excluded if the owner/operator of the unit meets four requirements:

(1) Has a Federally enforceable permit limiting the combustion of municipal solid waste to 30 percent of the total fuel input by weight.

(2) Notifies the Administrator that the unit qualifies for the exclusion.

(3) Provides the Administrator with a copy of the Federally enforceable permit.

(4) Records the weights, each calendar quarter, of municipal solid waste and of all other fuels combusted.

(c) *Cogeneration facilities.* The unit is excluded if it meets the three requirements specified in paragraphs (c)(1) through (3) of this section.

(1) The unit qualifies as a cogeneration facility under section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)).

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity and steam or other forms of energy used for industrial, commercial, heating, or cooling purposes.

(3) The owner/operator of the unit notifies the Administrator that the unit meets all of these criteria.

(d) *Commercial and industrial solid waste incineration units.* The unit is excluded if it is regulated under subparts CCCC or DDDD of this part and is required to meet the emission limitations established in those subparts.

(e) *Hazardous waste combustion units.* The unit is excluded if it meets either of the two criteria specified in paragraph (e)(1) or (2) of this section.

(1) The owner/operator of the unit is required to get a permit for the unit under section 3005 of the Solid Waste Disposal Act.

(2) The unit is regulated under 40 CFR part 63, subpart EEE (National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors).

(f) *Hospital/medical/infectious waste incinerators.* The unit is excluded if it is regulated under subparts Ce or Ec of this part (New Source Performance Standards and Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators).

(g) *Incinerators and air curtain incinerators in isolated areas of Alaska.* The incineration unit is excluded if it is used at a solid waste disposal site in Alaska that is classified as a Class II or Class III municipal solid waste landfill, as defined in § 60.3078.

(h) *Rural institutional waste incinerators.* The incineration unit is excluded if it is an institutional waste incinerator, as defined in § 60.3078, and located more than 50 miles from the boundary of the nearest Metropolitan Statistical Area.

(i) *Institutional boilers and process heaters.* The unit is excluded if it is regulated under 40 CFR part 63, subpart DDDDD (National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Institutional Boilers and Process Heaters).

(j) *Laboratory Analysis Units.* The unit is excluded if it burns samples of materials only for the purpose of chemical or physical analysis.

(k) *Materials recovery units.* The unit is excluded if it combusts waste for the primary purpose of recovering metals, such as primary and secondary smelters.

(l) *Pathological waste incineration units.* The institutional waste incineration unit or very small municipal waste combustion unit is excluded from this subpart if it burns 90 percent or more by weight (on a calendar quarter basis and excluding the weight of auxiliary fuel and combustion air) of pathological waste, low-level radioactive waste, and/or chemotherapeutic waste as defined in § 60.3078 and the owner/operator of the unit notifies the Administrator that the unit meets these criteria.

(m) *Small or large municipal waste combustion units.* The unit is excluded if it is regulated under subparts AAAA, BBBB, Ea, Eb, or Cb, of this part and is required to meet the emission limitations established in those subparts.

(n) *Small power production facilities.* The unit is excluded if it meets the three requirements specified in paragraphs (n)(1) through (3) of this section.

(1) The unit qualifies as a small power-production facility under section 3(17)(C) of the Federal Power Act (16 U.S.C. 796(17)(C)).

(2) The unit burns homogeneous waste (not including refuse-derived fuel) to produce electricity.

(3) The owner/operator of the unit notifies the Administrator that the unit meets all of these criteria.

(o) *Temporary-use incinerators used in disaster recovery.* The incinerator is excluded if it is used on a temporary basis to combust debris from a disaster or emergency such as a tornado, hurricane, flood, or act of bioterrorism and you comply with the requirements in § 60.3061.

(p) *Units that combust contraband or prohibited goods.* The unit is excluded if the unit is used by a government agency such as police, customs, agricultural inspection, or a similar

agency to destroy only illegal or prohibited goods such as illegal drugs, or agricultural food products that can not be transported into the country or across state lines to prevent biocontamination.

§ 60.2994 Are air curtain incinerators regulated under this subpart?

(a) Air curtain incinerators that burn less than 35 tons per day of municipal solid waste or air curtain incinerators located at institutional facilities burning any amount of institutional waste generated at that facility are subject to all requirements of this subpart, including the emission limitations specified in Table 2 of this subpart.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (4) of this section must meet only the requirements in §§ 60.3062 through 60.3069 and the title V operating permit requirements in §§ 60.3059 and 60.3060, and are exempt from all other requirements of this subpart.

(1) 100 percent wood waste.

(2) 100 percent clean lumber.

(3) 100 percent yard waste.

(4) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

Model Rule—Use of Model Rule

§ 60.2996 What is the purpose of the ''model rule'' in this subpart?

(a) The model rule provides the emission guidelines requirements in a standard regulation format. You must develop a State plan that is at least as protective as the model rule. You may use the model rule language as part of your State plan. Alternative language may be used in your State plan if you demonstrate that the alternative language is at least as protective as the model rule contained in this subpart.

(b) In the ''model rule'' of §§ 60.3000 to 60.3078, ''you'' means the owner or operator of an OSWI unit.

§ 60.2997 How does the model rule relate to the required elements of my State plan?

Use the model rule to satisfy the State plan requirements specified in § 60.2983(a)(4) and (5).

§ 60.2998 What are the principal components of the model rule?

The model rule contains nine major components, as follows:

(a) Compliance schedule.

(b) Waste management plan.

(c) Operator training and qualification.

(d) Emission limitations and operating limits.

(e) Performance testing.

(f) Initial compliance requirements.

(g) Continuous compliance requirements.

(h) Monitoring.

(i) Recordkeeping and reporting.

Model Rule—Compliance Schedule

§ 60.3000 When must I comply?

Table 1 of this subpart specifies the final compliance date. You must submit a notification to the Administrator stating whether final compliance has been achieved, postmarked within 10 business days after the final compliance date in Table 1 of this subpart.

§ 60.3001 What must I do if I close my OSWI unit and then restart it?

(a) If you close your OSWI unit but will reopen it prior to the final compliance date in your State plan, you must meet the final compliance date specified in Table 1 of this subpart.

(b) If you close your OSWI unit but will restart it after your final compliance date, you must complete emission control retrofit and meet the emission limitations on the date your OSWI unit restarts operation.

§ 60.3002 What must I do if I plan to permanently close my OSWI unit and not restart it?

You must close the unit before the final compliance date specified in Table 1 of this subpart.

Model Rule—Waste Management Plan

§ 60.3010 What is a waste management plan?

A waste management plan is a written plan that identifies both the feasibility and the methods used to reduce or separate certain components of solid waste from the waste stream in order to reduce or eliminate toxic emissions from incinerated waste.

§ 60.3011 When must I submit my waste management plan?

You must submit a waste management plan no later than 60 days following the initial performance test as specified in Table 5 of this subpart. Section 60.3031 specifies the date by which you are required to conduct your performance test.

§ 60.3012 What should I include in my waste management plan?

A waste management plan must include consideration of the reduction or separation of waste-stream elements such as paper, cardboard, plastics, glass, batteries, or metals; or the use of recyclable materials. The plan must identify any additional waste management measures and implement those measures the source considers practical and feasible, considering the effectiveness of waste management measures already in place, the costs of additional measures, the emissions reductions expected to be achieved, and any other environmental or energy impacts they might have.

Model Rule—Operator Training and Qualification

§ 60.3014 What are the operator training and qualification requirements?

(a) No OSWI unit can be operated unless a fully trained and qualified OSWI unit operator is accessible, either at the facility or can be at the facility within 1 hour. The trained and qualified OSWI unit operator may operate the OSWI unit directly or be the direct supervisor of one or more other plant personnel who operate the unit. If all qualified OSWI unit operators are temporarily not accessible, you must follow the procedures in § 60.3020.

(b) Operator training and qualification must be obtained through a State-approved program or by completing the requirements included in paragraph (c) of this section.

(c) Training must be obtained by completing an incinerator operator training course that includes, at a minimum, the three elements described in paragraphs (c)(1) through (3) of this section.

(1) Training on the 13 subjects listed in paragraphs (c)(1)(i) through (xiii) of this section.

(i) Environmental concerns, including types of emissions.

(ii) Basic combustion principles, including products of combustion.

(iii) Operation of the specific type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures.

(iv) Combustion controls and monitoring.

(v) Operation of air pollution control equipment and factors affecting performance (if applicable).

(vi) Inspection and maintenance of the incinerator and air pollution control devices.

(vii) Methods to monitor pollutants (including monitoring of incinerator and control device operating parameters) and monitoring equipment calibration procedures, where applicable.

(viii) Actions to correct malfunctions or conditions that may lead to malfunction.

(ix) Bottom and fly ash characteristics and handling procedures.

(x) Applicable Federal, State, and local regulations, including Occupational Safety and Health Administration workplace standards.

(xi) Pollution prevention.

(xii) Waste management practices.

(xiii) Recordkeeping requirements.

(2) An examination designed and administered by the instructor.

(3) Written material covering the training course topics that may serve as reference material following completion of the course.

§ 60.3015 When must the operator training course be completed?

The operator training course must be completed by the latest of the three dates specified in paragraphs (a) through (c) of this section.

(a) The final compliance date specified in Table 1 of this subpart.

(b) Six months after your OSWI unit startup.

(c) Six months after an employee assumes responsibility for operating the OSWI unit or assumes responsibility for supervising the operation of the OSWI unit.

§ 60.3016 How do I obtain my operator qualification?

(a) You must obtain operator qualification by completing a training course that satisfies the criteria under § 60.3014(c).

(b) Qualification is valid from the date on which the training course is completed and the operator successfully passes the examination required under § 60.3014(c)(2).

§ 60.3017 How do I maintain my operator qualification?

To maintain qualification, you must complete an annual review or refresher course covering, at a minimum, the five topics described in paragraphs (a) through (e) of this section.

(a) Update of regulations.

(b) Incinerator operation, including startup and shutdown procedures, waste charging, and ash handling.

(c) Inspection and maintenance.

(d) Responses to malfunctions or conditions that may lead to malfunction.

(e) Discussion of operating problems encountered by attendees.

§ 60.3018 How do I renew my lapsed operator qualification?

You must renew a lapsed operator qualification by one of the two methods specified in paragraphs (a) and (b) of this section.

(a) For a lapse of less than 3 years, you must complete a standard annual refresher course described in § 60.3017.

(b) For a lapse of 3 years or more, you must repeat the initial qualification requirements in § 60.3016(a).

§ 60.3019 What site-specific documentation is required?

(a) Documentation must be available at the facility and readily accessible for all OSWI unit operators that addresses the nine topics described in paragraphs (a)(1) through (9) of this section. You must maintain this information and the training records required by paragraph (c) of this section in a manner that they can be readily accessed and are suitable for inspection upon request.

(1) Summary of the applicable standards under this subpart.

(2) Procedures for receiving, handling, and charging waste.

(3) Incinerator startup, shutdown, and malfunction procedures.

(4) Procedures for maintaining proper combustion air supply levels.

(5) Procedures for operating the incinerator and associated air pollution control systems within the standards established under this subpart.

(6) Monitoring procedures for demonstrating compliance with the operating limits established under this subpart.

(7) Reporting and recordkeeping procedures.

(8) The waste management plan required under §§ 60.3010 through 60.3012.

(9) Procedures for handling ash.

(b) You must establish a program for reviewing the information listed in paragraph (a) of this section with each incinerator operator.

(1) The initial review of the information listed in paragraph (a) of this section must be conducted by the latest of three dates specified in paragraphs (b)(1)(i) through (iii) of this section.

(i) The final compliance date specified in Table 1 of this subpart.

(ii) Six months after your OSWI unit startup.

(iii) Six months after an employee assumes responsibility for operating the OSWI unit or assumes responsibility for supervising the operation of the OSWI unit.

(2) Subsequent annual reviews of the information listed in paragraph (a) of this section must be conducted not later than 12 months following the previous review.

(c) You must also maintain the information specified in paragraphs (c)(1) through (3) of this section.

(1) Records showing the names of OSWI unit operators who have completed review of the information in paragraph (a) of this section as required by paragraph (b) of this section, including the date of the initial review and all subsequent annual reviews.

(2) Records showing the names of the OSWI operators who have completed the operator training requirements under § 60.3014, met the criteria for qualification under § 60.3016, and maintained or renewed their qualification under § 60.3017 or § 60.3018. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(3) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

§ 60.3020 What if all the qualified operators are temporarily not accessible?

If all qualified operators are temporarily not accessible (*i.e.,* not at the facility and not able to be at the facility within 1 hour), you must meet one of the three criteria specified in paragraphs (a) through (c) of this section, depending on the length of time that a qualified operator is not accessible.

(a) When all qualified operators are not accessible for 12 hours or less, the OSWI unit may be operated by other plant personnel familiar with the operation of the OSWI unit who have completed review of the information specified in § 60.3019(a) within the past 12 months. You do not need to notify the Administrator or include this as a deviation in your annual report.

(b) When all qualified operators are not accessible for more than 12 hours, but less than 2 weeks, the OSWI unit may be operated by other plant personnel familiar with the operation of the OSWI unit who have completed a review of the information specified in § 60.3019(a) within the past 12 months. However, you must record the period when all qualified operators were not accessible and include this deviation in the annual report as specified under § 60.3051.

(c) When all qualified operators are not accessible for 2 weeks or more, you must take the two actions that are described in paragraphs (c)(1) and (2) of this section.

(1) Notify the Administrator of this deviation in writing within 10 days. In the notice, state what caused this deviation, what you are doing to ensure that a qualified operator is accessible, and when you anticipate that a qualified operator will be accessible.

(2) Submit a status report to the Administrator every 4 weeks outlining what you are doing to ensure that a qualified operator is accessible, stating when you anticipate that a qualified operator will be accessible and requesting approval from the

Administrator to continue operation of the OSWI unit. You must submit the first status report 4 weeks after you notify the Administrator of the deviation under paragraph (c)(1) of this section. If the Administrator notifies you that your request to continue operation of the OSWI unit is disapproved, the OSWI unit may continue operation for 90 days, then must cease operation. Operation of the unit may resume if you meet the two requirements in paragraphs (c)(2)(i) and (ii) of this section.

(i) A qualified operator is accessible as required under § 60.3014(a).

(ii) You notify the Administrator that a qualified operator is accessible and that you are resuming operation.

Model Rule—Emission Limitations and Operating Limits

§ 60.3022 What emission limitations must I meet and by when?

You must meet the emission limitations specified in Table 2 of this subpart on the date the initial performance test is required or completed (which is earlier). Section 60.3031 specifies the date by which you are required to conduct your performance test.

§ 60.3023 What operating limits must I meet and by when?

(a) If you use a wet scrubber to comply with the emission limitations, you must establish operating limits for four operating parameters (as specified in Table 3 of this subpart) as described in paragraphs (a)(1) through (4) of this section during the initial performance test.

(1) Maximum charge rate, calculated using one of the two different procedures in paragraphs (a)(1)(i) or (ii) of this section, as appropriate.

(i) For continuous and intermittent units, maximum charge rate is the average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(ii) For batch units, maximum charge rate is the charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(2) Minimum pressure drop across the wet scrubber, which is calculated as the average pressure drop across the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations; or minimum amperage to the wet scrubber, which is calculated as the average amperage to the wet scrubber measured during the most recent performance test demonstrating compliance with the particulate matter emission limitations.

(3) Minimum scrubber liquor flow rate, which is calculated as the average liquor flow rate at the inlet to the wet scrubber measured during the most recent performance test demonstrating compliance with all applicable emission limitations.

(4) Minimum scrubber liquor pH, which is calculated as the average liquor pH at the inlet to the wet scrubber measured during the most recent performance test demonstrating compliance with the HCl and SO_2 emission limitation.

(b) You must meet the operating limits established during the initial performance test beginning on the date 180 days after your final compliance date in Table 1 of this subpart.

§ 60.3024 What if I do not use a wet scrubber to comply with the emission limitations?

If you use an air pollution control device other than a wet scrubber or limit emissions in some other manner to comply with the emission limitations under § 60.3022, you must petition the Administrator for specific operating limits, the values of which are to be established during the initial performance test and then continuously monitored thereafter. You must not conduct the initial performance test until after the petition has been approved by the Administrator. Your petition must include the five items listed in paragraphs (a) through (e) of this section.

(a) Identification of the specific parameters you propose to use as operating limits.

(b) A discussion of the relationship between these parameters and emissions of regulated pollutants, identifying how emissions of regulated pollutants change with changes in these parameters, and how limits on these parameters will serve to limit emissions of regulated pollutants.

(c) A discussion of how you will establish the upper and/or lower values for these parameters that will establish the operating limits on these parameters.

(d) A discussion identifying the methods you will use to measure and the instruments you will use to monitor these parameters, as well as the relative accuracy and precision of these methods and instruments.

(e) A discussion identifying the frequency and methods for recalibrating the instruments you will use for monitoring these parameters.

§ 60.3025 What happens during periods of startup, shutdown, and malfunction?

The emission limitations and operating limits apply at all times except during OSWI unit startups, shutdowns, or malfunctions.

Model Rule—Performance Testing

§ 60.3027 How do I conduct the initial and annual performance test?

(a) All performance tests must consist of a minimum of three test runs conducted under conditions representative of normal operations.

(b) All performance tests must be conducted using the methods in Table 2 of this subpart.

(c) All performance tests must be conducted using the minimum run duration specified in Table 2 of this subpart.

(d) Method 1 of appendix A of this part must be used to select the sampling location and number of traverse points.

(e) Method 3A or 3B of appendix A of this part must be used for gas composition analysis, including measurement of oxygen concentration. Method 3A or 3B of appendix A of this part must be used simultaneously with each method.

(f) Adjust all pollutant concentrations, except for opacity, to 7 percent oxygen using Equation 1 in § 60.3076.

§ 60.3028 How are the performance test data used?

You use results of performance tests to demonstrate compliance with the emission limitations in Table 2 of this subpart.

Model Rule—Initial Compliance Requirements

§ 60.3030 How do I demonstrate initial compliance with the emission limitations and establish the operating limits?

You must conduct an initial performance test, as required under § 60.8, to determine compliance with the emission limitations in Table 2 of this subpart and to establish operating limits using the procedure in § 60.3023 or § 60.3024. The initial performance test must be conducted using the test methods listed in Table 2 of this subpart and the procedures in § 60.3027.

§ 60.3031 By what date must I conduct the initial performance test?

The initial performance test must be conducted no later than 180 days after your final compliance date. Your final compliance date is specified in Table 1 of this subpart.

Model Rule—Continuous Compliance Requirements

§ 60.3033 How do I demonstrate continuous compliance with the emission limitations and the operating limits?

(a) You must conduct an annual performance test for all of the pollutants in Table 2 of this subpart for each OSWI unit to determine compliance with the emission limitations. The annual performance test must be conducted using the test methods listed in Table 2 of this subpart and the procedures in § 60.3027.

(b) You must continuously monitor carbon monoxide emissions to determine compliance with the carbon monoxide emissions limitation. Three-hour rolling average values are used to determine compliance. Operation above the carbon monoxide emission limit in Table 2 constitutes a deviation from the emission limitation.

(c) You must continuously monitor the operating parameters specified in § 60.3023 or established under § 60.3024. Operation above the established maximum or below the established minimum operating limits constitutes a deviation from the established operating limits. Three-hour rolling average values are used to determine compliance unless a different averaging period is established under § 60.3024. Operating limits do not apply during performance tests.

§ 60.3034 By what date must I conduct the annual performance test?

You must conduct annual performance tests within 12 months following the initial performance test. Conduct subsequent annual performance tests within 12 months following the previous one.

§ 60.3035 May I conduct performance testing less often?

(a) You can test less often for a given pollutant if you have test data for at least three consecutive annual tests, and all performance tests for the pollutant over that period show that you comply with the emission limitation. In this case, you do not have to conduct a performance test for that pollutant for the next 2 years. You must conduct a performance test during the third year and no more than 36 months following the previous performance test.

(b) If your OSWI unit continues to meet the emission limitation for the pollutant, you may choose to conduct performance tests for that pollutant every third year, but each test must be within 36 months of the previous performance test.

(c) If a performance test shows a deviation from an emission limitation for any pollutant, you must conduct annual performance tests for that pollutant until three consecutive annual performance tests for that pollutant all show compliance.

§ 60.3036 May I conduct a repeat performance test to establish new operating limits?

Yes, you may conduct a repeat performance test at any time to establish new values for the operating limits. The Administrator may request a repeat performance test at any time.

Model Rule—Monitoring

§ 60.3038 What continuous emission monitoring systems must I install?

(a) You must install, calibrate, maintain, and operate continuous emission monitoring systems for carbon monoxide and for oxygen. You must monitor the oxygen concentration at each location where you monitor carbon monoxide.

(b) You must install, evaluate, and operate each continuous emission monitoring system according to the ''Monitoring Requirements'' in § 60.13.

§ 60.3039 How do I make sure my continuous emission monitoring systems are operating correctly?

(a) Conduct initial, daily, quarterly, and annual evaluations of your continuous emission monitoring systems that measure carbon monoxide and oxygen.

(b) Complete your initial evaluation of the continuous emission monitoring systems within 180 days after your final compliance date in Table 1 of this subpart.

(c) For initial and annual evaluations, collect data concurrently (or within 30 to 60 minutes) using your carbon monoxide and oxygen continuous emission monitoring systems. To validate carbon monoxide concentration levels, use EPA Method 10, 10A, or 10B of appendix A of this part. Use EPA Method 3 or 3A to measure oxygen. Collect the data during each initial and annual evaluation of your continuous emission monitoring systems following the applicable performance specifications in appendix B of this part. Table 4 of this subpart shows the required span values and performance specifications that apply to each continuous emission monitoring system.

(d) Follow the quality assurance procedures in Procedure 1 of appendix F of this part for each continuous emission monitoring system. The procedures include daily calibration drift and quarterly accuracy determinations.

§ 60.3040 What is my schedule for evaluating continuous emission monitoring systems?

(a) Conduct annual evaluations of your continuous emission monitoring systems no more than 12 months after the previous evaluation was conducted.

(b) Evaluate your continuous emission monitoring systems daily and quarterly as specified in appendix F of this part.

§ 60.3041 What is the minimum amount of monitoring data I must collect with my continuous emission monitoring systems, and is the data collection requirement enforceable?

(a) Where continuous emission monitoring systems are required, obtain 1-hour arithmetic averages. Make sure the averages for carbon monoxide are in parts per million by dry volume at 7 percent oxygen. Use the 1-hour averages of oxygen data from your continuous emission monitoring system to determine the actual oxygen level and to calculate emissions at 7 percent oxygen.

(b) Obtain at least two data points per hour in order to calculate a valid 1-hour arithmetic average. Section 60.13(e)(2) requires your continuous emission monitoring systems to complete at least one cycle of operation (sampling, analyzing, and data recording) for each 15-minute period.

(c) Obtain valid 1-hour averages for at least 75 percent of the operating hours per day for at least 90 percent of the operating days per calendar quarter. An operating day is any day the unit combusts any municipal or institutional solid waste.

(d) If you do not obtain the minimum data required in paragraphs (a) through (c) of this section, you have deviated from the data collection requirement regardless of the emission level monitored.

(e) If you do not obtain the minimum data required in paragraphs (a) through (c) of this section, you must still use all valid data from the continuous emission monitoring systems in calculating emission concentrations.

(f) If continuous emission monitoring systems are temporarily unavailable to meet the data collection requirements, refer to Table 4 of this subpart. It shows alternate methods for collecting data when systems malfunction or when repairs, calibration checks, or zero and span checks keep you from collecting the minimum amount of data.

§ 60.3042 How do I convert my 1-hour arithmetic averages into the appropriate averaging times and units?

(a) Use Equation 1 in § 60.3076 to calculate emissions at 7 percent oxygen.

(b) Use Equation 2 in § 60.3076 to calculate the 3-hour rolling averages for concentrations of carbon monoxide.

§ 60.3043 What operating parameter monitoring equipment must I install, and what operating parameters must I monitor?

(a) If you are using a wet scrubber to comply with the emission limitations under § 60.3022, you must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the value of the operating parameters used to determine compliance with the operating limits listed in Table 3 of this subpart. These devices (or methods) must measure and record the values for these operating parameters at the frequencies indicated in Table 3 of this subpart at all times.

(b) You must install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of any stack that could be used to bypass the control device. The measurement must include the date, time, and duration of the use of the bypass stack.

(c) If you are using a method or air pollution control device other than a wet scrubber to comply with the emission limitations under § 60.3022, you must install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor compliance with the site-specific operating limits established using the procedures in § 60.3024.

§ 60.3044 Is there a minimum amount of operating parameter monitoring data I must obtain?

(a) Except for monitor malfunctions, associated repairs, and required quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments of the monitoring system), you must conduct all monitoring at all times the OSWI unit is operating.

(b) You must obtain valid monitoring data for at least 75 percent of the operating hours per day for at least 90 percent of the operating days per calendar quarter. An operating day is any day the unit combusts any municipal or institutional solid waste.

(c) If you do not obtain the minimum data required in paragraphs (a) and (b) of this section, you have deviated from the data collection requirement regardless of the operating parameter level monitored.

(d) Do not use data recorded during monitor malfunctions, associated repairs, and required quality assurance or quality control activities for meeting the requirements of this subpart, including data averages and calculations. You must use all the data collected during all other periods in assessing compliance with the operating limits.

Model Rule—Recordkeeping and Reporting

§ 60.3046 What records must I keep?

You must maintain the 14 items (as applicable) as specified in paragraphs (a) through (n) of this section for a period of at least 5 years:

(a) Calendar date of each record.

(b) Records of the data described in paragraphs (b)(1) through (8) of this section:

(1) The OSWI unit charge dates, times, weights, and hourly charge rates.

(2) Liquor flow rate to the wet scrubber inlet every 15 minutes of operation, as applicable.

(3) Pressure drop across the wet scrubber system every 15 minutes of operation or amperage to the wet scrubber every 15 minutes of operation, as applicable.

(4) Liquor pH as introduced to the wet scrubber every 15 minutes of operation, as applicable.

(5) For affected OSWI units that establish operating limits for controls other than wet scrubbers under § 60.3024, you must maintain data collected for all operating parameters used to determine compliance with the operating limits.

(6) All 1-hour average concentrations of carbon monoxide emissions.

(7) All 3-hour rolling average values of carbon monoxide emissions and all 3-hour rolling average values of continuously monitored operating parameters.

(8) Records of the dates, times, and durations of any bypass of the control device.

(c) Identification of calendar dates and times for which continuous emission monitoring systems or monitoring systems used to monitor operating limits were inoperative, inactive, malfunctioning, or out of control (except for downtime associated with zero and span and other routine calibration checks). Identify the pollutant emissions or operating parameters not measured, the duration, reasons for not obtaining the data, and a description of corrective actions taken.

(d) Identification of calendar dates, times, and durations of malfunctions, and a description of the malfunction and the corrective action taken.

(e) Identification of calendar dates and times for which monitoring data show a deviation from the carbon monoxide emissions limit in Table 2 of this subpart or a deviation from the operating limits in Table 3 of this subpart or a deviation from other operating limits established under § 60.3024 with a description of the deviations, reasons for such deviations, and a description of corrective actions taken.

(f) Calendar dates when continuous monitoring systems did not collect the minimum amount of data required under §§ 60.3041 and 60.3044.

(g) For carbon monoxide continuous emissions monitoring systems, document the results of your daily drift tests and quarterly accuracy determinations according to Procedure 1 of appendix F of this part.

(h) Records of the calibration of any monitoring devices required under § 60.3043.

(i) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating limits, as applicable. Retain a copy of the complete test report including calculations and a description of the types of waste burned during the test.

(j) Records showing the names of OSWI unit operators who have completed review of the information in § 60.3019(a) as required by § 60.3019(b), including the date of the initial review and all subsequent annual reviews.

(k) Records showing the names of the OSWI operators who have completed the operator training requirements under § 60.3014, met the criteria for qualification under § 60.3016, and maintained or renewed their qualification under § 60.3017 or § 60.3018. Records must include documentation of training, the dates of the initial and refresher training, and the dates of their qualification and all subsequent renewals of such qualifications.

(l) For each qualified operator, the phone and/or pager number at which they can be reached during operating hours.

(m) Equipment vendor specifications and related operation and maintenance requirements for the incinerator, emission controls, and monitoring equipment.

(n) The information listed in § 60.3019(a).

§ 60.3047 Where and in what format must I keep my records?

(a) You must keep each record on site for at least 2 years. You may keep the records off site for the remaining 3 years.

(b) All records must be available in either paper copy or computer-readable format that can be printed upon request, unless an alternative format is approved by the Administrator.

§ 60.3048 What reports must I submit?

See Table 5 of this subpart for a summary of the reporting requirements.

§ 60.3049 What information must I submit following my initial performance test?

You must submit the information specified in paragraphs (a), (b) and (c) of this section no later than 60 days following the initial performance test. All reports must be signed by the facilities manager.

(a) The complete test report for the initial performance test results obtained under § 60.3030, as applicable.

(b) The values for the site-specific operating limits established in § 60.3023 or § 60.3024.

(c) The waste management plan, as specified in §§ 60.3010 through 60.3012.

§ 60.3050 When must I submit my annual report?

You must submit an annual report no later than 12 months following the submission of the information in § 60.3049. You must submit subsequent reports no more than 12 months following the previous report.

§ 60.3051 What information must I include in my annual report?

The annual report required under § 60.3050 must include the ten items listed in paragraphs (a) through (j) of this section. If you have a deviation from the operating limits or the emission limitations, you must also submit deviation reports as specified in §§ 60.3052 through 60.3054.

(a) Company name and address.

(b) Statement by the owner or operator, with their name, title, and signature, certifying the truth, accuracy, and completeness of the report. Such certifications must also comply with the requirements of 40 CFR 70.5(d) or 71.5(d).

(c) Date of report and beginning and ending dates of the reporting period.

(d) The values for the operating limits established pursuant to § 60.3023 or § 60.3024.

(e) If no deviation from any emission limitation or operating limit that applies to you has been reported, a statement that there was no deviation from the emission limitations or operating limits during the reporting period, and that no monitoring system used to determine compliance with the emission limitations or operating limits was inoperative, inactive, malfunctioning or out of control.

(f) The highest recorded 3-hour average and the lowest recorded 3-hour average, as applicable, for carbon monoxide emissions and for each operating parameter recorded for the calendar year being reported.

(g) Information recorded under § 60.3046(b)(6) and (c) through (e) for the calendar year being reported.

(h) If a performance test was conducted during the reporting period, the results of that test.

(i) If you met the requirements of § 60.3035(a) or (b), and did not conduct a performance test during the reporting period, you must state that you met the requirements of § 60.3035(a) or (b), and, therefore, you were not required to conduct a performance test during the reporting period.

(j) Documentation of periods when all qualified OSWI unit operators were unavailable for more than 12 hours, but less than 2 weeks.

§ 60.3052 What else must I report if I have a deviation from the operating limits or the emission limitations?

(a) You must submit a deviation report if any recorded 3-hour average parameter level is above the maximum operating limit or below the minimum operating limit established under this subpart, if any recorded 3-hour average carbon monoxide emission rate is above the emission limitation, if the control device was bypassed, or if a performance test was conducted showed a deviation from any emission limitation.

(b) The deviation report must be submitted by August 1 of that year for data collected during the first half of the calendar year (January 1 to June 30), and by February 1 of the following year for data you collected during the second half of the calendar year (July 1 to December 31).

§ 60.3053 What must I include in the deviation report?

In each report required under § 60.3052, for any pollutant or operating parameter that deviated from the emission limitations or operating limits specified in this subpart, include the seven items described in paragraphs (a) through (g) of this section.

(a) The calendar dates and times your unit deviated from the emission limitations or operating limit requirements.

(b) The averaged and recorded data for those dates.

(c) Durations and causes of each deviation from the emission limitations or operating limits and your corrective actions.

(d) A copy of the operating limit monitoring data during each deviation and any test report that documents the emission levels.

(e) The dates, times, number, duration, and causes for monitor downtime incidents (other than downtime associated with zero, span, and other routine calibration checks).

(f) Whether each deviation occurred during a period of startup, shutdown, or malfunction, or during another period.

(g) The dates, times, and durations of any bypass of the control device.

§ 60.3054 What else must I report if I have a deviation from the requirement to have a qualified operator accessible?

(a) If all qualified operators are not accessible for 2 weeks or more, you must take the two actions in paragraphs (a)(1) and (2) of this section.

(1) Submit a notification of the deviation within 10 days that includes the three items in paragraphs (a)(1)(i) through (iii) of this section.

(i) A statement of what caused the deviation.

(ii) A description of what you are doing to ensure that a qualified operator is accessible.

(iii) The date when you anticipate that a qualified operator will be available.

(2) Submit a status report to the Administrator every 4 weeks that includes the three items in paragraphs (a)(2)(i) through (iii) of this section.

(i) A description of what you are doing to ensure that a qualified operator is accessible.

(ii) The date when you anticipate that a qualified operator will be accessible.

(iii) Request approval from the Administrator to continue operation of the OSWI unit.

(b) If your unit was shut down by the Administrator, under the provisions of § 60.3020(c)(2), due to a failure to provide an accessible qualified operator, you must notify the Administrator that you are resuming operation once a qualified operator is accessible.

§ 60.3055 Are there any other notifications or reports that I must submit?

Yes, you must submit notifications as provided by § 60.7.

§ 60.3056 In what form can I submit my reports?

Submit initial, annual, and deviation reports electronically or in paper format, postmarked on or before the submittal due dates.

§ 60.3057 Can reporting dates be changed?

If the Administrator agrees, you may change the semiannual or annual reporting dates. See § 60.19(c) for procedures to seek approval to change your reporting date.

Model Rule—Title V Operating Permits

§ 60.3059 Am I required to apply for and obtain a title V operating permit for my unit?

Yes, if you are subject to an applicable EPA-approved and effective Clean Air Act section 111(d)/129 State or Tribal plan or an applicable and effective Federal plan, you are required to apply for and obtain a title V operating permit unless you meet the relevant requirements for an exemption specified in § 60.2993.

§ 60.3060 When must I submit a title V permit application for my existing OSWI unit?

(a)(1) If your existing OSWI unit is not subject to an earlier permit application deadline, a complete title V permit application must be submitted by the earlier of the dates specified in paragraphs (a)(1)(i) through (iii) of this section. (*See* sections 129(e), 503(c), 503(d), and 502(a) of the Clean Air Act and 40 CFR 70.5(a)(1)(i) and 71.5(a)(1)(i).)

(i) 12 months after the effective date of any applicable EPA-approved Clean Air Act section 111(d)/129 State or Tribal plan.

(ii) 12 months after the effective date of any applicable Federal plan.

(iii) 36 months after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(2) For any existing OSWI unit not subject to an earlier permit application deadline, the application deadline of 36 months after the promulgation of 40 CFR part 60, subpart FFFF, applies regardless of whether or when any applicable Federal plan is effective, or whether or when any applicable Clean Air Act section 111(d)/129 State or Tribal plan is approved by the EPA and becomes effective.

(b) If your OSWI unit is subject to title V as a result of some triggering requirement(s) other than those specified in paragraph (a) of this section (for example, an OSWI unit may be a major source or part of a major source), then your unit may be required to apply for a title V permit prior to the deadlines specified in paragraph (a). If more than one requirement triggers a source's obligation to apply for a title V permit, the 12-month time frame for filing a title V permit application is triggered by the requirement that first causes the source to be subject to title V. (*See* section 503(c) of the Clean Air Act and 40 CFR 70.3(a) and (b), 70.5(a)(1)(i), 71.3(a) and (b), and 71.5(a)(1)(i).)

(c) A ''complete'' title V permit application is one that has been determined or deemed complete by the relevant permitting authority under section 503(d) of the Clean Air Act and 40 CFR 70.5(a)(2) or 71.5(a)(2). You must submit a complete permit application by the relevant application deadline in order to operate after this date in compliance with Federal law. (*See* sections 503(d) and 502(a) of the Clean Air Act and 40 CFR 70.7(b) and 71.7(b).)

Model Rule—Temporary Use Incinerators Used in Disaster Recovery

§ 60.3061 What are the requirements for temporary use incinerators used in disaster recovery?

Your incinerator is excluded from the requirements of this subpart if it is used on a temporary basis to combust debris from a disaster or emergency such as a tornado, hurricane, flood, or act of bioterrorism, and you follow the requirements in paragraphs (a) or (b) of this section, depending on the extent of response necessary for disaster recovery.

(a) If the incinerator is used to combust debris in an area declared a State of Emergency by a State government, or the President, under the authority of the Stafford Act, has declared that an emergency or a major disaster exists in the area, then the incinerator is excluded from the requirements of this subpart.

(b) If the incinerator is used to combust debris in an area that is not declared a State of Emergency or major disaster, then you must meet the requirements of paragraphs (b)(1) through (b)(3) of this section, depending on the length of time the incinerator will be used at the same location.

(1) If the incinerator is used for less than 8 weeks at the same location, then it is excluded from the requirements of this subpart. You do not need to notify the Administrator of its use or meet the emission limits or other requirements of this subpart.

(2) If the incinerator will be used for 8 weeks or more at the same location, you must notify the Administrator that the temporary use incinerator will be used for 8 weeks or more and request permission to continue to operate the incinerator.

(i) The notification must be submitted in writing by the date 8 weeks after you start operation of the temporary use incinerator at its current location.

(ii) The notification must contain the date the incinerator started operation at its current location, identification of the disaster or emergency for which the incinerator is being used, a description of the types of materials being burned in the incinerator, a brief description of the size and design of the incinerator (for example, an air curtain incinerator or a modular starved-air incinerator), the reasons the incinerator must be operated for more than 8 weeks, and the amount of time for which you request permission to operate, including the date you expect to cease operation of the incinerator.

(3) If you submitted the notification containing the information in paragraph (b)(2)(ii) by the date specified in paragraph (b)(2)(i), you may continue to operate the incinerator for 8 additional weeks, which is a total of 16 weeks from the date the incinerator started operation in its current location. You do not have to meet the emission limits or other requirements of this subpart during this period.

(i) At the end of 16 weeks from the date the incinerator started operation in its current location, you must cease operation of the incinerator or comply with all requirements of this subpart, unless the Administrator has approved in writing your request to continue operation.

(ii) If the Administrator has approved in writing your request to continue operation, then you may continue to operate the incinerator until the date specified in the approval, and you do not need to comply with any other requirements of this subpart during the approved time period.

Model Rule—Air Curtain Incinerators That Burn Only Wood Waste, Clean Lumber, and Yard Waste

§ 60.3062 What is an air curtain incinerator?

(a) An air curtain incinerator operates by forcefully projecting a curtain of air across an open, integrated combustion chamber (fire box) or open pit or trench (trench burner) in which combustion occurs. For the purpose of this subpart and subpart EEEE only, air curtain incinerators include both firebox and trench burner units.

(b) Air curtain incinerators that burn only the materials listed in paragraphs (b)(1) through (4) of this section are required to meet only the requirements in §§ 60.3062 through 60.3068 and are exempt from all other requirements of this subpart.

(1) 100 percent wood waste.

(2) 100 percent clean lumber.

(3) 100 percent yard waste.

(4) 100 percent mixture of only wood waste, clean lumber, and/or yard waste.

§ 60.3063 When must I comply if my air curtain incinerator burns only wood waste, clean lumber, and yard waste?

Table 1 of this subpart specifies the final compliance date. You must submit a notification to the Administrator postmarked within 10 business days

after the final compliance date in Table 1 of this subpart.

§ 60.3064 What must I do if I close my air curtain incinerator that burns only wood waste, clean lumber, and yard waste and then restart it?

(a) If you close your incinerator but will reopen it prior to the final compliance date in your State plan, you must meet the final compliance date specified in Table 1 of this subpart.

(b) If you close your incinerator but will restart it after your final compliance date, you must meet the emission limitations on the date your incinerator restarts operation.

§ 60.3065 What must I do if I plan to permanently close my air curtain incinerator that burns only wood waste, clean lumber, and yard waste and not restart it?

You must close the unit before the final compliance date specified in Table 1 of this subpart.

§ 60.3066 What are the emission limitations for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Within 180 days after your final compliance date in Table 1 of this subpart, you must meet the two limitations specified in paragraphs (a)(1) and (2) of this section.

(1) The opacity limitation is 10 percent (6-minute average), except as described in paragraph (a)(2) of this section.

(2) The opacity limitation is 35 percent (6-minute average) during the startup period that is within the first 30 minutes of operation.

(b) The limitations in paragraph (a) of this section apply at all times except during malfunctions.

§ 60.3067 How must I monitor opacity for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Use Method 9 of appendix A of this part to determine compliance with the opacity limitation.

(b) Conduct an initial test for opacity as specified in § 60.8 within 180 days after the final compliance date in Table 1 of this subpart.

(c) After the initial test for opacity, conduct annual tests no more than 12 calendar months following the date of your previous test.

§ 60.3068 What are the recordkeeping and reporting requirements for air curtain incinerators that burn only wood waste, clean lumber, and yard waste?

(a) Keep records of results of all initial and annual opacity tests in either paper copy or computer-readable format that can be printed upon request, unless the Administrator approves another format, for at least 5 years. You must keep each record on site for at least 2 years. You may keep the records off site for the remaining 3 years.

(b) Make all records available for submittal to the Administrator or for an inspector's review.

(c) You must submit the results (each 6-minute average) of the initial opacity tests no later than 60 days following the initial test. Submit annual opacity test results within 12 months following the previous report.

(d) Submit initial and annual opacity test reports as electronic or paper copy on or before the applicable submittal date.

(e) Keep a copy of the initial and annual reports for a period of 5 years. You must keep each report on site for at least 2 years. You may keep the reports off site for the remaining 3 years.

§ 60.3069 Am I required to apply for and obtain a title V operating permit for my air curtain incinerator that burns only wood waste, clean lumber, and yard waste?

Yes, if your air curtain is subject to this subpart, you are required to apply for and obtain a title V operating permit as specified in §§ 60.3059 and 60.3060.

Model Rule—Equations

§ 60.3076 What equations must I use?

(a) *Percent oxygen.* Adjust all pollutant concentrations to 7 percent oxygen using Equation 1 of this section.

$$C_{adj} = C_{meas} * (20.9 - 7)/(20.9 - \%O_2) \qquad \text{(Eq. 1)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen.

C_{meas} = pollutant concentration measured on a dry basis.

(20.9–7) = 20.9 percent oxygen-7 percent oxygen (defined oxygen correction basis).

20.9 = oxygen concentration in air, percent.

$\%O_2$ = oxygen concentration measured on a dry basis, percent.

(b) *Capacity of a very small municipal waste combustion unit.* For very small municipal waste combustion units that can operate continuously for 24-hour periods, calculate the unit capacity based on 24 hours of operation at the maximum charge rate. To determine the maximum charge rate, use one of two methods:

(1) For very small municipal waste combustion units with a design based on heat input capacity, calculate the maximum charging rate based on the maximum heat input capacity and one of two heating values:

(i) If your very small municipal waste combustion unit combusts refuse-derived fuel, use a heating value of 12,800 kilojoules per kilogram (5,500 British thermal units per pound).

(ii) If your very small municipal waste combustion unit combusts municipal solid waste, use a heating value of 10,500 kilojoules per kilogram (4,500 British thermal units per pound).

(2) For very small municipal waste combustion units with a design not based on heat input capacity, use the maximum design charging rate.

(c) *Capacity of a batch very small municipal waste combustion unit.* Calculate the capacity of a batch OSWI unit as the maximum design amount of municipal solid waste it can charge per batch multiplied by the maximum number of batches it can process in 24 hours. Calculate the maximum number of batches by dividing 24 by the number of hours needed to process one batch. Retain fractional batches in the calculation. For example, if one batch requires 16 hours, the OSWI unit can combust 24/16, or 1.5 batches, in 24 hours.

(d) *Carbon monoxide pollutant rate.* When hourly average pollutant rates (E_h) are obtained (*e.g.*, CEMS values), compute the rolling average carbon monoxide pollutant rate (E_a) for each 3-hour period using the following equation:

$$E_a = \frac{1}{3}\sum_{j=1}^{3} E_{hj} \qquad \text{(Eq. 2)}$$

Where:

E_a = Average carbon monoxide pollutant rate for the 3-hour period, ppm corrected to 7 percent O_2.

E_{hj} = Hourly arithmetic average pollutant rate for hour ''j,'' ppm corrected to 7 percent O_2.

Model Rule—Definitions

§ 60.3078 What definitions must I know?

Terms used but not defined in this subpart are defined in the Clean Air Act and subpart A (General Provisions) of this part.

Administrator means the Administrator of the U.S. Environmental Protection Agency or his/her authorized representative or Administrator of a State Air Pollution Control Agency.

Air curtain incinerator means an incineration unit operating by forcefully projecting a curtain of air across an open, integrated combustion chamber (fire box) or open pit or trench (trench burner) in which combustion occurs. For the purpose of this subpart and subpart EEEE only, air curtain incinerators include both firebox and trench burner units.

Auxiliary fuel means natural gas, liquified petroleum gas, fuel oil, or diesel fuel.

Batch OSWI unit means an OSWI unit that is designed such that neither waste charging nor ash removal can occur during combustion.

Calendar quarter means three consecutive months (nonoverlapping) beginning on: January 1, April 1, July 1, or October 1.

Calendar year means 365 consecutive days starting on January 1 and ending on December 31.

Chemotherapeutic waste means waste material resulting from the production or use of anti-neoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Class II municipal solid waste landfill means a landfill that meets four criteria:

(1) Accepts, for incineration or disposal, less than 20 tons per day of municipal solid waste or other solid wastes based on an annual average;

(2) Is located on a site where there is no evidence of groundwater pollution caused or contributed to by the landfill;

(3) Is not connected by road to a Class I municipal solid waste landfill, as defined by Alaska regulatory code 18 AAC 60.300(c) or, if connected by road, is located more than 50 miles from a Class I municipal solid waste landfill; and

(4) Serves a community that meets one of two criteria:

(i) Experiences for at least three months each year, an interruption in access to surface transportation, preventing access to a Class I municipal solid waste landfill; or

(ii) Has no practicable waste management alternative, with a landfill located in an area that annually receives 25 inches or less of precipitation.

Class III municipal solid waste landfill is a landfill that is not connected by road to a Class I municipal solid waste landfill, as defined by Alaska regulatory code 18 AAC 60.300(c) or, if connected by road, is located more than 50 miles from a Class I municipal solid waste landfill, and that accepts, for disposal, either of the following two criteria:

(1) Ash from incinerated municipal waste in quantities less than one ton per day on an annual average, which ash must be free of food scraps that might attract animals; or

(2) Less than five tons per day of municipal solid waste, based on an annual average, and is not located in a place that meets either of the following criteria:

(i) Where public access is restricted, including restrictions on the right to move to the place and reside there; or

(ii) That is provided by an employer and that is populated totally by persons who are required to reside there as a condition of employment and who do not consider the place to be their permanent residence.

Clean lumber means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Clean lumber does not include wood products that have been painted, pigment-stained, or pressure-treated by compounds such as chromate copper arsenate, pentachlorophenol, and creosote.

Collected from means the transfer of material from the site at which the material is generated to a separate site where the material is burned.

Contained gaseous material means gases that are in a container when that container is combusted.

Continuous emission monitoring system or CEMS means a monitoring system for continuously measuring and recording the emissions of a pollutant from an affected OSWI unit.

Continuous OSWI unit means an OSWI unit that is designed to allow waste charging and ash removal during combustion.

Deviation means any instance in which an OSWI unit that meets the requirements in § 60.2991, or an owner or operator of such an OSWI unit:

(1) Fails to meet any requirement or obligation established by this subpart, including but not limited to any emission limitation, operating limit, or operator qualification and accessibility requirements;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any OSWI unit that meets requirements in § 60.2991 and is required to obtain such a permit; or

(3) Fails to meet any emission limitation, operating limit, or operator qualification and accessibility requirement in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is allowed by this subpart.

Dioxins/furans means tetra-through octachlorinated dibenzo-p-dioxins and dibenzofurans.

Energy recovery means the process of recovering thermal energy from combustion for useful purposes such as steam generation or process heating.

Institution means organizations having a governmental, educational, civic, or religious purpose such as schools, hospitals, prisons, government facilities, churches, and other similar establishments or facilities.

Institutional waste means solid waste combusted for reasons that do not include the recovery of heat for a useful purpose, or combusted without heat recovery or with only waste heat recovery (*i.e.*, no heat recovery in the combustion firebox), in an enclosed unit using controlled flame combustion that is a distinct operating unit of the institutional facility. Institutional waste also includes solid waste combusted on-site in an air curtain incinerator that is a distinct operating unit of the institutional facility that generated the waste.

Institutional waste incineration unit means any combustion unit that combusts institutional waste (as defined in this subpart), that is a distinct operating unit of the institutional facility that generated the waste. Institutional waste incineration units include field-erected, modular, and custom built incineration units operating with starved or excess air, and any air curtain incinerator that is a distinct operating unit of the institutional facility that generated the institutional waste (except those air curtain incinerators listed in § 60.2994(b)).

Intermittent OSWI unit means an OSWI unit that is designed to allow waste charging, but not ash removal, during combustion.

Low-level radioactive waste means waste material that contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable Federal or State standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or byproduct material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused,

in part, by poor maintenance or careless operation are not malfunctions.

Modification or modified OSWI unit means an OSWI unit you have changed on or after the date 6 months after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**] and that meets one of two criteria:

(1) The cumulative cost of the changes over the life of the unit exceeds 50 percent of the original cost of building and installing the OSWI unit (not including the cost of land) updated to current costs (current dollars). To determine what systems are within the boundary of the OSWI unit used to calculate these costs, see the definition of OSWI unit.

(2) Any physical change in the OSWI unit or change in the method of operating it that increases the amount of any air pollutant emitted for which section 129 or section 111 of the Clean Air Act has established standards.

Municipal solid waste means refuse (and refuse-derived fuel) collected from the general public and from residential, commercial, institutional, and industrial sources consisting of paper, wood, yard wastes, food wastes, plastics, leather, rubber, and other combustible materials and non-combustible materials such as metal, glass and rock, provided that:

(1) The term does not include industrial process wastes or medical wastes that are segregated from such other wastes; and

(2) An incineration unit shall not be considered to be combusting municipal waste for purposes of this subpart if it combusts a fuel feed stream, 30 percent or less of the weight of which is comprised, in aggregate, of municipal waste, as determined by § 60.2993(c).

Municipal waste combustion unit means, for the purpose of this subpart and subpart EEEE, any setting or equipment that combusts municipal solid waste (as defined in this subpart) including, but not limited to, field-erected, modular, and custom built incineration units (with or without heat recovery) operating with starved or excess air, boilers, furnaces, pyrolysis/combustion units, and air curtain incinerators (except those air curtain incinerators listed in § 60.2994(b)).

Other solid waste incineration (OSWI) unit means either a very small municipal waste combustion unit or an institutional waste incineration unit, as defined in this subpart. While not all OSWI units will include all of the following components, an OSWI unit includes, but is not limited to, the municipal or institutional solid waste feed system, grate system, flue gas system, waste heat recovery equipment, if any, and bottom ash system. The OSWI unit does not include air pollution control equipment or the stack. The OSWI unit boundary starts at the municipal or institutional waste hopper (if applicable) and extends through two areas:

(1) The combustion unit flue gas system, which ends immediately after the last combustion chamber or after the waste heat recovery equipment, if any; and

(2) The combustion unit bottom ash system, which ends at the truck loading station or similar equipment that transfers the ash to final disposal. The OSWI unit includes all ash handling systems connected to the bottom ash handling system.

Particulate matter means total particulate matter emitted from OSWI units as measured by Method 5 or Method 29 of appendix A of this part.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Reconstruction means rebuilding an OSWI unit and meeting two criteria:

(1) The reconstruction begins on or after 6 months after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**].

(2) The cumulative cost of the construction over the life of the incineration unit exceeds 50 percent of the original cost of building and installing the OSWI unit (not including land) updated to current costs (current dollars). To determine what systems are within the boundary of the OSWI unit used to calculate these costs, see the definition of OSWI unit.

Refuse-derived fuel means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including two fuels:

(1) Low-density fluff refuse-derived fuel through densified refuse-derived fuel.

(2) Pelletized refuse-derived fuel.

Shutdown means the period of time after all waste has been combusted in the primary chamber. For continuous OSWI, shutdown shall commence no less than 2 hours after the last charge to the incinerator. For intermittent OSWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. For batch OSWI, shutdown shall commence no less than 5 hours after the high-air phase of combustion has been completed.

*Solid waste me*ans any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges that are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (33 U.S.C. 1342), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2014).

Standard conditions, when referring to units of measure, means a temperature of 68 °F (20 °C) and a pressure of 1 atmosphere (101.3 kilopascals).

Startup period means the period of time between the activation of the system and the first charge to the unit. For batch OSWI, startup means the period of time between activation of the system and ignition of the waste.

Very small municipal waste combustion unit means any municipal waste combustion unit that has the capacity to combust less than 35 tons per day of municipal solid waste or refuse-derived fuel, as determined by the calculations in § 60.3076.

Waste heat recovery means the process of recovering heat from the combustion flue gases by convective heat transfer only.

Wet scrubber means an add-on air pollution control device that utilizes an aqueous or alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Wood waste means untreated wood and untreated wood products, including tree stumps (whole or chipped), trees, tree limbs (whole or chipped), bark, sawdust, chips, scraps, slabs, millings, and shavings. Wood waste does not include:

(1) Grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other private or public lands.

(2) Construction, renovation, or demolition wastes.

(3) Clean lumber.

Yard waste means grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs. Yard waste comes from residential, commercial/retail, institutional, or industrial sources as part of maintaining yards or other

private or public lands. Yard waste does not include two items:

(1) Construction, renovation, and demolition wastes.

(2) Clean lumber.

As stated in § 60.3000, you must comply with the following:

Tables to Subpart FFFF of Part 60

TABLE 1 TO SUBPART FFFF OF PART 60.—MODEL RULE—COMPLIANCE SCHEDULE

Complete this action	By this date [a]
Final compliance.[b].	Dates to be specified in State plan).[c]

[a] Site-specific schedules can be used at the discretion of the State.

[b] Final compliance means that you complete all process changes and retrofit of control devices so that, when the affected OSWI unit is brought on line, all process changes and air pollution control devices necessary to meet the emission limitations operate as designed.

[c] The date can be no later than 3 years after the effective date of State plan approval or 5 years after [DATE THE FINAL RULE IS PUBLISHED IN THE **Federal Register**], whichever is earlier.

As stated in § 60.3022, you must comply with the following:

TABLE 2 TO SUBPART FFFF OF PART 60.—MODEL RULE—EMISSION LIMITATIONS

For the air pollutant	You must meet this emission limitation [a]	Using this averaging time	And determining compliance using this method
1. Cadmium	18 micrograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Method 29 of appendix A of this part.
2. Carbon monoxide	5.0 parts per million by dry volume.	3-run average (1 hour minimum sample time per run during performance test, and 3-hour rolling averages mesured using continuous emissions monitoring system) [b].	Method 10, 10A, or 10B of appendix A of this part.
3. Dioxins/furans (total basis)	33 nanograms per dry standard cubic meter.	3-run average (1 hour minimum sample time per run).	Method 23 of appendix A of this part.
4. Hydrogen chloride	3.7 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 26A of appendix A of this part
5. Lead	226 micrograms per dry standard cubmic meter.	3-run average (1 hour minimum sample time per run).	method 29 of appendix A of this part.
6. Mercury	74 micrograms per dry standard cubmic meter.	3-run average (1 hour minimum sample time per run).	Method 29 of appendix A of this part.
7. Opacity	10 percent	6-run average (1 hour minimum sample time per run).	Method 9 of appendix A of this part.
8. Oxides of nitrogen	103 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 7, 7A, 7C, 7D, or 7E of appendix A of this part. ASME PTC 19–10–1981–Part 10 is an acceptable alternative to Method 7 and 7C only (IBR, see § 60.17(h)).
9. Particulate matter	0.013 grains per dry standard cubic foot.	3-run average (1 hour minimum sample time per run).	Method 5 or 29 of appendix A of this part.
10. Sulfur dioxide	3.1 parts per million by dry volume.	3-run average (1 hour minimum sample time per run).	Method 6 or 6C of appendix A of this part, ASME PTC 19–10–1981–Part 10 is an acceptable alternative to Method 6 only (IBR, see § 60.17(h)).

[a] All emission limitations (except for opacity) are measured at 7 percent oxygen, dry basis at standard conditions.
[b] Calculated each hour as the average of the previous 3 operating hours.

As stated in § 60.3023, you must comply with the following:

TABLE 3 TO SUBPART FFFF OF PART 60.—MODEL RULE—OPERATING LIMITS FOR INCINERATORS AND WET SCRUBBERS

For these operating parameters	You must establish these operating limits	And monitoring using these minimum frequencies		
		Date measurement	Data recording	Averaging Time
1. Charge rate	Maximum charge rate	Continuous	Every hour	Daily for batch units. 3-hour rolling for continuous and intermittent units.[a]
2. Pressure drop across the wet scrubber or amperage to wet scrubber.	Minimum pressure drop or amperage.	Continuous	Every 15 minutes	3-hour rolling.[a]
3. Scrubber liquor flow rate.	Minimum flow rate	Continuous	Every 15 minutes	3-hour rolling.[a]

TABLE 3 TO SUBPART FFFF OF PART 60.—MODEL RULE—OPERATING LIMITS FOR INCINERATORS AND WET SCRUBBERS—Continued

For these operating parameters	You must establish these operating limits	And monitoring using these minimum frequencies		
		Date measurement	Data recording	Averaging Time
4. Scrubber liquor pH	Minimum pH	Continuous	Every 15 minutes	3-hour rolling [a].

[a] Calculated each hour as the average of the previous 3 operating hours.

As stated in § 60.3039, you must comply with the following:

TABLE 4 TO SUBPART FFFF OF PART 60.—MODEL RULE—REQUIREMENTS FOR CONTINUOUS EMISSION MONITORING SYSTEMS (CEMS)

For the following pollutants	Use the following span values for your CEMS	Use the following performance specifications (P.S.) in appendix B of this part for your CEMS	If needed to meet minimum data requirements, use the following alternate methods in appendix A of this part to collect data
1. Carbon Monoxide	125 percent of the maximum hourly potential carbon monoxide emissions of the waste combustion unit.	P.S.4A	Method 10.
2. Oxygen	25 percent oxygen	P.S.3	Method 3A or 3B. ASME PTC 19–10–1981–Part 10 is an acceptable alternative to Method 3B only (IBR, see § 60.17(h)).

As stated in § 60.3048, you must comply with the following:

TABLE 5 TO SUBPART FFFF OF PART 60.—MODEL RULE—SUMMARY OF REPORTING REQUIREMENTS [a]

Report	Due date	Contents	Reference
1. Initial test report	a. No later than 60 days following the the initial performance test.	i. Complete test report for initial performance test; and	§ 60.3049.
		ii. The values for the site-specific operating limits.	§ 60.3049.
2. Waste management plan	a. No later than 60 days following the initial performance test.	i. Reduction or separation of recyclable materials; and.	§§ 60.3010 through 60.3012.
		ii. Identification of additional waste management measures and how they will be implemented.	§§ 60.3010 through 60.3012.
3. Annual report	a. No later than 12 months following the submission of the initial test report. Subsequent reports are to be submitted no more than 12 months following the previous report.	i. Company Name and	§§ 60.3050 and 60.3051.
		ii. Statement and signature by the owner or operator;.	§§ 60.3050 and 60.3051.
		iii. Date of report;	§§ 60.3050 and 60.3051.
		iv. Values for the operating limits;	§§ 60.3050 and 60.3051.
		v. If no deviations or malfunctions were reported, a statement that no deviations occurred during the reporting period;.	§§ 60.3050 and 60.3051.
		vi. Highest recorded 3-hour average and the lowest 3-hour average, as applicable, for each operating parameter recorded for the calendar year being reported;.	§§ 60.3050 and 60.3051.
		vii. Information for deviations or malfunctions recorded under § 60.2949(b)(6) and (c) through (e);.	§§ 60.3050 and 60.3051.

TABLE 5 TO SUBPART FFFF OF PART 60.—MODEL RULE—SUMMARY OF REPORTING REQUIREMENTS [a]—Continued

Report	Due date	Contents	Reference
		viii. If a performance test was conducted during the reporting period, the results of the test;.	§§ 60.3050 and 60.3051.
		ix. If a performance test was not conducted during the reporting period, a statement that the requirements of § 60.2934(a) or (b) were met; and.	§§ 60.3050 and 60.3051.
		x. Documentation of periods when all qualified OSWI unit operators were unavailable for more than 12 hours but less than 2 weeks.	§§ 60.3050 and 60.3051.
4. Emission limitation or operating limit deviation report.	b. By August 1 of that year for data collected during the first half of the calendar year. By February 1 of the following year for data collected during the second half of the calendar year.	i. Dates and times of deviation;	§§ 60.3052 and 60.3053.
		ii. Averaged and recorded data for those dates;.	§§ 60.3052 and 60.3053.
		iii. Duration and causes of each deviation and the corrective actions taken.	§§ 60.3052 and 60.3053.
		iv. Copy of operating limit monitoring data and any test reports;.	§§ 60.3052 and 60.3053.
		v. Dates, times, and causes for monitor downtime incidents; and	§§ 60.3052 and 60.3053.
		vi. Whether each deviation occurred during a period of start-up, shutdown, or malfunction §§ 60.3052 and 60.3053.	§§ 60.3052 and 60.3053.
5. Qualified operator deviation notification.	a. Within 10 days of deviation.	i. Statement of cause of deviation;	§ 60.3054(a)(1)
		ii. Description of efforts to have an accessible qualified operator; and.	§ 60.3054(a)(1)
		iii. The date a qualified operator will be accessible.	§ 60.3054(a)(1)
6. Qualified operation deviation status report.	a. Every 4 weeks following deviation.	i. Description of efforts to have an accessible qualified operator;.	§ 60.3054(a)(2)
		ii. The date a qualified operator will be accessible; and.	§ 60.3054(a)(2)
		iii. Request to continue operation	§ 60.3054(a)(2)
7. Qualified operator deviation notification of resumed operation.	a. Prior to resuming operation	i. Notification that you are resuming operation.	§ 60.3054(b).

[a] This table is only a summary, see the referenced sections of the rule for the complete requirements.

[FR Doc. 04–26741 Filed 12–8–04; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Thursday,

December 9, 2004

Part III

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

Pennsylvania Regulatory Program; Final Rules

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–143–FOR]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving a proposed amendment to the Pennsylvania regulatory program (the ''Pennsylvania program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Pennsylvania proposed to revise its program at 25 Pa. Code Chapters 86 and 89 regarding bonding and repair or compensation for damage to certain structures caused by subsidence due to underground mining operations and for replacement or restoration of water supplies impacted by subsidence due to underground mining operations. Through our approval of this amendment, we are also removing forty-seven required amendments to the Pennsylvania program. We required these amendments in a final rule published in the **Federal Register** on December 27, 2001 (66 FR 67010), in which we reviewed changes Pennsylvania made to its Bituminous Mine Subsidence and Land Conservation Act (BMSLCA) and implementing regulations. Pennsylvania revised its program to be consistent with the corresponding Federal regulations and SMCRA.

DATES: *Effective Dates:* December 9, 2004.

FOR FURTHER INFORMATION CONTACT: George Rieger, Director, Pittsburgh Field Division, Telephone: (717) 782–4036, e-mail: *grieger@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania's program and program amendments at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Submission of the Proposed Amendment

By letter dated August 27, 2003, the Pennsylvania Department of Environmental Protection (PADEP) sent us an amendment to its program (Administrative Record No. PA 841.64) under SMCRA (30 U.S.C. 1201 *et seq.*). Pennsylvania sent the amendment in response to the required program amendments at 30 CFR 938.16(hhhh) through and including (bbbbbb). Pennsylvania is proposing to amend its regulations at 25 Pa. Code 86.1, 86.151, 86.152, 89.5, 89.141, 89.142a, 89.143a, 89.144a, 89.145a, 89.146a, and 89.152 to satisfy the required amendments. Pennsylvania is also proposing additional regulation changes that relate to, but are not specifically required by, our required amendments. By letter dated September 3, 2003, PADEP revised its response to the required amendment at 30 CFR 938.16(ccccc) and its ancillary change to bonding requirements (Administrative Record No. PA 841.65).

We announced receipt of the proposed amendment in the September 22, 2003, **Federal Register** (68 FR 55106). In the same document, we opened the public comment period and provided the public with an opportunity to speak at scheduled public hearings on the amendment's adequacy. We held public hearings in Indiana, Pennsylvania, on October 15, 2003, at 3 p.m. and at 7 p.m. and in Washington, Pennsylvania, on October 16, 2003, at 3 p.m. and at 7 p.m. We entered a transcript of the public hearings into the administrative record (the Indiana hearings under Administrative Record Nos. PA 841.91 and PA 841.92, and the Washington hearings under Administrative Record Nos. PA 841.88 and PA 841.89). In a separate proposed rulemaking on the same day, we asked for comments on a proposed action to supersede certain sections of BMSLCA (68 FR 55134). The public comment period for both proposed rulemakings ended on October 22, 2003. During the hearings, we received 19 distinct sets of comments through written and oral testimony, from the following:

Industry—Pennsylvania Coal Association (PCA), Private Citizens—eight homeowners, and Businesses—The Hothouse Floral Company.

Citizen/Environmental Groups: Citizens for Pennsylvania's Future a/k/a PennFuture, Concern About Water Loss due to Mining (CAWLM), Sierra Club/Tri-States Citizen Network, Citizen Network, Mountain Watershed Association, Ten Mile Protection Network, Wheeling Creek Watershed Conservancy, and Citizen's Coal Council.

Testimony by legal counsel for State Representative William DeWeese.

In addition, we received further written comments from the PCA, the National Mining Association (NMA), the U. S. Environmental Protection Agency, Department of Labor, Mine Safety and Health Administration, several private citizens, and from two environmental groups (CAWLM & Tri-States Citizen Network).

III. OSM's Findings

Following are the findings we made under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17 concerning approval of Pennsylvania's amendment to its program and removal of our required amendments. In this final rule, we are approving the proposed changes to Pennsylvania's regulatory program as noted below. Additionally, in a separate final rule published in today's **Federal Register** we are superseding portions of BMSLCA. Approval of PADEP's proposed regulations along with the determinations made in the December 27, 2001, final rule and the superseding of portions of BMSLCA, have enabled us to remove the required amendments at 30 CFR 938.16(hhhh) through (bbbbbb). For easy cross-reference to our final rule of December 27, 2001, our findings below are arranged in the alphabetical order of the December 27, 2001, required amendments. Please see our December 27, 2001, final rule (66 FR 67010) for a full discussion of OSM's rationale for requiring these amendments to Pennsylvania's program. The December 27, 2001, final rule is made a part of the record for this action as well.

In the December 27, 2001, final rule, the required amendments from 30 CFR

938.16(hhhh) to 30 CFR 938.16(ccccc) describe changes we required Pennsylvania to make to BMSLCA, while the required amendments from 30 CFR 938.16(ddddd) to 30 CFR 938.16(bbbbbb) describe changes we required Pennsylvania to make to its regulations. In some cases, the changes Pennsylvania proposed to its regulations in the August 27, 2003, letter were sufficient to remove amendments we required to BMSLCA. The specific sections of BMSLCA where this occurred are noted below.

Finally, in its August 27, 2003, letter, PADEP also proposed several amendments to Chapters 86 and 89 that we did not specifically require in our December 27, 2001, final rule. These changes are discussed in a separate section following our discussion on the required amendments.

30 CFR 938.16(hhhh). Reference relating to bonding requirements.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5(b) of BMSLCA to delete the reference to Section 6(a) of BMSLCA, which no longer exists, and replace it with a reference to 6(b).

For a full explanation of PADEP's rationale in proposing removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55107). We accept PADEP's explanation that the error in cross referencing sections of BMSLCA will not interfere with PADEP's authority to require a bond or make its bonding requirements any less effective than the Federal bonding requirements. As a result, we are removing this required amendment and approving language in 5(b) of BMSLCA that was previously not approved.

30 CFR 938.16(iiii). Prompt replacement of water supplies.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.1(a)(1) of BMSLCA to require the prompt replacement of all water supplies affected by underground mining operations.

For a full explanation of PADEP's proposed action and argument for removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55107). PADEP proposed to amend its regulation at 25 Pa. Code 89.145a(b) to require the prompt replacement of water supplies. The proposed addition of the word ''prompt'' to Pennsylvania's regulations makes those regulations no less stringent than Section 720(a)(2) of SMCRA regarding prompt replacement of water supplies. Since BMSLCA was silent on when a water supply had to be replaced, the addition of the word ''prompt'' to Pennsylvania's regulations allows the removal of this required amendment to BMSLCA. Therefore, we are approving the regulatory change at 25 Pa. Code 89.145a(b) (see 30 CFR 938.16(rrrrr) below) and removing this required amendment.

30 CFR 938.16(jjjj). Two-year reporting limit on water supply effects.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove Section 5.1(b) of BMSLCA, which establishes a two-year limit on filing water supply damage claims. We made a similar finding in 30 CFR 938.16(yyyyy) with regard to the corresponding regulatory requirement in 25 Pa. Code 89.152(a)(4).

For a full explanation of PADEP's proposed action and argument for removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55107). PADEP proposed to amend its regulation at 25 Pa. Code 89.152(a) to remove the two year filing deadline with regard to claims involving water supplies protected under the Federal regulations. As discussed infra, we have determined that the changes to 25 Pa. Code 89.152(a) are no less effective than the Federal regulations regarding replacement of water supplies. However Section 5.1(b) of BMSLCA conflicts with this revised regulation in that it limits an operator's obligation to replace water supplies if the landowner's claim is not made within two years of the date of impact and, as initially determined in the December 27, 2001, final rule, is inconsistent with SMCRA and the Federal regulations. In a separate notice published in today's **Federal Register**, we are superseding Section 5.1(b) of BMSLCA to the extent that it would limit an operator's liability to restore or replace a water supply covered under Section 720 of SMCRA. Based on our approval of PADEP's proposed changes to its regulations at 25 Pa. Code 89.152(a) (see 30 CFR 938.16(yyyyy) below), coupled with the determinations made in the December 27, 2001, final rule and the superseding of Section 5.1(b) of BMSLCA as described above, we are removing this required amendment.

30 CFR 938.16(kkkk). Water supply replacement: promptness of actions.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the clause in Section 5.2(b)(2) of BMSLCA, which acknowledges that water supply claims may exist for periods up to three years prior to PADEP enforcement action because this does not provide for prompt replacement under Section 720(a)(2) of SMCRA.

For a full explanation of PADEP's rationale and revised regulation proposed for removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55108–09). PADEP stated that the language at Section 5.2(b)(2) of BMSLCA does not prevent it from taking enforcement action sooner than three years after the date of impact and that the three years is the outer limit for permanent water restoration/replacement. Coupled with PADEP's proposed change to its regulations at 25 Pa. Code 89.145a(b) requiring prompt replacement of water supplies, we have determined that the portion of the required amendment concerning the three year period that can elapse before enforcement action is taken can be removed. As a result, we are approving the regulatory change to 25 Pa. Code 89.145(a)(b) (see 30 CFR 938.16(rrrrr) below), approving language in Section 5.2(b)(2) of BMSLCA that was previously not approved, and we are removing this required amendment.

In a matter unrelated to this required amendment, but pertaining to Section 5.2(b)(2) of BMSLCA, we approved, in the December 27, 2001, final rule, the portion of Section 5.2(b)(2) that requires PADEP to investigate claims within 10 days of notification and to make a determination within 45 days of whether an operator affected a water supply to the extent that these time frames were consistent with, or more timely than, Pennsylvania's citizen complaint procedures (66 FR at 67016). PADEP's proposed change to 25 Pa. Code 89.146a(c), which we approved below, requires it to notify citizens of its determination within 10 days of completing its investigation. This regulation ensures that the Pennsylvania program is no less effective than the Federal requirements at 30 CFR 842.12 regarding time frames for citizen complaint procedures (see 30 CFR 938.16(wwwww) below).

30 CFR 938.16(llll). Denial of access for premining survey and its effect on affirmative proof of water supply contamination, diminution or interruption.

Required Amendment: We required Pennsylvania to submit a proposed amendment to delete the phrase, ''Wherever a mine operator, upon request, has been denied access to conduct a premining survey and the mine operator thereafter served notice upon the landowner by certified mail or personal service, which notice identified the rights established by Sections 5.1 and 5.3 and this section, was denied access and the landowner

failed to provide or authorize access within ten days after receipt thereof, then such affirmative proof shall include premining baseline data, provided by the landowner or the department, relative to the affected water supply.'' from Section 5.2(d) of BMSLCA. We took this action because limiting proof to premining baseline data is less effective than 30 CFR 817.121(j).

For a full explanation of PADEP's rationale for why the required amendment should be removed, see the September 22, 2003, proposed rule (68 FR at 55109). PADEP has stated that Section 5.2(d) of BMSLCA will not interfere with its ability to use evidence other than ''premining baseline information'' and provided an interpretation of its statute and regulations that it will allow the use of all evidence in cases of water supply impacts. Generally, courts grant deference to an agency's interpretation of a statute that the agency implements. We have determined that PADEP's interpretation is reasonable. Based on this interpretation, we have determined that it is no less effective than the Federal regulations that require replacement of all drinking, domestic and residential water supplies regardless of whether premining baseline data is provided. As a result, we are removing this required amendment and approving language in Section 5.2(d) of BMSLCA that was previously not approved.

30 CFR 938.16(mmmm). Relief of liability for water supply replacement when the adverse effect occurs more than three years after mining activity.

Required Amendment: We required Pennsylvania to submit a proposed amendment to delete Section 5.2(e)(2) of BMSLCA which provides a release of liability in cases where water supply impacts occur more than three years after mining activity because it eliminated an operator's liability, leaving no recourse for landowners.

After lengthy deliberations with PADEP concerning this required amendment, we determined that this section and its implementing regulation at 25 Pa. Code 89.152(a)(2) are no less effective than the Federal regulations because: (1) The application of the three year limit will not result in release of liability prior to the time that the Federal regulations would provide for jurisdiction to terminate; (2) PADEP can reassert jurisdiction if there is fraud, collusion or misrepresentation of a material fact; and (3) the three year limit does not affect a citizen's right to sue pursuant to Section 520 of SMCRA.

For a full discussion of OSM's considerations and the explanation of PADEP's rationale proposing removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55109). PADEP maintains that the start of the three year period is at the time of the last mining activity. PADEP proposes to amend its definition of underground mining activities at 25 Pa. Code 86.1 and 89.5 to include post closure mine pool maintenance. Water supplies are usually affected at the time of subsidence or upon the advance of mine workings into or adjacent to aquifers. After the mining is completed, the development of the post closure mine pool is the only mining-related factor that is likely to affect adjacent water supplies. The mine pool may take years to reach a stable elevation and require six months to a year to verify stabilization. Thus, the three year period will not start until PADEP is convinced that the mine pool has stabilized. The Federal regulations providing for termination of jurisdiction are based on the satisfaction of reclamation standards and not necessarily on the date of pool stabilization. Thus, the Federal regulations would normally allow a State to terminate jurisdiction before pool stabilization.

PADEP has also demonstrated (as discussed fully in the proposed rule) that it has the authority to require an operator to replace a water supply if an operator uses erroneous or fraudulent information because under Section 5.2(e) of BMSLCA such an operator has failed to meet the affirmative defense requirements. Lastly, Section 13 of BMSLCA created the right of citizens to sue. PADEP interprets Section 13 as not being affected by the three-year limit described in Section 5.2(e)(2). We have determined that PADEP's interpretation is reasonable. Accordingly, based on PADEP amending its definition of ''underground mining activities,'' and based on its reasonable interpretations of its statute and regulations that there is recourse for the landowner and there is a way to require the replacement of water supplies after the three years, we find these provisions for an operator's liability for water supply replacement to be no less effective than the Federal regulations. As a result, we are removing this required amendment and approving language in Section 5.2(e)(2) of BMSLCA that was previously not approved.

30 CFR 938.16(nnnn), (oooo), (qqqq), (rrrr). Compensation in lieu of water supply replacement.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove provisions in Sections 5.2(g) and (h) and 5.3 of BMSLCA, which allow an operator to provide compensation in lieu of restoring or replacing an affected water supply.

As previously noted in the December 27, 2001, final rule, Section 720 of SMCRA and the Federal rules unequivocally require replacement of a water supply. *See,* 66 FR at 67018. PADEP proposed to amend 25 Pa. Code 89.152 to provide for situations when an operator may not be required to restore or replace a water supply protected under Section 720 of SMCRA and for situations when an operator will not be required to restore or replace a water supply outside the protections of Section 720 of SMCRA. The proposed changes to the regulations addressing those water supplies protected under SMCRA do not provide for compensation in lieu of replacement of water supplies. Instead, these changes provide that in the rare circumstances that PADEP determines that a water supply meeting the requirements of 25 Pa. Code 89.145a(f) cannot be replaced, a payment for the fair market value of the property, or a payment for the difference between the fair market value prior to and after mining, can be made to the landowner.

However, the change to 25 Pa. Code 89.152 conflicts with portions of Sections 5.2(g) and (h) of BMSLCA because the statute limits PADEP's authority to require replacement of an Energy Policy Act (EPAct) water supply when instead an operator wants to compensate an owner. For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55111). While the Federal standards do not have a provision identical to Pennsylvania's regulations, these provisions are not inconsistent with the requirements of the Federal regulations authorizing compensation for property damage because the loss of an EPAct water supply would be considered material damage to the structure, which under 30 CFR 817.121(c)(5), would require the operator to compensate the owner for reduction in the fair market value of the structure. As a result, we are approving the proposed changes to 25 Pa. Code 89.152 (see 30 CFR 938.16(zzzzz) below). In a separate notice published in today's **Federal Register**, we are superseding Section 5.2(g) of BMSLCA to the extent that it would limit an operator's liability to restore or replace a water supply covered under Section 720 of SMCRA and we are superseding Section 5.2(h) of BMSLCA to the extent it would preclude Pennsylvania from

requiring the restoration or replacement of a water supply covered under Section 720 of SMCRA. Because of the changes Pennsylvania is proposing to its regulations at 25 Pa. Code 89.152 coupled with the determinations made in the December 27, 2001, final rule and the superseding of Sections 5.2(g) and (h) of BMSLCA as noted above, we are removing these required amendments and approving language in Section 5.3 of BMSLCA that was previously not approved.

30 CFR 938.16(pppp). Permanent alternate source definition.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the phrase, ''and of reasonable cost'' from Subsection 5.2(i) of BMSLCA because it could be interpreted to limit an operator's obligation to replace an affected water supply and could result in the landowner/water user incurring additional costs. This section provides that a permanent alternate source includes any well, spring, municipal water supply system or other supply approved by PADEP which is adequate in quantity, quality and of reasonable cost to serve the premining uses of the affected water supply.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, *see* the September 22, 2003, proposed rule (68 FR at 55113). PADEP proposes to modify its regulations at 25 Pa. Code 89.145a(f) to require that a restored or replaced drinking, domestic or residential water supply cannot cost the water user more to operate and maintain than the previous water supply. We approved this proposed regulation (see 30 CFR 938.16(uuuuu) below). Additionally, PADEP has provided an interpretation of its program that the ''reasonable cost'' standard in Section 5.2(i) of BMSLCA refers to the right of a property owner to a restored or replaced water supply that can be operated or maintained at a reasonable cost. This provision is not applied as a basis for relieving an operator of the liability for restoration or replacement of affected water supplies. With this interpretation and our approval of the proposed change to the regulation at 25 Pa. Code 89.145a(f), we have determined that Pennsylvania's program is no less effective than the Federal requirements for replacement of water supplies. Therefore, we are removing this required amendment and approving language in 5.2(i) of BMSLCA that was previously not approved.

30 CFR 938.16(ssss). Other remedies available under State law.

Required Amendment: We required Pennsylvania to submit a proposed amendment to make it clear that Section 5.3(c) of BMSLCA, relating to other remedies under State law, cannot negate or provide less protection than EPAct.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55114). PADEP provided an interpretation of this section that a landowner has full rights under BMSLCA while seeking remedies under other laws. We accept PADEP's interpretation of this portion of the statute. Because landowners or water supply users have the full protection of BMSLCA even while pursuing other avenues of redress, we have determined that this portion of the program is no less effective than the Federal regulations and we are removing this required amendment.

30 CFR 938.16(tttt). Prompt repair or compensation for structure damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.4 of BMSLCA to require prompt repairs or compensation in cases involving damage to EPAct structures (*i.e.*, noncommercial buildings, dwellings and structures related thereto).

For a full explanation of PADEP's rationale for removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55114). PADEP proposes to amend its regulation at 25 Pa. Code 89.142a(f)(1) to provide for the prompt repair of subsidence damage from underground mining operations or for the prompt compensation thereof (see 30 CFR 938.16(kkkkk) below). We have determined that this proposed regulation is no less effective than the Federal regulations requiring prompt replacement or compensation and we approved it. Since BMSLCA was silent on when a damaged structure had to be repaired, the addition of the word ''prompt'' to Pennsylvania's regulations at 25 Pa. Code 89.142a(f)(1) makes the Pennsylvania statute and regulations no less stringent than Section 720(a)(1) of SMCRA regarding prompt repair of, or compensation for, material damage to certain structures. Therefore, we are removing this required amendment.

30 CFR 938.16(uuuu). Repair of dwellings and permanently affixed appurtenant structures or improvements.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.4(a)(3) of BMSLCA to remove the phrase, ''in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application.''

The Pennsylvania statute provided for the repair or compensation of improvements to structures damaged by underground mining operations so long as the improvements were in place at the time of the permit application or at the time of the permit renewal and were completely within the boundary of the mine. The Federal definition of ''occupied residential dwelling and structures related thereto'' includes improvements related to EPAct structures. The Federal rules at 30 CFR 817.121(c)(2) protect such improvements if they were in place at the time of mining. There is no Federal requirement that the improvement be completely within the boundary of the mine. For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55115). In response to this amendment, PADEP proposes to amend its regulation at 25 Pa. Code 89.142a(f)(1)(iii) to remove the phrase corresponding to the above phrase from BMSLCA. We approved this proposed regulation (see 30 CFR 938.16(llll) below).

However, the change to 25 Pa. Code 89.142a(f)(1)(iii) conflicts with portions of Section 5.4(a)(3) of BMSLCA which still contain the above language. In a separate notice published in today's **Federal Register**, we are superseding the portion of Section 5.4(a)(3) of BMSLCA that states, ''in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application,'' to the extent it would limit an operator's liability for restoration of, or compensation for subsidence damages to, structures protected under Section 720 of SMCRA that were in existence at the time of mining. Because of our approval of Pennsylvania's proposed regulation at 25 Pa. Code 89.142a(f)(1)(iii), coupled with the determinations made in the December 27, 2001, final rule and the superseding of Section 5.4(a)(3) of BMSLCA as noted above, we have determined that the changes to Pennsylvania's program are no less effective than the Federal regulations and we are removing this required amendment.

30 CFR 938.16(vvvv). Relief of liability for structure damage repair or compensation when an operator is

denied access to conduct a premining or postmining survey.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove Section 5.4(c) of BMSLCA, which waives an operator's liability for damage repair and compensation in cases where landowners deny access for premining or postmining surveys because 30 CFR 817.121(c)(2) does not provide an exception to operator's liability for subsidence damage to EPAct structures.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55115). PADEP has proposed to revise its regulation at 25 Pa. Code 89.144a to provide that an operator's relief of liability for damage repair or compensation does not apply to EPAct structures if the landowner or PADEP can show by a preponderance of evidence that the damage resulted from the operator's underground mining operations (*see* 30 CFR 938.16(ppppp) below). We have determined that this proposed change in the regulations is no less effective than the Federal provisions relating to damage repair or compensation and we approved it. However, the change to 25 Pa. Code 89.144a conflicts with portions of Section 5.4(c) of BMSLCA which still contain this language. In a separate notice published in today's **Federal Register**, we are superseding Section 5.4(c) of BMSLCA to the extent it limits an operator's liability for repair of, or compensation for, subsidence damage to a structure covered under Section 720 of SMCRA. Based on Pennsylvania's proposed changes to 25 Pa. Code 89.144a, coupled with the determinations made in the December 27, 2001, final rule and the superseding of Section 5.4(c) of BMSLCA as described above, we are removing this required amendment.

30 CFR 938.16(wwww). Repair or compensation for damaged structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.5(a) of BMSLCA to make it clear that operators are responsible for repair or compensation in all cases where EPAct structures are damaged by subsidence from ''underground mining operations,'' not just for damage caused by the removal of coal. Section 720(a) of SMCRA requires prompt repair or compensation for material damage caused by underground coal mining operations, which includes many activities. We made a similar requirement at 30 CFR 938.16(bbbbbb) with regard to the implementing regulations at 25 Pa. Code 89.143a(a).

For a full discussion of the various terms and an explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55116). PADEP proposes to amend its regulation at 25 Pa. Code 89.143a(a) to change the term ''underground mining'' to ''underground mining operations.'' PADEP noted that the terms ''underground mining'' and ''underground mining operations'' are not defined in the BMSLCA and are used interchangeably in the statute (for example, the term ''underground mining operations'' used in Section 5.4 of BMSLCA and the term ''underground mining'' used in Section 5.5 of BMSLCA). Since these and related sections concern the same subject matter, repair and/or compensation of damage to structures, PADEP's regulatory definitions and its interpretation of its statute and regulations must be examined to satisfy this issue. We have determined that Pennsylvania's proposed change to 25 Pa. Code 89.143a(a) is no less effective than the Federal regulations regarding repair or compensation of structures damaged by underground mining operations since its definition of underground mining operations is consistent with that portion of the Federal definition of underground mining activities regarding underground operations. As a result, we are approving it (*see* 30 CFR 938.16(bbbbbb)) below. Further, we have determined that Pennsylvania's interpretation that BMSLCA is not limiting in this regard is a reasonable one and therefore we are removing this required amendment.

30 CFR 938.16(xxxx). Structure Damage—Six-month negotiation period and two-year claim filing period.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove Section 5.5(b) of BMSLCA which describes procedures for the resolution of structure damage claims. Section 5.5(b) provides a six-month negotiation period prior to intervention of PADEP. It also establishes a two-year period for filing subsidence damage claims. We required the amendment because the language could delay enforcement action by PADEP; did not provide for prompt repair or compensation as required by SMCRA; and was inconsistent with SMCRA which does not restrict the time for filing a damage claim. We made a similar requirement at 30 CFR 938.16(nnnnn) with regard to the implementing regulations at 25 Pa. Code 89.143a(c).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55116). To address this required amendment, PADEP has stated that under Section 9 of BMSLCA, it has the broad authority to issue enforcement orders prior to the six month negotiation period in order to carry out the enforcement provisions of BMSLCA. Additionally, PADEP amended its proposed regulation at 25 Pa. Code 89.143a(c) to eliminate the requirement that a landowner wait six months to file a claim and to eliminate the requirement that a landowner file a damage claim within two years with regard to structures protected under Federal regulations. We have determined that these changes make this regulation no less effective than the Federal regulations regarding damage repair or compensation and we approved them (see 30 CFR 938.16(nnnnn) below). We have determined that PADEP's interpretation of Section 9 of BMSLCA is reasonable since it removed the above noted regulatory language, making it clear that the six month time period does not limit earlier repair or compensation for protected structures.

However, the proposed change to 25 Pa. Code 89.143a(c) conflicts with portions of Section 5.5(b) of BMSLCA because the statute has the mandatory language that all claims shall be filed within two years. In a separate notice published in today's **Federal Register**, we are superseding the portion of Section 5.5(b) of BMSLCA that reads, ''All claims under this subsection shall be filed within two years of the date damage to the building occurred'' to the extent that it would limit an operator's liability for restoration of, or compensation for, subsidence damages to a structure covered under Section 720 of SMCRA. Based on our approval of PADEP's proposed amendment to 25 Pa. Code 89.143a(c), coupled with the determinations made in the December 27, 2001, final rule and the superseding of Section 5.5(b) of BMSLCA as noted above, we are removing this required amendment.

30 CFR 938.16(yyyy). Investigation and orders for repair of damaged structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.5(c) of BMSLCA to do three things: (1) Remove the following phrase relating to timeframes for enforcement orders, ''* * * within six months or a longer

period if the department finds that the occurrence of subsidence or subsequent damage may occur to the same building as a result of mining.'' We made a similar requirement in 30 CFR 938.16(ooooo) with regard to the implementing regulations at 25 Pa. Code 89.143a(d); (2) ensure that written damage determinations made by PADEP will take into account subsidence due to underground coal mining operations as required by SMCRA (we made a similar requirement at 30 CFR 938.16(bbbbbb) with regard to the implementing regulations at 25 Pa. Code 89.143a(d)(1)–(3)); and (3) ensure that the timeframes for investigation of claims of subsidence damage are consistent with Federal procedures for response to citizen complaints.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55117). With regard to the first requirement, PADEP stated that the language in 5.5(c) of BMSLCA reads that the compliance period is ''within six months'' and not a fixed six-month compliance period so that it has the ability to require shorter compliance period than six months. To support this interpretation, PADEP proposes to remove the six month period from its regulation at 25 Pa. Code 89.143a(d)(3) and proposes to add provisions relating to the prompt performance of actions required by enforcement orders. We approved these proposed changes (see 30 CFR 938.16(ooooo) below).

With regard to the second requirement, PADEP proposes to amend 25 Pa. Code 89.143a(d) to replace the term, ''underground mining,'' with ''underground mining operations.'' We approved this proposed change (see 30 CFR 938.16(bbbbbb) below).

With regard to the third requirement, PADEP proposes to amend 25 Pa. Code 89.143a(d)(1) to require claimant notification by PADEP within ten days of PADEP completing its investigation of the subsidence damage claim. We have determined that PADEP's interpretation of BMSLCA's ''within six months'' language in conjunction with the proposed regulatory change allows PADEP to issue orders requiring prompt compliance is no less effective than the Federal regulations which require abatement of notices of violations (*i.e.*, enforcement orders) within ninety days, including extensions, unless one of the exceptions of 30 CFR 843.12(c) applies. As a result, we are approving Pennsylvania's proposed regulation at 25 Pa. Code 89.143a(d)(1). As discussed earlier with required amendment 30 CFR 938.16(wwww), we have determined that PADEP's interpretation and regulation change replacing the term ''underground mining'' with ''underground mining operations,'' no less effective than the Federal regulations.

Finally, with regard to the proposed changes made to the regulations concerning investigation and notification of subsidence damages claims, we determined that since Section 5.5(c) of BMSLCA was ambiguous on the maximum time that could elapse between the completion of the investigation and the time the complainant was notified of the results, the revised regulation is no less effective than the Federal citizen complaint rule which requires notification within ten days of completion of the inspection. As a result, we are removing this required amendment.

30 CFR 938.16(zzzz). Issuance of orders and payment of escrow when an operator fails to repair or compensate a landowner for subsidence damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the following phrase from Section 5.5(f) of BMSLCA, ''* * * within six months or such longer period as the department has established or shall fail to perfect an appeal of the department's order directing such repair or compensation.''

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55118). PADEP addressed this amendment through an amendment to its regulation at 25 Pa. Code 89.143a(d) (*see* 30 CFR 938.16(ooooo) below). As discussed in the prior finding, the proposed amendment to 25 Pa. Code 89.143a(d) clarifies the requirement for prompt compliance, conditions time extensions for abatement on a determination that additional subsidence is expected to occur, and removes all references to ''six month'' compliance periods. PADEP's proposed change to 25 Pa. Code 89.143a(d) is no less effective than the Federal regulations.

We also agree with PADEP's explanation that the escrow provision found in Section 5.5(e) of BMSLCA eliminates our concern that a perfected appeal could stay an enforcement action. An enforcement action would require the operator to repair or compensate for material damage to a protected structure. Payment into the escrow account by the operator is comparable to the Federal regulation of 30 CFR 817.21(c)(2) which requires repair or compensation, thus eliminating the need for enforcement action. Based on the proposed changes to 25 Pa. Code 89.143a(d) and PADEP's explanation, we are removing this required amendment and approving language in 5.5(f) of BMSLCA that was previously not approved.

30 CFR 938.16(aaaaa). ''Pre-1994'' agreements relating to subsidence damage repair or compensation.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 5.6(c) of BMSLCA to remove provisions relating to agreements executed between April 27, 1966, and August 21, 1994.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55119). PADEP indicated that the agreements referenced under this section are no longer a cause for concern. PADEP also indicated that it believes that these agreements no longer play a role in the settlement of structure damage cases in Pennsylvania and observed that it has encountered no situation where repairs or compensation were denied on the basis of Section 5.6(c) of BMSLCA. On this basis, PADEP asserts that there is no need to amend Section 5.6(c) of BMSLCA. In the proposed rule, we requested that the public provide copies of these agreements if they exist. While we received unsigned copies of such agreements, we received none that were signed. As a result, we have determined that PADEP's assertion that such agreements do not influence structure damage claims is accurate. As a result, we are removing this required amendment and approving language in Section 5.6(c) of BMSLCA that was previously not approved.

30 CFR 938.16(bbbbb): Reference to ''pre-1994'' agreements.

Required Amendment: We required Pennsylvania to submit a proposed amendment to ensure that the provisions of Section 5.6(d) of BMSLCA reflect our decision in regard to 30 CFR 938.16(aaaaa).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55120). Because of our decision with regard to removing the required amendment at 30 CFR 938.16(aaaaa), we have determined that there is no need for this required amendment and we are removing it.

30 CFR 938.16(ccccc). Bonding for subsidence damage and water replacement.

Required Amendment: We required Pennsylvania to submit a proposed amendment to Section 6 of BMSLCA to

comply with the provisions of 30 CFR 817.121(c)(5) regarding when, and under what circumstances, the regulatory authority must require permittees to obtain additional performance bond and the amount of such bond. Specifically, we were concerned that the Pennsylvania program did not provide for an adjustment of the bond after subsidence damage occurs or did not require a bond or a bond increase for damage to land or water resources.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55120). PADEP indicated that it requires operators to post a subsidence bond prior to mining and that the amount of this bond is based on the value of land, improvements and developed water sources and projections of subsidence damage. The bonds are recalculated each time the permit is renewed and each time there is a change in the subsidence control plan area. In addition, PADEP has proposed to amend 25 Pa. Code 86.152(a) to change discretionary bond adjustments to mandatory adjustments. We have approved this proposed change (see the discussion for 25 Pa. Code 86.152(a) in the section titled, ''Ancillary Changes'' below). Lastly, for damaged water resources, PADEP asserts that a bond for damaged water resources is unnecessary because its existing regulation at 25 Pa. Code 86.168 requires a permittee to have liability insurance for the loss or diminution in quantity and quality of public or private sources of waters. The Federal regulations at 30 CFR 800.14 allow liability insurance in lieu of a performance bond. We have determined that the proposed changes PADEP is making to its regulation at 25 Pa. Code 86.152(a), and its liability insurance provisions of 25 Pa. Code 86.168, coupled with PADEP's explanation of its subsidence bond program make its proposed regulations no less effective than the corresponding Federal regulations at 30 CFR 817.121(c)(5). As a result, we are removing this required amendment.

30 CFR 938.16(ddddd). Definition of de minimis cost increase.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the definition of de minimis cost increase, which appears in 25 Pa. Code 89.5 (relating to definitions) because it could allow some increased operation and maintenance costs be passed on to the landowner or water user.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55120). PADEP proposed to eliminate the de minimis cost increase concept for water supplies protected under the Federal regulations in its regulation at 25 Pa. Code 89.145a(f). Pennsylvania's proposed regulation requires that the restored or replaced EPAct water supply shall not cost the landowner or the water user more to operate and maintain than the cost of the previous water supply. Elimination of de minimis cost increases for drinking, domestic, and residential water supplies is no less effective than the Federal regulations which require no increased operating and maintenance costs of replacement water supplies be passed on to landowners and water users. Therefore, we are removing this required amendment.

30 CFR 938.16(eeeee). Definition of fair market value.

Required Amendment: We required Pennsylvania to submit a proposed amendment to delete the definition of ''fair market value'' from 25 Pa. Code 89.5.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55121). PADEP noted that the term ''fair market value'' is used in cases where it has determined that affected water supplies cannot be replaced. We approved this concept under the required amendments at 30 CFR 938.16(nnnn), (oooo), (qqqq), and (rrrr). We determined that this definition will be necessary in providing compensation in those cases where a water supply cannot be replaced and the owner is compensated for the reduction of the fair market value of the structure due to the water loss. As a result, we are removing this required amendment and approving this definition.

30 CFR 938.16(fffff). Definition of permanently affixed appurtenant structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the phrase ''securely attached to the land surface'' in the definition of ''permanently affixed appurtenant structures'' in 25 Pa. Code 89.5 because the Federal definition of ''occupied residential dwelling and structures related thereto'' does not require such structures be securely attached to the land.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55121). To address this requirement, PADEP proposes to amend its regulations to delete the requirement for secure attachment to the land surface for the group of ''permanently affixed appurtenant structures'' that falls within the scope of the Federal regulations. This change will be accomplished by deleting the definition ''permanently affixed appurtenant structures'' from 25 Pa. Code 89.5 and by adding a description to 25 Pa. Code 89.142a(f)(1)(iii) that draws on the Federal definition of occupied residential dwellings and structures related thereto at 30 CFR 701.5, which does not have such restrictions. We have determined that these revised regulations are no less effective than the Federal requirements and as a result, we are approving them and removing this required amendment.

30 CFR 938.16(ggggg). Subsidence control plan—prevention of material damage to EPAct structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.141(d)(3) to expand its requirement that subsidence control plans include descriptions of the measures to be taken to prevent material damage to dwellings and related structures and noncommercial buildings when mining methods do not result in planned subsidence.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55122). PADEP proposes extensive changes to 25 Pa. Code 89.141(d) and 89.142a(d) to address our concern and to more clearly distinguish between requirements pertaining to mining that results in planned subsidence versus mining that does not result in planned subsidence. The proposed amendments establish different approaches to protecting noncommercial buildings, dwellings and related structures (EPAct structures) depending on the type of mining an operator plans to use. If plans involve mining that does not result in planned subsidence, an operator must take measures to prevent subsidence that would cause material damage to EPAct structures. If plans involve mining that is projected to result in planned subsidence, an operator must develop his plans around alternate measures, which are described in the discussion under 30 CFR 938.16(hhhhh). SMCRA and the Federal regulation at 30 CFR 784.20(b) require the permittee to describe preventative measures for EPAct structures. Since Pennsylvania's amended regulations will require preventative measures for EPAct structures, we have determined that the proposed change to 25 Pa. Code

89.141(d) and 89.142a(d) with regard to structures protected under SMCRA are no less effective than the corresponding Federal regulations. As a result, we are approving the proposed regulations and removing this required amendment.

30 CFR 938.16(hhhhh). Subsidence control plan—minimizing material damage to EPAct structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.141(d)(6) to require subsidence control plans to include descriptions of the measures to be taken to minimize material damage to dwellings and related structures and noncommercial buildings when mining methods are projected to result in planned subsidence because 89.141(d)(6) addressed irreparable damage but did not address situations where material damage may occur for EPAct structures as required by 30 CFR 784.20(b)(5) and (b)(7).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55123). In response to our concern, PADEP has proposed extensive amendments to 25 Pa. Code 89.141(d) and 25 Pa. Code 89.142a(d). These changes, which are also discussed under 30 CFR 938.16(ggggg), require subsidence control plans to include descriptions of the measures to be taken when planned subsidence is projected to result in material damage to an EPAct structure. The measures, which are described in proposed 25 Pa. Code 89.142a(d), include taking measures to minimize damage to the extent technologically and economically feasible; obtaining the landowner's consent to allow damage; and evaluating the need for damage minimization measures based on cost, health, and safety considerations. We have determined that these proposed changes require, as does the Federal rule at 30 CFR 784.20(b)(7), a description of the methods to be used in areas of planned subsidence to minimize material damage for EPAct structures, unless the owner consented to the material damage or the costs of the minimization methods would exceed the cost of repairs and the material damage does not threaten health or safety. Thus, the proposed changes make Pennsylvania's regulations no less effective than the Federal requirements and we are approving them and removing this required amendment.

30 CFR 938.16(iiiii). Measures to minimize material damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.142a(c)(3) to make it no less effective than 30 CFR 817.121(e), which imposes on the regulatory authority the obligation to require permittees to modify subsidence control plans to ensure the prevention of further material damage in the cases where the initial plan or operator's actions fail and provides the authority to suspend mining until such a plan is approved.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55123). PADEP proposes to amend 25 Pa. Code 89.142a(c)(3) to incorporate the provisions we requested by giving PADEP the discretion to suspend mining. We have determined that these proposed changes will make Pennsylvania's program no less effective than the Federal rule at 30 CFR 817.121(e) in dealing with situations where approved measures fail to prevent material damage or reduce the reasonably foreseeable use of public buildings and facilities, churches, schools, hospitals, impoundments with storage capacities of 20 acre-feet or more, bodies of water with volumes of 20 acre-feet or more, and aquifers or bodies of water that serve as significant sources for public water supply systems. We also note that the structures or features addressed by this proposed regulation are the same as those addressed by 30 CFR 817.121(d) and (e). As a result, we are approving the proposed regulation and removing this required amendment.

30 CFR 938.16(jjjjj). Prevention of material damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.142a(d) to ensure the prevention of material damage to occupied residential dwellings and community or institutional buildings (*i.e.*, EPAct structures) in areas where mining is not projected to result in planned subsidence because this subsection only addressed situations where irreparable damage was predicted but did not address situations where material damage may occur for EPAct structures, as provided at 30 CFR 817.121(a).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55124). PADEP proposes to address OSM's concern by amending 25 Pa. Code 89.142a(d) to require the prevention of material damage in cases where operators use mining methods that are not projected to result in planned subsidence. We have determined that this proposed change makes Pennsylvania's regulations no less effective than the Federal regulations in regard to the protection of EPAct structures. As a result, we are approving the proposed regulation and removing this required amendment.

30 CFR 938.16(kkkkk). Prompt repair or compensation for structure damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.142a(f)(1) to secure prompt repair or compensation to landowners. We made a similar requirement at 938.16(tttt) in regard to Section 5.4 of BMSLCA (*see* discussion under 30 CFR 938.16(tttt).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55124). PADEP proposes to amend 25 Pa. Code 89.142a(f)(1) as shown under 30 CFR 938.16(tttt). Since Pennsylvania has proposed to add the word ''prompt'' to its regulations, we have determined that 25 Pa. Code 89.142(a)(f)(1) is no less effective than the Federal rule at 30 CFR 817.121(c) which requires the prompt repair or compensation to landowners for material damage caused by subsidence and we are approving it. Since these proposed changes also satisfy the required amendment, we are removing it.

30 CFR 938.16(lllll). Repair of dwellings and permanently affixed appurtenant structures or improvements.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.142a(f)(1)(iii) to remove the phrase, ''in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application.'' This section is similar to Section 5.4(a)(3) of BMSLCA. *See* discussion under 30 CFR 938.16(uuuu).

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55124). PADEP proposes to amend 25 Pa. Code 89.142a(f)(1)(iii) as shown in the proposed resolution to 30 CFR 938.16(uuuu). Since the proposed regulation no longer has the limitations that were not in the Federal regulation at 30 CFR 817.121(c)(5), we have determined that this regulation is no less effective than the Federal rule and we are approving it and removing the required amendment. Also, we are superseding the language in Section 5.4(a)(3) of BMSLCA which serves as

the basis for this condition in a separate notice published in today's **Federal Register**.

30 CFR 938.16(mmmmm). Protection of utilities from underground mining activities.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.142a(g)(1) to require all underground mining activities, not just underground mining, be conducted in a manner consistent with 30 CFR 817.180. The term ''underground mining activities'' is defined at 30 CFR 701.5 to include surface operations incident to underground coal extraction or in situ processing and underground operations.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55124). In response to the required amendment, PADEP is proposing to revise 25 Pa. Code 89.142a(g)(1) to replace the term ''underground mining'' with ''underground mining operations.'' We have determined that this change, in combination with the protections already provided under existing 25 Pa. Code 89.67 (relating to surface mining activities associated with an underground mine and various utilities), is no less effective than the Federal regulations at 30 CFR 817.180 and we are approving it. As a result, we are removing this required amendment.

30 CFR 938.16(nnnnn). Statute of limitations on damage repair or compensation—claims must be filed with PADEP within two years of damage.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the phrase from 25 Pa. Code 89.143a(c) that states, ''* * * within 6 months of the date that the building owner sent the operator notification of subsidence damage to the structure * * *.'' Additionally, we required Pennsylvania to submit a proposed amendment to remove the phrase, ''within 2 years of the date damage to the structure occurred.'' We made a similar requirement at 30 CFR 938.16(xxxx) with regard to Section 5.5(b) of BMSLCA.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55125). Since 25 Pa. Code 89.143a(c) is substantively identical to Section 5.5(b) of BMSLCA, please see our discussion and proposed resolution under 30 CFR 938.16(xxxx), including proposed amendments to 25 Pa. Code 89.143a(c) and OSM supersession described under 30 CFR 938.16(xxxx). As noted in 30 CFR 938.16(xxxx), we have determined that the changes proposed by PADEP are no less effective than the Federal regulations and we are approving them. As a result, we are removing this required amendment.

30 CFR 938.16(ooooo). Investigation and orders for repair of damaged structures.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove the sentences from 25 Pa. Code 89.143a(d)(3) that state, ''* * * within 6 months of the date of issuance of the order. The Department may allow more than 6 months if the Department finds that further damage may occur to the same structure as a result of additional subsidence.'' We made a similar requirement at 30 CFR 938.16(yyyy) with regard to Section 5.5(c) of BMSLCA.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55125). This regulation is similar to 5.5(c) of BMSLCA. PADEP's proposal to amend 25 Pa. Code 89.143a(d)(3) as shown under 30 CFR 938.16(yyyy) is no less effective than the Federal regulations and we are approving it. The proposed regulation also satisfies the required amendment at 30 CFR 938.16(ooooo). See also the discussion under 30 CFR 938.16(yyyy) above for more information. We are removing this required amendment.

30 CFR 938.16(ppppp). Relief of liability for structure damage repair or compensation when operator is denied access to conduct a premining or postmining survey.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove 25 Pa. Code 89.144(a)(1), which provides a waiver of liability that is inconsistent with Federal regulations. This is the same issue that was raised under 30 CFR 938.16(vvvv) in regard to Section 5.4(c) of BMSLCA.

PADEP has proposed changes to 25 Pa Code 89.144(a)(1) that restrict this waiver so it cannot be raised in cases involving EPAct structures. *See* the proposed regulatory amendment and our supersession described under 30 CFR 938.16(vvvv). These amended regulations are no less effective than the Federal regulations and we are approving them. This approval satisfies the required amendment under 30 CFR 938.16(ppppp) and, as a result, we are removing it.

30 CFR 938.16(qqqqq). Water supply surveys—various issues.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.145a(a)(1) to: (1) Make it clear that the requirement that survey information need only be obtained to the extent that it can be collected without extraordinary efforts or the expenditure of excessive sums of money is only applicable as it applies to inconveniencing landowners; (2) remove the provision that allows for water supply surveys to be delayed until mining advances within 1,000 feet of a water supply; and (3) require permittees to submit information required by 25 Pa. Code 89.145a(a)(1)(i)–(vi) that is necessary to meet the provision of 30 CFR 784.20(a)(3) at the time of application for all existing drinking, domestic, or residential water supplies.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55125). With regard to the first concern, PADEP proposes to amend 25 Pa. Code 89.145a(a)(1) to replace the condition relating to ''extraordinary efforts or excessive sums of money'' with a condition relating to ''excessive inconvenience to the landowner,'' so it is clear that a survey will be conducted unless the landowner is excessively inconvenienced. This is no less effective than 30 CFR 784.20 that requires the permit applicant to conduct a water supply survey at its own expense.

With regard to the second and third concerns, state regulatory authorities must demonstrate that baseline data at the time of the permit application is adequate to develop the Probable Hydrologic Consequences and Cumulative Hydrologic Investigation Assessment documents and that any delayed water supply surveys would be completed before any adverse effect to the water supply. PADEP proposed amending 25 Pa. Code 89.145a(a)(1) to remove the 1,000-foot criterion and clarify the requirement to collect premining survey information prior to the time the water supply is susceptible to mining-related effects. The determination of when surveys must be completed will be made by PADEP technical staff based on information in the permit application, PADEP database information relating to the distances at which impacts have been documented to occur, and the reviewer's knowledge of conditions in the general area. Sampling distances specific to each mine and, if appropriate, to individual areas within a mine, will be established by permit condition. We agree that the approach that Pennsylvania proposes is reasonable since the environment of the individual permit will dictate when the

water supply will be susceptible to the effects of mining and that the entity best equipped to deal with this determination is PADEP since it has available the most unbiased experience and information.

With regard to the third concern, PADEP asserts that the proposed changes to 25 Pa. Code 89.145a, in combination with its proposal to gather appropriate premining information using the provisions of 25 Pa. Code Sections 89.34, 89.35 and 89.36, will make Pennsylvania's premining survey requirements as effective as Federal counterpart requirements. We agree that the baseline data information submitted with the permit application (25 Pa. Code 89.34–36 hydrologic information) and the changes to 25 Pa. Code 89.145a are adequate to develop the probable hydrologic consequences and cumulative hydrologic impacts of the area. Thus, we have determined that PADEP's proposed changes to 25 Pa. Code 89.145a and its interpretation to be no less effective than the Federal regulations and we are approving it. These actions satisfy the required amendment under 30 CFR 938.16(qqqqq) and as a result, we are removing it.

30 CFR 938.16(rrrrr). Water supply replacement—promptness of action and reasonably foreseeable uses.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.145a(b) to require the ''prompt'' restoration or replacement of water supplies and to clarify, if necessary, that the language at 25 Pa. Code 89.145a(b) is consistent with the actual use and the reasonably foreseeable use of the supply, regardless of whether the current owner has demonstrated plans for the use.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55127). PADEP proposes to address our concern regarding prompt restoration by amending 25 Pa. Code 89.145a(b) to incorporate a requirement for ''prompt'' action. The ''prompt'' issue was raised under 30 CFR 938.16(iiii) in regard to Section 5.1(a)(1) of BMSLCA. See the proposed regulatory amendment described under 30 CFR 938.16(vvvv) for further discussion. PADEP decided to address our concern regarding reasonably foreseeable uses of water supplies by amending 25 Pa. Code 89.145a(b) to require that restored or replacement water supplies must be adequate to serve the premining uses of the water supply *and* any reasonably foreseeable uses of the water supply. This is consistent with what we did when we approved the Federal definition of ''replacement of water supply,'' where we rejected a recommendation that replacement be limited to actual use. See 60 FR at 16726. Thus, we have determined that these changes are no less effective than the Federal regulations regarding the prompt replacement of water supplies and the standards for replacement of a water supply to its premining quantity and quality. As a result, we are approving the proposed regulations and removing this required amendment.

30 CFR 938.16(ssss). Water supply replacement—prompt provision of temporary water.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.145a(e)(1) to assure the prompt supply of temporary water to all landowners whose water supplies have been affected by underground mining operations regardless of whether the water supplies are within or outside of the area of presumptive liability.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55127). PADEP proposes to address our concern by amending 25 Pa. Code 89.145a(e) to include a paragraph that specifically addresses the provision of temporary water supplies when EPAct water supplies are affected by underground mining activities. This new requirement will apply regardless of the location of the affected water supply with respect to the rebuttable presumption area or the operator's rebuttal of the presumption of liability. We have determined that the proposed change to 25 Pa. Code 89.145a(e) is no less effective than the Federal regulations regarding replacement of water supplies because 30 CFR 701.5 (replacement of water supply) and 30 CFR 817.41(j) require the prompt replacement of a protected water supply on both a temporary and permanent basis, regardless of where the water supply is located. As a result, we are approving this proposed regulation and removing this required amendment.

30 CFR 938.16(ttttt). Quality and quantity of temporary water supplies.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.145a(e)(2) to require the restoration of water quantity in temporary water supplies to the same level as permanent water supplies, as noted in 25 Pa. Code 89.145a(f)(3) because the definition of ''replacement of water supply'' at 30 CFR 701.5 applies to both permanent and temporary water supplies.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55128). PADEP proposes to address OSM's requirement by amending former paragraph 25 Pa. Code 89.145(e)(2), which is paragraph (e)(3) under the current proposal, to delete the reference to premining water needs. Amended paragraph (e)(3) will require temporary water supplies to meet all needs of an affected water user, not just the water user's premining needs. We have determined that this change makes the Pennsylvania program no less effective than the Federal regulations and we are approving it. As a result, we are removing this required amendment.

30 CFR 938.16 (uuuuu). De minimis cost increase.

Required Amendment: We required Pennsylvania to submit a proposed amendment to revise 25 Pa. Code 89.145a(f)(1)(v) to make it clear that cost increases associated with the operation and maintenance of a restored or replacement water supply may not be passed on to the water user.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, *see* the September 22, 2003, proposed rule (68 FR at 55128). As explained in discussions under 30 CFR 938.16(pppp) and (ddddd), PADEP proposes to amend 25 Pa. Code 89.145a(f) to address our concern. The amendments require that, in the case of an EPAct water supply, the restored or replacement water supply shall cost no more to operate and maintain than the previous water supply. As discussed earlier, this change is no less effective than the Federal regulations regarding replacement of water supplies and we are approving it. As a result, we are removing the required amendment at 30 CFR 938.16(uuuuu).

30 CFR 938.16(vvvvv). Reasonably foreseeable use—adequate quantity.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.145a(f)(3)(i) and (ii), if necessary, to ensure that the phrase ''satisfy the water user's needs and the demands of any reasonably foreseeable uses'' is consistent with the actual use and the reasonably foreseeable uses.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, *see* the September 22, 2003, proposed rule (68 FR at 55129). PADEP has addressed our concerns by affirming that it will consider all reasonably foreseeable drinking, domestic and residential uses when evaluating the adequacy of

restored EPAct water supplies or replacements for EPAct water supplies. PADEP further affirms that evaluations will be based on the location and characteristics of the property as well as the apparent and documented needs of the current water user. Pennsylvania's interpretation of its program makes it no less effective than the Federal regulations at 30 CFR 701.5 regarding replacement of water supplies. As a result, we are removing the required amendment at 30 CFR 938.16(vvvvv).

30 CFR 938.16(wwwww). Water supply problems—investigation time frames.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.146a(c) to the extent the time frames for PADEP investigations are longer than those in Pennsylvania's approved citizen complaint procedures. This issue is discussed under 30 CFR 938.16(kkkk) in regard to Section 5.2(b)(2) of BMSLCA.

For a complete discussion, please see our finding for Section 5.2(b)(2) of BMSLCA under 30 CFR 938.16(kkkk). Section 5.2(b)(2) was the basis for the investigation timeframes in 25 Pa. Code 89.146a(c)(1). PADEP's proposal to revise 25 Pa. Code 89.146a(c) to impose on itself an obligation to report water supply problem investigations to claimants within 10 days of completing the investigation is no less effective than the Federal regulations at 30 CFR 842.12 regarding time frames for investigations of citizen complaints. As a result, we are approving this proposed regulation and removing this required amendment.

30 CFR 938.16(xxxxx). Relief of liability for water supply replacement when the adverse effect occurs more than three years after the mining activity.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.152(a) to remove paragraph (2), which provides for relief of an operator's liability when water supply impacts are due to underground mining activities that took place more than three years prior to the onset of water supply problems. *See* our discussion under 30 CFR 938.16(mmmm) in regard to 5.2(e)(2) of BMSLCA. Since we determined that Pennsylvania's amended definition of ''underground mining activities'' is no less effective than the Federal regulations and PADEP's interpretation reasonable, for the reasons given in our discussion at 30 CFR 938.16(mmmm), we are removing this required amendment.

30 CFR 938.16(yyyyy). Two-year reporting limit on water supply effects.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.152(a) to remove paragraph (4), which provides a release of liability when water supply problems are reported more than two years after the date of occurrence because SMCRA does not set a time limit for when an EPAct water supply claim must be made. For further information *see* our discussion under 30 CFR 938.16(jjjj) in regard to Section 5.1(b) of BMSLCA.

PADEP has proposed changes that will eliminate the two-year statute of limitations on filing claims involving EPAct water supplies. These changes will be accomplished through amendments to 25 Pa. Code 89.152(a) and through our action superseding Section 5.1(b) of BMSLCA to the extent it applies to EPAct water supplies. We have determined that Pennsylvania's proposed regulation at 25 Pa. Code 89.152(a) is no less effective than the Federal regulations and we are approving it and we are removing this required amendment.

30 CFR 938.16(zzzzz). Compensation in lieu of water supply replacement.

Required Amendment: We required Pennsylvania to submit a proposed amendment to remove 25 Pa. Code 89.152(a)(5)(i), which provides for a release of liability in cases where operators have addressed their water supply replacement obligations through a property purchase or by compensating a landowner for the resultant reduction in fair market value of the affected property. See our discussion under 30 CFR 938.16(nnnn), (oooo), (qqqq) and (rrrr) regarding compensation in lieu of water supply replacement.

PADEP has proposed changes that will limit the conditions under which an EPAct water supply claim can result in compensation. PADEP proposes to amend 25 Pa. Code 89.152(a) to establish specific conditions that must be satisfied in situations where EPAct water supplies may not be restored or replaced. We have superseded conflicting provisions in Sections 5.2(g) and (h) of BMSLCA in a separate rulemaking published in today's **Federal Register**. For these reasons discussed under 30 CFR 938.16(nnnn), (oooo), (qqqq) and (rrrr), we have determined that the proposed changes to 25 Pa. Code 89.152(a) are not inconsistent with the Federal regulations and we are approving them. We have also determined that approval of these proposed regulations satisfies the requirements of the required amendment at 30 CFR 938.16(zzzzz) and therefore, we are removing it.

30 CFR 938.16(aaaaaa). Compensation in lieu of water supply replacement—relief of liability under voluntary agreements.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code 89.152(a)(5)(ii) to delete the provision allowing compensation in lieu of restoration or replacement of affected water supplies. We further directed that the amendment must clarify that agreements to replace a water supply or provide for replacement of an alternate supply of water must meet the requirements established in the Federal definition of ''replacement of water supply'' at 30 CFR 701.5. See discussion under 30 CFR 938.16(nnnn), (oooo), (qqqq) and (rrrr) regarding compensation in lieu of water supply replacement.

PADEP addressed the required amendment through proposed amendments to 25 Pa. Code 89.152 as described in the discussion under 30 CFR 938.16(nnnn), (oooo), (qqqq) and (rrrr). As noted earlier, we have determined that the proposed changes to 25 Pa. Code 89.152(a) are not inconsistent with the Federal regulations. We are therefore approving these changes and are removing the required amendment at 30 CFR 938.16(aaaaaa).

30 CFR 938.16(bbbbbb). ''Underground mining operations'' and notification of mining.

Required Amendment: We required Pennsylvania to submit a proposed amendment to 25 Pa. Code Sections 89.141(d), 89.141(d)(9), 89.142a(a), 89.142a(f)(1), 89.142a(f)(2)(i), 89.142a(h)(1), 89.142a(h)(2), 89.142(a)(i)(1), 89.143a(a), 89.143a(d)(1), 89.143a(d)(2), 89.143a(d)(3), 89.155(b)(1) and (2) and 89.155(c) to be no less stringent than Section 720(a) of SMCRA which uses the term ''underground mining operations'' and includes more activities than just the extraction of coal.

For a full explanation of PADEP's rationale for proposed removal of this required amendment, see the September 22, 2003, proposed rule (68 FR at 55130). PADEP proposes to address our concern by amending 25 Pa. Code Sections 89.141(d), 89.141(d)(9), 89.142a(a), 89.142a(f)(1), 89.142a(f)(2)(i), 89.142a(h)(1), 89.142a(h)(2), 89.142a(i)(1), 89.143a(a), 89.143a(d)(1), 89.143a (d)(2), 89.143a(d)(3) to incorporate the term ''underground mining operations.'' These changes will make the respective parts of Chapter 89 no less stringent than SMCRA and we are approving them.

PADEP is, however, proposing to leave 25 Pa. Code Sections 89.155(b)(1) and (2) and 89.155(c) unchanged. These requirements pertain to notifications operators must provide to overlying property owners, utilities and government entities, to inform them of planned mining. OSM was initially concerned that activities such as development activities and blasting would not be cause for operators to notify these parties. However, PADEP interprets its definition of ''underground mining'' at 25 Pa. Code 89.5 to include these activities as a part of the process of extraction of coal in an underground mine. Therefore, property owners, utilities, and political subdivisions would be notified of these activities as part of the requirements of 25 Pa. Code Sections 89.155(b)(1) and (2) and 89.155(c). Based on Pennsylvania's interpretation of its definition, which we find reasonable, these requirements make Pennsylvania's notification requirements no less effective than Federal counterpart requirements. Accordingly, we agree that there is no need to amend 25 Pa. Code Sections 89.155(b)(1) and (2) or 89.155(c) to incorporate the term ''underground mining operations'' and, based on PADEP's interpretation, we are approving the term ''underground mining'' in 25 Pa. Code 89.155(b)(1) and (2) and 89.155(c). Therefore, we are removing this required amendment.

Ancillary Changes

PADEP is proposing some changes to 25 Pa. Code Chapters 86 and 89 that we did not specifically require in the final rule of December 27, 2001, but relate to requirements imposed by the rule. These changes are as follows:

25 Pa. Code 86.1, Definitions and 25 Pa. Code 89.5, Definitions

PADEP is proposing to amend the definition of ''underground mining activities'' in 25 Pa. Code 86.1 and 89.5 to use the phrase ''support facilities located underground'' rather than ''underground support facilities.'' The change was made to insure that surface facilities in support of underground operations are not included in the term underground mining operations. This change only clarifies the existing regulation and does not limit the coverage of the definition. Therefore, we have determined that this change is no less effective than part (b) of the Federal definition of ''underground mining activities'' at 30 CFR 701.5 which also refers to underground operations. PADEP made a similar change to the definition of underground mining operations at 25 Pa. Code 89.5. We also have determined that this change to be no less effective than the Federal regulations and we are approving it.

25 Pa. Code 86.151(b)(2)

PADEP is also proposing a change to its bonding regulations at 25 Pa. Code 86.151(b)(2) in addition to the changes to that section proposed to satisfy the required amendment at 30 CFR 938.16(ccccc). This proposed change clarifies the requirement to maintain subsidence bonds for a period of 10 years after the completion of underground mining operations. The former language defined the period of liability as extending for 10 years from completion of ''mining and reclamation operations''—a vague term that was not defined in the BMSLCA or Pennsylvania's regulations. PADEP explained that this change will maintain the status quo regarding the liability period for subsidence bonds. It also avoids confusion over whether the 10 year period extends from completion of underground mining operations or underground mining activities, which includes surface operations that would not be subject to the subsidence bond. We have determined that the proposed amendment does not constitute a substantive change in Pennsylvania's approved program and is not inconsistent with Section 509 of SMCRA which requires liability for the duration of the mining and reclamation.

25 Pa. Code 86.152(a)

PADEP's proposed change to 25 Pa. Code 86.152(a) adds a provision to the end of the subsection clarifying that the requirement to periodically reevaluate and adjust the bonds is not a basis for extending the coverage of subsidence bonds beyond the requirements of Sections 5, 5.4, 5.5, and 5.6 of BMSLCA. PADEP has indicated that this provision will ensure that subsidence bonds will be recalculated on the basis of projected costs of repairing land and structure damage and not on the basis of other obligations such as water supply replacement. We have determined that PADEP's methods of assuring that water supplies will be replaced through liability insurance are no less effective than the Federal regulations (see 30 CFR 938.16(ccccc) above). As a result, we have determined that the clarification to this section about its subsidence bond does not alter that finding and is no less effective than 30 CFR 817.121(c)(5) and we are approving it.

25 Pa. Code 89.5, Definitions

PADEP is proposing to add definitions of the terms ''EPAct structures'' and ''EPAct water supplies'' under the definitions at 25 Pa. Code 89.5. In its August 27, 2003, submission to us, PADEP noted that these definitions are derived from descriptions in Section 720(a) of SMCRA and the definitions of the terms ''drinking, domestic or residential water supply,'' and ''occupied residential dwelling and structures related thereto'' in 30 CFR 701.5. PADEP is adding these definitions to identify structures and water supplies covered under the Federal program and to distinguish them from structures and water supplies covered exclusively under State law. PADEP's definition of EPAct structures refers to structures that are subject to repair and compensation requirements under Section 720(a) of SMCRA. PADEP's definition of EPAct water supplies refers to water supplies that are subject to replacement under Section 720(a) of SMCRA. Additionally, PADEP notes that wells and springs that serve only agricultural, commercial or industrial enterprises, except to the extent the water supply is for direct human consumption or human sanitation or domestic use, are not included. PADEP has used these terms throughout its proposed regulations to differentiate structures and water supplies covered under the Federal regulations from those covered exclusively under the State program. We have determined that these definitions will ensure that Pennsylvania will protect all water supplies and structures protected under the Federal regulations. Therefore, these definitions are no less effective than the Federal provisions and we are approving them.

25 Pa. Code 89.142a(c)

PADEP made an editorial correction in this section changing the term ''surface features'' to ''features listed in subparagraph (i)–(v).'' This section provides that unless the subsidence control plan demonstrates that subsidence will not cause material damage to or reduce the reasonably foreseeable use of the features listed in this section, underground mining will be prohibited beneath or adjacent to the features. PADEP made this change to assure that features such as aquifers, which are not surface features, are protected under this section. We have determined that this clarification will not limit the types of features to be protected under this provision and therefore, it is no less effective than the Federal regulations at 30 CFR 817.121(d) which also refers to features and we are approving it.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment (Administrative Record No. PA 841.68), and received responses from the groups noted above in ''Section II. Submission of the Proposed Amendment.'' On the same day that we published and opened the comment periods for this amendment, we published and opened the comment period for the proposed action to supersede certain sections of BMSLCA. Comments were submitted for both proposed actions. While the comments were considered for both actions, some comments are more appropriately addressed in the final rule superseding portions of BMSLCA than in this rule. The comments and our response to those comments are incorporated by reference into this rule. For a full discussion of PCA's comments on Sections 5.4(a)(3), 5.4(c), and 5.2(g) and (h) of BMSLCA and Tri-States' comments on Sections 5.2(g) and (h), please see the final rule (PA–141–FOR) superseding portions of BMSLCA that is published in today's **Federal Register**.

This rulemaking generated a wide range of comments in writing and at public hearings. The majority of the comments specifically addressed the proposals submitted by PADEP to satisfy the required amendments of the December 27, 2001, final rule. However, there were many comments submitted that were not responsive to this rulemaking.

We received a number of comments about the importance of replacing water supplies and repairing structures. Sometimes these comments were included with a specific point about a topic of this rulemaking, and sometimes the comments appear to have been made to emphasize the importance of meeting the basic requirements of EPAct. Because comments related to the basic requirements of EPAct were considered in the December 27, 2001, rulemaking and were addressed at that time, we have not responded to them again as part of this rulemaking.

We received many general comments expressing concerns about the potential impacts of underground mining to a range of hydrologic resources. The comments primarily mentioned impacts to streams, springs, and ponds. In addition, the comments mentioned provisions of the Federal Clean Water Act, the Pennsylvania Clean Streams Law, and Pennsylvania regulations related to the placement of fill material in waters of the Commonwealth of Pennsylvania. This rulemaking concerns proposed revisions to the Pennsylvania program submitted to address requirements under the Federal EPAct and implementing regulations. EPAct established new requirements for the replacement of drinking, domestic, and residential water supplies and the repair or compensation of damage to occupied dwellings and structures related thereto and noncommercial buildings. EPAct did not revise any of the existing SMCRA provisions concerning the protection of the overall hydrologic balance relative to streams, springs, aquifers, and ponds. In addition, EPAct did not revise any SMCRA standards related to the implementation of the Federal Clean Water Act. Because comments related to the basic hydrologic protection requirements of SMCRA were considered in the rulemaking efforts at the time they were implemented, we have not responded to them again as part of this rulemaking.

We received a number of comments expressing concerns about how property owners are not allowed to control the subsidence damage abatement process. The comments ranged from expressing a desire to be able to choose their own contractors to disappointment that mining could result in significant disruption to their lives without their approval. We also received comments alleging that coal companies delay settlements with property owners and general complaints that agencies were not meeting their regulatory responsibilities. In 1992, EPAct put into place basic requirements that mining companies repair or compensate for damage to occupied dwellings and structures related thereto and noncommercial buildings and that they replace adversely affected drinking, domestic, and residential water supplies. The Federal requirements did not address how property owners and mining companies are to agree on the selection of contractors or the timing of mining activities. Because this rulemaking concerns amendments proposed to address deficiencies noted in OSM's December 27, 2001, final rule, comments on such matters are outside the scope of this final rule.

Finally, there were several comments that characterized the December 27, 2001, rulemaking as an attempt by OSM to require the State program to be a ''mirror image'' of the Federal EPAct regulations, and indicated that we were applying the same approach for this rulemaking. The comments clearly mischaracterize the process OSM used to evaluate the adequacy of Pennsylvania's amendments and proposals to resolve identified deficiencies. Our December 27, 2001, final rule and this final rule incorporate provisions specific to the Pennsylvania program, such as protection of agricultural structures and water supplies (*e.g.*, premining uses of the supply or any reasonably foreseeable uses of the supply). In addition, this final rule acknowledges the appropriateness of BMSLCA's compensation provision for the property's diminished value in the instances where it is technically impossible to develop an equivalent replacement of the water supply. We applied ''no less stringent than'' and ''no less effective than'' review standards when evaluating proposed changes to the statute and regulations, respectively.

We will address the comments we received according to the pertinent required amendment.

30 CFR 938.16(hhhh) Reference relating to bonding requirements.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(iiii) Prompt replacement of water supplies.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(jjjj) Two-year reporting limit on water supply effects.

We received comments from three citizens expressing support for eliminating the two year limit on filing water supply damage claims requirement from Section 5.1(b) of BMSLCA and the corresponding regulation at 25 Pa. Code 89.152(a)(4) (Administrative Record Nos. PA 841.70, 841.74 and 841.79). We agree with the commenters that statute of limitations, as it applies to water supplies protected under EPAct, is not consistent with SMCRA and the Federal regulations.

PCA opposed PADEP's proposed resolution to this required amendment because it believes that Pennsylvania is authorized by Section 101(f) of SMCRA to impose reasonable conditions on the rights of property owners to pursue claims for domestic water loss. This section provides that the primary authority for developing, authorizing, issuing, and enforcing regulations for surface mining and reclamation operations should rest with the States. PCA indicated that further discussion of this point was included in its response to 30 CFR 938.16(nnnnn). While we agree with PCA that Pennsylvania has the right to promulgate regulations, this provision must be read in conjunction with Sections 503 and 505 of SMCRA which provide for our review of State statutes and regulations to determine if they are as effective as, and not

inconsistent with, the Federal program. For more information on our response to PCA regarding this issue, please see our response to comments on 30 CFR 938.16(nnnnn).

We also received comments from Tri-State (Administrative Record No. PA 841.94). Tri-State indicated that it did not want separate protections for EPAct and non-EPAct water supplies. Tri-State recommended that Section 5.1(b) of BMSLCA be superseded.

We acknowledge Tri-State's concerns with water supply replacement. However, Federal regulations only require restoration of drinking, domestic or residential water supplies affected by underground mining operations. If a State program provides for protection of water supplies that are outside the scope of SMCRA protection, those provisions are more stringent than SMCRA and cannot be construed as inconsistent with SMCRA. As a result, we are superseding Section 5.1(b) of BMSLCA to the extent it would apply to water supplies covered under Section 720 of SMCRA and approving PADEP's regulation change at 25 Pa. Code 89.152. For more information and response to comments regarding the superseding of Section 5.1(b) of BMSLCA, see our final rule on superseding portions of BMSLCA published today in the **Federal Register**.

30 CFR 938.16(kkkk) Water supply replacement: Promptness of actions.

The Sierra Club (Administrative Record No. PA 841.75), Tri-State (Administrative Record No. PA 841.94), and one citizen (Administrative Record No. PA 841.70) commented that a three-year period was too long for a landowner to be without a water supply. The Sierra Club also commented that even with the implementation of the proposed resolution to this required amendment, Pennsylvania's program could still allow three years for establishment of a permanent replacement water supply. These comments center around language in the BMSLCA that provides that PADEP can issue orders requiring the provision of a permanent alternate source where the contamination, diminution or interruption does not abate within three years of the date the supply was affected. The changes PADEP has made to 25 Pa. Code 89.145a(b), regarding prompt replacement of water supplies, coupled with the changes to 25 Pa. Code 89.146a(c), regarding insuring that the citizen complaint procedures are followed, will insure that water supplies are replaced as promptly as possible. We acknowledge that it may take up to three years or, in rare cases, even longer to provide permanent replacement, depending on the individual site conditions. Additionally, PADEP stated that the three year period is the outer limit for permanent water restoration or replacement and that it can take enforcement action sooner than three years. The proposed addition of the ''prompt'' standard to its regulations will give PADEP the tool it needs to insure that operators are working diligently and timely in attempting to provide a permanent water supply replacement. We have determined that PADEP's interpretation, along with the proposed regulatory amendments Pennsylvania submitted, is no less effective than the Federal requirements for water replacement because the Federal regulations have no specific time frames for providing permanent restoration or replacement of water supplies. Tri-State was also concerned that PADEP's interpretation differs from a previous interpretation and that PADEP could easily change its interpretation again. We disagree that Pennsylvania's actions are arbitrary because PADEP now is adding the ''prompt'' standard to its water supply replacement requirement, thus it is reasonable that its interpretation must be adjusted accordingly. Additionally, our approval is based on the amended regulation and its interpretation. Any significant changes would be subject to 30 CFR 732.17. As a result, we are approving the changes Pennsylvania made to 25 Pa. Code Sections 89.145a(b) and 89.146a(c).

30 CFR 938.16(llll). Denial of access for premining survey and its effect on affirmative proof of water supply contamination, diminution or interruption.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(mmmm). Relief of liability for water supply replacement when the adverse effect occurs more than three years after mining activity.

PCA opposes the proposed resolution to this required amendment because it believes that BMSLCA provides that claims must be submitted three years after mining activity has occurred (Administrative Record No. PA 841.84). Further, PCA does not agree with PADEP's interpretation that the phrase, ''3 years after mining activity occurs'' includes post closure mine pool maintenance as the change to the definition of underground mining activities in 25 Pa. Code Sections 86.1 and 89.5 indicates. According to PADEP, it has always interpreted the term ''mining activity,'' as applied to underground mines, to mean the last aspect of reclamation. PADEP has advised us that the last aspect of reclamation includes management of the post closure mine pool. PADEP is clarifying this meaning by revising its definition of underground mining activities to include specifically post closure mine pool maintenance. We have determined that PADEP's interpretation of its program with regard to when underground mining activities are completed will insure that impacts to all water supplies protected under the Federal regulations will be covered under the Pennsylvania program. As a result, we are approving the changes to the definition of underground mining activities and we are removing this required amendment. If PCA is not satisfied with Pennsylvania's change to its definitions, it must work through Pennsylvania's regulatory review process to address any concerns.

30 CFR 938.16(nnnn), (oooo), (qqqq), (rrrr). Compensation in lieu of water supply replacement.

Tri-State (Administrative Record No. PA 841.94) commented that it opposes any regulation that does not mandate replacement of a water supply or the prohibition on mining areas that provide recharge for a water source. Tri-State further commented that Sections 5.2(g) and (h) and 5.3 of BMSLCA allow operators to destroy water supplies and escape liability for replacement and the Sierra Club (Administrative Record No. PA 841.75) commented that purchase of property in lieu of replacement of water supplies should not be allowed. Additionally, legal counsel for Representative William DeWeese of Greene County recommended (Administrative Record No. PA 841.89) that where a landowner does not want his water replaced, but PADEP determined that the water supply could be replaced in the future, any compensation for the water supply should be placed into escrow for future development of the water supply.

We believe the commenters misinterpreted PADEP's change to its regulation and what we approving. We are not approving compensation to landowners in lieu of replacement of water supplies. The only time that a landowner may waive establishment of a water supply is when it is not needed for the postmining land use. Even then, the regulatory authority must determine that a supply is available for future development. What we are approving is PADEP's change to 25 Pa. Code 89.152(a) which recognizes that in rare instances a water supply cannot be replaced. While Federal requirements are silent on how property owners are to be treated when it is impossible to replace an adversely affected water

supply with a supply meeting the requirements of the EPAct, Pennsylvania's proposals to authorize a payment to the landowner are not inconsistent with Federal provisions requiring compensation to property owners for the diminution in fair market value to their property.

There is nothing in the Pennsylvania regulations that allows an operator to escape liability for water supply replacement of drinking, domestic or residential water supplies. All replaced or restored drinking, domestic or residential water supplies must meet the standards of 25 Pa. Code 89.145a regarding quality and quantity. In the rare cases where PADEP has determined that a water supply meeting the criteria at 25 Pa. Code 89.145a cannot be developed, compensation for reduction of fair market value of the affected property served by the water supply is required at a minimum. Therefore, Pennsylvania's regulations place affirmative obligations on the operator for restoration or replacement of such supplies and do not allow acceptance of a substandard drinking, domestic or residential replacement or restoration water supplies. As a result, we are approving Pennsylvania's regulation changes and we are removing this required amendment.

Please *see* our response in the final rule superseding portions of BMSLCA, published in today's **Federal Register**, regarding Tri-State's comments that Section 5.3 of BMSLCA conflicts with amended 25 Pa. Code 89.152, its opposition to two classes of water supplies, and PCA's comments on this required amendment.

30 CFR 938.16(pppp). Permanent alternate source definition.

Tri-State (Administrative Record No. PA 841.94) commented that PADEP's changes to 25 Pa. Code Sections 89.5 and 89.145a(f) conflict with Section 5.2(i) of BMSLCA which makes the Pennsylvania program less effective than the Federal regulations. We disagree with the comment. As a matter of course, PADEP must interpret statutes when creating regulations to enforce those statutes. Generally, courts grant deference to an agency's interpretation of a statute that the agency implements. The regulations, which Pennsylvania amended, clearly state a restored/replaced EPAct water supply ''shall not cost the landowner or water user more to operate and maintain than the previous water supply.'' Thus, Pennsylvania's interpretation is also part of the implementing regulations.

PCA (Administrative Record No. PA 841.84) commented that it does not oppose the proposed resolution for this required amendment, but it believes we applied the wrong standard of review to the definition of Pennsylvania's de minimis cost provisions at 89.145a(f). PCA believes litigation in Pennsylvania established the de minimis cost provisions and our requirement to modify them was unnecessary.

We disagree with PCA's characterization of the de minimis provisions of Pennsylvania's regulations. The ''de minimis'' cases decided by the Environmental Hearing Board (EHB) do not set forth law of general application across the State of Pennsylvania. Those cases only decided the issue based on the specific facts of the individual cases. While the concept of a de minimis cost increase (*i.e.* a cost that cannot be calculated) for operating and maintenance costs for replacement water supplies is acceptable in the Federal regulations, Pennsylvania's characterization of de minimis costs as $60 per year or a 15% increase of the annual operating cost of the previous water supply does not fit that concept. Under the Pennsylvania definition of de minimis cost increase, landowners could be forced to pay more operating and maintenance costs for a replacement water supply than they did for the premining water supply. Requiring a landowner to pay these costs is less effective than the Federal regulations that require operators to absorb any increased operating and maintenance costs. As a result, we are approving Pennsylvania's proposed changes to its regulations at 25 Pa. Code Sections 89.5 and 89.145a(f).

30 CFR 938.16(ssss). Other remedies available under State law.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(tttt). Prompt repair or compensation for structure damage.

We received no direct comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(uuuu). Repair of dwellings and permanently affixed appurtenant structures or improvements.

We received comments from PCA and NMA regarding the superseding of Section 5.4(a)(3) of BMSLCA with regard to this required amendment. Please see our responses to these comments in our final rule notice published in today's **Federal Register** in which we are superseding portions of BMSLCA.

30 CFR 938.16(vvvv). Relief of liability for structure damage repair or compensation when an operator is denied access to conduct a premining or postmining survey.

We received comments from a citizen (Administrative Record No. PA 841.74) indicating that operators should not be relieved of liability for subsidence damage due to underground mining where a landowner denies access to the operator for a premining survey.

With regard to structures protected by the Federal regulations, we agree in principle with the comment, but recognize the difficulty of implementing repairs when access for premining surveys has been denied. With the change to Pennsylvania's regulations at 25 Pa. Code 89.144a(b), the relief of liability for denial of operator access for a premining survey for EPAct protected structures does not apply. However, all parties involved in the repair or compensation of damage from subsidence must fully recognize the importance of a premining survey in accurately documenting the extent of damage. Without these surveys, property owners and the regulatory authority must, by a preponderance of evidence, establish the specific instances of damage that is attributed to the subsidence from underground mining. Initial Federal regulations provided that a landowner who did not allow access for a premining survey would only forfeit the presumption of liability of damage (the presumption of liability concept was later suspended from the Federal regulations). The Federal regulations did not, and still do not, provide for relief of an operator's liability when access to conduct a survey was denied. We believe that PADEP's language as amended in 25 Pa. Code 89.144a(b) is consistent with the goals of encouraging landowners to allow premining surveys while preserving their rights for repair or compensation of subsidence damage that is caused by underground mining. As a result, we are approving the changes to Pennsylvania's program and we are removing this required amendment.

30 CFR 938.16(wwww). Repair or compensation for damaged structures.

We received a comment from Tri-State (Administrative Record No. PA 841.94) that Section 5.4(c) of the BMSLCA should be changed to allow all landowners, whether or not their structures are protected under EPAct, to have the same protections as the Federal regulations.

PADEP is revising its regulations to provide protections consistent with the Federal regulations regarding EPAct structures. However, BMSLCA provides additional repair and compensation provisions that are applicable to structures not protected under EPAct. There is nothing in the Federal

regulations preventing a State from adopting different standards for non-Federally protected structures and water supplies than for Federally protected structures and water supplies.

30 CFR 938.16(xxxx). Structure Damage—Six-month negotiation period and two-year claim filing period.

We received comments from two citizens (Administrative Record Nos. PA 841.79 and 841.70), Tri-State (Administrative Record No. PA 841.94), and PCA (Administrative Record No. 841.84). The citizens and Tri-State indicated that no limit should be placed on landowners to file claims of subsidence related damage. Additionally, one of the citizens indicated that a bond should be in place to pay subsidence damage in the event that a company goes bankrupt; the bonds will then be available for damage repair. Our review determined that the revision to 25 Pa. Code 89.143a(c) is no less effective than the Federal regulations regarding current and future subsidence damage claims. Any subsidence damage to protected structures occurring from mining after the effective date of the 1994 amendments to BMSLCA must be repaired or compensated for by the operator. There is nothing in 25 Pa. Code 89.143a(c), as it is currently written, that is contrary to this requirement. As for the comment regarding bonding, Pennsylvania requires a subsidence bond to be submitted at the time of permitting and 25 Pa. Code 86.152 requires that the bond be adjusted when future reclamation changes. This bond covers the potential damage to property and will be available for damage repairs in the event of a company's bankruptcy.

PCA commented that PADEP should not have the ability to issue orders for damage repair, except for emergency situations, for six months following the first report of damage. PCA believes landowners and operator should be afforded the opportunity within the six months to resolve a subsidence claim amicably.

PCA's suggestion is not in accordance with Federal requirements for investigating citizen complaints at 30 CFR 842.12 and taking enforcement actions at 30 CFR 843.12(c), both of which may have a time period shorter than six months. As noted in the preamble to the September 22, 2003, proposed rule (68 FR at 55117), PADEP indicated that it has the authority to take enforcement action prior to the expiration of the six-month negotiation period. This authority is found in Section 9 of BMSLCA. While taking enforcement actions prior to the expiration of the six month period will focus on requirements for emergency temporary repair measures, there is no guarantee that this is the only case where enforcement actions will be taken.

As noted further in the preamble of the September 22, 2003, proposed rule regarding the proposed resolution to 30 CFR 938.16(yyyy), BMSLCA requires PADEP to make an investigation within 30 days following receipt of a claim of subsidence damage. Within 60 days of an investigation, PADEP must issue a written order directing the operator to compensate or cause repairs to be made. While there is nothing in SMCRA or the approved program prohibiting negotiations between a landowner and an operator, we expect PADEP to follow its approved procedures regarding investigation of any citizen complaint it receives. As a result, a citizen complaint investigation could require issuance of an enforcement order prior to the expiration of the six-month negotiation period. PADEP's removal of the six-month period from its regulations at 25 Pa. Code 89.143a(d)(3) makes the program no less effective than the Federal regulations for citizen complaint investigation and issuance of enforcement actions. As a result, we are approving their regulation change and removing this required amendment.

30 CFR 938.16(yyyy). Investigation and orders for repair of damaged structures.

We received a comment from PCA (Administrative Record No. PA 841.84) that it opposes the proposed resolution for this section to the extent that it would result in PADEP issuing enforcement orders requiring repair or compensation in other than emergency situations sooner than 6 months after subsidence damage was first discovered for the reasons set forth above.

See our response to PCA's comments to 30 CFR 938.16(xxxx) regarding the elimination of the six month period. For the same reasons as given in that section, we are removing this required amendment.

30 CFR 938.16(zzzz). Issuance of orders and payment of escrow when an operator fails to repair or compensate a landowner for subsidence damage.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(aaaaa). ''Pre-1994'' agreements relating to subsidence damage repair or compensation.

We received comments from CAWLM (Administrative Record Nos. PA 841.95 and PA 841.97) regarding the proposed resolution to this required amendment. CAWLM believes that we should supersede Section 5.6(c) of BMSLCA which provides for a release of duty to repair or compensate for subsidence damage if agreements for such a release were made between 1966 and 1994.

In our proposed rule, we asked for examples of such agreements because PADEP believes these agreements do not exist for either pre- or post 1966 structures. We did not receive any signed agreements in response to our request. While copies of unsigned agreements were provided, these do not establish that such agreements are in existence. As a result, we believe that Section 5.6(c) of BMSLCA will not affect the protections of the Federal program and we are removing the required amendment.

30 CFR 938.16(bbbbb): Reference to ''pre-1994'' agreements.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(ccccc). Bonding for subsidence damage and water replacement.

We received comments on the proposed resolution of this required amendment from Penn Future (Administrative Record No. PA 841.78), Tri-State (Administrative Record No. PA 841.94), legal counsel to Representative William DeWeese of Greene County (Administrative Record No. PA 841.89), and two private citizens (Administrative Record Nos. PA 841.74 and 841.79). The commenters noted that use of liability insurance in lieu of bond for replacement or restoration of water supplies is not an appropriate mechanism. Penn Future noted that citizens may be forced to sue insurance companies or mining companies to obtain their benefits and asserts that this is not as effective as having bonds for replacement or restoration. Additionally, Penn Future indicated that PADEP has historically required operators to submit liability insurance policies that provide only the minimum coverage instead of tailoring the policies to the specific potential liabilities of water supply restoration or replacement of individual mines.

Tri-State noted that the proposed resolution does not satisfy the Federal requirement of 30 CFR 817.121(c)(5) regarding an increase of bond if damage repair or compensation or water supply replacement or restoration are not completed within certain time frames. Tri-State does not believe that PADEP's change to 25 PA Code 86.152(a) requiring mandatory bond adjustments coupled with its subsidence bond requirements and use of liability insurance policies for water supply replacement are as effective as the

requirements of 30 CFR 817.121(c)(5). Tri-State indicated that PADEP's program will not require additional bond for damages if the damages are not repaired or arrangements made for compensation after 90 days. Tri-State indicated that Pennsylvania's program should be amended to require adjustment of the subsidence bond within 90 days where the amount of subsidence damage liability remaining outstanding exceeds the amount of the subsidence bond posted. Tri-State also provided comments similar to Penn Future with regard to the use of liability insurance for replacement or restoration of water supplies. In addition, Tri-State noted that liability insurance is not as effective as bonds for water supply replacement or restoration because it cannot be adjusted upward after damages have occurred as bonds can be.

The legal counsel to Representative William DeWeese (Administrative Record No. PA 841.89) indicated that Pennsylvania should conduct a financial review of operators to insure that they have sufficient capital to restore water supplies in the event of an economic downturn. If there is not sufficient capital to withstand a downturn, the operator should be required to purchase subsidence insurance.

We disagree with the commenter's position that Pennsylvania's subsidence bond and applicable adjustment requirements are in conflict with the bonding requirements at 30 CFR 817.121(c)(5) with regard to subsidence damage to occupied dwellings and surface lands. The requirement at 30 CFR 817.121(c)(5) was put into place to guarantee the repair of damage to occupied dwellings and surface lands in the event of a forfeiture by an operator. Under the provision, operators that do not complete damage repairs within 90 days must provide additional performance bond in the amount of the estimated cost of the dwelling and land repairs if the permittee will be repairing, or in the amount of the decrease in value if the permittee will be compensating the owner for the damage to an occupied dwelling. The bond must be in place until the repair, compensation, or replacement is completed.

The Pennsylvania program requires a subsidence bond prior to the issuance of the permit. The bond covers the damage to occupied dwellings, agricultural structures, businesses, and surface lands. To implement this requirement, PADEP requires a subsidence amount based upon an actual assessment of the value of the land and structures overlying the area to be undermined. At the time that the permit is issued, the subsidence bond, which must be requested after the damage under the Federal provision, is already in place under the Pennsylvania program. In terms of having an initial bond amount to cover subsidence damage to occupied dwellings and land, this approach is more effective than the minimum Federal standard.

The commenter appears to be primarily at issue with the degree to which the initial bond amount plus the periodic adjustments under the Pennsylvania program are consistent with the Federal requirements at 817.121(c)(5) which require a modification to the bond amount at 90 days following damage if repairs are not complete. To illustrate the concern, the commenter provided a hypothetical example where, under certain conditions, the amount of the unrepaired damages could exceed the Pennsylvania subsidence bond. The commenter stated that this situation would be in conflict with the 90 day adjustment requirement at 30 CFR 817.121(c)(5).

We do not agree that the commenter has applied the requirement at 30 CFR 817.121(c)(5) appropriately to the bonding process as proposed by Pennsylvania. The 90 day adjustment requirement at 30 CFR 817.121(c)(5) only applies to operations that do not have a bond that is already designed to cover the anticipated damage. Pennsylvania has chosen to require a bond prior to permit issuance that will cover the anticipated damages from subsidence to structures and land. Because there is a bond in place, the 90-day adjustment requirement of 30 CFR 817.121(c)(5) no longer applies and Pennsylvania must now conduct the appropriate reviews and adjustments required by 30 CFR 800.15(a). At 30 CFR 800.15(a), Pennsylvania is under the obligation to adjust the permittee's bond from time to time as the cost of future reclamation changes. In addition, 30 CFR 800.15(a) allows Pennsylvania to fulfill the requirement by setting a schedule. This is consistent with the proposal by Pennsylvania to adjust bonds as needed at the time of permit renewal or a change to the subsidence control plan. Under 25 Pa. Code 86.152(a), Pennsylvania also has the discretionary authority to conduct the reviews and require an adjustment sooner, if necessary. We find no reason to disapprove Pennsylvania's proposal with regard to the bonding of subsidence impacts to structures and land.

We also disagree with the commenter's position that use of liability insurance policies to cover water supply restoration or replacement is not appropriate. Both the Federal regulations and Pennsylvania's regulations allow the use of insurance policies in lieu of the increased bond provisions of 30 CFR 817.121(c)(5). The Federal regulations at 30 CFR 800.14(c) provide that ''An operator's financial responsibility under Sec. 817.121(c) of this chapter for repairing material damage resulting from subsidence may be satisfied by the liability insurance policy required under Sec. 800.60.'' Pennsylvania's regulations at 25 Pa. Code 86.168(c) provides that liability insurance shall include a rider covering loss or diminution in quantity or quality of public or private sources of water. Subsection (g) provides that a bond or an individual insurance policy as required under Subsection (c) may be provided in lieu of liability insurance to cover replacement or restoration of water supplies.

The commenter also expressed concerns regarding the proper amount of insurance an operator must carry. Pennsylvania's minimum coverage for property damage is $500,000 per person and $1 million aggregate. This amount exceeds the minimum coverage required by Federal regulations at 30 CFR 800.60 which require only $300,000 for each occurrence and $500,000 aggregate.

Pennsylvania's regulations allowing liability insurance to substitute for water supply replacement and the minimum amount of insurance the regulations require an operator to have are no less effective than the Federal regulations. The commenters' concerns regarding the mechanics of claim collection and whether specific amounts of insurance are sufficient for individual cases are issues that will be addressed in our oversight of Pennsylvania's implementation of its approved program.

Finally, there is no provision in the Federal regulations for requiring operators to purchase subsidence insurance, nor are there any provisions requiring a review of an operator's financial solvency if the operator uses a collateral or surety bond. The Federal regulations rely on bonding or liability insurance to secure repair or replacement in the event operators are unable to fulfill their obligations. We have determined that the existing provisions of Pennsylvania's statute and regulations and the changes proposed in this amendment provide to be no less effective than the bonding provisions of the Federal regulations.

30 CFR 938.16(ddddd). Definition of de minimis cost increase.

We received comments on the proposed resolution of this required amendment from a citizen (Administrative Record No. PA 841.74), Tri-State (Administrative Record No. 841.94), and CAWLM (Administrative Record No. PA 841.97). The commenters were opposed to Pennsylvania's definition of de minimis cost increases at 25 Pa. Code 89.5 and the regulations implementing it at 25 Pa. Code 89.145a. The commenters believe that costs for operation and maintenance of replacement water supplies beyond those for the premining water supplies should be paid by the operator. Tri-State further indicated the proposed resolution should be adopted for non-EPAct structures as well as for EPAct structures. CAWLM indicated that agreements between operators and landowners for a one-time payment of increased costs favors operators and can result in agreements that will not cover the additional operating and maintenance costs of a replacement supply.

We are approving Pennsylvania's proposed changes to 25 Pa. Code 89.145a(f)(5) because they are no less effective than the Federal regulations regarding payment of operating and maintenance costs of EPAct replacement water supplies. For EPAct protected water supplies, operators will be required to pay operating and maintenance costs that are in excess of the costs to operate and maintain the water supply that existed prior to mining. While Tri-State would like the Federal protections to apply to non-EPAct protected supplies, there is no Federal requirement that Pennsylvania must adopt the same protection standards for water supplies not covered by EPAct. The Federal definition of ''Replacement of water supply'' at 30 CFR 701.5 specifically recognizes that payment of the increased costs can be satisfied by a one-time payment in an amount that covers the *present* worth of the increased costs. This lump sum payment may be preferable to the water supply owner because it eliminates the possibility that the operator may not pay the annual increased costs due to bankruptcy or financial difficulties. We have determined that Pennsylvania's proposed change to its regulations requiring payment of cost increases for operating and maintaining replacement water supplies are no less effective than the Federal requirements and we are approving them. Because of these proposed regulation changes, we are removing this required amendment.

30 CFR 938.16(eeeee). Definition of fair market value.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(fffff). Definition of permanently affixed appurtenant structures.

We received comments from Tri-State (Administrative Record No. PA 841.94) and PCA (Administrative Record No. PA 841.84). Tri-State commented that it supported PADEP's deletion of ''permanently affixed appurtenant structures'' from 25 Pa. Code Section 89.5 in favor of a broader definition of structures related to occupied residential dwellings. Tri-State cautions against too narrow a definition of ''occupied'' in this context, however. Tri-State commented that it did not want Pennsylvania's regulations to give broader protection to EPAct covered structures and the structures related thereto than to non-EPAct protected.

PCA commented that landowners should be required to take steps to protect property not permanently affixed to the ground. PCA believes that structures that are easily removed are not fixtures and therefore not real property requiring protection from subsidence damage.

As we noted in an earlier response, there is nothing in the Federal regulations preventing a State from adopting different standards for non-Federally protected structures and water supplies than for Federally protected structures and water supplies. Therefore, in response to Tri-State's comment, Pennsylvania is allowed to provide protections to any structures or water supplies as long as it meets the minimum Federal standards. If Tri-State wants Pennsylvania to provide additional protections, it must work with PADEP through Pennsylvania's regulatory review process.

With regard to PCA's comment, the responsibility to move or dismantle these structures lies with the operator and not the landowner. The Federal regulations at 30 CFR 817.121(a) requires the permittee to take steps to prevent or minimize material damage, not the landowner. In many cases, structures not permanently affixed to the ground surface cannot be easily moved or dismantled by the landowner. The landowner would have to incur costs to move or dismantle these structures. One of the purposes of SMCRA was to ''assure that the rights of surface landowners and other persons with a legal interest in the land or *appurtenances* thereto are fully protected.'' 30 U.S.C. 1202(b) (emphasis added). Additionally, the definition of occupied residential dwelling and structures related thereto protects ''any building, structure or facility installed on, above or below, or a combination thereof, the land surface if that building structure or facility is adjunct to or used in connection with an occupied residential dwelling.'' This regulation describes examples of such structures to include garages, storage sheds, and greenhouses. Structures such as these may not be permanently affixed to the ground surface, yet it may be difficult to dismantle or move them. Both the Federal regulations, and now Pennsylvania's regulations, provide that operators must repair or compensate landowners for damages to these structures.

30 CFR 938.16(ggggg). Subsidence control plan—prevention of material damage to EPAct structures.

We received a comment from Tri-State (Administrative Record No. PA 841.94), indicating that regardless of whether a surface structure is located over a conventional room and pillar mine or over a longwall mine, the mine operator's subsidence control plan should not be approved unless the prevention of material damage is demonstrated.

The Federal regulations at 30 CFR 784.20(b)(7) provide the requirements for subsidence control plans. These regulations provide that for areas where planned subsidence is projected to be used (such as in a longwall mine), the subsidence control plan is to contain a description of methods to be employed to minimize damage from planned subsidence to non-commercial buildings and occupied residential dwellings and structures related thereto; or the written consent of the owner of the structure or facility that minimization measures not be taken; or, unless the anticipated damage would constitute a threat to health or safety, a demonstration that the costs of minimizing damage exceed the anticipated costs of repair. Pennsylvania's proposed regulation change at 25 Pa. Code 89.141(d) provides a similar requirement. The Federal regulations do not provide for disapproving a subsidence control plan for an area of planned subsidence because it does not provide for prevention of material damage, and therefore, we cannot require Pennsylvania to include such a provision in its program. We have determined that Pennsylvania's proposed revisions to its regulations are no less effective than the Federal regulations regarding the requirements for subsidence control plans.

30 CFR 938.16(hhhhh). Subsidence control plan—minimizing material damage to EPAct structures.

See response to comments in 938.16(jjjjj) below.

30 CFR 938.16(iiiii). Measures to minimize material damage.

See response to comments in 938.16(jjjjj) below.

30 CFR 938.16(jjjjj). Prevention of material damage.

We received comments from Tri-State (Administrative Record No. PA 841.94), and the Sierra Club (Administrative Record No. PA 841.75). Tri-State indicated that the modifications contained in the PADEP's proposed regulations are inadequate in that these regulations do not require mine operators to prevent material damage to all structures. Tri-State recommended that PADEP modify its draft regulations to make prevention of such material damage mandatory for both room and pillar and longwall mines. Tri-State also noted that regulations pertaining to longwall mining only require that a mine operator recognize material damage to surface structures and then only to the extent technologically and economically feasible. Tri-State believes that longwall mine operators must be required by regulations to develop technology to make the prevention of material damage feasible. Tri-State concluded by indicating that, until damage prevention is required, Pennsylvania's regulatory program will not be as effective as the Federal minimum requirements.

The Sierra Club noted that both State and Federal regulations now require the prevention of material damage to public buildings, such as schools, churches, hospitals, and large lakes. The rules do not distinguish between the types of mining. PADEP's proposed rule would change ''prevent'' to ''minimize'' in addressing material damage to these buildings if longwall mining is proposed. The Sierra Club objects to the change because it would allow longwall mining to cause material damage while other types of mining would have to prevent such damage.

We believe the commenters have misunderstood the Federal requirements. The Federal regulations at 30 CFR 817.121(a)(2) require that if a permittee employs mining technology that provides for planned subsidence in a predictable and controlled manner (such as longwall mining), the permittee must take necessary and prudent measures, consistent with the mining method employed, to minimize material damage to the extent technologically and economically feasible to non-commercial buildings and occupied residential dwellings and structures related thereto. There is no Federal requirement that requires a permittee to take measures to prevent material damage when employing mining techniques that provide for planned subsidence.

If permittees employ mining techniques that do not result in planned subsidence (such as in conventional room and pillar mines), then the permittee must adopt measures consistent with known technology that prevent subsidence from causing material damage to the extent technologically and economically feasible, maximize mine stability, and maintain the value and reasonably foreseeable use of surface lands.

In response to the Sierra Club comments, the Federal regulations at 30 CFR 817.121(d) provide that underground mining activities shall not be conducted beneath or adjacent to (1) public buildings and facilities; (2) churches, schools, and hospitals; or (3) impoundments with a storage capacity of 20 acre-feet or more or bodies of water with a volume of 20 acre-feet or more, unless the subsidence control plan demonstrates that subsidence will not cause material damage to, or reduce the reasonably foreseeable use of, such features or facilities. Pennsylvania's regulation at 25 Pa. Code 89.142a(c) provides the same protections to these structures as do the Federal regulations. Moreover, PADEP's proposed regulation at 25 Pa. Code 89.141(d)(3) recognizes the specific protections afforded to structures under 25 Pa. Code 89.142a(c) and does not, in any way, waive those protections.

PADEP's proposed change to its regulations at 25 Pa. Code 89.142a(d) provides the same protections for EPAct structures that the Federal regulations require. As a result, we have determined that this section is no less effective than the Federal counterpart.

30 CFR 938.16(kkkkk). Prompt repair or compensation for structure damage.

We received comments from one citizen (Administrative Record No. PA 841.73) and from Tri-State (Administrative Record No. PA 841.94). The citizen commented that homeowners should be treated fairly with prompt financial compensation. Tri-State indicated it did not want us to accept as adequate PADEP's proposed change to 25 Pa. Code 89.142a(f)(l)(ii) and, instead, require an amendment to Section 5.4(a)(3) of BMSLCA. Tri-State does not believe amending the regulation without amending the corresponding statutory provision is adequate.

Our review has determined that Section 5.4(a)(3) of BMSLCA and the regulation at 25 Pa. Code 89.142a(f)(1)(ii) are not in conflict with regard to the requirement that repairs or compensation for structural damage be made promptly. While BMSLCA is silent on the promptness of repairs or compensation, there is nothing in this portion of the statute preventing prompt repairs or compensation. PADEP is proposing to include the prompt standard in its regulations interpreting this portion of BMSLCA. This interpretation will make the Pennsylvania program as effective as the Federal regulations regarding promptness of repairs or compensation.

30 CFR 938.16(lllll). Repair of dwellings and permanently affixed appurtenant structures or improvements.

PCA provided comments to the proposed resolution of this required amendment (Administrative Record No. PA 841.84). PCA opposes the proposed resolution of 30 CFR 938.16 (uuuu) and 30 CFR 938.16(lllll) and the proposed amendment to 25 Pa. Code 89.142a(f)(l) which would obligate mine operators to repair or compensate for mine subsidence damage to dwellings constructed after the owner knew or should have known that mining would be occurring beneath his property within the next 5 years. PCA believes that these provisions are designed to discourage property owners, who have knowledge that mining is imminent, from building new structures in locations where they could be damaged and to encourage such persons to build in areas which will not be undermined. PCA also noted that there is nothing unreasonable, nor is there anything in SMCRA or OSM's regulations, which would preclude local municipalities from enacting a zoning ordinance to prohibit new construction in areas that are unstable or prone to subsidence or slips. PCA maintains that such a local zoning ordinance would be reasonable and justified because it would ensure that the local tax base is not reduced by avoidable damage to new structures.

Section 720(a)(1) of SMCRA requires the prompt repair or compensation for material damage resulting from subsidence to certain structures. There is no requirement that the structure be in place at the time of permit application or renewal even though the water replacement provisions of Section 720(a)(2) are limited to only those drinking, domestic or residential water supply from wells or springs in existence prior to the application for a surface coal mining and reclamation permit. Congress saw fit to limit the provision of water supply replacement to supplies in existence at the time of permit application, but did not provide a similar restriction to structures. The

issue of what recently constructed non-commercial buildings or occupied dwellings or related structures are protected under EPAct arose when a commenter to the Federal EPAct regulations stated that a permittee is not obligated to repair subsidence-related damage to a building constructed after mining occurred. 60 FR at 16735. OSM agreed, stating ''the requirement should not apply to structures which did not exist at the time of mining.'' *Id.* This makes it clear that if the building or dwelling/structure existed at the time of mining, the operator is obligated to repair or compensate. To uphold PCA's position would effectively put a limit on a landowner's property rights for as much as five years and eliminate repair or compensation requirements to a class of structures depending on when they were built. SMCRA did not envision such a limitation.

PCA is correct in its assertion that there is no provision in SMCRA preventing local municipalities from enacting an ordinance preventing constructing of dwellings under certain circumstances. However, SMCRA would apply to protected structures even if constructed in violation of such an ordinance. As a result, we are approving PADEP's proposed changes to its regulations and we are removing this required amendment.

30 CFR 938.16(mmmmm). Protection of utilities from underground mining activities.

We received no comments in opposition to the proposed resolution of this required amendment. However, we did receive comments from the legal counsel for Representative William DeWeese of Greene County (Administrative Record No. PA 841.89) regarding a case where residents of Greene County lost access to free natural gas because of a dispute with a gas company and the inability of the homeowners to hook up to the company's distribution line. She indicated that she would like there to be language in PADEP's regulations that require PADEP to bring parties together in cases where personal gas supplies are affected to decide how the parties are going to share the costs to replace the supplies.

PADEP's changes to 25 Pa. Code 89.142a(f)(1)(iii) provide that operators must repair, restore, replace or compensate owners for material damages to customer-owned utilities.

We have determined that this proposed regulation is no less effective than the Federal regulations requiring repair or compensation for damages to occupied dwellings and structures related thereto. PADEP has the regulations in place for insuring that damages to utilities are repaired or landowners receive compensation for those damages. If there are questions regarding the compensation aspects of the case pointed out by Representative DeWeese's legal counsel, the parties involved should file a citizen's complaint with PADEP.

30 CFR 938.16(nnnnn). Statute of limitations on damage repair or compensation—claims must be filed with PADEP within two years of damage.

We received comments from PCA (Administrative Record No. PA 841.84). PCA indicated that SMCRA is completely silent on the issue of whether claims for subsidence damage to dwellings and claims for the replacement of domestic water supplies must be filed within any defined time frame. Of equal importance, OSM has never promulgated any regulation which interprets SMCRA as allowing for the filing of such claims at any time. PCA further indicated that in the absence of any express prohibition in SMCRA on placing limits on the time within which subsidence damage claims must be filed, there is no basis for OSM to conclude that Pennsylvania's decision to do so is not authorized by 30 U.S.C. 1201(f). Indeed, in the absence of any express limitation-of-action period on a Federal statutory claim the Courts will traditionally provide for one. PCA indicated that when a statute creating a right-of-action does not specify a limitation-of-action period, it cannot be assumed that Congress intended that there be no time limit on the action.

PCA further indicated that the justification for Pennsylvania creating these new statutory claims for homeowners was a desire to preserve its local ad valorem tax base. This goal is not fostered if homeowners can wait 5 or 10 or 25 years to file their claims. On the other hand, it is fostered if claimants are encouraged to file their claims promptly, and a reasonable statute of limitations certainly encourages the timely filing of subsidence damage claims.

We disagree with PCA's characterization of SMCRA and the Federal regulations with regard to a statute of limitations. Pennsylvania advanced similar arguments regarding statutes of limitations that we addressed in the December 27, 2001, final rule (66 FR at 67014, 67023–24). Our response to those comments is incorporated by reference into this rule. PCA has not provided any compelling reason for us to reassess the position stated in that final rule. For more information on this issue see our response to comments under 30 CFR 938.16(xxxx).

30 CFR 938.16(ooooo). Investigation and orders for repair of damaged structures.

For a discussion of the comments received with regard to this issue, *see* our response to comments under 30 CFR 938.16(yyyy).

30 CFR 938.16(ppppp). Relief of liability for structure damage repair or compensation when operator is denied access to conduct a premining or postmining survey.

We received comments from PCA (Administrative Record No. PA 841.84). PCA opposes the proposed resolution of 30 CFR 928.16 (vvvv) and 30 CFR 938.16 (ppppp) and the proposed amendment to 25 Pa. Code 89.144(a)(1). PCA indicated that BMSLCA and 25 Pa. Code 89.144(a)(l) do not deny any owner of a dwelling or institutional structure the right to file a subsidence damage claim. Instead, these provisions of the Pennsylvania program merely condition this right by providing that, in return for being given a right to file a statutory subsidence damage claim, the structure owner must grant the mine operator an opportunity to conduct a premining and a post-mining inspection.

PCA further noted that with respect to the pre-mining inspection condition, few dwellings or institutional structures do not have some normal damage caused by weathering and wear and tear. The nature of this damage is often indistinguishable from certain types of damage that can be caused by mine subsidence. To assure that operators are not required to pay compensation equal to the cost of repair (the Pennsylvania compensation standard which is different from OSM's) for ''damages'' they did not cause, the Pennsylvania General Assembly and the Environmental Quality Board (EQB) concluded structure owners should not be allowed to file subsidence damage claims unless they allow the mine operator access to their structures to establish a pre-mining baseline of its condition.

We recognize the importance of pre-mining surveys and encourage all landowners to obtain them. However, as we noted in the preamble to the December 27, 2001, final rule, the absolute removal of the right to repair or compensation if the operator is denied access to the property is not in accordance with the requirements of SMCRA. In the preamble, we said:

> Pennsylvania has failed to account for information that the homeowner or the regulatory authority possesses. It is possible that the homeowner may hire someone to

conduct a survey. In Pennsylvania's scenario, the homeowner would have no relief under Act 54 even though he had relevant information that showed causation.

* * * * *

Additionally, in the preamble to the March 31, 1995, Federal rules on subsidence (60 FR at 16741), OSM discussed the effect of a landowner denying access to a property and concluded that in any enforcement proceeding OSM or the regulatory authority may take the effect of the denial into account in determining what weight, if any, to give to the rebuttable presumption of causation. Even though the Federal rules concerning the presumption were suspended, this part of the preamble clearly indicates OSM's intent that enforcement actions would proceed even if landowners denied permission to operators to conduct premining surveys. There are no passages in the preamble or the regulations that relieve operators of their duty to repair or compensate landowners for subsidence damage to covered structures. 66 FR at 67022.

Pennsylvania's proposed revision of 25 Pa. Code 89.144a will eliminate the concern we expressed in the December 27, 2001, final rule. The changes to this section, as applied to EPAct structures, require that if, by a preponderance of evidence, a landowner can show damage to be caused by underground mining, the right to repair or compensation will be retained. This protects both the landowner and operator by both encouraging pre-subsidence surveys and insuring only that damages caused by underground mining are subject the repair or compensation provisions.

PCA also stated that property owners have a legal obligation to mitigate their own potential damage. The Federal regulation at 30 CFR 817.121(a)(2) allows a structure owner to waive minimization measures. However, this waiver does not eliminate ''any requirement pursuant to paragraph 817.121(c) to repair damage from subsidence.'' (60 FR at 16734).

We also received a comment from legal counsel to Representative William DeWeese of Greene County (Administrative Record No. PA 841.89) indicating that in the case where a landowner refuses an operator right of entry to conduct a premining survey, BMSLCA requires affirmative proof that an operator caused the damage, while under the regulations, the standard for proof is a preponderance of evidence. She believes that there are two standards.

We note that the reference to affirmative proof in BMSLCA was for water supplies while the preponderance of evidence reference in the regulations was for structures. Even so, we do not agree that these are two standards. Both are evidentiary terms and are consistent with each other. ''Affirmatively proving'' is a general reference to what a party must do to prove facts that are in dispute. In civil cases, the degree of proof is by a preponderance of evidence. As we noted above, the use of preponderance of the evidence is no less effective than the Federal regulations in requiring repair or compensation for damages to structures. As a result, we are approving the proposed changes to Pennsylvania's program.

30 CFR 938.16(qqqqq). Water supply surveys—various issues.

We received comments from Tri-State (Administrative Record No. PA 841.94), the Sierra Club (Administrative Record No. PA 841.75), and CAWLM (Administrative Record No. PA 841.97). Tri-State indicated that citizens have a right to have a deadline for premining sampling of water supplies before being impacted by mining. Tri-State does not agree with the proposed resolution that pre-mining sampling occur ''before the supply is susceptible to impacts from mining'' as found at 25 Pa. Code 89.145a(a)(l). Tri-State is concerned with whether water supply owners will be provided the results of the premining survey in time to have their own survey done, if they disagree with the mine operator's results. To remedy this concern, Tri-State recommends that PADEP's rule be rewritten to require that premining surveys be completed prior to the time a water supply is susceptible to mining-related effects and prior to mining within 2500 feet of the water supply.

The Sierra Club and CAWLM also suggested that premining sampling be conducted prior to mining within 2500 feet of a water supply.

We acknowledge the commenters desire to have water supplies sampled sufficiently in advance of mining to give landowners and water supply users sufficient time to prepare for adverse effects to the supply. However, we do not believe substituting one arbitrary standard for another meets the requirements of OSM's March 9, 1999, letters to Tri-State Citizens Mining Network and the Interstate Mining Compact Commission that provide for delays in water supply samples as long as the permit application contains sufficient information to develop the Probable Hydrologic Consequences and Cumulative Hydrologic Impact Assessment. The commenters give no evidence of why sampling prior to mining advancing within 2500 ft. of a water supply will give any more reliable information than PADEP's prior standard of 1000 ft. Water supplies can be impacted by underground mining far in advance of the 2500 ft. standard the commenters are proposing. We believe that PADEP's proposed language change at 25 Pa. Code 89.145a(a)(1) requiring sampling prior to the time a water supply is susceptible to mining-related effects will provide that all water supplies are adequately sampled in a timely manner regardless of their location relative to the mining operation.

30 CFR 938.16(rrrrr). Water supply replacement—promptness of action and reasonably foreseeable uses.

We received comments from Tri-State (Administrative Record No. PA 841.94), the Sierra Club (Administrative Record No. PA 841.75), CAWLM (Administrative Record No. PA 841.97), and a citizen (Administrative Record No. PA 841.74). Tri-State recommended that the reasonably foreseeable use determination of 25 Pa. Code 89.145a(b) be made by PADEP and not the operators. They also recommended that the foreseeable use determination provision be replaced with a requirement that replacement water supplies be equivalent to the supply that existed prior to mining. The Sierra Club and CAWLM echoed the citizen's comment. CAWLM also suggested that, if we accept PADEP's rule regarding reasonably foreseeable use, only a homeowner (and not PADEP or an operator) is qualified to determine what a reasonably foreseeable use would entail.

In our December 27, 2001, final rule, we determined that PADEP's concept that a replacement water supply that takes into account the reasonably foreseeable uses of that supply is no less effective than the Federal standard requiring an equivalent replacement. For a full discussion of our decision with regard to the concept of reasonably foreseeable use, see our final rule in the December 27, 2001, **Federal Register** (66 FR at 67011–12). Because reasonably foreseeable uses as a standard for water supply replacement was addressed and approved in the December 27, 2001, rulemaking, comments recommending its disapproval are not applicable to this rulemaking. In PADEP's current amendment, the only water supply replacement issue is the requirement that PADEP take into account both the premining uses of the water supply and any reasonably foreseeable uses of the supply. We disagree with CAWLM's comment that only a homeowner (and not PADEP or an operator) is qualified to determine reasonably foreseeable

uses. While homeowners are a source of information to consider when determining the reasonably foreseeable uses of a supply, there may be important domestic and residential uses that the current homeowner might not identify in determining minimum thresholds for supply replacement.

30 CFR 938.16(sssss). Water supply replacement—prompt provision of temporary water.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(ttttt). Quality and quantity of temporary water supplies.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(uuuuu). De minimis cost increase.

See comments and our responses to 30 CFR 938.16(ddddd) earlier in this rulemaking.

30 CFR 938.16(vvvvv). Reasonably foreseeable use—adequate quantity.

We received comments from the Sierra Club (Administrative Record No. PA 841.75), Tri-State (Administrative Record No. PA 841.94), and CAWLM (Administrative Record Nos. PA 841.92 and 841.97).

Tri-State recommended changing PADEP's requirement that a replacement water supply meet current and reasonably foreseeable uses be changed to require replacement water supplies to be made equivalent to premining water supplies. These comments were echoed by the Sierra Club and CAWLM. For an explanation of our approval of PADEP's standards for replacement of water supplies, please see our response to comments in 30 CFR 938.16(rrrrr) shown earlier in this rulemaking.

30 CFR 938.16(wwwww). Water supply problems—investigation time frames.

We received no comments in opposition to the proposed resolution of this required amendment.

30 CFR 938.16(xxxxx). Relief of liability for water supply replacement when the adverse effect occurs more than three years after the mining activity.

See our response to comments under 30 CFR 938.16(mmmm) shown earlier in this rulemaking.

30 CFR 938.16(yyyyy). Two-year reporting limit on water supply effects.

See our response to comments under 30 CFR 938.16(jjjj) shown earlier in this rulemaking.

30 CFR 938.16(zzzzz). Compensation in lieu of water supply replacement.

We received comments from Tri-State (Administrative Record No. PA 841.94). Tri-State recommends preservation of water resources by requiring operators to identify all actual and potential water supplies within the permit area. Tri-State further recommended that PADEP should require operators to demonstrate that a suitable replacement water source is available if identified supplies are impacted. Tri-State also indicated that compensation in lieu of water supply replacement should not be allowed.

We believe Tri-State's concerns with identifying the actual and potential water supplies in a permit are answered by the Pennsylvania program at 25 Pa. Code 89.34(a) which requires operators to submit the results of a groundwater inventory of existing wells, springs and other groundwater resources for the proposed permit and adjacent areas and by 25 Pa. Code 89.36(c) which provides that the operation plan shall include a description of the measures which will be taken to replace water supplies which are contaminated, diminished or interrupted by underground mining activities. We approved these provisions in our December 27, 2001, final rule (66 FR at 67031 and 67032). In providing for protection of water resources, the Federal regulations allow operators to affect drinking, domestic or residential water supplies as long as temporary and permanent water supply replacements are promptly provided. Regarding Tri-State's comment on compensation in lieu of water supply replacement, please *see* our response to 30 CFR 938.16(nnnn), (oooo), (qqqq), (rrrr) shown earlier in this rulemaking.

30 CFR 938.16(aaaaaa). Compensation in lieu of water supply replacement—relief of liability under voluntary agreements.

PCA commented (Administrative Record No. PA 841.84) that it opposed the proposed resolution of this required amendment to the extent that it is based on superseding of Section 5.2(h) of BMSLCA. We addressed PCA's concerns regarding superseding of Section 5.2(h) of BMSLCA in a final rule published elsewhere in today's **Federal Register** (*see* our final rule regarding PA–141–FOR).

30 CFR 938.16(bbbbbb). ''Underground mining operations'' and notification of mining.

We received no comments in opposition to the proposed resolution of this required amendment.

Comments on PADEP's ancillary changes

As we noted above, PADEP proposed some changes to its regulations at 25 Pa. Code Chapters 86 and 89 that we did not specifically require in our December 27, 2001, final rule. We received the following comments regarding these changes:

Comments on the definitions of EPAct structures and EPAct water supplies:

The legal counsel for Representative William DeWeese of Greene County (Administrative Record No. PA 841.89) indicated dissatisfaction with the distinction between EPAct and non-EPAct structures. She indicated that all structures should be treated equally and that EPAct structures should retain the same protections as non-EPAct structures. We understand these concerns. However, the Federal standard for review of State program amendments is whether they are no less effective than the Federal counterparts. In this case, PADEP's use of the definition of EPAct structures will insure protections that are no less effective than the Federal protections for these structures. Accordingly, the Federal regulations require that we approve this definition.

Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i) and Section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program (Administrative Record No. PA 841.66). On September 26, 2003 (Administrative Record No. PA 841.69), MSHA's Wilkes Barre, Pennsylvania, office wrote us indicating that it did not have any comments or concerns with the amendment. On October 21, 2003 (Administrative Record No. PA 841.86), MSHA's Arlington, Virginia, office wrote to us noting that there appears to be no conflict with the Mine Safety and Health Administration's regulation.

Environmental Protection Agency (EPA) Comments

Under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from EPA (Administrative Record No. PA 841.66). EPA responded on October 14, 2003, (Administrative Record No. PA 841.81) indicating that it has determined that there are no apparent inconsistencies with the Clean Water Act or other statutes and regulations under its jurisdiction. However, EPA further indicated that it is concerned about subsidence impacts on streams due to high extraction underground mining methods. EPA observed that some headwater streams have lost water due to subsidence cracks in stream beds causing the streams to dry up at times and changes to flow patterns. EPA encourages utilization of mining techniques that can minimize these effects or, in the alternative, mitigation

measures that restore streams to premining conditions.

While EPA's comments regarding streams are beyond the scope of the current rulemaking, we appreciate its interest in the mining program. We will forward these concerns to PADEP.

V. OSM's Decision

Based on the above findings, we approve the amendment Pennsylvania sent to us on August 27, 2003, and as revised on September 3, 2003. We are approving the rules proposed by Pennsylvania with the provision that they be fully promulgated in substantively identical form to the rules submitted to, and reviewed by, OSM and the public. We are also removing the required amendments at 30 CFR 938.16(hhhh) through and including (bbbbbb). With regard to those required amendments which required removal of, or modification to, sections of BMSLCA, we are now approving those sections that were formerly disapproved to the extent noted in this final rule and the final rule also published in today's **Federal Register** regarding supersession of certain parts of BMSLCA.

To implement this decision, we are amending the Federal regulations at 30 CFR Part 938.12, 938.15 and 938.16 which codify decisions concerning the Pennsylvania program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting it purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of Subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under Sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and Section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects 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. Pennsylvania does not regulate any Native Tribal lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior 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.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (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. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal

regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfounded mandate.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 26, 2004.

Brent Wahlquist,

Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, 30 CFR part 938 is amended as set forth below:

PART 938—PENNSYLVANIA

■ 1. The authority citation for part 938 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

§§ 938.12, 938.15, 938.16 [Amended]

■ 2. Section 938.12 is amended as follows: Paragraphs (a)(2), (a)(3), (a)(4), (a)(7), (a)(8), (a)(9) and (a)(10) are removed and reserved. Paragraphs (a)(14) through and including (a)(30) are removed.

■ 3. Section 938.15 is amended in the table by adding a new entry in chronological order by ''*Date of final publication*'' to read as follows:

§ 938.15 Approval of Pennsylvania regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	* * * * *
August 27, 2003	December 9, 2004	25 Pa. Code 86.1 modification of definition of underground mining activities, 86.151(b)(2), 86.152(a), 89.5, Addition of definitions of EPAct structures and EPAct water supplies; removal of definition of permanently affixed appurtenant structures; modification of definitions of underground mining activities and underground mining operations, 89.141(d), 89.142a(a), (c) through (i), 89.143a(a), (c) and (d), 89.144a(a) and (b), 89.145a(a), (b), (e) and (f), 89.146a(c)(2), and 89.152(a) and (b). In BMSLCA, Sections 5.2(b)(2), 5.2(d), 5.2(e)(2), 5.2(i), 5.3(a), 5.3(b), 5.3(c), 5.5(c), 5.5(f), 5.6(c), and 5.6(d).

§ 938.16 [Amended]

■ 4. Section 938.16 is amended by removing paragraphs (hhhh) through and including (bbbbbb).

[FR Doc. 04–26928 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–141–FOR]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: We are superseding portions of Pennsylvania's Bituminous Mine Subsidence and Land Conservation Act (BMSLCA) to the extent that they are inconsistent with the requirements of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act).

EFFECTIVE DATE: December 9, 2004.

FOR FURTHER INFORMATION CONTACT: George Rieger, Director, Pittsburgh Field Division, Telephone: (717) 782–4036, e-mail: *grieger@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' *See* 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania's program and program amendments at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Background on the Action

Pursuant to Section 505(b) of SMCRA and 30 CFR 730.11(a), we are superseding portions of the following sections of BMSLCA: 5.1(b) (52 P.S. 1406.5a(b)), 5.2(g) (52 P.S. 1406.5b(g)), 5.2(h) (52 P.S. 1406.5b(h)), 5.4(a)(3) (52 P.S. 1406.5d(a)(3)), 5.4(c) (52 P.S. 1406.5d(c)), 5.5(b) (52 P.S. 1406.5e(b)) to the extent identified for each section as noted below in ''Section III. OSM's Findings.'' We are also revising our disapprovals published in the **Federal Register** on December 27, 2001 (66 FR 67010), to be consistent with this action regarding these sections of BMSLCA. We are taking these actions because we have determined that there are aspects of these sections that are inconsistent with SMCRA and the Federal regulations.

When we disapproved these sections in the final rulemaking published in the **Federal Register** on December 27, 2001 (66 FR 67010), we also imposed requirements, codified at 30 CFR 938.16, to amend BMSLCA related to these sections. Pennsylvania challenged these disapprovals and required amendments, along with others contained in that same December 27, 2001, **Federal Register** notice, by filing a lawsuit against OSM in U.S. District Court for the Middle District of

Pennsylvania. During settlement discussions Pennsylvania agreed to implement regulatory changes to address the issues raised in these particular disapprovals, as well as others. We are now superseding these sections of the statute to the extent noted in this notice so that there will be no confusion regarding the status of those portions of BMSLCA listed above that conflict with the revised regulations we are simultaneously approving in a separate notice. In that separate notice, we are also removing the requirements to amend these sections of BMSLCA.

These sections are being superseded for essentially the same reasons cited under ''Director's Findings'' in a notice of final rulemaking published in the **Federal Register** on December 27, 2001 (66 FR 67010). Accordingly, that notice is a part of the record for this action as well.

On September 22, 2003, we published a notice of proposed rulemaking in the **Federal Register** concerning the proposed action to supersede the above sections of BMSLCA (68 FR 55134). In the same document, we opened the public comment period and scheduled public hearings on the proposed action to supersede sections of BMSLCA. We held the public hearings in Indiana, Pennsylvania, on October 15, 2003, at 3 p.m. and at 7 p.m. and in Washington, Pennsylvania, on October 16, 2003, at 3 p.m. and at 7 p.m. We entered a transcript of the public hearings into the administrative record (the Indiana hearings under Administrative Record Nos. PA 841.91 and PA 841.92 and the Washington hearings under Administrative Record Nos. PA 841.88 and PA 841.89). The public comment period ended on October 22, 2003.

In a separate proposed rulemaking published in the **Federal Register** on September 22, 2003 (68 FR 55106), we asked for comments on regulatory changes and clarifications that Pennsylvania submitted to OSM to satisfy the required amendments published in the **Federal Register** on December 27, 2001 (68 FR 55106). In the September 22, 2003, proposed rule, we also announced that we would take testimony and comments for these changes and clarifications during the same public hearings scheduled for the proposed action to supersede sections of BMSLCA. During the hearings for both rulemakings, we received 18 distinct sets of comments through written and oral testimony. Comments were received from the following:

Industry: Pennsylvania Coal Association (PCA).

Private Citizens: Eight homeowners.

Businesses: The Hothouse Flora Company.

Citizen/Environmental Groups: Citizens for Pennsylvania's Future a/k/a PennFuture; Concern About Water Loss due to Mining (CAWLM); Sierra Club/Tri-States Citizen Network; Mountain Watershed Association; Ten Mile Protection Network; Wheeling Creek Watershed Conservancy; and Citizen's Coal Council. Testimony by legal counsel for State Representative William DeWeese.

We received written comments from the PCA, the National Mining Association (NMA), the U.S. Environmental Protection Agency, Department of Labor, Mine Safety and Health Administration, several private citizens, and from two environmental groups (CAWLM & Tri-States Citizen Network). In this final rule, we will only reply to those comments pertaining to the superseding of portions of BMSLCA. In a separate final rule published this date, we will reply to comments regarding Pennsylvania's submission of regulatory changes and clarifications (*see* PA–143–FOR).

III. OSM's Findings

Pursuant to Section 505(b) of SMCRA and 30 CFR 730.11(a), the Secretary is superseding the following provisions of BMSLCA to the extent that they are inconsistent with, or preclude implementation of, SMCRA. In a separate final rule published in today's **Federal Register**, we are approving proposed changes to Pennsylvania's regulatory program and removing the required amendments at 30 CFR 938.16(hhhh) through (bbbbbb) (*see* the final rule on PA–143–FOR).

We are superseding the following sections of BMSLCA to the extent noted:

Section 5.1(b). We are superseding Section 5.1(b) to the extent that it would limit an operator's liability to restore or replace a water supply covered under Section 720 of SMCRA. Section 5.1(b) provides that:

(b) A mine operator shall not be liable to restore or replace a water supply under the provisions of this section if a claim of contamination, diminution or interruption is made more than two years after the supply has been adversely affected.

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.1(b) to the extent noted above. We are making this determination because we have found Section 5.1(b) to be inconsistent with the requirements of SMCRA and the Federal regulations to the extent that it limits an operator's liability for replacement of water supplies protected under Section 720 of SMCRA. In this superseding notice, we are making it clear that Section 5.1(b) is superseded only to the extent noted above. Our reasons for superseding Section 5.1(b) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR at 67014–67015) for a complete discussion of this section.

Section 5.2(g). We are superseding Section 5.2(g) of BMSLCA to the extent that it would limit an operator's liability to restore or replace a water supply covered under Section 720 of SMCRA. Section 5.2(g) provides that:

(g) If an affected water supply is not restored or reestablished or a permanent alternate source is not provided within three years, the mine operator may be relieved of further responsibility by entering into a written agreement providing compensation acceptable to the landowner. If no agreement is reached, the mine operator, at the option of the landowner, shall:

(1) Purchase the property for a sum equal to its fair market value immediately prior to the time the water supply was affected; or

(2) Make a one-time payment equal to the difference between the property's fair market value immediately prior to the time the water supply was affected and at the time payment is made; whereupon the mine operator shall be relieved of further obligation regarding contamination, diminution or interruption of an affected water supply under this act. Any measures taken under Sections 5.1 and 5.3 and this section to relieve a mine operator of further obligation regarding contamination, diminution or interruption of an affected water supply shall not be deemed to bar a subsequent purchaser of the land on which the affected water supply was located or any water user on such land from invoking rights under this section for contamination, diminution or interruption of a water supply resulting from subsequent mining activity other than that contemplated by the mine plan in effect at the time the original supply was affected.

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.2(g) to the extent noted above. We are making this determination because we have found that the limitation on an operator's liability for water supply replacement in Section 5.2(g) to be less

stringent than Section 720 of SMCRA and less effective than 30 CFR 817.41(j) which require restoration or replacement of protected water supplies without exception. In this superseding notice, we are making it clear that Section 5.2(g) is superseded only to the extent noted above.

Our reasons for superseding Section 5.2(g) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR 67018) for a complete discussion of this section.

Section 5.2(h). We are superseding Section 5.2(h) of BMSLCA to the extent that it would preclude Pennsylvania from requiring the restoration or replacement of a water supply covered under Section 720 of SMCRA. Section 5.2(h) provides that:

(h) Prior to entering into an agreement with the mine operator pursuant to subsection (g), the landowner may submit a written request to the department [Department of Environmental Resources] asking that the department review the operator's finding that an affected water supply cannot reasonably be restored or that a permanent alternate source, as described in subsection (i), cannot reasonably be provided. The department shall provide its opinion to the landowner within sixty days of receiving the landowner's request. The department's opinion shall be advisory only, including for purposes of assisting the landowner in selecting the optional compensation authorized under subsection (g). The department's opinion shall not prevent the landowner from entering into an agreement with the mine operator pursuant to subsection (g), and such opinion shall not serve as the basis for any action by the department against the mine operator or create any cause of action in a third party, provided the operator otherwise complies with subsection (g).

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.2(h) to the extent noted above. We are making this determination because we have found Section 5.2(h) to be less stringent than Section 720 of SMCRA and less effective than 30 CFR 817.41(j) which require restoration or replacement of protected water supplies without exception. In this superseding notice, we are making it clear that Section 5.2(h) is superseded only to the extent noted above. Our reasons for superseding Section 5.2(h) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR 67018–67019) for a complete discussion of this section.

Section 5.4(a)(3). We are superseding the portion of Section 5.4(a)(3) of BMSLCA that states, ''in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application,'' to the extent it would limit an operator's liability for restoration of, or compensation for, subsidence damages to structures protected under Section 720 of SMCRA that were in existence at the time of mining. This provision is being superseded to the extent that it may exclude certain structures from the repair and compensation provisions of SMCRA.

Section 5.4(a)(3) provides that:

5.4. Restoration or compensation for structures damaged by underground mining.

(a) Whenever underground mining operations conducted under this act cause damage to any of the following surface buildings overlying or in the proximity of the mine:

* * * * *

(3) Dwellings used for human habitation and permanently affixed appurtenant structures or improvements in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application; or

* * * * *

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.4(a)(3) to the extent noted above. We are making this determination because we have found that the limitation on an operator's liability for repair or compensation for subsidence damage to structures protected under Section 720 of SMCRA in Section 5.4(a)(3) to be less effective than the Federal regulations at 30 CFR 701.5 and 817.121(c)(2). These Federal regulations require repairs or compensation for damage to occupied dwellings and structures related thereto existing at the time of mining, regardless of whether they are permanently affixed or whether they are in place on the effective date of the application for a mine permit or a renewal of that permit. In this superseding notice, we are making it clear that Section 5.4(a)(3) is superseded only to the extent noted above. Our reasons for superseding Section 5.4(a)(3) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR 67021) for a complete discussion on this section.

Section 5.4(c). We are superseding Section 5.4(c) of BMSLCA to the extent it limits an operator's liability for repair of, or compensation for, subsidence damage to a structure covered under Section 720 of SMCRA. Section 5.4(c) provides that:

(c) A mine operator shall not be liable to repair or compensate for subsidence damage if the mine operator, upon request, is denied access to the property upon which the building is located to conduct premining and postmining surveys of the building and surrounding property and thereafter serves notice upon the landowner by certified mail or personal service, which notice identifies the rights established by Sections 5.5 and 5.6 and this section, the mine operator was denied access and the landowner failed to provide or authorize access within ten days after receipt thereof.

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.4(c) to the extent noted above. We are making this determination because we have found that the limitation on an operator's liability for repair or compensation for subsidence damage to structures covered under Section 720 of SMCRA in Section 5.4(c) to be less effective than the Federal regulations at 30 CFR 817.121(c)(2). The Federal regulations do not provide for relief of an operator's liability for repair or compensation for subsidence damage to protected structures due to underground coal mining operations when a landowner does not allow access to the property for a premining survey. In this superseding notice, we are making it clear that Section 5.4(c) is superseded only to the extent noted above. Our reasons for superseding Section 5.4(c) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR 67022) for a complete discussion on this section.

Section 5.5(b). We are superseding the portion of Section 5.5(b) of BMSLCA that reads, ''All claims under this subsection shall be filed within two years of the date damage to the building occurred'' to the extent that it would limit an operator's liability for

restoration of, or compensation for, subsidence damages to a structure covered under Section 720 of SMCRA. Section 5.5(b) provides that:

(b) If the parties are unable to agree within six months of the date of notice as to the cause of the damage or the reasonable cost of repair or compensation, the owner of the building may file a claim in writing with the Department of Environmental Resources, a copy of which shall be sent to the operator. All claims under this subsection shall be filed within two years of the date damage to the building occurred.

After consideration of all comments received in response to our proposed rulemaking of September 22, 2003 (68 FR 55134), we are making a final determination to supersede Section 5.5(b) to the extent noted above. We are making this determination because we have found that the limitation on an operator's liability for repair or compensation for subsidence damage in Section 5.5(b) to be inconsistent with the requirements of SMCRA and the Federal regulations. Neither SMCRA nor the Federal regulations provide for a time limitation to file subsidence damage claims. In this superseding notice, we are making it clear that Section 5.5(b) is superseded only to the extent noted above. Our reasons for superseding Section 5.5(b) are essentially the same as we expressed in our December 27, 2001, final rule. Please *see* our December 27, 2001, **Federal Register** (66 FR 67023–24) for a complete discussion on this section.

Please note that we are superseding only the provisions of BMSLCA to the extent noted above in this notice. These provisions, as noted above, cannot be implemented or enforced by any party in a manner inconsistent with this superseding as they would apply to a water supply or structure covered by Section 720 of SMCRA.

IV. Summary and Disposition of Comments

Public Comments

We received comments from the Pennsylvania Coal Association (PCA) and the National Mining Association (NMA) of a general nature on our proposed rule to supersede the above noted sections of Pennsylvania's Bituminous Mine Subsidence and Land Conservation Act (BMSLCA) that were not directed specifically to those sections of BMSLCA. We will respond first to these comments and then respond to the specific comments according to the section of BMSLCA they pertain to.

General Comments

PCA provided written and oral comments at the public hearings (Administrative Record Nos. PA 841.71 and PA 841.88) and by letters dated October 15, 2003 (Administrative Record No. PA 841.85), October 22, 2003 (Administrative Record No. PA 841.84), and November 12, 2003 (Administrative Record No. PA 841.96). PCA indicated that there exists no factual basis for OSM to conclude that any provision of Act 54 should be ''superseded,'' and PCA requests that OSM respond to these comments by citing specific factual instances where the implementation of the sections of BMSLCA proposed to be superseded, as applied, have resulted in actual inconsistencies with SMCRA or OSM's regulations.

We disagree with PCA's premise that there exists no factual basis for this action. Pennsylvania Department of Environmental Protection (PADEP) stated in its August 27, 2003, proposal that twenty-two of the required amendments from the December 27, 2001, final rule involved changes to BMSLCA. It asserts that the General Assembly is the only State entity with the authority to make the statutory changes required by the December rule and that our superseding of portions of BMSLCA will enable Pennsylvania to promulgate regulations to respond to some of the requirements of our December 27, 2001, final rule. PADEP contends that without this action, some of the regulations PADEP is proposing would have conflicted with BMSLCA. Therefore, to alleviate Pennsylvania's concerns and to remove any ambiguity regarding the status of those portions of BMSLCA described above, we are superseding them.

PCA further commented that Pennsylvania has, for over nine years, been regulating the subsidence impacts of bituminous underground mining in accordance with the very provisions of Act 54 which OSM now proposes to ''supersede.'' Throughout this nine year period, OSM has been fully willing to ''share'' enforcement authority with PADEP, reserving the right to ''directly enforce'' its interpretation of Federal law in circumstances where it found that citizens of Pennsylvania were being denied their ''rights'' under SMCRA or OSM's regulations. PCA noted that, despite nine years of ''dual enforcement,'' there have been only a few instances when OSM saw any need to ''directly enforce'' some aspect of its subsidence control program. PCA requested that OSM respond to PCA's comment that OSM has had no cause, for over nine years, to conclude that the Pennsylvania subsidence control program has deprived anyone of their ''rights'' under Federal law.

As provided for under a July 28, 1995, **Federal Register** notice (60 FR 38685–38689), OSM and Pennsylvania have had an enforcement agreement to provide for the implementation of the EPAct water supply replacement and structure requirements of Section 720 of SMCRA. Since 1995, we have had to utilize our enforcement authority in two instances where the Pennsylvania program was unable to require the necessary corrective action. In those cases, landowners' rights under SMCRA were protected. While previous enforcement actions can provide information on the adequacy of State program requirements, our standard of review of State program amendments requires a determination that the State regulations are no less effective than the Federal regulations. In this case, this determination is being made without regard to a State's past enforcement of its program because the regulations being reviewed here are necessary to insure future compliance.

PCA provided further comments noting that SMCRA does not impose the standard of review applied by OSM in this case and does not require that a State program ''mirror'' that of OSM's. Instead, SMCRA specifically recognizes that each State should be free to develop its own program of laws and regulations governing subsidence control which is tailored to its specific needs and interests. PCA cited a court case from the United States Court of Appeals for the Third Circuit in support of this argument.

OSM's standard for review for superseding part of a State law or regulation is whether the State's law or regulation is inconsistent with, or precludes implementation of, provisions of the Act or its implementing regulations. The very limited actions taken in this notice are fully in accord with that standard, as explained in each action.

PCA also asserts that OSM only had four concerns with BMSLCA in 1995 and no other concerns were expressed by OSM until the December 27, 2001, final rule. We disagree with this characterization because in the July 28, 1995, **Federal Register** notice, PADEP disclosed twelve significant situations where BMSLCA did not provide water replacement or repair to structures, as required by EPAct. Additionally, once we received the formal amendment in 1998, we sent lengthy letters to PADEP expressing our concerns; please see the December 27, 2001, rule for details.

NMA provided general comments via e-mail dated October 22, 2003 (Administrative Record No. PA 841.83). NMA stated that there is no basis for OSM to supersede the above noted provisions of Pennsylvania's BMSLCA because OSM has not identified any evidence that the Pennsylvania program is inconsistent with SMCRA or is resulting in a deprivation of Federal rights under the Energy Policy Act Amendments of 1992.

We do not agree with this comment. As explained above for each action, the provisions being superseded either limit an operator's liability or preclude corrective action by Pennsylvania in ways inconsistent with Federal law. Pennsylvania agrees that these actions are necessary because of its concern that revisions to make its regulations consistent with Federal law would make the regulations inconsistent with BMSLCA. Therefore, OSM is superseding specific language in six sections of BMSLCA to the extent that the provisions are inconsistent with, or preclude implementation of, SMCRA.

NMA further stated that Pennsylvania's statutory provisions must be evaluated in a holistic, not a piecemeal, fashion. NMA stated that OSM is applying the incorrect standard to determine whether or not the State law should be superseded. OSM should not compare the State and Federal rules line by line and disapprove the State law if there is any difference between them. Instead, OSM must evaluate whether the State law is more or equally protective as a whole, not piece by piece. NMA noted that Pennsylvania provided superior rights to property owners when compared to the Federal rules in many respects. Therefore, OSM must take the whole package into account before deciding whether a State's statute and program is equal to or better than what SMCRA provides. In addition, the failure to use a holistic approach will improperly require every State program to be a mirror of the Federal rules. Such a result may be easier for OSM, but it would also be contrary to SMCRA and judicial precedent, and it would be bad public policy. NMA concluded their comment by stating that a piecemeal approach will discourage States from experimenting or creating innovative solutions to solve problems.

We agree that a State's statutory provisions need not match Federal provisions line for line. However, in this case, Federal law expressly imposed obligations on operators which State law expressly limited in a manner inconsistent with Federal law. This inconsistency limited the rights of other parties provided for by Federal law.

NMA stated that the Federal Government, and this Administration in particular, espouses principles of States Rights, comity, and Federalism, however, none of these principles are respected by OSM's action in this rule. NMA further stated that Pennsylvania is among the most experienced regulators of mining activity in the United States and that to suggest, without evidence to support it, that the Pennsylvania legislature is not adequately protecting the rights of its citizens is inappropriate. NMA also stated that, contrary to OSM's statement at 68 FR 55137, this rule does have Federalism implications because the State provisions do not conflict with any of SMCRA's provisions and that OSM has provided no evidence of problems ''on the ground'' with these provisions in almost a decade. NMA concludes that OSM has no basis to supersede these duly enacted provisions of State law.

NMA has misstated the proposed rule's implications with regard to the principles of State's Rights and Federalism. While we acknowledge Pennsylvania's experience in mine regulation, our review is restricted to a determination of whether the provisions are consistent with SMCRA and the regulations. Consistent with State's Rights and Federalism concepts, Pennsylvania provisions that provide for more stringent land use and environmental controls than SMCRA or its implementing regulations cannot be, and are not, construed as inconsistent with SMCRA. State provisions that provide less stringent controls are inconsistent with SMCRA. This review and approval process is specifically required under SMCRA and has no implications with regard to the principles of States Rights or Federalism.

NMA further questioned how enforcement would occur under the set-aside proposals. NMA thought that it is unclear how provisions are to be enforced if the Pennsylvania statute is superseded.

We have superseded the above portions of BMSLCA only to the extent that they limited protections or responsibilities mandated by SMCRA and the Federal regulations. These sections of BMSLCA remain in the regulatory program for Pennsylvania and we have limited their application only to the extent stated in this notice. By superseding these provisions to the extent noted above we are only ensuring that they are not applied in a manner inconsistent with SMCRA or the Federal regulations.

Statute specific comments:

Sections 5.2(g) and (h)

PCA provided comments regarding our proposed superseding of Sections 5.2(g) and 5.2(h) of BMSLCA in its October 15, 2003, letter. PCA believes that these sections are not inconsistent with SMCRA or OSM's own interpretation of its regulations relating to the replacement and restoration of domestic water supplies. PCA noted our statements from the proposed rule that rare cases may exist where the operator cannot develop an adequate replacement water supply. OSM's view that such instances will be ''rare,'' may well be the case in other States but in Pennsylvania replacement or restored supplies often must meet ''drinking water'' criteria, a far more stringent requirement than imposed by Federal law. Consequently, it is more likely, in Pennsylvania, that it will prove impossible to provide an ''adequate'' replacement supply than would be the case in other States. This is a change in position from PCA's previous statement that ''[t]hese cases are indeed rare in Pennsylvania [and] [t]hat to the best of PCA's knowledge, Sections 5.2(g) and (h) have never been exercised since enactment of Act 54.'' (Administrative Record No. PA 841.71). PCA believes that superseding these sections which allow compensation in lieu of replacement will put Pennsylvania's operators at a disadvantage.

PCA further states that OSM's ''interpretation'' of these two sections of BMSLCA is flawed, in part, because PADEP itself appears to have improperly interpreted the language of these sections. Section 5.2(g) does not have to be read to mean that if three years pass and a property owner has not had its domestic water supply restored or replaced that the operator is relieved of its obligation to try and provide such a supply and the only remedy available to the property owner is ''fair compensation.'' Instead, because BMSLCA is generally to be construed in a manner which would enable Pennsylvania to retain primary jurisdiction over the regulation of underground coal mining, an alternative and supportable interpretation of Section 5.2(g) is that, with respect to water supplies protected by Federal law, operators are required to promptly and diligently attempt to restore the affected domestic water supply or to replace it with an adequate alternative supply for at least 3 years, unless it can be sooner shown that it will be impossible to do so.

PCA also requests that we should wait and see if there is a problem with these

sections of BMSLCA, and if there is, then supersede the statute. Finally, PCA requests that we get an opinion from an appropriate State official as to whether BMSLCA can be interpreted in a manner that avoids a conflict with SMCRA.

We disagree with PCA's comment. Generally, courts grant deference to an agency's interpretation of a statute that the agency implements. PADEP's interpretation that Sections 5.2(g) and (h) are inconsistent with the regulations it has submitted to us is reasonable. PADEP's proposed regulations eliminate a provision allowing an operator to escape liability for replacement or restoration of an EPAct protected water supply by executing a purchase agreement with a landowner. These changes, at 25 Pa. Code 89.152, have been approved in a separate rulemaking published in today's **Federal Register**. These changes make Sections 5.2(g) and (h) inconsistent with the regulatory provisions.

PCA's suggested alternate reading of Section 5.2(g) of BMSLCA is not Pennsylvania's interpretation of that section of the statute. As Pennsylvania noted in its submission to us, ''The existing provisions of Sections 5.2(g) and (h) limit PADEP's authority to require a replacement water supply when an operator decides to pursue a settlement involving compensation. If PADEP is to have authority to require replacement water supplies in situations where it determines that a replacement water supply meeting the standards in § 89.145a(f) can be developed, OSM must supersede these provisions to the extent they would interfere with PADEP actions requiring replacement of EPACT water supplies.'' Pennsylvania's interpretation is more in line with the language of BMSLCA. Additionally, PCA's alternate interpretation does not provide for prompt replacement of water supplies because it allows an operator three years across the board to attempt replacement.

As stated before, our standard of review is not a ''wait and see'' approach, but whether the State's laws and regulations are no less stringent than SMCRA and no less effective than the Federal regulations. Lastly, we did get opinions from State officials who concluded that certain sections of BMSLCA conflicted with SMCRA and Pennsylvania's proposed regulations. These opinions are in the form of the August 27, 2003, State program submission.

We received comments from Tri-State in a letter dated November 4, 2003 (Administrative Record No. PA 841.94). Tri-State believes our superseding of portions of Sections 5.2(g) and 5.2(h) of BMSLCA alone are inadequate because Section 5.3 was not superseded. Tri-State believes that Section 5.3 must also be superseded to avoid a conflict between BMSLCA and the regulations Pennsylvania is proposing to enact to satisfy the requirements of 30 CFR 938.16.

Tri-State further indicates that it does not approve of the different protections accorded to EPAct water supplies vs. non-EPAct water supplies.

Finally, Tri-State believes that the three year statute of limitations should be deleted because in older mines and even modern room and pillar mines, water loss can occur from pillar failure long after mining ceases.

We disagree with Tri-State's characterization of Section 5.3. In our review of BMSLCA, we found that Section 5.3 is needed because it provides the ability for landowners and operators to determine the manner and means to restore or replace an affected water supply. Also, it provides for situations when an operator will not be required to restore or replace a water supply outside the protections of Section 720 of SMCRA.

We understand Tri-State's concerns regarding differing standards between Federally and State protected water supplies and structures, but there is nothing in the Federal regulations that prohibits a State from implementing different sets of rules for Federally protected structures and water supplies than for those structures and supplies protected only by the State. As long as Pennsylvania's regulations applying to structures and water supplies protected under Section 720 of SMCRA are no less effective than the Federal regulations, we will approve them.

With regard to Tri-State's concern about the three year statute of limitation, we believe that the steps taken by Pennsylvania including: (1) Amending its definition of ''underground mining activities'' to include mine pool stabilization; (2) demonstrating that it has the authority to require an operator to replace a water supply if an operator uses erroneous or fraudulent information; and, (3) its interpretation that Section 13 of BMSLCA will not be affected, demonstrates that there is recourse for the landowner and there is a way to require the replacement of water supply after the three years. These steps make the operator liable for water supply replacement and are no less effective than the Federal regulations.

Section 5.4(a)(3)

PCA provided a comment on this section in its October 15, 2003, letter. PCA noted that Pennsylvania law provides protection to all dwellings in place when its laws have changed to impose greater obligations on mine operators and, since 1994, has provided protection for structures built after 1994, if they are in place at a time when the operator is (or should be aware) that the structure exists. However, the Pennsylvania General Assembly decided not to provide such protection to the persons who, with knowledge that mining will occur beneath their property within the next five years, voluntarily assume the risk of future subsidence damage by building a new structure, the location and value of which could seriously impede the operators ability to implement its already developed and approved mining plan. PCA notes that even though underground mining in Pennsylvania, unlike underground mining in other States, is a regular occurrence in areas where new structures are being built, and Pennsylvania affords protection to far more structures than Federal law does, OSM has concluded that Pennsylvania's program is not ''consistent'' with SMRCA and OSM's regulations. PCA believes that OSM has apparently done so because Pennsylvania law provides that persons who ''elect'' to build a new dwelling with knowledge that it might be damaged should be not be permitted to profit from their folly and should, like all other property owners, have an obligation to take reasonable steps to mitigate their own potential for damage.

Finally, PCA asserts that this section does not deny property owners a right to file a subsidence claim if they did not know their dwelling would be undermined. The purpose of BMSLCA is to discourage property owners who knew mining was imminent and would impose a moratorium of no more than 5 years on construction. PCA claims that there are several unique factors that contributed to the development of Section 5.4(a)(3): underground mining occurs more frequently under residential area than in other States, prevents bad land use planning, and requires a homeowner to mitigate their damages.

We disagree with PCA's characterization that BMSLCA is no less effective than the Federal regulations regarding operators' obligations to repair or compensate. While it may be prudent to preclude or limit the construction of residences on areas about to be subsided, Federal regulation provides for repair or compensation for all residences in existence at the time of mining.

Sections 5.4(c)

PCA submitted comments regarding Section 5.4(c) of BMSLCA in its October 15, 2003, letter. PCA indicated it is aware of no instances where the provisions of Act 54 relating to premining inspections imposed by Section 5.4(c) of BMSLCA, or the two year statute of limitations imposed by Section 5.5(b) of BMSLCA, or the provisions of Section 5.4(a)(3) of BMSLCA, relating to the time when a structure must have been built in order to be ''protected,'' or any of the other provisions of BMSLCA which OSM proposes to supersede, were found by OSM to have created any need for ''Federal enforcement.'' PCA indicated that it is aware of instances where OSM knew that property owners were reluctant to allow mine operators premining access to their property to take premining mitigation measures, yet did nothing to ''enforce'' their alleged Federal ''right'' to deny such access.

PCA's characterization of the Federal program is incorrect. A premining survey is a homeowner's right; it is not an obligation placed on the homeowner. As such, it would be inconsistent for homeowners to lose the protections afforded under EPAct because they declined to exercise their rights. The Federal regulations provide no penalty for homeowners electing to not allow an operator to perform a premining inspection.

PCA further commented on Section 5.4(c) that it does not deny any owner of a dwelling the right to file a subsidence damage claim. Instead, this section of BMSLCA merely conditions this right by providing that in return for being given a right to file a statutory subsidence damage claim the structure owner must grant the mine operator an opportunity to conduct a premining and a postmining inspection. PCA further indicated that to assure that operators are not required to pay compensation equal to the cost of repair (the Pennsylvania compensation standard which is different from, and more stringent than, OSM's) for ''damages'' they did not cause, the Pennsylvania General Assembly concluded homeowners should not be allowed to file subsidence damage claims unless they allow the mine operator access to their dwelling to establish a premining baseline of its condition.

We understand PCA's concerns with premining surveys. We, along with PADEP, actively encourage landowners to secure premining surveys to prove, to all concerned parties, the precise damage caused by subsidence. However, there is nothing in SMCRA, the Federal regulations, or the approved Pennsylvania program that would prohibit underground mining because a pre-subsidence survey by the operator has not been completed. As we noted earlier, a landowner who refuses to allow an operator access to conduct a premining survey will have to provide proof that underground mining operations have caused damage to his property. While both Pennsylvania and OSM encourage landowners to allow premining surveys, their failure to do so will not stop underground mining, but only make it more difficult to prove the extent of damages from mining.

NMA provided comments regarding this section in its e-mail of October 22, 2003. NMA disagreed with our proposed superseding of Pennsylvania provisions that relieved the operator of the responsibility to repair or compensate for structure damage if the property owner denied access for premining or postmining surveys. NMA stated that premining surveys are another example of State statutory provisions that are consistent with SMCRA and therefore should be approved by OSM. A requirement to conduct a premining survey protects everyone: operators and landowners, in the event that there is a claim for damage from subsidence in the future. This is a perfectly rational and common sense approach to ensure that legitimate claims for subsidence damage are promptly compensated, and at the same time protects operators from claims for damage for which they are not legally responsible. Coupled with reasonable notice provisions to ensure protection of property owners and their rights, these provisions are not only consistent with the letter and spirit of Section 720, but should be added to the Federal regulations. NMA stated that OSM has offered no rational basis to second-guess the determination by Pennsylvania that these provisions will enhance the process and provide fair protection for all parties for subsidence claims. The agency has not even recognized the benefits of pre-subsidence surveys to property owners, in that it will facilitate legitimate claims for subsidence damage.

We agree that premining and postmining surveys are important tools in the process of ensuring appropriate structure repair/compensation by mine operators. However, even though surveys are an important tool in reclamation process, the Federal rules requiring repair or compensation for damage to non-commercial buildings and dwellings and related structures (30 CFR 812.121(c)(2)) do not provide or allow an exception to the obligation to repair or compensate when an operator's underground mining operation has caused subsidence damage.

Section 5.1(b) and 5.5(b)

PCA and NMA provided similar comments (PCA in its letter of October 15, 2003, and NMA in its e-mail of October 22, 2003) on these sections. PCA indicated that SMCRA is silent on the issue of whether claims for subsidence damage to dwellings and claims for the replacement of domestic water supplies must be filed within any defined time frame. PCA believes that by superseding Sections 5.5(b) and 5.1(b) of BMSLCA, OSM is necessarily interpreting SMCRA as precluding any time limitation on the filing of subsidence damage claims. This interpretation effectively establishes a new regulatory requirement that all states must accept for processing any claim for subsidence damage to dwellings and any claim for the replacement or restoration of domestic water supplies no matter how long the property owner waits to file such a claim. PCA submits that OSM is required to engage in formal rulemaking before promulgating a new standard of general applicability. It is not free to issue ''regulations'' with a national scope in the context of ruling on a State program.

PCA also indicated that, in the absence of any express prohibition in SMCRA on placing time limits on the time within which subsidence damage claims must be filed, there is no basis for OSM to conclude that Pennsylvania's decision to do so is not authorized by 30 U.S.C. 1201(f).

PCA and NMA believe that there are reasons why statutes of limitation are imposed on ''damage'' claims in every jurisdiction in the United States, and they relate to a legitimate interest of the State in barring claims that are premised on stale evidence and which are not pursued until memories have faded and evidence is lost or destroyed. The provisions of both State law and Federal law, which grant the owners of dwellings and the users of domestic water supplies a statutory right to pursue a claim for damages or water supply replacement/restoration are, quite simply, statutory tort remedies.

PCA and NMA further note that in the absence of any express prohibition in SMCRA on placing limits on the time within which subsidence damage claims must be filed, there is no basis for OSM to conclude that Pennsylvania's decision to do so is not authorized by 30 U.S.C. Section 1201(f). Indeed, in the absence of any express limitation action

period on a Federal statutory claim, the Courts will traditionally provide for one. When a statute creating a right of action does not specify a limitations of action period, it is not assumed that Congress intended that there be no time limit at all on the action.

PCA and NMA believe that OSM's proposed decision with respect to Sections 5.5(b) and 5.1(b) of BMSLCA should not be finalized and these sections should be found to be fully consistent with SMCRA and OSM's own regulations.

Federal law does not have time limitations on citizens' rights to seek compensation, repair or replacement. We certainly agree that it is prudent to file claims soon after damage occurs and expect that, in most cases, that will occur. To delay means not only living with the damage, but possibly weakening a claim of cause and effect related to subsidence that occurred long before. However, that does not alter the fact that imposing a time limit on an owner's right to compensation, repair or replacement is inconsistent with Federal law. Therefore, we have superseded that aspect of BMSLCA to the extent that it limits an operator's liability.

PCA also refers to 30 U.S.C. 1201(f). That section of SMCRA accounts for each State's diversity and provides that because of that diversity, the States should regulate surface mining and reclamation operators. We agree that the States should be the primary enforcer of surface coal mining operations. However at Section 503(a) of SMCRA, a State may assume primacy over its regulatory program if its laws are in accordance with SMCRA and its regulations are consistent with the Federal regulations.

Section 101(g) of SMCRA requires this national consistency to ''insure that competition in interstate commerce among sellers of coal produced in different States will not be used to undermine the ability of the several States to improve and maintain adequate standards on coal mining operations within their borders.'' 30 U.S.C. 1201(g).

PCA again states that this is an action in tort. We disagree and have previously addressed this issue in our December 27, 2001, rule at 66 FR 67058, which is part of the record of this rulemaking. We also contend that the rationale in the Carlson Mining decision, which was discussed in the December 27, 2001, final rule would also apply to structure damage.

With regard to the rest of PCA's arguments, we disagree with PCA's characterization of the SMCRA and the Federal regulations. Pennsylvania and PCA advanced the same or very similar arguments that we addressed in the December 27, 2001, final rule (66 FR at 67014–67015, 67023–67024 and 67058). PCA has not provided any compelling reason for us to reassess the position stated in that final rule.

Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i) and Section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program (Administrative Record No. PA 841.66). We received no comments directed specifically to the superseding of these sections.

Environmental Protection Agency (EPA) Comments

Under 30 CFR 732.17(h)(11)(i) we requested comments on the amendment from EPA (Administrative Record No. PA 841.66). EPA's response did not specifically address the superseding of the sections of BMSLCA noted above. More information concerning EPA's response can be found in the final rule published elsewhere in this **Federal Register** where we approved an amendment to the Pennsylvania program (PA–143–FOR).

V. OSM's Decision

It is generally not necessary to use Section 505 of SMCRA or 30 CFR 730.11(a) with regard to proposed amendments to approved State regulatory programs because 30 CFR 732.17(g) provides that ''No such change to laws or regulations shall take effect for purposes of a State program until approved as an amendment.'' In this instance, however, Pennsylvania has actually implemented unapproved statutory and regulatory changes and has raised Section 505 in court pleadings. Pennsylvania contends that its changes have become effective and that Section 505 is applicable. The provisions disapproved in the December 27, 2001, final rule are ineffective as a matter of Federal law (*see* Section 505 of SMCRA) and, according to Pennsylvania, effective as a matter of State law. This situation is unusual in that certain provisions of BMSLCA conflict with SMCRA as well as provisions which go beyond and do not conflict with SMCRA.

Therefore, to avoid any doubt whatsoever concerning the Secretary's intentions in this unusual and significant matter, and because the Secretary has determined that the following State laws are inconsistent with SMCRA and its implementing regulations, the Secretary, pursuant to Section 505 of SMCRA and 30 CFR 730.11(a), supersedes 5.1(b) (52 P.S. 1406.5a(b)), 5.2(g) (52 P.S. 1406.5b(g)), 5.2(h) (52 P.S. 1406.5b(h)), 5.4(a)(3) (52 P.S. 1406.5d(a)(3)), 5.4(c) (52 P.S. 1406.5d(c)), 5.5(b) (52 P.S. 1406.5e(b)) to the extent noted above. In this final rule, we are modifying the language of our previous disapproval of the noted sections of BMSLCA to make it clear that our superseding of the above noted sections applies only to structures and water supplies protected under Section 720 of SMCRA. The modified language will be codified at 30 CFR 938.13.

We note that this action also resolves the need for the required actions related to these sections. They are being removed under a separate notice also published in today's **Federal Register** (*see* PA–143–FOR).

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under Sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and

reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and Section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects 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. Pennsylvania does not regulate any Native Tribal lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior 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.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (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. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the Pennsylvania submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 29, 2004.

Rebecca W. Watson,

Assistant Secretary, Land and Minerals Management.

■ For the reasons set out in the preamble, 30 CFR part 938 is amended as set forth below:

PART 938—PENNSYLVANIA

■ The authority citation for part 938 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 1. Amend section 938.12 to revise paragraphs (a)(1), (a)(5), (a)(6), (a)(11), (a)(12) and (a)(13) to read as follows:

§ 938.12 State statutory, regulatory, and proposed program amendment provisions not approved.

(a) * * *

(1) Section 5.1(b) (52 P.S. 1406.5a(b)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(1).

* * * * *

(5) Section 5.2(g) (52 P.S. 1406.5b(g)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(2).

(6) Section 5.2(h) (52 P.S. 1406.5b(h)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(3).

* * * * *

(11) Section 5.4(a)(3) (52 P.S. 1406.5d(a)(3)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(4).

(12) Section 5.4(c) (52 P.S. 1406.5d(c)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(5).

(13) Section 5.5(b) (52 P.S. 1406.5e(b)) of BMSLCA is not approved to the extent noted in 30 CFR 938.13(a)(6).

* * * * *

■ 2. Add § 938.13 to read as follows:

§ 938.13 State statutory and regulatory provisions set aside.

(a) The following provisions of Pennsylvania's Bituminous Mine Subsidence and Land Conservation Act (BMSLCA) are inconsistent with the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and are superseded to the extent noted effective December 9, 2004.

(1) Section 5.1(b) (52 P.S. 1406.5a(b)) of BMSLCA is superseded to the extent that it would limit an operator's liability to restore or replace a water supply covered under section 720 of SMCRA.

(2) Section 5.2(g) (52 P.S. 1406.5b(g)) of BMSLCA is superseded to the extent that it would limit an operator's liability to restore or replace a water supply covered under section 720 of SMCRA.

(3) Section 5.2(h) (52 P.S. 1406.5b(h)) of BMSLCA is superseded to the extent it would preclude Pennsylvania from

requiring the restoration or replacement of a water supply covered under section 720 of SMCRA.

(4) The portion of section 5.4(a)(3) (52 P.S. 1406.5d(a)(3)) of BMSLCA that states, ''in place on the effective date of this section or on the date of first publication of the application for a Mine Activity Permit or a five-year renewal thereof for the operations in question and within the boundary of the entire mine as depicted in said application,'' is superseded to the extent it would limit an operator's liability for restoration of, or compensation for, subsidence damages to structures protected under section 720 of SMCRA that were in existence at the time of mining.

(5) Section 5.4(c) (52 P.S. 1406.5d(c)) of BMSLCA is superseded to the extent it limits an operator's liability for repair of, or compensation for, subsidence damage to a structure covered under section 720 of SMCRA.

(6) The portion of Section 5.5(b) (52 P.S. 1406.5e(b)) of BMSLCA that states, ''All claims under this subsection shall be filed within two years of the date damage to the building occurred'' is superseded to the extent that it would limit an operator's liability for restoration of, or compensation for, subsidence damages to a structure covered under section 720 of SMCRA.

(b) [Reserved]

[FR Doc. 04–26927 Filed 12–8–04; 8:45 am]

BILLING CODE 4310–05–P

Federal Register

Thursday,
December 9, 2004

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods; Notice of Public Meeting; Availability of Draft Guidance for Records Access Authority; Final Rules and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 2002N–0277]

RIN 0910–AC39

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and immediate subsequent recipients of food. The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and is necessary to help address credible threats of serious adverse health consequences or death to humans or animals. The requirement to establish and maintain records is one of several tools that will help improve FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the information will improve FDA's ability to quickly notify the consumers and/or facilities that might be affected by the outbreak.

DATES: *Effective Date*: This final rule is effective February 7, 2005.

Compliance Dates: The compliance date is December 9, 2005; except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2005; and except that for very small businesses that employ 10 or fewer full-time equivalent employees, the compliance date is December 11, 2006.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1400.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Legal Authority

The events of September 11, 2001, have highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), subtitle A—Protection of Food Supply, section 306, which amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 414, Maintenance and Inspection of Records (21 U.S.C. 350c). (In the regulation itself, which is codified in title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act is referred to as ''the act.'' Thus, when the regulation is quoted in this preamble, the term ''the act'' will be used to refer to the Federal Food, Drug, and Cosmetic Act. However, in this preamble, we refer to the Federal Food, Drug, and Cosmetic Act as ''the FD&C Act'' to distinguish it from the Bioterrorism Act.) Section 414(b) of the FD&C Act provides, in part, that the Secretary of Health and Human Services (the Secretary), may by regulation establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that are required to be kept by these regulations are those needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. Section 306(d) of the Bioterrorism Act provides that the Secretary ''shall'' issue regulations establishing recordkeeping requirements under section 414(b) of the FD&C Act no later than 18 months after enactment of the Bioterrorism Act, that is, by December 12, 2003.

In addition, the Bioterrorism Act adds a new section 414(a) to the FD&C Act

that provides records inspection authority to FDA. Section 414(a) of the FD&C Act provides that, if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons who manufacture, process, pack, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Section 306 of the Bioterrorism Act also amends section 704(a) of the FD&C Act (21 U.S.C. 374(a)) to authorize FDA inspections of all records and other information described in section 414 of the FD&C Act, when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

In addition, section 306(c) of the Bioterrorism Act amends section 301 of the FD&C Act (21 U.S.C. 331) to make it a prohibited act to refuse to permit access to, or copying of, any record as required by section 414 or 704(a) of the FD&C Act; or to fail to establish or maintain any record as required by section 414(b) of the FD&C Act; or to refuse to permit access to, or verification or copying of, any such required record; or for any person to use to his own advantage, or to reveal, other than to the Secretary or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceeding under the FD&C Act, any information acquired under authority of section 414 of the FD&C Act.

To implement these provisions, on May 9, 2003 (68 FR 25188), FDA issued a proposed rule to require the establishment and maintenance of records to identify the immediate previous sources and immediate subsequent recipients of food. In addition to section 306 of the Bioterrorism Act, which amends the FD&C Act as described previously, FDA is relying on section 701(a) of the FD&C Act (21 U.S.C. 371(a)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the FD&C Act.

II. Highlights of the Final Rule and Summary of the Significant Changes Made to the Proposed Rule

A. Highlights of this Final Rule

The highlights of this final rule are described briefly in the following paragraphs, and are discussed in more detail later in the preamble of this document:

- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in part 1 (21 CFR part 1) subpart J of this final rule (i.e., recordkeeping and access requirements);
- The following persons or facilities are excluded from all of the regulations in subpart J of this final rule: Farms; restaurants; those performing covered activities when the food is subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*); and foreign persons, except foreign persons who transport food in the United States.
- The following persons or facilities are excluded from the requirement to establish and maintain records in §§ 1.337 and 1.345 of subpart J of this final rule, but are subject to the record availability requirements in §§ 1.361 and 1.363 for existing records: (1) Fishing vessels not engaged in processing as defined in § 123.3(k) (21 CFR part 123.3(k)); (2) retail food establishments that employ 10 or fewer full-time equivalent employees; (3) nonprofit food establishments that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States; and (4) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart J of this final rule.
- Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J of this final rule as to the finished container, except §§ 1.361 and 1.363.
- Persons who distribute food directly to consumers are excluded from the requirement in § 1.345 to establish and maintain records to identify the immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.
- Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of subpart J of this final rule.
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J of this final rule.
- The regulations in subpart J of this final rule do not require duplication of existing records if those records contain all of the information required by the subpart. Furthermore, persons can supplement existing records with any new information required by this final rule instead of creating an entirely new record containing both existing and new information.
- Persons who manufacture, process, pack, distribute, receive, hold, or import food in the United States must establish and maintain the following records to identify the immediate previous sources and immediate subsequent recipients for all food they receive and release, unless otherwise excluded from the requirements of subpart J of this final rule:
  - Name, address, telephone number and, if available, fax number, and e-mail address of the immediate previous source and subsequent recipient;
  - Adequate description;
  - Date received or released;
  - For persons who manufacturer, process, or pack food, the lot or code number or other identifier;
  - Quantity and how the food is packaged; and
  - Name, address, telephone number and, if available, fax number, and e-mail

address of the transporter who transported the food to and from you.

• Persons who have possession, custody, or control of food in the United States for the sole purpose of transporting the food, or foreign persons who transport food in the United States, regardless of whether they have possession, custody, or control of the food for the sole purpose of transporting that food (transporters), can meet the requirements of subpart J of this final rule by:

(1) Establishing and maintaining the records listed in § 1.352(a); or

(2) Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) contained in 49 CFR 373.101 and 373.103 as of the date of publication of this final rule; or

(3) Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the DOT's Surface Transportation Board (STB) contained in 49 CFR 1035.1 and 1035.2 as of the date of publication of this rule; or

(4) Establishing and maintaining specified information that is in the records required of international air transporters on air waybills by the Warsaw Convention as Amended at the Hague, 1995 and by Protocol No. 4 of Montreal, 1975 (Warsaw Convention); or

(5) Entering into an agreement with a nontransporter immediate previous source (if located in the United States) or immediate subsequent recipient (if located in the United States) to establish, maintain, or establish and maintain, the required records in options 1 or 2 of the previous paragraphs. The agreement must contain certain elements specified in § 1.352(e).

• If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food.

• If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

• If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

• If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

• Transporters of food (or specified persons who agree to establish and maintain required records under agreements with transporters) in the United States must retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food.

• Transporters of food (or specified persons who agree

to establish and maintain required records under agreements with transporters) in the United States must retain records for 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the transporter receives or releases the food.

• Records must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request.

• Failure to establish or maintain records or refusal to permit access to or verification or copying of any record is a prohibited act under section 301 of the FD&C Act.

• The compliance date for the records establishment and maintenance requirements is December 9, 2005, except that the compliance date for small businesses employing fewer that 500, but more than 10 full-time equivalent employees is June 9, 2005, and the compliance date for very small businesses that employ 10 or fewer full-time equivalent employees is December 11, 2006.

B. Significant Changes FDA Made to the Proposed Rule

FDA made the following significant changes to the proposed rule:

• All foreign persons, except foreign persons who transport food in the United States, are excluded from all of the requirements in subpart J of this final rule. A foreign person transporting food in the United States is subject to the requirements for transporters in the subpart.

• Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of subpart J of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363.

• Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363.

• Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J.

• Transporters can meet their obligation to establish and maintain records in the following ways: (1) Keeping the records listed in § 1.352(a); (2) keeping the records listed in § 1.352(b), which contain information also currently required of roadway interstate transporters under the FMCSA regulations as of the date of publication of this final rule; (3) keeping the records listed in § 1.352(c), which contain information also currently required of rail and water interstate transporters under the STB regulations as of the date of publication of this final rule; (4) keeping the records listed in § 1.352(d), which contain information also currently required of international air transporters on air waybills under the Warsaw Convention; or (5) entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. The agreement must contain certain elements specified in § 1.352(c). Intrastate transporters must also establish and maintain records under this final rule and can meet this obligation by complying with either § 1.352(a), (b), (c), (d), or (e).

• Foreign persons who transport food in the United States, whether or not

they have possession, custody, or control of the food for the sole purpose of transporting, must comply with § 1.352 of subpart J of this final rule.

- The exclusion for pet food not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (BSE rule) (62 FR 30935, June 5, 1997) has been deleted.
- The definition of ''farm'' now states that washing, trimming of outer leaves, and cooling produce are part of harvesting.
- The definition of ''farm'' now includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership.
- ''Holding'' has been defined and means ''storage of food.'' Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
- ''Packaging'' has been defined and means ''the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)).''
- Recipe has been defined to mean the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.
- The partial exclusion for retail food establishments has been replaced with a partial exclusion for persons who distribute food directly to consumers. Persons who distribute food directly to consumers are excluded from establishing and maintaining records required by § 1.345 to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. Persons who distribute food to businesses must establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients to the extent that information is reasonably available, for example when the purchaser has an established commercial account.
- The exclusion for retail facilities that are located in the same general physical location as a farm has been replaced with an exclusion for all retail food establishments that employ 10 or fewer full-time equivalent employees.
- An exclusion has been added for nonprofit food establishments.
- ''Nonprofit food establishment'' has been defined and means:

> * * * a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

- The requirement to record a ''responsible individual'' when identifying the immediate previous source, immediate subsequent recipient, and transporters has been deleted.
- The requirement to record ''lot or code number or other identifier'' has been deleted for all covered entities, except persons who manufacture, process, or pack food.
- The definition of perishable food has been deleted.
- The record retention periods for nontransporters have been changed to: (1) 6 months for food for which a significant risk or spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.
- The record retention periods for transporters (or specified persons who agree to establish and maintain required records under agreements with transporters) have been changed to 6 months for any food having a significant risk or spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk or spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.
- The record availability requirements have been changed from 4 hours/8 hours to ''as soon as possible, not to exceed 24 hours from the time of receipt of the official request.''
- The compliance date for these regulations has changed to December 9, 2005. Small businesses have June 9, 2005, of this final rule to come into compliance with these regulations, and very small businesses have December 11, 2006, of this final rule to come into compliance with these regulations.
- The qualifying language ''food intended for consumption in the United States'' has been removed from this final rule to ensure that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is intended for consumption are subject to this final rule unless otherwise exempt.

III. Comments on the Proposed Rule

FDA received approximately 212 timely submissions in response to the proposed rule, which raised approximately 220 major issues. To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

(Comment 1) Some comments state that it would be beneficial for the agency to provide the food industry with a model form that could be used to record all the required information, with the option for the industry to use this form or established recordkeeping systems. One comment requests that the agency develop and provide respective freeware that could be available as a compact disc (CD) or downloaded from the FDA Web site well in advance of the compliance date of the final rule. A few comments request that the regulations make clear that the model form is guidance and is not mandatory. One comment suggests that as a way to show that the model form is guidance, the agency should place the model form in an appendix to the regulations.

Several comments object to the inclusion of a model form in the regulations. The comments oppose using any ''one-size fits all'' generic form as an example or requirement. The comments suggest that affected businesses should decide the format in which the required records should be kept as dictated by specific business practices. The comments express concern that example forms might become informal requirements out in the field even though originally only meant as guidance.

One comment recommends that the agency provide further examples of

scenarios, rather than model forms, where records would be in compliance and noncompliance with the final regulations.

In addition, several comments state that most food companies currently maintain the chain-of-distribution information that is required by these regulations. However, the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. The recordkeeping systems are designed to provide the necessary information to remove food from the market and prevent more food presenting the same risk from entering the market. The comments state that the regulations should not prescribe any specific manner or form of maintaining the information.

(Response) The provisions describe the specific information a covered entity must keep, but do not specify the form or type of system in which those records must be maintained. As stated in both the proposed and final § 1.330, these provisions do not require duplication of existing records if those records contain all of the information required by subpart J of this final rule. If a person subject to these provisions keeps records of all of the information as required by subpart J in compliance with other Federal, State, or local regulations, or for any other reason, e.g., as a result of its own business practices, then those records may be used to meet these requirements. Such records may include, but are not limited to, purchase orders, bills of lading, invoices, and shipping documents. Moreover, entities do not have to keep all of the information required by this final rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new data required by this final rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Our intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. FDA received numerous comments, as discussed further in section III.G of this document on ''Can existing records satisfy the requirements of this subpart?'' that agreed with this approach to not specify the type and format of the records and to allow flexibility to use existing recordkeeping systems. In addition, comments state that individual companies are in a better position to decide in what format records are needed based on knowledge of applicable business practices and cost structures. For these reasons, FDA has not included a model form in this final rule.

(Comment 2) Several comments state that the food industry has repeatedly demonstrated the ability to identify and remove product from grocery store shelves very quickly. The comments suggest that the diversion of substantial resources that would be necessary to implement the agency's proposed regulations would not further food security, but instead would diminish the overall efficiency of the food distribution system, which is necessary to serve food safety and security needs and commercial purposes.

Further, some comments assert that the regulations are directed toward enabling the Government to trace a product, rather than ensuring that companies are able to trace the product through all the links in the chain of custody of a food ingredient or product. The comments state that the intent of the Bioterrorism Act was to ensure the existence of a system that fully engages the institutional knowledge and logical procedures that already enable the companies responsible for the production and distribution of food to maintain an orderly and efficient nationwide supply chain and that also currently make it possible to effect rapid recalls when necessary. The comments state that the proposed regulations fail to capitalize on the efficiencies of time and resources available through effective public/private coordination, exemplified by the efforts that currently support effective recalls.

(Response) FDA recognizes that some of the food industry currently has existing records that may satisfy all or part of these regulations; however, not all of the food industry is currently able to conduct such traceback investigations. Notwithstanding the ability of some of the food industry to conduct such investigations, Congress authorized FDA through the Bioterrorism Act to issue regulations requiring the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold or import food to enable FDA to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. FDA believes the information required to be established and maintained in records in these regulations is necessary to enable FDA to conduct an efficient and effective tracing investigation, independent of what the food industry may be able to do. FDA reiterates that it is not dictating the form or type of system to be used to satisfy these requirements in these regulations. If the food industry already keeps all of the information required by this final rule, then existing records can be used to comply with this final rule. Further, FDA anticipates working closely with the food industry in any tracing investigation.

In addition, recently FDA was significantly hampered in identifying the source of contaminated food during a trace back investigation following a Hepatitis A outbreak due to contaminated green onions. This outbreak involved a distributor who purchased green onions from a variety of firms in no predictable pattern and distributed them without recording brand and lot information. The distributor did not keep records of the previous sources of the green onions, which might have indicated a particular supplier of green onions during the specified exposure time period. It was impossible for investigators to determine, from the distributor, the identity of the supplier of the green onions that were sent to the implicated restaurant, and therefore FDA had to spend time investigating all potential suppliers of the green onions to identify the one supplier that supplied the restaurant. Speedy trace back would have enabled FDA to prevent further distribution of contaminated products sooner, thereby preventing more illnesses.

Further, 20 percent of all tracing investigations are prematurely terminated due to deficiencies in recordkeeping. A reduction of just one premature termination could prevent at least 53 people from becoming ill. Requiring adequate records to complete a tracing investigation reduces trace-back times by 8 days. This increased efficiency facilitates preventive action in 15 to 18 percent of outbreaks. The speed with which a tracing investigation can be conducted is of vital importance in reducing the number of people who could potentially become ill. Access to records that do not exist or that do not contain sufficient information (with no requirement to retain them or make them available in a timely fashion) is not an efficient and effective way to conduct a tracing investigation during a public health emergency involving

serious adverse health consequences or death to humans or animals.

(Comment 3) One comment states that established industry practice with regard to investigating product defects and conducting product recalls is consistent with the terms of the Bioterrorism Act allowing for the rapid identification of the immediate previous source and immediate subsequent recipient of foods. The comment asserts that the industry's response to the events of September 11, 2001, has strengthened these existing practices. The comment explains that as an inevitable result of industry's commitment to Responsible Care Security Code No. 7 and increased requests from customers, emphasis is now shifting from security at fixed plant sites and major distribution centers to security of products throughout the value chain. This shift in emphasis enhances industry's existing traceback capabilities. The comment asserts that the controls needed to effectively trace the source and recipient of foods are already in place.

(Response) As explained in the response to comment 2, these provisions are intended to help ensure that FDA has the information it needs to identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 4) One comment asserts that when food presents a risk of serious adverse health consequences or death to humans or animals, a class I recall is used and can quickly eliminate problems, whereas recordkeeping, at best, will get a message to the retail locations where products were placed on sale to consumers. The comment questions the benefit of the copious amounts of information and possible implementation of an intricate new product tracking system required by the regulations. The comment asserts that class I recalls will continue to be the appropriate means by which a potential hazard is handled and that requiring the expenditure of significant resources to develop a new system in the absence of a Congressional mandate or a genuine need is questionable. The comment recommends that FDA continue to rely upon the proven capabilities of class I recalls and cooperation with the food industry. The comment suggests that FDA should develop a system to contact the appropriate companies to engage their assistance in addressing threats to the food supply, rather than requiring the onerous recordkeeping specified in the regulations.

(Response) This comment assumes that the contaminated food and its whereabouts are known completely, which may not always be the case. As such, the need exists for records to be able to trace forward fully to all locations where the food was shipped, as well as trace backwards to locate any similarly contaminated food shipped to all other locations. Moreover, class I recalls are voluntary measures only. In the Bioterrorism Act, Congress has given FDA the means both to establish requirements for establishment and maintenance of records, and to administratively detain, on its own initiative, food for which FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals (section 303 of the Bioterrorism Act). In addition, the records are needed not only to help remove contaminated food from the market place, but also to help identify the source of the contamination.

(Comment 5) A few comments state that, in the event of a serious product issue or life-threatening situation, the only responsible action to take is to warn the public through the media to prevent further use or distribution of the product. The communication vehicle used to disseminate the warning should be based on the severity of potential harm or health consequences. Use of the media also is necessary to influence facilities to check their store stock and for consumers to check their refrigerators and pantries for the affected product.

(Response) FDA agrees that the use of warnings to the public about specific products is important. Indeed, FDA has used this approach many times. Nonetheless, records will ensure that FDA can perform trace forward to remove the problem food from the market and traceback to identify the source of the problem. These recordkeeping requirements will also enable FDA to identify the problem food more specifically and, thus, FDA can target its public warnings on the specific problematic food.

(Comment 6) A few comments request that the agency add a ''pipeline provision'' that allows the use of NA (not available) in place of information where ingredient records were not maintained. The comments state that many ongoing processing operations will have some ingredients on site that have been purchased and housed in facilities for some time prior to the implementation of these regulations. In these cases, it would be a significant manpower burden (or perhaps not possible at all) to obtain or attempt to recreate all the required information on the source of those ingredients. The comments note that these ingredients have been used in food production without incident and it would be unlikely they would be involved in an act of terrorism.

(Response) There is no requirement to establish and maintain records for food ingredients you received before the compliance date of these regulations. Under that scenario, however, you must establish and maintain records of that food when you release it after the compliance date of the regulations. For example, if a commercial bread bakery receives flour, eggs, and salt before the compliance date of this final rule, it does not need to keep records of the immediate previous source of when it received that food. Once the bakery uses these ingredients to bake the bread and releases the bread to nonconsumers after the compliance date of the rule, the bakery must keep the records required by § 1.345 of this final rule regarding the immediate subsequent recipients of the bread.

(Comment 7) One comment recommends the use of United Code Council standards, a system of globally recognized and implemented standards that enables traceability of products and identification of trading parties/recipients, through all locations of the supply chain.

(Response) FDA does not agree. The agency has determined that the least burdensome way of issuing the recordkeeping requirements is to specify the information that must be contained in the records, but not the format in which the records are kept. Indeed, the agency received numerous comments that argued that covered entities should be allowed to use existing records and systems.

(Comment 8) One comment requests that source labeling, including country-of-origin labeling, be required as a component of an effective traceback program in the event of a food emergency. The comment states that some industries have already developed technologies such as barcodes, stamps, stickers, or tags to identify the source of produce as well as software to assist in more accurate traceback to the grower/packer level.

(Response) FDA does not agree. At this time, FDA does not believe this information is necessary to enable a traceback. FDA believes the requirements of the final regulations for the establishment and maintenance of records to identify the immediate previous sources and immediate subsequent recipients of food in order to address credible threats of serious

adverse health consequences or death to humans or animals are sufficient.

(Comment 9) Some comments ask that the agency generate more publicity on the regulations and provide the industry with educational materials and training. One comment states that because food wholesale distributors have no significant contact with FDA personnel and procedures, they have a limited understanding of the requirements. One comment asks that the agency help promote and educate the industry abroad on the recordkeeping regulations. Another comment asks that FDA provide materials in other languages. One comment asks that the agency develop a strong communications program to disseminate the new regulations once they become final because the fresh produce industry and its transportation partners are highly diverse and fragmented. The comment states that independent truckers in particular need to be made aware of the regulations because the fresh produce industry in the United States relies heavily on independent truckers to move fresh fruits and vegetables to market quickly.

(Response) FDA conducted extensive outreach on the proposed recordkeeping rule, including having relevant FDA staff attend 6 international meetings and more than 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act requirements. On May 7, 2003, FDA held a public meeting (via satellite downlink) to discuss the recordkeeping and administrative detention proposed rules. See 68 FR 16998 (April 8, 2003) or *http://www.cfsan.fda.gov/~dms/fsbttraz.html*. Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later rebroadcast to Europe, Asia, Africa, and the Pacific (areas in different time zones). FDA has also provided transcripts of the broadcast in English, French, and Spanish (the three official World Trade Organization languages) on the agency's Web site. In addition to this outreach to the affected industry, FDA has conducted outreach on the proposed rule to States.

FDA plans similar outreach directed to stakeholders following publication of the final rule implementing the recordkeeping provisions of the Bioterrorism Act. Our outreach will include the following:

- Materials and events for the media;
- Domestic outreach meetings to States and industry;
- International outreach to U.S. trading partners;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and State and local government representatives of the new regulations and their requirements; and
- Cooperative arrangements with other Federal agencies to ensure that information on the final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included on FDA's Web site at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

(Comment 10) Several comments suggest that, to lessen the burden to the food industry, FDA needs to coordinate with other local, Federal, and State government security programs in establishing the final recordkeeping regulations.

(Response) In issuing these recordkeeping regulations, FDA has stated that records established and maintained as a result of local, State, or other Federal regulations, or as a matter of routine business practice, need not be duplicated if the records contain all the information required by these regulations. Further, if existing records contain some, but not all, of the required information, persons may supplement existing records with the additional information required under this final rule.

(Comment 11) One comment asks that the final rule require that upstream entities provide all the required information to downstream entities in the food distribution system. The comment states that distribution centers that receive and store food and retail outlets that hold and sell food do not know and should not be required to determine many of the information items required under the proposed regulation. The comment states that requiring that any information be passed through the system from the first point of distribution, preferably through electronic means, would alleviate some of the burden of the recordkeeping requirements on downstream entities.

(Response) The agency does not agree completely that distribution centers and retail outlets do not know many of the information items. The agency agrees, however, that including information pertaining to lot or code numbers of foods in the required records is not practical for distribution centers and retail outlets, given current business practices. FDA has, therefore, deleted this requirement. Instead, the final regulation now only requires that persons who manufacture, process, or pack food keep records on the lot or code number or other identifier of the food, and only to the extent this information exists. Moreover, to minimize the burden this regulation may have on affected parties, FDA is not specifying the form or format of the records that must be established and maintained and is not requiring electronic records.

(Comment 12) Several comments applaud the agency's efforts in proposing a rule that appears to be designed to work with the food industry as efficiently and effectively as possible to address credible threats without imposing undue burdens. One comment urges the agency to issue the final regulations as expeditiously as possible to enhance compliance with the provisions of the Bioterrorism Act. The comment states that, by finalizing the regulations in conjunction with the interim final rules entitled ''Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (the registration interim final rule) (68 FR 58894, October 10, 2003) and ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (the prior notice interim final rule) (68 FR 58974, October 10, 2003), the education and training that will be necessary for compliance with the regulations can be done together and the internal policy and procedures for companies can be designed to meet all of the obligations under the final rule. The comment further states that this is the reason that Congress intended regulations to be issued within 18 months of the effective date of the Bioterrorism Act.

(Response) The agency has acted expeditiously in issuing all of the regulations under the Bioterrorism Act and has developed and published final regulations as quickly as possible. With respect to education and training, as stated previously, the agency intends to conduct extensive outreach to stakeholders for this final rule that is similar to outreach the agency conducted for the registration and prior notice interim final rules.

(Comment 13) One comment requests clarification regarding the level of recordkeeping that will be expected at each facility maintained by a vertically integrated company. The comment explains that a vertically integrated company has various facilities involved in the growing and processing of bulk ingredients as well as the manufacturing and marketing of finished products. Some of the requirements for recordkeeping could result in duplication of effort if each facility within the company is required to

maintain separate records, even though the overall records are available at company headquarters or some central location. One comment requests that the final rule clarify what is meant by the term ''released'' and the relationship of this term to holding legal title, or ownership of the food. Another comment suggests that FDA clarify that only at such time as the food leaves the possession and control of one firm and enters into the possession and control of another firm, whether or not via a transporter, would the recordkeeping requirement apply. The comment maintains that any other interpretation of the statute would impose a crushing burden of internal tracking systems and paperwork that would detract from most firms' abilities to do business and is well beyond the intent of the Bioterrorism Act.

(Response) The records required by these regulations are those that FDA needs for inspection to identify the immediate previous sources and the immediate subsequent recipients of food. ''Immediate previous source'' has been defined in § 1.328 of the final rule to mean ''a person who owns food or who holds, processes, packs, imports, receives, or distributes food or food packaging, and that last had an article of food before transferring it to another person.'' Unless otherwise exempt (i.e., a farm), a ''vertically integrated company'' would be required to identify the sources of all food received from its immediate previous sources. Once the vertically integrated company receives the food and keeps information on its immediate previous sources, that vertically integrated company does not need to keep additional records until it releases the food to another person. Unless otherwise exempt, at the time the vertically integrated company releases the food, it is required to identify the immediate subsequent recipients of that food.

As an example, if a company buys food from its immediate previous source (company A), then the company further processes the food, holds the food, transports the food, and distributes the food to a grocery store, then the vertically integrated company would only have to keep records on its immediate previous source (company A) and its immediate subsequent recipient (grocery store). The vertically integrated company need not keep records of all the covered activities (manufacturing, processing, packing, transporting, etc.) conducted by that company while it has the food.

Of course, when the integrator has any records or other information available to FDA under sections 414 and 704(a) of the FD&C Act, then FDA would have access to those records if FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

B. Foreign Trade Issues

(Comment 14) Several comments representing foreign governments and international associations agree in principle to the recordkeeping requirements provided the requirements are based on a sound risk assessment and do not restrict trade more than necessary to effectively address potential risks. Some comments note that there is no risk assessment provided to justify the proposed measures required by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement). Several comments representing foreign governments and businesses request that FDA work with foreign governments to develop common standards and requirements and to facilitate trade flow. Some foreign comments argue that the result of the onerous recordkeeping burden in the regulations will be the elimination of many legitimate and safe food distribution businesses and a serious reduction in global food trade. One comment suggests that the regulations will adversely impact trade, as they are likely to increase uncertainty and costs for foreign exporters. Small and medium sized foreign companies in particular may be prevented from continuing to export to the United States for these reasons. One comment is concerned that the regulations may lead to the unintended consequence of foreign countries imposing the same requirements of U.S. goods in foreign trade.

(Response) FDA considers that these foreign trade comments are now moot, given the scope of these final regulations. These final regulations do not apply to foreign persons, except foreign persons transporting food in the United States, who are treated no differently than domestic food transporters under these final regulations. FDA does not believe that foreign persons who transport food in the United States will incur additional costs as a result of these regulations, because FDA assumes that they will choose to comply with § 1.352 of this final rule by establishing and maintaining the records already required by FMCSA. See the response to comment 82, later in this document.

C. Comments on Who is Subject to This Subpart? (Proposed § 1.326)

1. General

(Comment 15) Several comments seek clarification on who is covered by the proposed regulation. Comments ask if the provisions of the regulations apply to port facilities, such as warehouses, or storage and inspection facilities in land, sea, or airports that belong to private companies and government bodies for food control in the country of shipping and/or origin.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to these regulations. ''Person'' is defined in section 201(e) of the FD&C Act (21 U.S.C. 321 (e)) and includes any ''individual, partnership, corporation, and association.'' Therefore, any person located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico who manufactures, processes, packs, transports, distributes, receives, holds, or imports food is included within the term ''person''. ''Holding'' has been defined in § 1.328 of the final rule to mean ''storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.'' Accordingly, port facilities, such as warehouses, or storage facilities that are located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico are subject to these regulations as they are ''persons'' who are holding food.

(Comment 16) One comment seeks clarification on whether the proposed regulation applies to a carrier's freight brokers. The comment states that, although these brokers never have actual physical possession of freight, they act as the middleman for carriers and shippers and have knowledge of where the freight came from and where it went. A few comments ask that FDA clarify that customs brokers are excluded from the regulations. The comment indicates that because § 1.326 of the proposed regulations applies to, inter alia, persons that ''import'' food, it could be interpreted to include customs brokers, who act only as agents for the importer. A comment notes that customs brokers have only the information needed to file an entry on behalf of the actual importer and to obtain release of the food from U.S. Customs and Border Protection (CBP). However, according to the comment, customs brokers do not own food or hold, process, pack, import, receive, or distribute food for purposes other than

transportation. The comment notes that applying the recordkeeping requirements to customs brokers would cause redundant and burdensome recordkeeping requirements for them.

(Response) FDA clarifies that the recordkeeping requirements do not apply to brokers who act only to facilitate distribution, sale, or transportation of food by processing information or paperwork associated with these functions. Brokers who do not directly manufacture, process, pack, transport, distribute, receive, hold, or import food are not subject to the requirements of the regulation.

(Comment 17) One comment asks that FDA specify whether the regulation applies to the importer of record or to the initial U.S. recipient when the merchandise enters the country. The comment notes that this clarification could affect who is responsible for the establishment and maintenance of records.

(Response) The final rule applies to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States, unless the person qualifies for an exclusion in § 1.327 of the final rule. An importer of record or an initial U.S. recipient that is involved in one or more of the identified activities must establish and maintain the required records.

(Comment 18) Several comments express concern because the proposed regulation applies only to domestic, for-hire transporters, and foreign transporters that enter the United States, as well as domestic private transporters, are not covered. Comments state that the regulation should apply uniformly to all transporters, foreign and domestic, for-hire and private, to ensure that no group has an unfair competitive advantage.

(Response) All persons transporting food in the United States must meet the requirements of subpart J of this final rule, regardless of whether they are ''for hire'' or ''private.'' FDA notes, however, that if a manufacturer located in the United States transports the food in its own company trucks, then it must comply with the recordkeeping requirements for nontransporters as opposed to those applicable to transporters because FDA does not need the facility to keep duplicative records of the food while it is in that facility's control. However, if a foreign person, such as a person who manufactures food, transports food in the United States, it must comply with the requirements for transporters, even if it transports the food in the United States itself. This ensures that FDA will have the ability to traceback the food that is transported in the United States, even if the facility from which the food originates is an exempt foreign facility under subpart J.

(Comment 19) One comment notes that CBP's current requirements apply to trucking companies that transport imported food into the United States. The comment suggests that FDA coordinate with CBP to get data from them in the event of a threat to the nation's food supply, rather than develop its own distinct recordkeeping regulations.

(Response) The records required to be kept by these regulations are those FDA needs to help identify the immediate previous sources and immediate subsequent recipients of food. Section 1.361 of the final rule allows FDA access to transporters' existing records when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. When conducting a traceback, FDA needs access to the required records at each point in the distribution chain for the implicated food. Thus, FDA will expect to obtain applicable records from transportation companies in the distribution chain. Although FDA may contact, and coordinate tracebacks with, other Federal agencies, including CBP, the agency expects transportation companies to comply with the recordkeeping and access provisions of these regulations. FDA notes that entities keeping records to satisfy CBP's regulations may use those same records to satisfy some or all of the requirements of this final rule if those records contain some or all of the information required by subpart J of this final rule. Entities also can supplement existing records with any new data required by this regulation, instead of creating an entirely new record containing both existing and new information.

(Comment 20) A few comments ask FDA to clarify what constitutes ''holding'' food, who FDA considers to be ''holders of food,'' and under what circumstances food is being held in transport. The comment notes that the lack of clarity leaves a carrier's terminal operating facility, gas stations, truck stops, and even trucks themselves vulnerable to being considered as ''holders of food'' and thereby subject to burdensome reporting requirements. Comments also ask FDA to exclude trucks, truck terminals, and facilities from the definition of ''holding,'' stating that this would be consistent with the intent of the law and the realities of the trucking industry's business practices. One comment asks whether food held for short periods of time in a trucking terminal during cross-dock operations meets the definition of ''holding.'' One comment states that there are certain areas in the supply chain that provide temporary space for food during transit and that these areas should not be considered to be ''holding'' or ''storing'' food and subject to the recordkeeping requirements. The comment notes that some sites serve as transitory staging areas where produce is momentarily held before transportation and that, because of the perishable nature of the product and the desire to transport the fresh commodity rapidly, produce moves from these staging areas as quickly as possible.

(Response) ''Holding'' means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. The recordkeeping requirements in §§ 1.337 and 1.345 of this final rule apply to persons who ''hold'' food for purposes other than transportation. As defined in § 1.328 of this final rule, a ''transporter'' is:

> * * * a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that person has possession, custody, or control of that food for the sole purpose of transporting the food.* * *

Truck terminals or similar facilities that are part of the transportation process and merely provide a location for trucks to transfer possession, custody, or control to another entity are not subject to the requirements in §§ 1.337 and 1.345 of the final rule, unless possession, custody, or control is transferred to that terminal or facility.

(Comment 21) One comment seeks clarification on whether a ''customer,'' such as an office complex, would be required to maintain records if it receives and stores a food, such as bottled water, in the customer's own storage area for subsequent distribution to the various offices within the complex. The comment also asks whether, for bottled water, such a customer would also be the immediate previous source for bottles that are returned to the bottler for reuse.

(Response) FDA has added an exclusion to the final rule for persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food. This exclusion covers person such as a hotel concierge, the reception desk in an apartment building, and an office complex that

receives bottled water as described by the comment. FDA has added this exclusion because such persons are not parties to the transaction and records from such person are not necessary to identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death.

The comment also asks whether, for bottled water, such a customer would also be the immediate previous source for bottles that are returned to the bottler for reuse. A customer who returns bottles to the bottler would be the nontransporter immediate previous source of the bottles (§ 1.328 of the final rule). As with other sources of its bottles (e.g., a bottle manufacturer), the bottler would be required to keep records of bottles received from customers for reuse.

(Comment 22) One comment asks that FDA clarify in the regulation that domestic grain-handling, feed manufacturing/ingredient or processing facilities dedicated solely to exporting bulk or processed agricultural commodities to other countries are exempt from the recordkeeping requirement unless the commodities, products, or byproducts they handle are introduced into U.S. commerce. The comment states that this clarification would be consistent with the statutory language and FDA's proposed regulations.

(Response) The proposed rule applied to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for consumption in the United States, unless the person qualifies for an exclusion in § 1.327. This provision has been changed in the final rule. The Bioterrorism Act does not limit the recordkeeping authority to food that is consumed in the United States. FDA's intent in the proposed rule was to apply the recordkeeping provisions to the full reach of section 306 of the Bioterrorism Act with respect to domestic persons. In contrast, the registration interim final rule that FDA issued under section 305 of the Bioterrorism Act only requires those facilities that manufacture, process, pack, or hold food for consumption in the United States to register. The proposed recordkeeping rule inadvertently added the same qualifier as is in the registration interim final rule: That is, it only applied to food that was ''intended for consumption in the United States.'' FDA is removing this qualifying language from the final rule to ensure that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to this final rule unless otherwise exempt. FDA believes this coverage is necessary because foods intended for export could easily be diverted into domestic commerce. In addition, not everyone in the food supply chain may know if the food is intended for consumption in the U.S. or intended solely for export. Therefore, such a limitation in this rulemaking could create holes in a tracing investigation. Further, FDA is concerned that exempting foods intended for export from the recordkeeping regulations could lead to such foods being targeted for tampering and reintroduction into domestic commerce because they would prove more intractable to tracing investigations.

(Comment 23) One comment asks whether small growers who provide a raw agricultural commodity to a cooperative must keep records and whether the cooperative must list all of the growers.

(Response) Growers of raw agricultural commodities that meet the definition of ''farm'' in § 1.328 are excluded from the requirements of subpart J of this final rule. A cooperative that accumulates raw agricultural commodities from growers, and does not meet the exemption for retail food establishments that employ 10 or fewer full-time equivalent employees in § 1.327(f) of the final rule, is subject to the requirements in § 1.337 of the final rule regarding the immediate previous sources of food. Distribution of food from the cooperative directly to consumers is excluded from the requirements of § 1.345 of the final rule regarding the immediate subsequent recipients of food.

2. Intrastate

(Comment 24) One comment agrees that the requirement for U.S. domestic firms, whether shipping interstate or intrastate, to establish and maintain records as provided in the proposed regulation will maximize FDA's capability to implement traceback procedures within the borders of the United States. Another comment states that a finding that a certain food is intentionally contaminated—even if only distributed or sold locally—could have widespread, nationwide, even international, economic implications. The comment states that the recent ''mad cow'' episode in Canada demonstrates that restrictions might be imposed on the distribution and sale of implicated products, or consumers across the country may decide not to buy the products thus impacting the economy as a whole. As a result, the comment states that FDA is correct in concluding that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food should be subject to the recordkeeping requirements whether or not they directly engage in interstate activities involving food.

However, another comment states that FDA's intent to assert jurisdiction over food, whether or not it enters interstate commerce, may be unconstitutional. The comment notes that this assertion of power to regulate food in intrastate commerce is inconsistent with limitations imposed by the Commerce Clause of the U.S. Constitution, which generally authorizes Congress to regulate purely interstate commerce only. The comment further states that FDA should have assumed that Congress did not intend to violate the Constitution, and should revise the proposed rule accordingly. Another comment states that the FDA is proposing that domestic persons must maintain appropriate records as stipulated by the proposed regulations regardless of whether their food enters interstate commerce. The comment adds that appropriate State, local, and municipal regulatory bodies have authority to regulate domestic persons who manufacture, process, pack, transport, distribute, receive, or hold food intended for human or animal consumption, when intended solely for intrastate commerce in the United States. The comment argues that the proposed regulations regarding recordkeeping should not be expanded beyond what has been set forth in the Bioterrorism Act.

Another comment states that the FMCSA has guidelines for determining whether carriers and drivers are engaged in interstate commerce and provides the following definition in 49 CFR part 390.5:

> Interstate commerce means trade, traffic, or transportation in the United States—(1) Between a place in a State and a place outside of such State (including a place outside of the United States);
>
> (2) Between two places in a State through another State or a place outside of the United States; or
>
> (3) Between two places in a State as part of trade, traffic, or transportation originating or terminating outside the State or the United States.

(Response) In the preamble to the proposed rule, FDA sought comments on its tentative conclusion that it has authority to require recordkeeping by persons engaged only in intrastate commerce. FDA also sought comments on how many intrastate persons would not be covered by one of the exclusions

from the recordkeeping requirements (e.g., the farm or restaurant exemption). Based on consideration of the received comments and further review of the provision of the Bioterrorism Act that provides FDA with the authority to require the establishment and maintenance of records by all ''persons'' who engage in specified activities involving food, FDA has concluded that the Bioterrorism Act gives FDA authority to require persons to establish and maintain records, whether or not they engage in interstate commerce, as long as they fall within Congress's power to legislate in this area.

FDA is mindful that its interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (See *Solid Waste Agency of Northern Cook County* v. *U.S.*, 531 U.S. 159 (2001).) The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the Commerce Clause of the Constitution (Article I, section 8). Based on these considerations, FDA is retaining § 1.326(b) as proposed, with the result that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States (unless otherwise exempt) must establish and maintain records, even if food from the facility does not enter interstate commerce.

The plain language of new section 414 of the FD&C Act does not exclude a facility from recordkeeping because food from such facility does not enter interstate commerce. Notably, sections 301 and 304 (21 U.S.C. 331 and 334) of the FD&C Act demonstrate that Congress has included a specific interstate commerce nexus (e.g., has explicitly required interstate commerce) in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret the Bioterrorism Act as not limiting recordkeeping only to those persons with a direct connection to interstate commerce. Congress's power to legislate under the Commerce Clause is very broad. We acknowledge that such power is not without limits, see *United States* v. *Lopez*, 514 U.S. 549, 567 (1995); *U.S.* v. *Morrison*, 529 U.S. 598, 618 (2000), but these limits have to be construed in light of relevant and enduring precedents.

In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), noting that:

> * * * although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'* * * (*Lopez*, 514 U.S. at 556.)

This principle applies squarely to the recordkeeping provision of the Bioterrorism Act. Accordingly, given the collective impact on commerce of intrastate manufacturing, processing, packing, transporting, distributing, receiving, or holding of food in the United States, FDA has concluded that the requirement to establish and maintain records should apply regardless of whether the food enters interstate commerce. Thus, FDA is retaining § 1.326(b) as proposed. See also response to comment 82 below for an expanded discussion of the collective impact on commerce of intrastate transportation of food.

This is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that, in any action to enforce the FD&C Act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress's goal in enacting the Bioterrorism Act, because the potential harm from bioterrorist attacks or other food-related emergencies can be great, whether or not the food moves from one State to another. The usefulness of recordkeeping also can be significant in food emergencies where interstate shipment has not occurred.

3. Foreign Facilities

(Comment 25) Several comments assert that FDA lacks the statutory authority to apply the recordkeeping and records inspection provisions of the Bioterrorism Act to foreign facilities. According to the comments, section 306 of the Bioterrorism Act does not indicate, expressly or by inference, that Congress intended the provisions of that section to apply to overseas persons or facilities. They also contend that nothing in the legislative history of the Bioterrorism Act indicates Congress intended that section 306 of the Bioterrorism Act should apply to foreign facilities. The comments point out that there is a longstanding presumption in the law that legislation does not apply outside the borders of the United States, unless Congress clearly and expressly states such an intent. The comments state that, under governing case law, FDA may not infer legislative intent to give a statute extraterritorial reach.

A few comments indicated that FDA failed to provide legal justification for applying the regulation to foreign facilities. The comments pointed out that FDA's stated belief that this was the most efficient and effective strategy for obtaining needed information on food from foreign countries cannot overcome the clear indications that Congress did not intend section 306 of the Bioterrorism Act to apply to foreign entities.

One comment suggests that FDA clarify that the recordkeeping requirements do not apply outside of the United States, but serve only as a guideline to facilitate a rapid response through cooperation at intergovernment and international industry levels. One comment states that it has been acknowledged in the context of recent CBP initiatives that CBP has no jurisdiction in foreign countries. The comment notes that, consequently, mutual agreements on cooperation between CBP and some foreign governments have been reached to address together their shared security objectives. Comments suggested that FDA pursue a similar approach for safety and security of foods.

One comment asks what action FDA can take against foreign companies that do not establish and maintain the records required under section 306 of the Bioterrorism Act. A few comments state that the fact that section 306 of the Bioterrorism Act does not provide any mechanisms for enforcement of the recordkeeping and records access requirements against foreign persons supports the position that Congress did not intend that section to apply to foreign entities.

(Response) Because FDA has decided, for policy reasons, to exempt foreign facilities that do not manufacture, process, pack, distribute, hold, or import food in the United States from the requirements of the rule, FDA does not need to decide this jurisdictional issue. FDA is exempting all foreign persons (except for foreign persons who transport food in the United States) from the final regulation because FDA does not believe such records would be needed. Much of this information is available to the Secretary from facilities required to provide prior notice under part 1, subpart I. FDA intends to work with the competent authorities in foreign countries to access records during public health emergencies to obtain additional information, if necessary. However, the final rule explicitly provides that persons who transport food in the United States are subject to subpart J of this final rule.

(Comment 26) One comment questions FDA's determination that it can perform its Bioterrorism Act

mission of tracking shipments by exempting Mexican and Canadian motor carriers from the recordkeeping requirements while requiring U.S. motor carriers to comply with the recordkeeping requirements. The comment notes that, based on CBP figures for Mexico-domiciled carriers, referenced in the ''Economic Impact Estimates'' section of the proposed rule, 63,000 out of 80,000 carriers operating across the southern border are Mexico-domiciled. The comment points out that, therefore, the majority of cross-border FDA-regulated shipments at the southern border may be exempt from the requirements of the regulation.

(Response) FDA agrees. The final rule provides that foreign persons who transport food in the United States are subject to this final rule. A ''transporter'' is now defined as:

* * * a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, trail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether the foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.* * *

Thus, even if a foreign manufacturing facility transports its own manufactured food into the United States, it is considered a ''transporter'' under subpart J of this final rule and must comply with the requirements applicable to transporters.

(Comment 27) One comment seeks clarification regarding application of the recordkeeping requirements to certain ownership-partnership relationships involving a U.S. trucking company and a Canadian or Mexican trucking company. The comment asks, for example, whether a Canadian subsidiary of a U.S. trucking company is subject to the recordkeeping requirements. The comment states that a Canadian trucking company may be in partnership with a U.S. company, and the percentage of U.S. ownership is established in each partnership. Another example provided by the comment is that a Mexican motor carrier may have a contractual or interline relationship with a U.S. company. The comment asks whether the recordkeeping requirements apply to the foreign transporters with these U.S. relationships.

(Response) The final rule applies to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Thus, any person who transports food in the United States is subject to these recordkeeping requirements with respect to that food that enters the United States. The partnership or contractual status with a U.S. company does not affect the application of these requirements to a foreign person if they are transporting food in the United States, because such persons are already covered by this final rule by virtue of transporting food in the United States.

(Comment 28) One comment seeks clarification on whether residency in a territory of the United States affects applicability of the regulation. One comment questions FDA's authority to apply the proposed regulation to the Caribbean jurisdictions of the U.S. Virgin Islands and the Commonwealth of Puerto Rico. The comment contends that the regulations would be burdensome to grocery operators or other retailers in the Caribbean jurisdictions who do not export to the Continental United States, but would not deter bioterrorism acts in the Continental United States or in the Caribbean jurisdictions. The comment asserts that the proposed regulation will jeopardize the island economies of the Caribbean jurisdictions by increasing unnecessary expenses to the food retailing activity, which is already more expensive than in the Continental United States, by adding, among other expenses, the maritime transportation cost to the goods.

(Response) The final rule applies to persons that manufacture, process, pack, hold, transport, distribute, receive, or import food in the United States. Section 201(a)(1) of the FD&C Act defines the term ''State'' as, ''any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico'', and section 201(a)(2) of the FD&C Act defines the term ''Territory'' as, ''any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone).'' Accordingly, any person in the 50 States of the United States, or in any Commonwealth or Territory of the United States, that performs a covered activity is subject to the requirements of this final rule. This includes both Puerto Rico (because, for purposes of the FD&C Act, it is considered a State) and the U.S. Virgin Islands (because, as a U.S. territory, it is considered a State for purposes of the FD&C Act).

D. Comments on Who is Excluded From All or Part of the Regulations in This Subpart? (Proposed § 1.327)

1. General

(Comment 29) Several comments argue that because the Bioterrorism Act specifically excludes those foods under the jurisdiction of USDA, alcoholic beverages should also be excluded, as they are already regulated by the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) as well as by CBP. One comment requests that FDA secure a legislative amendment to the Bioterrorism Act that exempts wines and spirits and other alcoholic beverages from its application, in the same way meat, poultry, and egg products under the jurisdiction of the USDA are excluded from its scope.

Another comment states that the importer's records enable a product to be traced from the point of importation to its destination, as well as back to the producer/supplier. The comment states that substantial information about a product imported legally into the United States is already held in the TTB database.

(Response) Unlike products regulated under the exclusive jurisdiction of USDA under the FMIA, the PPIA, or the EPIA, Congress did not exempt alcoholic beverages from the scope of the recordkeeping requirements. FDA has not excluded alcoholic beverages from the scope of this final rule because FDA believes that these records are needed to help the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. Further, FDA reiterates that, to the extent that you already keep the information required by this final rule to comply with TTB requirements, or for any other reason, you do not need to establish and maintain duplicative records.

In addition, securing a ''legislative amendment'' to the Bioterrorism Act, as the comment suggests, is beyond the scope of this rulemaking.

(Comment 30) One comment suggests that FDA add an exclusion that covers persons who transport food for the U.S. military and U.S. Government agencies with respect to that food. Those entities are sophisticated and able to establish their own requirements. Transporters of food for those entities should not be subject to potentially duplicative FDA standards.

(Response) Congress did not provide for an exemption for food that is transported for the U.S. military or any other U.S. Government agency from the scope of the recordkeeping requirements. FDA believes that these records are needed to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or

animals. Again, with respect to the comment's assertion that transporters of food for those entities should not be subject to potentially duplicative FDA standards, FDA agrees. There is no requirement to keep duplicative records. FDA reiterates that to the extent that you already keep the information required by this final rule, you do not need to establish and maintain duplicative records.

(Comment 31) One comment questions whether there are provisions for the exemption of beekeepers who bottle and sell small amounts of honey and other beehive products, even if they keep their hives on the property of others, as is frequently done for pollination purposes or the production of honey from sites other than the beekeepers' own property.

(Response) Congress did not provide for an exemption for beekeepers who bottle and sell small amounts of honey and other beehive products. FDA believes that these records are needed to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. Unless these entities fall within a specified exemption, they are subject to the requirements of this final rule. For example, some of the beekeepers may fall within the exemption for farms or retail food establishments that employ 10 or fewer full-time equivalent employees. In addition, beekeepers are not required to keep records of sales directly to consumers.

(Comment 32) One comment requests clarification on how imported food samples that do not enter commerce will be handled based on the regulations. These food samples have the intended end use of analysis, experimentation, and/or subsequent destruction within approved company premises. The samples may be carried into the United States as personal baggage of company representatives or sent unaccompanied. The comment points out that food carried in personal baggage is exempt from the registration interim final rule only if the food is for personal enjoyment/use. Another foreign comment states that the recordkeeping requirement should not apply to commercial samples. The comment states that new exporters cannot be expected to engage in recordkeeping requirements concerning exports before testing marketing opportunities.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is intended for consumption by humans or animals are subject to these regulations. The recordkeeping requirements would not apply to food samples that are used for quality assurance, research or analysis purposes, as long as the food samples are not consumed by humans or animals. Samples of food are considered to be for quality assurance, research or analysis purposes, rather than human consumption, when they are in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis, destroyed after analysis, or destroyed following a reasonable retention period after analysis. The analysis may include sensory examination, such as organoleptic examination for determining tea quality or detecting the presence of histamines. Evidence that an article of food is for quality assurance, research, or analysis purposes only might include, among other evidence, markings on the food and shipping documents. Food samples intended for consumption via test marketing, such as tasting at trade shows or product promotional tasting events, are subject to this subpart.

The recordkeeping rule, however, exempts all foreign persons, except foreign persons who transport food in the United States. Therefore, the foreign exporter of the samples mentioned by the comment's is not required to establish and maintain records under this final rule. With respect to the comments assertion that the registration interim final rule exempts food carried in personal baggage for personal use, FDA notes that it is the prior notice interim final rule (part 1, subpart I) that exempts these products, not the registration interim final rule (part 1, subpart H). The registration interim final rule applies to all domestic and foreign facilities that manufacture, process, pack, or hold food that will be consumed in the United States, unless otherwise exempted. This includes facilities performing covered activities with respect to commercial samples if those samples will be consumed in the United States. See response to comment 67 at 68 FR 58911 through 58912 (October 10, 2003). As detailed in the response to comment 22, this final rule does not distinguish between food consumed in the United States and food that is exported.

(Comment 33) One comment indicates that the proposal is silent as to whether firms producing finished food products or food additives and ingredients intended solely for export must comply with the recordkeeping requirements. The comment argues that because this regulation applies to foods for consumption in the United States, producers of such products should be exempt from the recordkeeping requirements.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to these regulations. If the food is intended solely for export, the person producing that food in the United States would still be subject to these regulations with respect to that food.

2. Farms

(Comment 34) Several comments ask if foreign farms, including fish farms (aquaculture) fall under the regulation's farm exemption.

(Response) Section 306 of the Bioterrorism Act specifically exempts farms from these regulations. The definition of a farm includes aquaculture facilities. In addition, foreign persons (except for foreign persons who transport food in the United States), including foreign farms, are excluded from all of these regulations.

(Comment 35) One comment states that FDA has not clarified whether producers who ship live food animals to the United States will be required to keep records on their farm operations, as their products will be ''finished'' in another country, may have been raised on more than one farm, and may not be considered as going directly to the consumer for consumption. The comment strongly urges the FDA not to require farmers shipping live animals to the United States to incur the additional cost, time, and work involved in maintaining records, beyond those which are currently being maintained for their operations, solely for the purpose of this regulation.

(Response) Farms are excluded from these regulations, as are foreign persons, except for foreign persons who transport food in the United States. Therefore, foreign farmers who ship live food animals to the United States are exempt from this final rule (unless they transport the animals into the United States themselves). FDA notes, however, that although foreign exporters of food into the United States are exempt from these recordkeeping requirements, they must comply with the prior notice regulations issued under the Bioterrorism Act (part 1, subpart I). FDA also notes that an importer of live food animals into the United States would be required to establish and maintain records under these regulations given

that importers are not exempt from this final rule.

(Comment 36) One comment states that, although the proposed rule exempts farms, it may still result in a recordkeeping burden for them. The comment states that, in practice, the farmer will be expected to generate paperwork so that those delivering and dropping products off at the farm will be able to comply with the final rule. Although farms may be exempt on the face of the rule, the comment states that, in reality, farmers will have to generate large amounts of paperwork for their suppliers, truckers, and buyers. The comment states that the final rule needs to make clear that farmers will not be responsible, or expected to generate, paperwork for those complying with this rule.

(Response) Farms are specifically exempted from the requirements of these regulations. Only those persons subject to these regulations must establish and maintain records of the immediate previous sources and immediate subsequent recipients of food that they manufacture, process, pack, transport, distribute, receive, hold, or import. This final rule does not require a farm to establish or maintain records for those who are subject to this regulation.

3. Restaurants

(Comment 37) Several comments state that retail food stores offer a variety of services and conveniences to consumers, including foods that are prepared in-store and ready for immediate consumption, and that the restaurant-type facilities in the retail store should be excluded from the recordkeeping requirements.

One comment notes that the proposed rule includes an exemption for restaurants, which are defined as facilities that sell food directly to consumers for immediate consumption. The comment asserts that many convenience stores make such sales of prepared foods, but convenience stores are included in the proposed rule's definitions as an example of retail facilities. In the comment's view, convenience stores that sell food for immediate consumption should be exempt from the proposed rule. There is no reason why convenience stores that sell prepared foods should have greater regulatory burdens than any other type of entity that sells prepared foods. The comment further states that the restaurant exemption as currently proposed leads to results that are difficult to justify. The comment asks why, for example, should a convenience store that sells lunchmeat be required to comply with a costly system of recordkeeping, while a delicatessen that sells precisely the same product to the same consumer is exempt? The comment states that the only sensible answer to these unjustifiable inconsistencies is to exempt retailers that sell food to consumers for immediate consumption from the requirements of the regulation.

(Response) FDA agrees with these comments. Section 306 of the Bioterrorism Act exempts restaurants from recordkeeping requirements. There is no similar exemption in section 306 for retail facilities. In the proposed rule, FDA exercised the agency's discretion and proposed excluding retail facilities from the requirement to establish and maintain records of the immediate subsequent recipients of food when the food is sold directly to consumers (68 FR 25188 at 25192). As explained therein, the Bioterrorism Act expressly states that the Secretary may require the establishment and maintenance of records by persons who ''distribute'' food, and therefore retail facilities could be subject to all of the provisions in subpart J of this final rule if FDA thought it was necessary to address credible threats of serious adverse health consequences or death to humans or animals.

FDA recognizes that some facilities that are predominantly retail distribute some food to businesses (that then may further distribute the food before it is consumed) and that some facilities that are predominantly nonretail distribute some food to consumers. FDA concludes that to require such facilities to keep records of each individual recipient consumer would be too burdensome, and not necessary to help address credible threats of serious adverse health consequences or death to humans or animals. If a traceback or trace forward is necessary, FDA can learn from sickened consumers the sources of the food they purchased, or notify consumers generally about food that presents a threat. Therefore, FDA is changing the final rule from the proposal so that it does not require records of subsequent recipients for sales directly to consumers, regardless of whether the seller is a retailer or another type of entity. The final rule excludes persons who distribute food directly to consumers from keeping records of those transactions. Moreover, if a person prepares and sells food directly to consumers for immediate consumption, then those sales qualify for the restaurant exemption.

However, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

Furthermore, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363.

4. Fishing Vessels

FDA received no comments on this issue and has made no changes to the definition for fishing vessels or to the exemption in the final rule.

5. Retail Facilities

(Comment 38) One comment states that it operates a business that is essentially the same as any other retailer (although they sell to restaurants). Sales to its customers are recorded using a checkout register, and thus, it should not be required to keep records of individual items purchased by customers. Requiring such records from it, but not requiring retailers to keep such records, would be unfair and would be extremely burdensome.

(Response) The business described in the comment is not treated differently than other retailers. Persons who distribute food to businesses do not qualify for the exclusion for sales to consumers in § 1.327(d) of the final rule. Thus, sales of food to restaurants require the establishment and maintenance of records of the immediate subsequent recipient, as codified in § 1.345 of the final rule, to the extent that information is reasonably available to you. Information is reasonably available to you if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations. Thus, for example, information is reasonably available to you when the purchaser has an established commercial account to which the food purchases are charged in an identifiable manner. Accordingly, § 1.327(e) of the final rule provides that persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to

the extent the information is reasonably available. For purposes of this section, ''retail food establishment'' is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

In addition, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements of this subpart, except the records access provisions for existing records under §§ 1.361 and 1.363. Given the large number of establishments that would be excluded and the significant cost reduction, FDA has analyzed the impact on its ability to efficiently and effectively conduct a tracing investigation to address credible threats of serious adverse health consequences or death. FDA believes the information as to the source of the food of concern sold at these establishments may be obtainable from a larger retail food establishment that is covered by the regulations and sold the same food. Specifically, many of the foods sold at very small retail food establishments are nationally distributed and are also sold at covered retail establishments. If there is an outbreak and product could also be traced to a covered retailer, then FDA could use that retailer's records to identify the source of the food.

Moreover, given the relatively small size of the exempted establishments, the exempted establishments are likely to have fewer products and suppliers than other retail establishments and are therefore more likely to be able to provide FDA with source information even if they are exempted from records establishment requirements. With larger retailers, the records of immediate previous sources are more critical to isolating quickly potential sources of food that poses a threat of serious adverse health consequences or death to humans or animals. The exclusion is based on the number of employees at each retail food establishment and not the entire company, which may own numerous retail stores.

(Comment 39) One comment argues that distributors for direct selling companies should be exempt from the requirement to maintain records concerning immediate subsequent recipients. The proposed regulation would have a significant impact on the direct selling industry. Independent distributors sell product not only to consumers, but also to other independent distributors in their network to support each others' businesses and enable them to fulfill customer orders.

In addition, FDA should acknowledge the unique, closed distribution model of the direct selling business and exempt independent distributors in a direct selling organization from the requirement to maintain records concerning the immediate previous source. In the closed distribution model of direct selling, the direct selling company is the source of all products sold by its distributors. Distributors typically obtain the products they redistribute directly from the direct selling company with which they are associated. Under the proposed regulations, the direct selling company will maintain records that identify the carriers and the distributors who are the immediate subsequent recipients of the product. Any records maintained by the distributor regarding the immediate previous source for such shipments would be wholly duplicative of the records held by the direct selling company.

(Response) Whether these ''independent distributors'' are subject to the requirement to establish and maintain records to identify the immediate subsequent recipients depends on the nature of their customers. Section 1.327(d) of this final rule excludes persons who distribute food directly to consumers from the requirement in § 1.345 of this final rule to establish and maintain records of the nontransporter and transporter immediate subsequent recipients. As discussed in response to comment 37, FDA concluded that to require such records would be too burdensome and not necessary to help address credible threats of serious adverse health consequences or death to humans or animals. Thus, independent distributors are not required to maintain records of subsequent recipients who are consumers. Independent distributors, however, are required to keep records of subsequent recipients who are not consumers. However, an independent distributor who qualifies as a retail food establishment under § 1.327(e) of the final rule that also distributes food to persons who are not consumers is required to identify the nontransporter and transporter immediate subsequent recipients as to those transactions only to the extent the information is reasonably available. FDA needs such records to quickly and effectively traceback and trace forward in the event of a food-related emergency. However, an independent distributor who qualifies as a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements in this subpart, except the record access provisions for existing records under §§ 1.361 and 1.363.

(Comment 40) One comment asserts that there is no added public health protection from requiring retailers to establish and maintain records of the immediate previous holder of a food product. The proposed rule ensures that all information desired by FDA (e.g., the product and lot number going to a particular retail store) is already recorded by both the distributor of the product and by the transporter of the product. Therefore, traceability of a product will exist without requiring the retailer to also keep that information. The comment believes that the added burden of requiring retailers to establish and maintain records on immediate previous sources of the food it receives is not necessary based on the limited public health and safety benefit that would result.

(Response) As discussed in response to comment 37 of this document, the Bioterrorism Act did not exempt retail food establishments from recordkeeping requirements. FDA decided to exclude persons who distribute food directly to consumers from the requirement to establish and maintain records of subsequent recipients because sick consumers can provide information as to where they obtained food in a traceback, and FDA can notify consumers of a food threat in a trace forward. In the case of a traceback from a retailer, the retailer's records of the immediate previous sources are needed by FDA to address credible threats of serious adverse health consequences or death to humans or animals. In a traceback, it is unlikely that a retailer's source for certain foods would be apparent. Accordingly, in order for FDA to be able to identify the retailer's immediate previous nontransporter and transporter sources, to gain access to those sources records and identify its sources or other recipients of the food, the retailer has to have records identifying those sources. Therefore, the final rule requires retailers to establish

and maintain records containing this information. However, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in subpart J of the final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 41) One comment states that a ''retail facility'' is defined as a facility that sells food directly to consumers only. Thus, a warehouse store or ''cash and carry'' store that sells food both to consumers and to commercial accounts would not qualify for this exemption. As the name implies, a ''cash and carry'' store sells food products to anyone who wishes to buy bulk quantities in cash transactions (e.g., from an individual consumer planning a party or providing for a large family to intermittent supply to restaurants). Such stores typically do not retain detailed records of cash sales. For cash and carry stores that do engage in regular commercial transactions, or which provide credit to commercial customers, ordinary business practices should normally generate records that could be tailored to serve the requirements of the proposed rule. FDA should clarify that, if an entity conducts both exempt and nonexempt activities at the same location, it would be required to retain records only with respect to its nonexempt activities. Under such a clarification, a ''cash and carry'' store that sells food to individual consumers would not be required to maintain records regarding its retail sales to consumers. The comment requests that the agency adopt and confirm this interpretation.

(Response) FDA agrees. Section 1.327(d) of the final rule excludes persons who distribute food directly to consumers from the requirement to establish and maintain records of the immediate subsequent recipients of food. Therefore, a ''cash and carry'' store is not required to maintain records regarding its sales to consumers. However, under § 1.327(e) of the final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to only those transactions involving nonconsumers and only to the extent the information is reasonably available. For purposes of this section of this document, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in subpart J of this final rule, except record access provisions for existing records under §§ 1.361 and 1.363.

(Comment 42) One comment states that, in the case of control state retail operations, keeping detailed information on the immediate subsequent recipients would impose an administrative burden. Although retailers are generally exempt from keeping records pertaining to their customers, the exemption is lost when, as is the case with control states, retail stores sell to other retailers, in this case restaurants, taverns, and bars who subsequently resell the alcoholic beverages being purchased to end-use customers. The retail store transactions are essentially the same type of ''over the counter'' transactions that take place between the stores and individual consumers. Some information is usually and customarily maintained (e.g., the information pertaining to the licensed purchaser and what is being purchased), although in some cases such information is not generally secured and retained. The comment further notes that some of the information sought (e.g., lot and other product identifiers) is neither generally secured, nor is it maintained.

(Response) Section 1.327(d) of the final rule excludes persons who distribute food directly to consumers from the requirement to establish and maintain records of the immediate subsequent recipients of food. As discussed in response to comment 37 of this document, such sales are excluded because FDA can learn from sickened consumers about the sources of food they purchased or notify consumers generally about food that presents a threat. However, this rationale is not applicable when, as described in the comment, retail stores sell to other retail stores. Under § 1.327(e) of the final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to only those transactions and only to the extent the information is reasonably available. In addition, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements in subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

In regard to lot identification numbers, retailers are not required to maintain this information. The final rule only requires that persons who manufacture, process, or pack food record lot or code numbers or other identifiers of that food (and only to the extent this information exists) (§§ 1.337(a)(4) and 1.345(a)(4) of the final rule).

(Comment 43) One comment argues that the proposed retail exemption (§ 1.327(d)) must be a complete exemption, including an exemption from recordkeeping regarding suppliers, identical to the exemption given to restaurants. The comment states that today retailers and restaurants compete in the burgeoning take home and carryout market. FDA's proposal gives an unfair and unnecessary advantage to restaurants, which are expanding out of in-restaurant dining into areas formerly served by retailers and carryout establishments. A full exemption for retailers presents no lessening of food safety safeguards.

(Response) ''Restaurant'' is defined to mean ''a facility that prepares and sells food directly to consumers for immediate consumption.'' This means that an establishment that prepares and sells food that is capable of being eaten immediately, with no further preparation, is considered a restaurant. This definition and the corresponding exemption for restaurants in § 1.327(b) of the final rule includes activities such as a restaurant preparing and selling food to a consumer to be consumed at a later time, as long as the food is

capable of being immediately consumed without further preparation or processing. For example, a restaurant may prepare and sell pies from a counter that consumers purchase and take home for later consumption. This activity qualifies for the restaurant exemption as long as the food is prepared and sold directly to a consumer for immediate consumption.

In addition, a restaurant/retail facility is excluded from all of the requirements in subpart J of this final rule if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales. FDA notes that many facilities that otherwise would be excluded as restaurants under the final rule sell a small amount of food that they do not prepare for immediate consumption. For example, some restaurant/retail facilities have small packaged goods gift shop areas that sell food. The entire facility is excluded from all of the requirements in subpart J if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales. FDA exercised its discretion and excluded restaurant/retail facilities whose nonrestaurant food sales are less than 10 percent of their total food sales because many facilities that would otherwise qualify as restaurants make such sales as an incidental activity (Ref. 14). FDA believes that, were it not to provide such an exclusion, the exemption for restaurants would be undermined because many facilities that prepare and sell a high percentage of their food for immediate consumption also sell a small amount of packaged goods that they do not prepare themselves for sale to consumers (e.g., beverages, chips, candy, condiments, and sweeteners) and otherwise would be subject to the rule as to those sales.

Conversely, if a restaurant/retail facility's sales of food it does not prepare and sell for immediate consumption are 10 percent or more of its total food sales, FDA believes that such sales are a significant portion of the facility's activities. Such a facility's retail food sales are exempt only from the requirement to establish and maintain records of sales to consumers. The restaurant/retail facility's sales of food it prepares and sells for immediate consumption remain exempt from all of the requirements of subpart J of this final rule. As noted earlier, retail facilities are required to keep records of sales to nonconsumers only to the extent that information is reasonably available.

Section 306 of the Bioterrorism Act specifically exempts restaurants, but not retailers. FDA believes persons, including retailers, must establish and maintain records of immediate previous sources to ensure that FDA can quickly and effectively conduct a traceback in a food-related emergency. However, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 44) Several comments state that, although they make every effort to provide food to their customers in a timely and efficient manner, a small percentage of the food that is in a grocery store is sent to a reclamation center from which it is either returned to the manufacturer or sent to food banks. Reclamation centers are currently the largest single source of food donations for food banks. Food may be sent to reclamation centers if its packaging is damaged or if it is past the ''best if used by'' date. The system for sending food to reclamation centers is simple: The unsaleable products are collected in banana cartons and then shipped to the center where the food is sorted and either donated to charitable organizations, such as food banks, or returned to the manufacturers. No records are kept by the store of the foods shipped to the reclamation center.

The comment states that FDA's regulations should consider reclamation centers and food banks to be ''consumers'' for purposes of the recordkeeping regulations. Specifically, food retailers do not currently track the foods that are sent to reclamation centers, nor is there a mechanism available to do so. The requirement to develop and implement new recordkeeping systems would be a serious disincentive to corporate food donations and, again, would serve no purpose with respect to food security. If it is not necessary to track product to individual consumers to enhance food security, no purpose is served by monitoring those products that are sent through reclamation centers to consumers. Any products that are returned to the manufacturer are removed from the food distribution system so they will not reach consumers and their whereabouts need not be accounted for. Accordingly, FDA should broaden the exclusion for retailers to include food products that are routed to consumers through reclamation centers.

(Response) FDA agrees. FDA is exempting nonprofit food establishments that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States. ''Nonprofit food establishment'' has been defined to mean:

> * * *a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).* * *

Congress gave FDA the discretion to issue regulations regarding the establishment and maintenance of records under section 306 of the Bioterrorism Act. Charitable food establishments, such as food banks, stand in place of the consumer and FDA will treat them as consumers for purposes of this final rule. Therefore, grocery stores, catering facilities, and others giving a charitable donation of food to a food bank, soup kitchen, or other similar charitable entity are not required to keep records of the immediate subsequent recipients of the food, and the charitable food establishment does not need to keep records of the immediate previous sources of that food or the immediate subsequent recipients of that food. FDA has determined that it does not need records of food donated to food banks to address credible threats of serious adverse health consequences or death to humans or animals. In the event of a traceback investigation, FDA believes that it is likely to have the ability to trace the immediate previous source of contaminated food by other means. Unless the source of the contamination is at the food bank itself, other consumers of that same food obtained from a grocery store are likely to identify that grocery store as a link in the chain-of-distribution of the contaminated product. In the case of a trace forward investigation, records will likely exist from the donor of the food to the charitable food establishment. FDA believes that the likelihood of the existence of such records is great given the tax benefits available to the persons donating goods to establishments that are 501(c)(3) establishments under the Internal Revenue Code. Therefore, FDA does not believe that exempting such charitable entities from these requirements would interfere with the goals of the Bioterrorism Act or subpart J of this final rule.

With respect to the ''reclamation centers'' mentioned by the comment, FDA understands that most reclamation centers are actually owned by the

grocery store or grocery chain. Such reclamation centers will be treated as if they are part of the grocery store and must keep the records that must be kept by the grocery store. For instance, if food from the reclamation center is donated to a food bank, the exclusion described previously applies. If food is sold to consumers, the exclusion for foods sold directly to consumers applies. If food is returned to the manufacturer, or sold to another nonconsumer, the reclamation center must keep records of the immediate subsequent recipients of food, to the extent this information is reasonably available.

(Comment 45) Several comments state that, although retailers will not be required to keep track of foods sold to consumers, retailers will be required to keep records on those immediate subsequent recipients who are wholesalers or other retailers. The comments add that, unless the recordkeeping exclusion applies to all foods that are sold from the store, it is essentially meaningless. Food retailers do not know whether a person who comes into a store and buys food will be using the food for personal consumption or for a business purpose. To cover the possibility that a purchase was intended for business purposes would essentially require a retailer to record all consumer transactions. The comments state that this would not increase food security or consumer confidence. The comments also state that the trust of consumers is of tantamount importance and requiring documentation of all consumer transactions will diminish that trust without furthering the goal of food security.

(Response) Although retailers must keep records of immediate subsequent recipients of food who are not consumers, retailers are not required to do so unless that information is reasonably available, for example, when the purchaser has an existing commercial account. (See response to comment 38 of this document.) Retailers need not ask the status of each purchaser, and retailers will not be required to record every consumer transaction. Under § 1.327(e) of this final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only, and only to the extent the information is reasonably available.

FDA notes that there is an exclusion with respect to food that is manufactured, processed, packed, held, received, or transported for personal consumption. Such activities are excluded from the rule because if a traceback or trace forward investigation is necessary, FDA can learn from sickened consumers the sources of the food they purchased, or notify consumers generally about food that presents a threat. Whether food is for personal consumption depends on many factors, but FDA would consider food prepared in a private home and transported for other than business purposes to qualify for this exclusion. An example of food covered by this exclusion includes food prepared for ''pot luck'' suppers.

(Comment 46) One comment believes that direct marketing facilities should be explicitly exempted from maintaining records of immediate subsequent recipients. The comment believes that direct marketers that sell their food directly to consumers are functionally no different than brick-and-mortar retail establishments. Moreover, FDA's proposal already explicitly exempts other entities that sell food directly to consumers (farms, some roadside stands, and restaurants). Direct marketers thus should be exempt from another and different mandated recordkeeping protocol. Direct marketers already must meet the recordkeeping requirements of taxing authorities. Adding another enormous, needless recordkeeping requirement for consumers who purchase their food directly would do nothing to achieve the aims of the Bioterrorism Act at the expense of increased costs to marketers and, thus, their customers. The comment urges FDA to revise the exclusion for retail facilities by explicitly stating that direct marketing facilities are likewise exempt from the one-down requirements of § 1.345.

(Response) Neither the proposed nor final rule distinguishes between persons that sell to consumers as direct marketers, including those selling products over the Internet, and other persons selling to consumers from establishments. Therefore, if a direct marketer sells food directly to a consumer, he or she is exempt from establishing and maintaining records of the immediate subsequent recipients of that food. Under § 1.327(e) of this final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only, and only to the extent the information is reasonably available. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.) For a further discussion of ''direct sellers'' responsibilities under this rulemaking, see response to comment 50 in the following paragraphs.

(Comment 47) One comment states it is not clear in the proposed regulations whether retail bakeries and delicatessens are subject to these regulations. Although the registration requirements exempt them entirely, the recordkeeping rule only contains an exemption from establishing and maintaining records with the names of ''immediate subsequent recipients of foods sold directly to consumers.'' This implies that they still need to keep track of ingredient lots used in each production. In such operations, production usually consists of a wide variety of products made daily and in very small quantities. Keeping track of ingredients used in each and every product made daily is virtually impossible, and if required, would financially break every retail bakery or delicatessen, most of which are already struggling to compete in the dwindling market being taken over by supermarket chains. The comment requests that FDA look seriously at totally exempting any retail food operation with 10 or less employees from any of the requirements of the proposed regulations, particularly recordkeeping. If this is not possible, the comment proposes that FDA consider an alternative choice if they do not keep records of ingredients used in products, that if any contaminated ingredient is found, or brought to their attention, that they agree to destroy all manufactured products currently in stock (made from this ingredient or not). This alternative would have the same safety effect, but would be a lot less costly than keeping records.

(Response) A bakery or delicatessen is excluded from all of the requirements in subpart J of this final rule if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

Food is for immediate consumption when the food is capable of being eaten immediately with no further preparation. However, if the bakery or delicatessen does not qualify for the restaurant/retail facility exclusion in § 1.327(b) of this final rule, there is also an exclusion for retail food establishments that may apply. Under § 1.327(f) of this final rule, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except the record access requirements for existing records. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(Comment 48) One comment states it appears that rather than exempting convenience stores that sell food for immediate consumption, FDA has proposed a partial exemption such that records need be kept only for the nonexempt activities, but that is not clear in the proposed rule. FDA should either take a functional approach that allows facilities that sell food to consumers for immediate consumption to have a full exemption, or FDA should clarify that convenience stores and other facilities that make sales for immediate consumption need not maintain records for that part of their operation.

(Response) Convenience stores and other covered facilities that sell to consumers are an example of a mixed-type facility. Food that the convenience store prepares and sells directly to consumers for immediate consumption (i.e., hot dogs, hot pretzels), is exempt from subpart J of this final rule under the restaurant exemption. Under § 1.337 of this final rule, the facility is required to keep records of the nontransporter and transporter immediate previous sources for all other food. The facility is not required to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients for sales of food to consumers, but must establish and maintain records to identify immediate subsequent recipients of food who are not consumers, as required by § 1.345 of this final rule, when such information is reasonably available, as discussed in response to comment 38. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 49) Some comments state they are engaged in marketing products directly to the consumer through direct sales, mail order, Internet sales, and/or retail sales and urge FDA to clarify the scope of ''retail facilities'' to include independent distributors in direct sales forces, mail order companies, or Internet sales operations, because it is apparent that neither Congress nor FDA intended for the recordkeeping requirement to encompass records of individual sales to consumers.

(Response) As described in response to comment 37, persons are not required to establish and maintain records to identify the nontransporter and transporter subsequent recipients of food distributed directly to consumers (§ 1.327(d) of this final rule). Further, as described in response to comment 50, these regulations do not distinguish between direct marketers and others selling food from a retail establishment. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 50) One comment states that because direct sellers might also sell to other direct sellers either for consumption or for resale to other consumers, it is possible that the proposed recordkeeping requirements of the regulation might be construed to apply to them. The comment strongly suggests that were the requirements to apply to their businesses, many individuals would be discouraged from entering into direct sales. Individuals who are attracted to direct selling because of the ease of entry into the business would surely not welcome the additional paperwork and bureaucratic requirements necessitated by the proposal. Although perhaps appropriate for larger businesses, these requirements would provide a severe disincentive to their way of doing business. Additionally, given the sheer numbers of salespeople potentially involved, and the generally small size of the sales transactions consummated by direct sellers, the massive paperwork generated by direct sellers under the recordkeeping requirements could actually be counterproductive to efforts to enhance bioterrorism preparedness. The comment states that, given the unique, micro-entrepreneurial nature of operations of individual direct sellers and the questionable (at best) benefit to national security that might be achieved by applying this regulation to them, direct sellers should be exempt from the extensive recordkeeping requirements with respect to both immediate previous sources and immediate subsequent recipients. The comment also notes that other retailing operations are exempt (at least in part) from the proposed regulation, and believes that an exemption for direct sellers is consistent with the retailing exemption and the Bioterrorism Act.

(Response) ''Direct sellers'' are not required to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients for sales directly to consumers. Direct sellers that qualify as a retail food establishment under § 1.327(e) are required to establish and maintain records for sales to other direct sellers, when such information is reasonably available. FDA explains the rationale for distinguishing between sales to consumers and businesses in response to comment 40. Direct sellers, like other covered persons, are required to establish and maintain records to identify the nontransporter and transporter immediate previous sources of food, as required by § 1.337 of this final rule. However, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.) Thus, if a direct seller qualifies as a retail food establishment and employs 10 or fewer full-time equivalent employees, it is exempt from all recordkeeping requirements under this rule, except for the record access provisions for existing records.

(Comment 51) One comment states the Secretary has the full discretion to determine who shall be required to maintain records and what records shall be kept. Congress has clearly communicated its intention to protect small businesses by stating: ''The Secretary shall take into account the size of the business in promulgating regulations under this section.'' The comment states that individual direct sellers who distribute nutritional or related products should be exempt from the requirement to maintain records under the proposed rule.

(Response) As stated in the proposed rule, FDA carefully considered the size of a business when developing these regulations. FDA found that most products and ingredients pass through

at least one very small business when moving through the distribution process. If FDA were to exempt all very small businesses with 10 or fewer employees, not just those in the retail sector, this would create a ''Swiss Cheese'' approach to trace back, as there would be a potential failure of entities to keep records throughout the distribution chain. The number of very small entities account for a large fraction of the total number of food establishments. We used U.S. Census data to estimate the percentage of the total number of food establishments that are very small, as well as their revenues, by sector and report them in table A of this document. The fraction of the total number of facilities that are very small ranges from an estimated 73 percent of convenience outlets to 90 percent of transporters.

TABLE A.—ESTIMATED TOTAL NUMBER OF VERY SMALL FOOD ESTABLISHMENTS

Sector	% of establishments That Are Very Small	% of Food Industry Revenue From Very Small Establishments
Manufacturers	77	15
Wholesalers	81	14
Transporters	90	16
Grocery outlets	88	18
Convenience outlets	73	18
Importers	82	14
Mixed-type facilities	82	15

Moreover, many of our failures in a typical trace back investigation (i.e., unclassified scenarios) have been at the wholesaler (distributor) level. As noted in the table A of this document, 81 percent of the wholesalers are considered very small. We also would have significant concerns if 90 percent of the transporters (as very small entities) were excluded from the requirements to establish and maintain records.

In light of the previous information, FDA does not believe we would have an effective recordkeeping system if we were to exempt all very small entities from the rule. Unlike the very small retailers who are at the end of the distribution chain only, a full exemption by size would create holes throughout the distribution chain and would not provide FDA adequate assurances that, in the event of a threat of serious adverse health consequences or death, FDA would be able to conduct an efficient and effective tracing investigation.

However, ''individual direct sellers'' as described in the comment who qualify as retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

In addition, FDA has considered the size of a business in establishing compliance dates for this final rule. Further, the final rule exempts direct sellers who are otherwise subject to the recordkeeping requirements of this rule and who sell food products directly to consumers from keeping records of the immediate subsequent recipients of that food.

(Comment 52) Several comments state FDA should interpret the exemption from maintaining records for immediate subsequent recipients of food to expressly include retail farm supply and feed stores that sell finished product directly to consumers and final purchasers. For instance, the comments note that many small rural feed manufacturers also have a retail outlet in their facilities that sell bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and to final purchasers for their own animals. These products are not resold by the purchaser-customer. Maintaining records of these sales is not common practice today, would represent a costly burden to such enterprises, many of which are small businesses, and would not demonstrably enhance human or animal protection from bioterrorism-related threats.

(Response) The exclusion in § 1.327(d) of this final rule from establishing and maintaining records of immediate subsequent recipients for food distributed directly to consumers applies to sales of bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and final purchasers for their own animals, unless the feed is to be used in animals that will be sold as food. If the feed is to be fed to food-producing animals, then the purchasers are not considered consumers since they are purchasing the food for a business (i.e., for the food-producing operation). The feed will remain in the food distribution system, and FDA needs records to help address credible threats of serious adverse health consequences or death to humans or animals. Therefore, under § 1.327(e), persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

6. Retail Facility/Roadside Stands

(Comment 53) One comment is concerned that the retail exemption only applies to facilities, such as roadside stands that employ 10 or fewer

full-time employees, and that are located in the same general physical location as farms that sell unprocessed food grown or raised on those farms. The comments note that the exclusion does not apply to processed foods, even if they are sold directly to the consumers from the retail facility in the same general location as the farm, unless all the ingredients in that processed food were grown or raised on that farm. Consequently, persons handling processed foods, such as baked goods, jams, jellies, maple syrup, and ''processed'' items such as hams and sausages from animals grown and processed into meat products on the farm would fall under the provisions of the final rule. Also, any persons handling products that were ''imported'' from off the farm would be subject to the final rule. The processed food provision is a burden for those involved in roadside stands that operate outside of the normal seasonal harvest period or sell processed foods. They could not purchase goods from neighbors or bring in goods from other areas under the exemption or include ingredients from a nonfarm source. The comment asks that this limitation affecting farm markets be removed from the final rule.

(Response) FDA has changed the exclusion in proposed § 1.327(d)(2) and has now provided an exclusion for all retail food establishments that employ 10 or fewer full-time equivalent employees from all of the regulations in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363, regardless of whether the food being sold is processed or unprocessed. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

7. Persons Under the Exclusive Jurisdiction of USDA

(Comment 54) One comment states that proposed §§ 1.327 and 1.328 distinguish between those foods that will be subject to the requirements of the final rule, and those foods that will be exempt. In doing so, the proposed rule refers to other federal statutes (e.g., the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act), as a means to provide the regulated community with the relevant details as to whether and when their conduct will come within the scope of the regulations being proposed. Although statutory references such as these may suffice to inform farms, food manufacturers, restaurants, and other food-related facilities that deal with these statutes on a daily basis whether and when they will be subject to FDA's final rule, that is clearly not the case with motor carriers. Therefore, the comment states that FDA should explain what food is subject to the final rule in layman's language to avoid any confusion. The comment further recommends that FDA attach a list of the applicable or the exempted foods as an appendix to the final rule.

In addition, a foreign comment states that meat, poultry, and eggs are exempt under the proposed rule because the United States deems current risk management systems associated with these products to be sufficiently stringent. The comment states that, in Australia, these products are subject to strict regulatory and certification requirements as ''prescribed goods'' under Australian legislation (the Export Control Act 1982), which the USDA audits. A range of other Australian products, such as milk and fish, are also prescribed goods and are subject to the same certification process. The comment, therefore, argues that all prescribed goods should qualify for an exemption on these grounds.

(Response) The rule does not impose any requirements with regard to food to the extent it is within USDA's exclusive jurisdiction under FMIA, PPIA, or EPIA. Under the FMIA, USDA regulates cattle, sheep, swine, equines, goats, and ''meat food products.'' Under the PPIA, USDA regulates poultry and ''poultry products.'' Under the Egg Products Inspection Act, USDA regulates some eggs and ''egg products.''

Any person that manufactures, processes, packs, transports, distributes, receives, holds, or imports some foods subject to exclusive USDA jurisdiction is exempt from these regulations with respect to that food while it is under USDA's exclusive jurisdiction.

FDA has decided not to attach an appendix to the final rules highlighting which foods are within the scope of this final rule. If questions remain, FDA will determine whether it needs to issue additional guidance on this subject.

With respect to the comment regarding Australian meat, poultry, eggs, milk, and fish, FDA notes that all foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of the final rule under § 1.327(h). However, domestic persons who import these foreign products are required to comply with these recordkeeping regulations to the extent that they are FDA-regulated food products.

(Comment 55) One foreign comment requests that FDA identify the list of persons that are excluded from all or part of the regulation in accordance with § 1.327.

(Response) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this final rule under § 1.327(h). The term ''person'' includes an individual, partnership, corporation, and association (section 201 of the FD&C Act (21 U.S.C. 321(e))).

8. Foreign Facilities if Food Undergoes Further Manufacturing/Processing

There were no comments received on this issue. However, FDA has decided to exempt foreign persons, except foreign persons who transport food in the United States, from this rulemaking. This is discussed in detail under section III.C of this document entitled ''Comments on Who is Subject to This Subpart?'' (Proposed § 1.326).

9. Pet Food

(Comment 56) Two comments requested clarification on whether the exemption from the recordkeeping requirements for non-BSE regulated pet food manufacturers applies to foreign manufacturing facilities.

(Response) All foreign persons, except foreign persons who transport food in the United States, are excluded from all of these regulations under § 1.327(h) of this final rule. In addition, the final rule deletes the proposed exclusion for non-BSE regulated pet food. Accordingly, all persons who manufacture, process, pack, transport, distribute, receive, hold, or import animal feed in the United States, including pet food, are subject to the requirements of this final rule, unless otherwise exempted.

(Comment 57) FDA received three comments from four national animal feed trade associations. One disagrees with the proposal to exempt pet food entities that are not subject to the BSE rule. It comments that it was an error to attempt to combine provisions of the BSE rule with a Bioterrorism rule. Because the BSE rule was solely designed to prevent the introduction and amplification of BSE, the comment is concerned that the recordkeeping requirements of the BSE rule do not fully address the recordkeeping provisions of the Bioterrorism Act. In addition, it comments that the health and safety of pets should not be compromised and, therefore, all animal food should be treated equally under the final rule and pet food companies should be required to maintain the same level of records as other animal feed companies. The comment also notes that creating an exempt category of food products (i.e., certain pet foods) could result in a gap in the recordkeeping

system established by the Bioterrorism Act.

Two additional animal feed associations submitted a combined comment that for simplicity FDA should adopt the same recordkeeping requirements for all animal food, pet food, and food intended for food-producing animals. One comments that entities already complying with the BSE rule should comply but all other animal feed and pet foods should be exempt from the recordkeeping requirement because of the low risk of serious adverse health consequence. Two comments state that they agree with FDA's risk assessments that animal feed and pet food have a lower risk and therefore needs fewer requirements than human food.

One other comment supports the proposed provision stipulating that BSE-regulated pet food entities should comply with the recordkeeping regulations. A foreign comment questions the need for the inclusion of any animal feed or pet food in the rule. Several comments, foreign and domestic, request clarification on which foreign establishments are subject to the recordkeeping requirements under the proposed non-BSE rule exclusion.

(Response) In the final rule, FDA has deleted the non-BSE pet food exclusions, and the final rule now requires all animal feed and pet food entities to establish and maintain records for 1 year. Therefore, the definition of pet food in the proposed rule is no longer needed and has been deleted. FDA was persuaded by the comments from three national trade organizations that: (1) Using the scope of the BSE rule as the criterion for exempting certain pet foods is inappropriate and would result in insufficient recordkeeping coverage to protect the public from bioterrorism; (2) creating an exclusion for certain pet foods could create a gap in the recordkeeping system; and (3) for simplicity, FDA should adopt the same recordkeeping requirements for all animal food, including pet food. FDA believes that contaminated animal food can be a link to human foodborne illness. People could be at risk through direct contact with animal food or through unintentional cross-contamination of cooking surfaces or utensils. Animals may also become infected and serve as a reservoir for exposing other animals and humans to disease. In 2002, dog chew treats were contaminated with *Salmonella enteritidis* (*Salmonella*) and became a vehicle to transmit *Salmonella* into homes. As a consequence, many pet owners became ill, and one person died (Ref. 15). Although FDA continues to believe that the consequences of a potential terrorist attack or food-related emergency are greater for food for food-producing animals than for pet food, compelling arguments have been raised against the proposal to create exclusions for certain pet food entities. Therefore, FDA believes that applying the recordkeeping requirements uniformly to all animal foods is most consistent with the intent of the Bioterrorism Act.

The final rule requires records for all animal food, including pet food, to be retained for 1 year after the dates you receive and release the food. FDA believes that a 1-year period of records retention is appropriate because food for food producing animals tends to have a faster turnover rate than many kinds of human food. In addition, since pet foods are typically the sole source of food for pets, such foods tend not to be stored as long as many human foods.

(Comment 58) One comment states that the recordkeeping requirements for animal food foreign establishments should be limited to the final establishment handling the product prior to export to the United States.

(Response) Section 1.327(h) of this final rule excludes all foreign persons, except foreign person who transport food in the United States, from all requirements in this final rule.

(Comment 59) One comment asks FDA to officially recognize its country's BSE regulations as equivalent to the U.S. BSE regulations.

(Response) FDA declines to respond to this request because it is outside the scope of this rulemaking.

(Comment 60) One comment asks that suppliers and transporters of animal food not be required to retain any additional information other than what is contained in their current records.

(Response) FDA agrees in part with this comment. This rule only requires additional records to be established and maintained to the extent the information does not already exist.

10. Food Contact Materials

(Comment 61) Several comments state that, although they agree with FDA's decision not to apply the proposed regulations to outer packaging, the same logic that supports that exclusion applies equally to food contact materials. One comment states that applying the recordkeeping requirements to food contact substances would create an unreasonable and unjustified burden on the industry and its suppliers. One comment states that, under FDA's proposed approach, there is no limit to the suppliers of components and precursor substances who would be required to establish and maintain records. Removing food contact facilities from the ambit of the recordkeeping regulations is consistent with the clear intent of the Bioterrorism Act and FDA's mandate to ensure the safety of the U.S. food supply in the least burdensome means possible.

Several comments state it is unrealistic to believe that a terrorist attack on the food supply will be carried out through food contact substances. As a technical matter, it would be virtually impossible to insert a poison in contact materials with a sustained release mechanism to contaminate food, without the full cooperation of the materials manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. Food contact manufacturers and food processors have routine procedures in place to ensure that their contact materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage. Accordingly, there is no reason to believe that applying the recordkeeping requirements to food contact substances would further the purpose of the Bioterrorism Act or FDA's stated goal of the proposed regulations.

Another comment states that excluding outer food packaging from the requirements has little practical meaning because nearly all packaging companies handle both outer packaging and food contact substances. The comment further states that FDA's assumption that half of the manufacturers and distributors of packaging handle only outer packaging materials (68 FR 25188 at 25212) may be true for suppliers in other packaging segments, but is simply incorrect when it comes to the cartonboard segment of the industry. The comment states that packaging companies in that segment will find it more expedient to keep records on all materials—both outer packaging and contact substances—rather than to document only the food contact materials, because many of the same materials can be used for both purposes, and it would be prohibitively expensive to segregate these uses. The comment notes that this would result in a recordkeeping requirement for nearly all facilities that manufacture packaging and packaging components, and all of their suppliers, if FDA retains the proposed approach.

One comment states the inclusion of ''immediate food packaging'' and ''food contact substances'' in the definition of ''food'' creates a difficult and

unnecessary compliance effort throughout the supply chain. The comment suggests that FDA remove the requirement to establish and maintain records on ''immediate food packaging'' and ''food contact substances'' after such materials are either accompanying or affixed to the food, thus eliminating duplicative tracking and burdensome paperwork. If records are kept on the food, the comment states that those same records could be used to trace the packaging and labeling materials to the farm and point of initial contact with the food. From there, the material's original manufacturing/processing facility can be identified, where detailed records on the immediate subsequent transporter and recipient (likely the farm) will be maintained according to the regulations.

(Response) FDA agrees with these comments in part. FDA is finalizing the definition of ''food'' as proposed and is not excluding food contact substances from the definition. As discussed in the following paragraphs and provided in §§ 1.327(i) and (j) of this final rule, however, FDA is using our discretion to exclude specified persons and activities from recordkeeping requirements for packaging and food contact substances.

These comments raise the question of what Congress intended ''food'' to mean for purposes of recordkeeping and access. In construing the recordkeeping and access provisions of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (*Chevron* step one)? *Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have focused directly on the question presented and have articulated clearly its intention. *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 842–843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''food,'' FDA may define ''food'' in a reasonable fashion (*Chevron* step two). *Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

The agency has determined that, in enacting section 306 of the Bioterrorism Act, Congress did not speak directly and precisely to the meaning of ''food.'' The FD&C Act has a definition of ''food'' in section 201(f). It is a reasonable assumption that, when the term ''food'' is used in the Bioterrorism Act, section 201(f) applies. However, although there may be ''a natural presumption that identical words used in different parts of the same Act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid* * *.''*Atlantic Cleaners & Dyers, Inc.* v. *U.S.*, 286 U.S. 427, 433 (1932). Accord: *U.S.* v. *Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2000). Thus, the same word may be given different meanings, even in the same statute, if different interpretations are what Congress intended. *Atlantic Cleaners & Dryers, Inc.*, supra.

Even before the Bioterrorism Act amendments, the term ''food'' was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical ''(other than food)'' in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit noted that Congress meant to exclude only ''articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value'' and not all substances defined as food by section 201(f) of the FD&C Act. *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983). Similarly, section 409(h)(6) of the FD&C Act defines a food contact substance as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding *food* if such use is not intended to have any technical effect in *such food* (emphasis added).'' This definition makes sense only if ''food'' is interpreted to exclude materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[1]

Thus, it is in this larger statutory context, that FDA has evaluated section 306 of the Bioterrorism Act to determine whether the meaning of the word ''food'' is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether Congress's intent is ambiguous. *Pharmaceutical Research & Manufacturers of America* v. *Thompson*, 251 F. 3d 219, 224 (D.C. Cir. 2001). Section 306 of the Bioterrorism Act amends the FD&C Act by adding section 414 to the FD&C Act. In section 414, ''food'' is used in conjunction with other words to describe which FDA-regulated articles are subject to recordkeeping and access requirements. In describing the conditions for record access by FDA, section 414(a) of the FD&C Act requires a reasonable belief as to an ''article of food.'' In describing the purpose for which recordkeeping may be required, section 414(b) of the FD&C Act refers to ''food, including its packaging.'' Elsewhere in the recordkeeping provisions, section 414 of the FD&C Act refers to ''food,'' ''food safety,'' ''a food to the extent it is within the exclusive jurisdiction of [USDA],'' and ''recipes for food.''

The Bioterrorism Act is silent as to the meaning of ''food.'' Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other possibilities noted in the previous paragraph, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. *Martini* v. *Federal Nat'l Mortgage Association*, 178 F. 3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281 (1988). Indeed, the analysis should not be confined to the specific provision in isolation because the meaning or ambiguity of a term may be evident only when considered in a larger context. *FDA* v. *Brown & Williamson Tobacco Corp.*, supra at 132 (2000).

FDA has considered other sections of the Bioterrorism Act and has concluded that the meaning of ''food'' in the Bioterrorism Act is ambiguous. FDA previously considered the meaning of ''food'' in section 305 of the Bioterrorism Act, governing registration of food facilities, and concluded that it is ambiguous (68 FR 58894). Section 305 of the Bioterrorism Act amends the FD&C Act by adding section 415 to the FD&C Act (21 U.S.C. 350d). In section 415(a)(1) of the FD&C Act, the word ''food'' is modified by the phrase ''for consumption in the United States.'' It is not clear whether this modifying phrase limits the definition of ''food'' to food that is ingested, a narrower definition of ''food'' than that in section 201(f) of the FD&C Act. In addition, the definition of ''facility'' in section 415(b)(1) of the FD&C Act exempts ''farms; restaurants; other retail establishments.'' It is not clear whether the phrase ''other retail establishments'' includes retailers of food contact materials; the legislative history indicates that it does not,

[1] FDA's long-standing interpretation of the FD&C Act's definition of color additive, section 201(t), is an additional example of where ''food'' is used more narrowly than as defined in section 201(f) of the FD&C Act. A color additive is defined in section 201(t) as a substance that ''when applied to a food is capable of imparting color thereto * * *.'' The agency's food additive regulations distinguish between color additives and ''colorants,'' the latter being used to impart color to a food contact material (21 CFR 178.3297(a)). See also 21 CFR 70.3(f). Thus, ''food'' as it appears in the statutory definition of color additive, necessarily excludes food contact materials.

thereby giving rise to additional ambiguity about which definition of ''food'' applies to section 415.

FDA also considered the meaning of ''food'' in section 307 of the Bioterrorism Act, governing prior notice of imported food shipments, and concluded that it is ambiguous (68 FR 58974). Section 307 of the Bioterrorism Act amends the FD&C Act by adding section 801(m) to the FD&C Act. Section 801(m) of the FD&C Act refers to an ''article of food.'' However, the legislative history of section 307 of the Bioterrorism Act indicates that packaging materials are not subject to section 307, and can be read to imply that Congress was not relying on the definition of food in section 201(f) of the FD&C Act, thereby giving rise to ambiguity about which definition of ''food'' applies to section 307 of the Bioterrorism Act.

FDA also considered the meaning of ''food'' in section 303 of the Bioterrorism Act, governing administrative detention, and concluded that it is ambiguous. FDA determined that use of the definition of ''food'' in section 201(f) of the FD&C Act is consistent with the language of section 303 of the Bioterrorism Act. Section 303 repeatedly uses the term ''food'' without adjectives, except for a reference to ''perishable foods,'' which is not used to limit the reach of the section. FDA also determined that use of the definition of ''food'' in section 201(f) of the FD&C Act is consistent with the use of the term in judicial enforcement actions (e.g., seizures and injunctions) that may be instituted under administrative detention.

The ambiguity surrounding Congress's use of ''food'' in sections 303, 305, 306, and 307 of the Bioterrorism Act, coupled with the lack of a definition of the term in the Bioterrorism Act, support a conclusion that the meaning of ''food'' in the Bioterrorism Act is ambiguous. Having concluded that the meaning of ''food'' in the Bioterrorism Act and in section 306 of the Bioterrorism Act in particular is ambiguous, FDA has considered how to define the term to achieve a ''permissible construction'' of the records establishment and maintenance provisions. *Chevron, USA, Inc.* v. *NRDC*, Inc., supra at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information it evaluated at step one of the analysis. *Bell Atlantic Telephone Co.* v. *FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the records establishment and maintenance provisions, to use the definition of ''food'' in section 201(f) of the FD&C Act.

Use of the definition of ''food'' in section 201(f) of the FD&C Act is consistent with the language of section 306 of the Bioterrorism Act. Section 306 does not contain language qualifying the meaning of food. Furthermore, section 414(b) of the FD&C Act authorizes the Secretary to require certain records to identify the immediate previous sources and recipients of ''food, including its packaging.'' In addition, section 306(b) of the Bioterrorism Act amended section 704(a) of the FD&C Act, governing factory inspections, to provide that in the case of persons engaging in covered activities with regard to ''foods, the inspection shall extend to all records and other information described in section 414* * *.'' The inspection referenced in section 306(b) of the Bioterrorism Act is one of ''any factory, warehouse or establishment in which [food] is manufactured, processed, packed or held* * *.'' FDA's longstanding interpretation is that ''food'' in section 704 of the FD&C Act has the same meaning as in section 201(f) of the FD&C Act.

Use of the definition of ''food'' in section 201(f) of the FD&C Act is also consistent with other sections of the Bioterrorism Act. Section 414(a) of the FD&C Act refers to an article of food that is ''adulterated.'' ''Adulterated'' is defined in section 402 of the FD&C Act (21 U.S.C. 342), and ''food'' in that section has the meaning provided in section 201(f) of the FD&C Act. See, e.g., *Natick Paperboard Corp.* v. *Weinberger*, 525 F.2d 1103 (1st Cir. 1975). Furthermore, using the definition of ''food'' in section 201(f) of the FD&C Act for section 306 is consistent with the interpretation of ''food'' in section 303 of the Bioterrorism Act, providing for administrative detention. When the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA may need to administratively detain the food under section 303 of the Bioterrorism Act and access relevant records under section 306 of the Bioterrorism Act. FDA is therefore retaining its interpretation of ''food'' in section 306 of the Bioterrorism Act to mean ''food'' as defined in section 201(f) of the FD&C Act. Food subject to section 306 of the Bioterrorism Act thus includes, but is not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed (including pet food), food and feed ingredients and additives (including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients), infant formula, beverages (including alcoholic beverages and bottled water), live food animals (such as hogs and elk), bakery goods, snack foods, candy, and canned foods.

Although ''food'' for purposes of section 306 of the Bioterrorism Act means the same as in section 201(f) of the FD&C Act, FDA is using its discretion to exclude some food from the record establishment and maintenance provisions. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are excluded from all the requirements of subpart J of this final rule, except §§ 1.361 and 1.363. Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except the record access provisions for existing records under §§ 1.361 and 1.363. FDA determined that requiring such persons to establish and maintain records is not necessary in order to address credible threats of serious adverse health consequences or death to humans and animals.

(Comment 62) One comment states that food packaging other than immediate food-contact packaging defined as ''food'' in the FD&C Act should not be included within the scope of this final rule. This appears to be consistent with FDA's intent in that the term ''packaging'' is neither defined nor used in the proposed rules.

One comment states that the inner packaging that is in direct contact with the food provides a barrier to contamination from outer packaging components. Therefore, the comment agrees with FDA's conclusion that shipping containers and outer packaging not in direct contact with food poses only a small risk from contamination and should be omitted from recordkeeping requirements.

One comment believes strongly that ''packaging'' is not ''food'' for purposes of the Bioterrorism Act. Even if FDA disagrees, the agency is urged to exclude from the recordkeeping obligation all

materials that are separated from edible food by a ''functional barrier.'' In other words, at a minimum, any materials that are separated from edible food by a functional barrier should be regarded as a type of ''outer packaging'' for which recordkeeping is not required. The comment states that FDA has long recognized the use of a functional barrier in determining what types of materials can be used in a packaging product. If a functional barrier (such as aluminum foil) is present in a packaging laminate, there is no expectation of migration of any material through the functional barrier. Therefore, the comment strongly requests that any materials on the exterior side of a functional barrier be excluded from the recordkeeping regulation. Because there is no expectation of migration of any material through a functional barrier, the likelihood that such materials could be used to adulterate food is extremely remote.

One comment states the reference to packaging does not mandate recordkeeping by packaging suppliers or transporters. Indeed, the reference to ''packaging,'' in addition to ''food,'' indicates a distinction between the two terms in the view of the drafters. The law and Congressional intent would be satisfied by a food processor maintaining records identifying the source of the finished packaging for the food product. In the unlikely event that food packaging is the target of terrorists, records in the hands of food processors regarding their packaging suppliers will allow FDA to follow the history of the packaging and its components. The regulation as proposed by FDA extends far beyond what was intended by Congress. To follow Congressional intent, the comment states FDA needs to revise the proposed regulation to provide only that food processors have records identifying the suppliers of their packaging.

(Response) FDA agrees with the comments in part. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 of this final rule (records access for existing records) with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of subpart J of this final rule. In addition, persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363 of this final rule. For example, a manufacturer and transporter of candy bar wrappers are not required to establish and maintain records as to the wrappers because they do not place food (candy bars) directly in contact with its finished container (wrappers). A manufacturer of candy bars, who places the candy bars in the wrappers, is required to keep records as to the sources of the wrappers and the recipients of the candy bars as a whole (not the candy bar and wrapper separately). Once the candy bar is placed in the wrapper, all persons who manufacture, process, pack, transport, distribute, receive, hold, or import the wrapped candy bar are required to keep records of the wrapped candy bar, but not to keep separate records with respect to the wrapper. FDA notes that the ''food'' in contact with the finished container refers to articles used by people in the ordinary way that most people use food primarily for taste, aroma, or nutritive value and not all substances defined as food by section 201(f) of the FD&C Act. The requirements for packaging and food contact substances are reflected in the following table.

TABLE B.—PACKAGING AND FOOD CONTACT SUBSTANCES

SUBSTANCE	ACTIVITY	COVERAGE
Packaging (Defined as the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances (§ 1.328).	Manufacture, process, pack, transport, distribute, receive, hold, or import	Excluded from all provisions of the rule unless person also engages in covered activity with respect to food, in which case subject to §§ 1.361 and1.363 (record access) (See § 1.327(i))
Food contact substance, other than the finished container that directly contacts food	Manufacture, process, pack, transport, distribute, receive, hold, or import	Excluded from all provisions of the rule, except §§ 1.361 and 1.363 (record access) (See § 1.327(j))
Finished container that contacts food	Place food directly in contact with its finished container	No exclusions, subject to record establishment, maintenance, and access (See § 1.327(k))
Finished container that contacts food	All other activities with respect to finished container	Excluded from all provisions of the rule, except §§ 1.361 and 1.363 (record access) (See § 1.329(k))

E. Comments on What Definitions Apply to This Subpart? (Proposed § 1.328)

1. General Comments

(Comment 63) One comment states that FDA should clarify the meaning of ''responsible individual.'' The meaning of the term ''responsible individual'' is the same as other terms mentioned in other sections, such as ''emergency contact.'' Moreover, it is not clear what responsibilities are included in this term.

(Response) FDA agrees with the comment that there is little utility for the record of each commercial transaction involving the distribution of food to contain the name of a responsible individual given that individuals change jobs within and among companies very often, making it unlikely that the person in the record will have responsibility for the food at issue when FDA seeks to effect a traceback. Therefore, FDA deleted the requirement that a name of a ''responsible individual'' be included in each record. To the extent this information is available, FDA will use the registration contact information for

facilities subject to registration requirements under § 1.232. FDA believes that, for facilities not subject to the registration interim final rule, an independent requirement to provide this emergency contact information with the records being kept will not be useful. The stated purpose of having such a contact name is to obtain help in accessing the records. However, to find that information, FDA would have already obtained the records without this emergency contact information.

(Comment 64) One comment states that FDA should clarify the meaning of ''Adequate description.'' FDA must establish and publish the minimum parameters of the products description.

(Response) An adequate description of the food would include the brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce). This type of description saves time and resources during a tracing investigation because it allows FDA to narrow its focus to the appropriate product during the investigation.

(Comment 65) One comment requests that FDA clarify the meaning of ''Holding.''

(Response) FDA has defined ''holding'' in § 1.328 of this final rule to mean ''storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.''

(Comment 66) One comment states that FDA uses the word ''Importer'' but does not define it.

(Response) The word ''importer'' does not appear in the final regulation. FDA will not define it for purposes of this regulation.

2. The FD&C Act

There were no comments on this issue.

3. Domestic Person

There were no comments on this issue; however, FDA has deleted the word ''domestic'' and instead defines the word ''person'' consistent with its definition in section 201(e) of the FD&C Act. FDA believes that the term ''domestic person'' is no longer needed because it is exempting foreign persons, except for foreign persons who transport food in the United States, from the requirements of subpart J of this final rule.

4. Farm

(Comment 67) Several comments assert that FDA's proposed definition of farm is too narrow and would require recordkeeping by farms that minimally process their produce for further marketing. The comments claim that many fresh produce farms incorporate packing and holding activities, and that minor manufacturing/processing activities should be considered incidental to the packing and storage activities. Accordingly, to give effect to the legislative intent to exclude farms, the comments argue that the definition of ''farm'' should include typical fresh produce post-harvest farming operations such as packing/packaging, washing, grading, waxing, sizing, cooling, application of inventory control items (e.g., price lookup stickers (PLUs) or universal product codes (UPCs)), conventional storage, controlled-atmosphere storage, transportation from the fields, transportation to storage or processing facilities, and transportation from the farm. According to the comments, these activities should be included in the definition of ''farm'' whether they are conducted in the field or in a packinghouse.

Some comments believe that the proposed definition of ''farm'' should be modified to include certain of the activities defined as manufacturing/processing, regardless of whether the foods that are the focus of these activities are consumed on that farm or one with common ownership or are offered for sale elsewhere, at least insofar as these activities relate to raw agricultural commodities. The comments state that the specific manufacturing/processing activities that should be included within the definition of ''farm'' are at least the following activities: Cutting, at least when this activity is applied to harvest of a farm crop; trimming; washing; labeling, at least when this activity is applied to containers that are not intended for direct consumer purchase; and packaging, at least when this activity is applied to containers that are not intended for direct consumer purchase. The comments also suggest that FDA should consider allowing farms to engage in milling and grinding without voiding the statutory exemption to section 306 of the Bioterrorism Act granted to farms, insofar as these activities are common farm activities.

(Response) In response to these comments and to ensure that FDA is fulfilling Congress's intent to exempt ''farms,'' FDA has revised the definition of farm in the final rule to state that a ''farm'' means ''a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both'', and that ''[w]ashing, trimming of outer leaves, and cooling produce are considered part of harvesting.''

FDA considers several of the activities identified in the comments to be ''packing or holding,'' including sorting, grading, wrapping, and boxing harvested food for the sole purpose of transporting this food off the farm. FDA also considers placing stickers on produce grown or consumed on a farm to be part of ''packing.'' FDA notes that the definition of ''farm'' includes facilities that pack or hold food, provided all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. Thus, a farm that performs these packing and holding activities will not necessarily cease to be a farm and therefore cease to be exempt from these regulations. Similarly, FDA considers several of the activities identified in the comment (waxing, milling, and grinding) to be manufacturing/processing. A farm that performs these activities will not necessarily cease to be a farm because the definition of ''farm'' includes facilities that manufacture/process food, provided that all food used in these activities is consumed on that farm or another farm under the same ownership.

FDA is aware that a number of other activities may affect an establishment's status as a ''farm'' under this final rule. Thus, the agency is providing the following additional clarification. First, FDA considers application of a pesticide to a crop to be an integral part of growing and harvesting crops and therefore considers the activity to be covered by the ''farm'' definition. Therefore, an establishment devoted to the growing and harvesting of crops that applies a pesticide to its crops is a ''farm'' as defined in this final rule.

In addition, FDA recognizes that an activity such as placing a raw agricultural commodity directly into consumer-ready packages is likely to provide better protection to fragile produce, such as berries, than placing the produce into a larger bin or box for transport off the farm, with consumer packaging of the produce further down the distribution chain. ''Manufacturing/processing'' as defined in § 1.328 means ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.'' Thus, simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) is more akin to packing, even if the containers are ultimately received by the consumer. Under § 1.328 of this final rule, a farm may engage in this packing activity so long as all of the involved produce is grown or consumed on the farm or a farm

under the same ownership. Accordingly, a farm that simply places a raw agricultural commodity into containers, such as placing berries in clamshells, is not ''manufacturing/processing.''

Finally, a farm that transports its products from the field does not cease to be a ''farm'' because such transportation is considered incidental to traditional farming activities.

(Comment 68) One comment states that FDA's definition of ''farm'' should be size-neutral, and apply equally to integrated livestock and poultry facilities, as long as the activities engaged in at such locations are limited to ''growing or raising'' farm animals for human food, but do not extend to further processing of food-producing animals into meat, milk, or eggs (such as occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale for humans or animals.

(Response) The proposed rule's definition of ''farm'' had no size limitation, and neither does the final rule's definition. FDA agrees that integrated livestock and poultry facilities are ''farms,'' to the extent that these operations are devoted to raising animals for food, the growing of crops, or both, and otherwise engage in only those activities included in the farm definition. FDA considers milking cows and collecting eggs from chickens to be ''harvesting'' when applied to animals, because these activities are akin to harvesting crops.

5. Food

FDA received a number of comments regarding using the definition of ''food'' in section 201(f) of the FD&C Act, which includes food contact substances within its scope. These comments are addressed in section III.D.10, entitled ''Food Contact Materials.'' For the reasons stated therein, FDA has decided to retain the definition of food as proposed; however, the final rule exempts persons who manufacture, pack, transport, distribute, receive, hold, or import food contact substances, other than the finished container that directly contacts the food, from all requirements of subpart J of this final rule, except §§ 1.361 and 1.363. Further, persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363 (regarding access to existing records).

6. Foreign Facility

(Comment 69) One comment asks whether ''foreign facility'' includes warehouses in ports belonging to shipping companies, land transport or air lines, sealed container deposits, public organization facilities of the foreign government and of other federal agency representatives (such as FDA or USDA) in the country of origin and/or shipment. Another comment states that FDA's definition of foreign facility is too inclusive. The comments suggest that only foreign manufacturers and exporters should be required to keep records of their partners, such as packing facilities and holding facilities.

(Response) FDA has deleted the definition of foreign facility in the final rule. FDA notes that foreign persons, except foreign persons who transport food in the United States, are excluded from all of these regulations in subpart J of this final rule.

7. Manufacturing/Processing

There were no comments on this issue.

8. Nontransporter

(Comment 70) Two comments state that many nontransporters own trucks or other vehicles and transport food as an incidental part of their operations. For example, many food distributors deliver food by truck to their customers and also may transport food returns. These entities should not be classified as transporters for their distribution practices that are incidental to the nontransporters' holding, processing, packing, importing, or receiving of food. The comments ask that the final rule clarify that an entity is either a transporter or a nontransporter, and that FDA will not consider the same entity a transporter for some purposes and a nontransporter for other purposes. The final rule should confirm that a food distributor is a nontransporter. A food distributor should not automatically be considered a transporter simply because it delivers food using its own truck fleet. If FDA were to consider the same company a transporter for some purposes and a nontransporter for other purposes, this would create tremendous confusion regarding what records are required to be retained.

(Response) Both the proposed and final rule define a transporter as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food. A person who owns food, or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation is not a transporter, even if the person also transports food. In the example presented in the comment, a manufacturer that owned its own trucks to deliver food would not be considered a transporter. However, because FDA has exempted all foreign persons except those who transport food in the United States from this rule, foreign persons who transport food in the United States are subject to the requirements applicable to transporters regardless of whether that person has possession, custody, or control of the food for the sole purpose of transporting that food.

(Comment 71) One comment states that the proposed definition of ''nontransporter'' reads as follows: ''Nontransporter means a person who owns food or who holds, processes, packs * * *'' The same reference to a ''person'' is included in the definitions of ''nontransporter immediate previous source'' and ''nontransporter immediate subsequent recipient.'' The comment asks whether the proposed rules apply to firms and other legal entities and/or physical persons. Any other solution would, in the comment's view, neither be appropriate nor practicable.

(Response) The maintenance and inspection of records provisions in section 306 of the Bioterrorism Act apply to ''persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food.'' The term ''person'' has the same meaning as in section 201(e) of the FD&C Act and includes individuals, partnerships, corporations, and associations.

In addition, as explained further in response to comment 13, intra-company transfers of food are not subject to additional recordkeeping requirements. Once a covered person (including individuals, partnerships, corporations, and associations) receives food and keeps information on its immediate previous sources, that person or company does not need to keep additional records until it releases the food to another person or company. Unless otherwise exempt, at the time that person or company releases the food, it is required to identify the immediate subsequent recipients of that food.

9. Nontransporter Immediate Previous Source

There were no comments on this issue.

10. Nontransporter Immediate Subsequent Recipient

There were no comments on this issue.

11. Perishable Food

(Comment 72) Several comments propose that FDA use existing National Institute of Standards and Technology (NIST) Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life to define ''perishable food.'' One comment states that the definition of ''perishable food'' proposed by FDA is inconsistent with prevailing regulatory definitions of that term. The NIST Handbook defines ''perishable food'' as ''any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days of the date of packaging.'' ''Semi-Perishable food'' means ''any food for which a significant risk for spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date of packaging.'' ''Long Shelf-Life food'' is defined as ''any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than six months after the date of packaging, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.'' These definitions have a history of use and acceptance by industry and government, and were developed 30 years ago by the National Conference of Weights and Measures, working in conjunction with state agencies responsible for the regulation of foods. The comments note that the National Conference undertook this task to assist in the establishment of a uniform method for presenting open code date labeling for foods. The definitions have since been adopted by numerous states and local jurisdictions with open date code regulations.

Several comments also question why records should be maintained for an additional 22 months after a product has been consumed. The comments state that 6 months is sufficient time to maintain records necessary for any traceback investigation related to food safety or security risks in the produce industry. One comment estimates that few, if any foods, would qualify as perishable as defined by FDA. The comment has identified only a few foods sold at retail that are ''not heat-treated, not frozen and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions,'' namely bread, fish, and store prepared food.

One comment supports the following revised definition of the term ''perishable food.'' Perishable food means food that may have been thermally processed or otherwise preserved in a manner so as to prevent the quality of the foods from being adversely affected if held for 90 days or less under normal shipping and storage conditions. The comment agrees with FDA's decision to divide the food products subject to the record maintenance requirement into perishable and nonperishable groupings, but disagrees with the 7-day aspect of the proposed rule's definition of perishable. In addition, the comment does not believe that whether a food has been subjected to heat treatment or thermal processing should be a factor in differentiating between perishable and nonperishable food. The comment's members consider as ''perishable'' those juice products that have a shelflife of 90 days or less. If 90 days was substituted for 7 days in the definition of ''perishable,'' this would result in retention of records for perishable products for at least 4 times their shelflife.

One comment states that FDA should harmonize the Bioterrorism regulations with the other current regulatory provisions such as the Perishable Agricultural Commodities Act, where available. The definition for ''perishable food'' should include all fresh fruits and vegetables where the original kind or character has not been changed. The comment states that the effects of the following operations should not be considered as changing a commodity into a food of a different kind or character: Water, steam, or oil blanching; chopping; color adding; curing; cutting; dicing; drying for the removal of surface moisture; fumigating; gassing; heating for insect control; ripening and coloring; removal of seed, pits, stems, calyx, husk, pods, rind, skin, peel, etc.; polishing; precooling; refrigerating; shredding; slicing; trimming; washing with or without chemicals; waxing; adding sugar or other sweetening agents; adding ascorbic acid or other agents used to retard oxidation; mixing several kinds of sliced, chopped, or diced fruits or vegetables for packaging in any type of containers; or comparable methods of preparation. (For example, fresh iceberg lettuce, romaine and carrots would be included, as well as fresh-cut and packaged salads; fresh green beans would be included; frozen or canned green beans would not; fresh oranges would be included; frozen concentrated orange juice would not.)

One comment states that the proposed definition of ''perishable food'' excludes many products (including milk, which sometimes has a shelflife of up to 15 days) that are handled and treated as perishable in the food distribution system. The comment states that FDA should amend the definition so that perishable foods are those that are refrigerated or those that will be adversely affected if held longer than 20 days. The comment asserts that such a change would make the regulation more consistent with industry practice.

One comment states that the ''perishable food'' definition is confusing because the definition begins by stating that perishable foods are foods that are ''not heat-treated, not frozen and not otherwise preserved * * * '' Confusion arises because pasteurized milk is heat treated, and FDA's qualification of the three criteria is somewhat awkward and combined with an extensive use of negatives.

(Response) FDA agrees in part with the comments, but has decided not to define ''perishable food'' in this final rule. FDA defined perishable food in the proposal for the purpose of establishing a shorter record retention time for those foods as opposed to nonperishable foods. FDA has concluded that this objective can be achieved by inserting language directly in § 1.360(b) of this final rule using similar criteria as the NIST definitions for perishable, semi-perishable and long shelf-life food. FDA agrees that the proposed definition is too restrictive for purposes of these final regulations. Therefore, FDA has changed the record retention requirements in § 1.360(b) of this final rule to require record retention for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container. However, transporters, or nontransporters retaining records on behalf of transporters, are required to retain for 6 months records for any food having a significant risk of spoilage, loss of value,

or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving ''perishable'' food will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

(Comment 73) FDA requested comments on whether persons subject to the proposed rule always or usually know at the time a perishable food is released whether or not it is intended to be processed into nonperishable food. Two comments state that distributors have no way of knowing whether a perishable food will be processed into a nonperishable food by other parties. Buyers do not always disclose how the product will be used and may utilize it in more than one way. Therefore, producers of perishable food will have to retain records for the longer period, if they are held accountable for the further distribution and use of their products as nonperishable food.

(Response) FDA agrees with the comments that covered persons may not know at the time they release food if it is intended to be processed into a food that meets the 2-year record retention requirement. FDA clarifies that the retention period depends upon the status of the food at the time you release a food to your immediate subsequent recipient, regardless of whether it is intended or not to be processed into nonperishable food in the future.

12. Pet Food

There were no comments on the definition of pet food, however, FDA has decided to include all animal feeds, including pet food, under these regulations. Therefore, there is no longer a need to define the term ''pet food'' and FDA has deleted this definition from the final rule.

13. Recipe

(Comment 74) Three comments state that the proposed definition of recipe is internally inconsistent and ambiguous, and request clarification of its precise meaning. One comment characterizes the proposed definition as confusing and nearly nonsensical. The comment suggests that this definition be removed and that instead § 1.362 of this final rule be modified to add, for example, ''Notwithstanding the exclusion of recipes for food from this subpart, all of the ingredients in a food are subject to this subpart.''

Four comments state that the provisions in the proposed rule are inconsistent with the protection of recipes required by the Bioterrorism Act. The Bioterrorism Act and accompanying legislative history make it clear that the records authority does not apply to recipes. The comments urge FDA to further clarify that information on both the quantitative and qualitative ingredients in a proprietary formula are not covered by the proposed recordkeeping requirements or by the records access authority. According to the comments, in its ordinary meaning, a ''recipe'' includes three elements: The ingredients, the quantities, and the procedure. However, the fundamental element, and the one which in most cases is the most commercially sensitive, is the ingredient list. The comments state that it is not reasonable to define ''recipe'' to exclude the list of ingredients to obtain access to the list. The comments state that FDA is exceeding its statutory authority under the Bioterrorism Act.

Other comments are concerned about trade secret, sensitive, and/or proprietary information regarding recipe ingredients. One comment notes that food manufacturers are explicitly exempted from disclosing the specific contents of their flavor mixtures by section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)) and 21 CFR 101.4(b)(1) and 101.22(h)(1). The comment states that the purpose of this exemption is to protect a food manufacturer's trade secrets and excluding the identity of the individual ingredients of the food from the definition of ''recipe'' negates trade secret protection. The comment states that the complete lists of ingredients used in flavor formulas and seasoning blends are considered closely held trade secrets and should be considered part of the meaning of recipe. Flavors and spices are highly proprietary and, in many products, distinguish one manufacturer's product from another's. Disclosure on the label, or disclosure through the exercise of FDA's record access authority would be highly damaging to the food manufacturer whose ''secret formula'' entered the public domain. The comment states that it is unlikely that a product specific formulation would be relevant to an investigation. Therefore, the comment believes persons subject to the final rule should only have to establish and maintain records on nutrition facts.

Another comment similarly states that many products will be affected by the proposed definition, and ingredients and quantities must be protected. Many products are unique and were expensive to develop. Reverse engineering as well as trial and error can lead to duplication of products that can have very serious consequences for companies. FDA must find a solution to this challenge so as to not impede its investigations and at the same time protect the recipes of the involved companies.

(Response) FDA is changing the definition of ''recipe'' to clarify that a recipe consists of all three elements necessary to make a food: (1) A list of ingredients, (2) ingredient quantity information, and (3) instructions for combining the ingredients. Therefore, FDA is defining recipe to mean ''the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.''

To address credible threats of serious adverse health consequences or death to humans or animals and to conduct tracing investigations, it is critical that FDA have access to the ingredients and the sources of the ingredients of food.

Some comments express concern about the disclosure of ingredients to the public. FDA understands the comments' concerns about protecting the confidentiality of nonpublic information. Several statutes and the agency's information disclosure regulations at parts 20 and 21 (21 CFR parts 20 and 21) govern the agency's ability to disclose information to the public. For example, section 301 of the FD&C Act prohibits any person from using to his own advantage or revealing, other than to the Secretary or other officers or employees of the Department, or to the courts, any information acquired under authority of section 414 and 704 concerning any method or process which as a trade secret is entitled to protection. Furthermore, the records provisions in the Bioterrorism Act recognize that FDA may obtain trade secret or confidential information and direct the Secretary to ''take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of [such information]'' (21 U.S.C. 414(c)). FDA is planning to reemphasize

in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained. Therefore, FDA disagrees that a manufacturer would be harmed by disclosing ingredient information to FDA.

Moreover, the FD&C Act currently requires manufacturers to disclose the ingredients they use to the public on food labels. One comment notes that section 403(i)(2) of the FD&C Act excludes spices, flavorings, and some colors from the label requirement. The exemption in section 403(i)(2) of the FD&C Act from disclosing specific spices, flavorings, and colors to the public on the label does not prohibit FDA from obtaining this information under the Bioterrorism Act. As previously discussed, if this information is legally protected from public disclosure, FDA will not release it to the public.

(Comment 75) A comment states that FDA's procedures for the exercise of its records access authority should embody recognition of the special status of confidential ingredients, as follows: First, FDA should provide that it will not routinely seek access to records that would require the disclosure of confidential ingredient information; second, if FDA concludes that it needs access to information about ingredients, it should present a written explanation to the custodian of the records that sets forth the basis for the agency's conclusion; and third, FDA should seek records access in an orderly manner, beginning with ingredients other than flavors and spices. The comment states that it will not be possible for FDA to assess simultaneously each ingredient in a product as the potential source of the problem that is being investigated. Given that flavor and spice information is highly confidential and that the low levels of use of those ingredients make it unlikely that one of them will be the source of the problem investigated, it is reasonable to provide that requesting information on flavors and spices will occur only as a ''last resort.'' Finally, FDA should provide for special procedures to ensure that, when flavor and spice information is obtained, it is properly protected from disclosure, whether advertently or otherwise. The comment urges FDA to implement a system to adequately safeguard against the inadvertent release of proprietary and confidential information. Among other things, such information should be shared within FDA only to the limited extent necessary to conduct the particular investigation that resulted in the disclosure. The comment asserts that highly proprietary information about product formulas should not be widely distributed within the agency, and all persons who are made privy to the information should be reminded explicitly of the confidential nature of the information. Moreover, the comment states that FDA should amend its public information regulations to provide expressly that information obtained under the records access authority is exempt from disclosure under one or more of the exemptions under the Freedom of Information Act (FOIA) (5 U.S.C. 552).

(Response) FDA's procedure for accessing records is outside the scope of this final rule. FDA will consider these comments when it develops guidance for its investigations outlining how FDA intends to implement its access authority in section 414(a) of the FD&C Act. Such guidance will be subject to public comment under FDA's good guidance practice regulations (CGPs) § 10.115 (21 CFR 10.115).

14. Restaurant

(Comment 76) Many comments suggest that caterers supplying interstate conveyances are preparing meals for direct consumption by the consumer and should be excluded as restaurants. Some comments state that the manufacturer/processor of a sandwich should be treated the same, whether the sandwich is served in a restaurant, offered for sale in a vending machine, delivered as carryout, served on a hospital patient's tray, or served on a train or airplane. The comments note that, in the past, FDA has referred to ''level playing fields.'' In this case, exempting of conveyance caterers is the only way to regulate even-handedly. If restaurants and retailers are to be exempt, these comments believe that caterers should also be exempt.

The comments further state that just because FDA has historically inspected the facilities providing food to interstate conveyances under the Public Health Service Act does not mean that these facilities should be considered processors under this security regulation. The comments view the proposed distinction between a snack bar on the train selling sandwiches to consumers for immediate consumption (considered an exempted restaurant) and a facility that provides the sandwiches to an airplane or train for later consumption (considered a covered processing establishment) as an arbitrary and illogical distinction, because they view the risk associated with that sandwich as the same between the two facilities.

The comments view their industry as similar to a large restaurant or hotel kitchen, which produces a wide variety of meals within a matter of hours. The comments state that inflight catering is not regulated under the same rules as a food processing plant because the same rules would not fit the inflight catering industry. Food in a processing plant may be prepared weeks to a year before consumption. The comments state that the only difference between the catering and the restaurant service is that the catering meals are generally consumed 1 to 4 hours after departing from the kitchen rather than immediately consumed, as in the restaurant industry.

(Response) FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not provide food directly to the consumer for immediate consumption. In fact, the food is prepared and provided to several possible intermediaries before reaching the consumer, such as the packer, transporter, and/or distributor, before reaching the interstate conveyance (e.g., airplanes, passenger trains, and cruise ships) that actually provides the food directly to the consumer for immediate consumption. FDA believes the risk is substantially higher when the food is not prepared and served directly to consumers for immediate consumption, but rather goes through a number of intermediaries before it reaches the consumer. In a traceback investigation, it is critical for FDA to be able to identify each entity that handled the suspect food. FDA would lose this ability if interstate conveyance caterers were exempted. In addition, this requirement is consistent with the registration interim final rule, which requires interstate conveyance caterers to register as manufacturers/processors.

(Comment 77) Several comments urge FDA to reconsider the proposed regulations for airline caterers. The comments state that these proposed requirements are onerous, unnecessary, and are being unfairly applied to that industry and would bury the industry in volumes of information. The comments note that the same rationale FDA used for partially exempting retail facilities should apply to airline caterers as well.

The comments further state that the airline catering industry currently must be in compliance with many Government regulatory agencies (FDA, Federal Aviation Administration (FAA), USDA, Environmental Protection Agency, Transportation Security Administration (TSA)), and that they have strict specifications for products and vendors, whereas most food service

operations do not. The comments also note that they currently employ security companies to monitor their staff, the food processes in which they prepare meals, the equipment the food items are loaded into, and the process of how it gets on board the aircraft. They also state that their customers have always expected traceability of all products used on their flights as part of their food safety and hygiene audits to resolve flight passenger complaints, food poisoning reports, and for other purposes, but not to the extent that is required by the proposed rule.

One comment states that it is a member of the International Flight Catering Association and International Inflight Food Service Association and adheres to practices of the ''World Food Safety Guideline'' as set forth by the two associations of inflight food services. Another comment states that all employees have been certified by the FAA through fingerprinting and 10-year background checks, and inhouse security personnel are responsible for checking what is placed on aircraft. Another comment maintains control of all inputs and outputs of production and states that documentation is in place for all items received and for all items produced.

(Response) For the reasons stated in response to comment 76 of this document, FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not provide food directly to consumers for immediate consumption. However, these final regulations state that duplication of existing records is not required if those records contain all of the information required by subpart J of this final rule. Therefore, if a covered person keeps records of all of the information as required by subpart J in order to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. As the comment notes, the airline catering industry currently has the capability to trace all food products on their flights. These regulations do not dictate the format or system in which the required records are maintained. The airline catering industry can use existing tracing mechanisms to comply with these regulations to the extent those mechanisms contain the required information.

(Comment 78) Some comments state that these proposed regulations would require a substantial and costly change in the way meals are delivered and processed. The comments urge FDA to consider whether the air and rail industries can bear the additional expense of these proposed regulations, as numerous ingredients are included in each meal that is prepared and boarded. The comments state that compliance with the traceability regulations depicted in the rule would require so many revamped processes and additional personnel that their organizations would likely not recover from the fiscal implications. The comments further state that they would have to completely change the way they produce and package meals for their customers, going to unprecedented lengths to ensure strict batch preparation. As an example, the comments note that with their current processes, they can determine shipment origin and location of the entire meal; however, it would be impossible to trace each individual ingredient going into the package. For example, meat from one lot number of ham could be put into sandwiches along with other ingredients from different sources and fruit or chips, and then loaded onto numerous flights. This level of batch control would make the production of these sandwiches and meals cost prohibitive.

The comments further state that the impact on the airline industry from September 11, 2001, has been tremendous. The airline industry is facing unprecedented challenges, and the way business is conducted has been altered forever. The comments note that reductions and bankruptcy filings by the various airlines have been extreme and have resulted in immense reductions in the airline catering business. The airlines' decisions to significantly cut back, eliminate food service, and reduce the load capacity on airplanes and number of flights continue to impact the interstate conveyance catering business. The comments urge FDA to consider these conditions because it will be difficult for the airline catering business to absorb the costs of proposed regulations into its current pricing structure. The comments conclude that they would be forced to pass these costs onto the already struggling airline industry.

(Response) For the reasons stated in the previous paragraphs, FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not prepare and sell food directly to the consumer for immediate consumption. However, the comment's concern about having to ''go to unprecedented lengths to ensure strict batch preparation'' misconstrues the proposed requirement. In the final rule, FDA deleted the requirement in § 1.337(a) for a nontransporter to provide information reasonably available to identify the specific source of each ingredient used to make every lot of finished product, and instead put that requirement in § 1.345(b) of this final rule because it is unlikely that a person would have that information reasonably available at the time records are created to identify the immediate previous sources of the food.

FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA's intent to mandate reengineering of long-standing existing processes. Accordingly, the final rule requires linking incoming with outgoing product only when this information is reasonably available.

Although the definition of restaurant has not changed from the proposed definition, FDA exercised its discretion and added language to the restaurant exclusion in § 1.327(b) of this final rule to account for incidental sales of food that a restaurant/retail facility does not prepare itself (e.g., food it purchases from a manufacturer for sale to consumers). See the discussion earlier in section III.E.14 of this document.

15. Retail Facility

As explained in response to comment 40 of this document, for purposes of § 1.327(e) of this final rule, ''retail food establishment'' is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from the requirements in subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of the document for a further discussion of FDA's rationale underlying this exclusion.)

16. Transporter

There were no comments on this definition. However, FDA is changing the definition to make clear that foreign persons that transport food in the United States are subject to these requirements regardless of whether they have possession, custody, or control of that food for the sole purpose of transporting that food.

17. Transporter's Immediate Previous Source

There were no comments on this definition.

18. Transporter's Immediate Subsequent Recipient

There were no comments on this definition.

19. You

There were no comments on this definition.

F. Comments on Do Other Statutory Provisions and Regulations Apply? (Proposed § 1.329)

There were no comments on this issue.

G. Comments on Can Existing Records Satisfy the Requirements of This Subpart? (Proposed § 1.330)

(Comment 79) Several comments state that the final rule requires additional or more detailed data than what is already maintained and recommend that the FDA and CBP work together with industry to avoid any unnecessary burdens. A few comments requested that we also work closely with TSA and FAA as those agencies consider modifications of their own rules. The comments urge close coordination between the FDA and those other agencies to avoid inconsistent or redundant regulations.

Several comments state that the proposed regulations do not strike a proper balance in that some of the data elements requested are unnecessary (redundant) and too burdensome on an industry already highly regulated by several agencies requiring the same or similar information. For example, the air cargo industry currently establishes and maintains industry air waybills, bills of lading and commercial invoices, which are required by CBP to be maintained for a period of 5 years. Moreover, CBP will be proposing a new set of mandatory advanced notice information, including other data elements, that could satisfy FDA in its effort to establish a complete tracing of activities.

(Response) FDA based the requirements of the final rule on what records are needed by the Secretary for inspection to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. Section 1.330 of subpart J of this final rule states that duplication of existing records is not required if those records contain all of the information required by subpart J. If a person keeps records of all of the information as required by subpart J to comply with other Federal, State, or local regulations (including those of TSA or FAA), or for any other reason, then those records may be used to meet these requirements. In addition, where a person currently has existing records that contain some, but not all, of the required information, only records for the nonexisting information needs to be created.

(Comment 80) One comment notes that CBP's current requirements would apply to a trucking company transporting imported food into the United States and manifest data would be maintained. The comment states that FDA could easily coordinate with CBP to get the data from them in the event a threat to the nation's food supply is discovered, rather than develop its own distinct recordkeeping regulations.

(Response) The Bioterrorism Act authorizes the Secretary (and, by delegation, FDA) to require the establishment and maintenance of records to address credible threats of serious adverse health consequences or death to humans or animals. As discussed in response to comment 79, subpart J of this final rule does not require duplication of existing records if those records contain all of the information required by subpart J. Therefore, to the extent information you keep for purposes of complying with CBP satisfies the provisions of subpart J, you do not need to keep duplicate records.

(Comment 81) One comment states that past situations have demonstrated that FDA already has a policy and good track record for finding and refusing adulterated products and products that could pose a problem to the American public. The comment questions how the final rule is going to improve upon existing recordkeeping.

(Response) As explained in the proposed rule (68 FR 25188), FDA has been involved in traceback investigations where not all necessary records were established and maintained to enable FDA to conduct a complete tracing investigation. By issuing these regulations, FDA believes that the likelihood of such a situation recurring will be reduced. As discussed in response to comment 93 of this document, for those covered persons already establishing and maintaining records that contain all of the required information in subpart J of this final rule, duplication of those existing records is not necessary. (See response to comment 2 of this document for further discussion on FDA's past experiences with traceback failures.)

(Comment 82) Several comments recommend that, for accuracy and regulatory consistency, the final rule should recognize that compliance with the bill of lading regulations of DOT's FMCSA will constitute compliance with the transporter's obligations under proposed § 1.352. The comments note that bills of lading and freight/expense bills for motor carriers are legal documents and contain sufficient information for the agency to be able to fulfill its Bioterrorism Act responsibilities. The information to be included on the bill of lading and freight/expense bills is prescribed by the United States Department of Treasury at 49 CFR 373.101 and 373.103.

(Response) FDA agrees in part with the comments. The final rule has been revised from the proposal. The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. First, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(a) of this final rule. Second, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(b) of this final rule, which are included within the current requirements for roadway interstate transporters under FMCSA regulations as of the date of publication of this final rule (49 CFR 373.101 and 373.103). Third, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(c) of this final rule, which are included within the current requirements for rail and water interstate transporters under STB regulations as of the date of publication of this final rule (49 CFR 1035.1 and 1035.2). Fourth, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(d) of this final rule, which are included with the current requirements for international air transporters under the Warsaw Convention. Fifth, transporters can meet the requirements of this final rule by entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. Such agreements must

contain the elements specified in § 1.352(e) of this final rule. Failure by the immediate previous source or immediate subsequent recipient who enters into an agreement under § 1.352(c) of this final rule to keep such records is a prohibited act under § 1.363 of this final rule.

FDA notes that the FMCSA and STB regulations only apply to interstate transporters, and this final rule applies to both interstate and intrastate transporters. Intrastate transporters will be subject to the requirements of this final rule because FDA has determined that imposing such requirements on intrastate transporters comports with the Constitution, and these requirements are necessary to allow FDA to identify the immediate previous sources and immediate subsequent recipients of food in order to address credible threats of serious adverse health consequences or death. Intrastate transporters can meet this obligation by complying with either § 1.352(a), (b), (c), (d), or (e) of this final rule.

As a practical matter, because the final rule's requirements for interstate shipments can be satisfied by existing records relating to interstate shipments, the final rule only establishes new requirements for (1) *intrastate transporters*; and (2) *intrastate shipments* conveyed by *interstate transporters*. FDA estimates that there are approximately 115,000 intrastate carriers, and based on DOT data, almost one million commercial drivers report intrastate travel. In reviewing the truck tonnage by commodity, approximately 12 percent of the intrastate shipments are of FDA-regulated food products. The average distance these products are shipped is 231 miles, which means many shipments are intrastate, especially in the larger western states.

For some foods, distribution may be limited primarily to intrastate transportation, depending on the time of year and state. Many businesses have their own delivery trucks that are used intrastate, several use employee vehicles for deliveries, and many rent vehicles to deliver product. These vehicles are used to deliver all types of food products—refrigerated, cooked, as well as fresh food and produce, and grocery items. Some local firms pick up their own merchandise from ''warehouse'' facilities to stock their own locations. Many of these ''warehouses'' (commonly referred to as ''bin warehouses'') may receive product via interstate transporter and subsequently deliver to a variety of intrastate retail customers via many different intrastate means.

Data on the volume of foods that move in intrastate commerce are maintained by individual state Departments of Agriculture and by DOT. For example, from CA, LA, TX alone, DOT reports over 12 percent of intrastate truck tonnage is FDA-regulated products. Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003, there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

Most seafood consumed in FL is transported only intrastate, but in OK, most seafood is transported interstate. In 2002, there was an outbreak in NJ and FL linked to seafood. Intrastate records assisted us in pinpointing the portion of the Indian River, FL that was causing the problem. In reviewing egg tracebacks from 1996 to 2003, 35 percent of the tracebacks that resulted in farm investigations were intrastate. This past summer, the state of Oregon (OR) was able to stop a sprout-associated outbreak from becoming a serious one by tracing back to a WA sprouter just over the border from OR after some initial cases but before the *Salmonella* serotype had been identified. The sprouts were recalled. If the sprouter had been located in OR so that the sprouts were not transported interstate, it would have been problematic to a traceback investigation for FDA to be limited to records only from interstate transporters.

The NC green onion traceback investigation in 2003, which was part of the largest Hepatitis A outbreak that has ever occurred in the United States, is another example of the importance of intrastate records. There, the amount of time spent on the traceback within that State was twice as long as the other three tracebacks done in other states because the distributor in NC did not have records. Traceback from the TN outbreak took over a month, the GA traceback took a month, and Pennsylvania (PA) traceback took a week. Because we had no intrastate records in the NC outbreak, the traceback was determined to be inconclusive after two months, which meant that we would not have been able to identify the farms involved if it had not been for the other outbreaks.

This year, there was an *Escherichia coli* (*E. coli*) O157:H7 outbreak associated with bagged lettuce product in CA that was only in intrastate commerce. That traceback might have been lost had records not have been available. Exempting intrastate transporters could significantly impede FDA's ability rapidly and effectively to respond to a public health emergency involving a food transported within a state, particularly if the adulteration occurred during transport and the food was delivered to multiple sources within the State. In scenarios where time is of the essence to prevent serious injuries or death on a large scale, having records available becomes even more critical. In addition, not only must FDA be able to rapidly obtain records, it is imperative that FDA be assured that those records contain certain essential information to allow FDA to prevent further harm in an efficient and effective manner.

Additional examples of circumstances involving food products that have significant intrastate manufacturing/processing or distribution are provided in the following paragraphs:

- An intrastate sandwich/snack food company that sells to retail outlets for consumption had an outbreak of *Listeriosis* or *Salmonellosis* that was traced back to the sandwiches. The product was completely distributed using the company trucks within the state. FDA was unable to determine which sandwiches caused the outbreak. The sandwiches were delivered to retail customers, and it was impossible to track which sandwiches went to which retailer. The transporter did not track which product was delivered to which location. In this case, the firm had to recall all of its products.
- Retail stores regularly purchase food, especially locally grown produce, from ''truck farmers.'' These farm trucks travel from store to store within a state, sometimes selling an entire truckload to a store, other times a portion. There is no manifest or record other than a bill of sale—e.g., 200 cantaloupes from Farmer Brown. If the contamination occurred on the truck, FDA would not have a record from the truck of all other delivery sites.
- Several days into the investigation of a Hepatitis A outbreak from chicken salad in one city, FDA learned that the chicken was ''cubed'' at another facility in another city within the state, and transported to the ''manufacturing facility.'' The source of the outbreak was the site where the chicken was ''cubed'' by an ill employee; however, there were no records to indicate when the cubed product was shipped or received by the salad manufacturing facility.

(Comment 83) One comment suggests that the final regulation should clarify that ''transportation record'' includes the various documents that may be developed by a company that contain the information specified in the regulation. They do not believe that it would be necessary to include all of this information in one shipping document. The comment notes that industry currently collects much of the data that would be requested by FDA but these data are not found in one document, and in some instances, may be found at various locations within the manufacturing facility. Significant time and expense could be involved in making the modifications to the company's computer and recordkeeping systems to have a system that develops a transportation record that contains all of this information on one form. Such a requirement would be unreasonably onerous, particularly if the company's system is designed to make certain that the company can provide all of this information to the agency within the specified time. The respondent asks the agency to clarify in the final rule that it is not necessary to develop one transportation record that contains all of the information in a single form.

(Response) FDA confirms that it is not necessary to develop one record that contains all of the information. FDA's intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. The final regulation has been clarified to explicitly provide in § 1.360 that you must create the required records when you receive and release food, except to the extent that the information is contained in existing records. FDA is requiring that specific information be kept by a covered person, but is not specifying the form or type of system in which those records must be maintained. The required information may be contained entirely in one record or spread among many different records. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records are available to FDA under the record availability requirements in § 1.361 of this final rule.

(Comment 84) A few comments note that the recordkeeping requirements under existing FDA regulations, such as Substances Prohibited From Use in Animal Food or Feed (21 CFR part 589), Current Good Manufacturing Practice for Medicated Feeds (21 CFR part 225), and Fish and Fishery Products (seafood Hazard Analysis Critical Control Point (HACCP)) (21 CFR part 123) should be sufficient and deemed adequate to meet the requirements under the Bioterrorism Act and that FDA should not introduce additional, stand alone, recordkeeping systems.

(Response) As discussed in response to comment 79, § 1.330 of the final regulation states that duplication of existing records is not required if those records contain all of the information required by subpart J of this final rule. That includes records kept under the regulations identified in the comment.

(Comment 85) One comment states that it would be beneficial if FDA announced the suitability of records kept under existing requirements well ahead of the implementation deadline under the Bioterrorism Act.

(Response) FDA is not able to determine what records currently exist throughout the entire food industry that satisfy these regulations due to the diversity and complexity of the food industry and the various existing Federal, State, and local regulations that require recordkeeping, as well as varying business practices. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records are available to FDA under the record availability requirements in § 1.361 of this final rule. FDA points out that the earliest compliance date of this final rule is December 9, 2005, and that many persons are not required to comply with this final rule for up to 2 years after publication. Therefore, FDA believes that it has provided sufficient time for persons to determine what, if any, additional information must be kept to comply with these provisions well ahead of the compliance date of this final rule.

(Comment 86) A few comments note that most food companies currently maintain the chain of distribution information that FDA proposed, but the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. The comments state that it should be of no concern to FDA and, therefore, not the subject of the regulations to prescribe any specific manner or form of maintaining the information.

(Response) As discussed in response to comments 1 and 83 of this document and in the proposed rule, FDA's intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. FDA is requiring specific information be kept by a covered person, but not specifying the form or type of system in which those records must be maintained. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records be made available to FDA under the record availability requirements in § 1.361 of this final rule. To satisfy the requirements in this final rule, paper or electronic records or a combination of the two may be used.

H. Comments on What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Sources and Immediate Subsequent Recipients? (Proposed §§ 1.337 and 1.345)

1. General Comments

(Comment 87) Several comments state that the information required by the recordkeeping regulations exceeds the information required by the Bioterrorism Act, thereby exceeding FDA's statutory authority. Some of these comments state that according to the Bioterrorism Act, the regulations need to provide that those persons subject to the recordkeeping requirement maintain the ''one-up and one-back'' information in a records maintenance system in which the information is reasonably accessible to FDA upon request. The comments ask that FDA consider the diversity and complexity of the food industry and allow for more flexibility. They contend that the name and address of the person from whom an article of food was received or to whom it was shipped and a description of the article of food should be sufficient. The comments further suggest that not all companies require or need the same type of identification as other members in the food chain, e.g., lot numbers and identity preserved ingredients. They request that, because of this diversity in the supply chain, the agency not define rigid identification requirements. The comments contend that this flexibility is in keeping with the intent of the Bioterrorism Act and will avoid dramatic changes to what are currently efficient and effective business practices.

(Response) FDA disagrees that the information required by the rule exceeds FDA's authority under the Bioterrorism Act. The Bioterrorism Act authorizes FDA to require records needed to ''allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death in humans or animals.'' FDA believes the information it is requiring to be

established and maintained meets this standard.

Information such as the specific name of the food will allow FDA to limit its investigation to the implicated food. For example, if FDA has a reasonable belief that a shipment of cheddar cheese is contaminated, traceback or trace forward would be better facilitated if the records contained the identifier ''cheddar.'' This would help FDA narrow its investigation and increase the speed of the trace. The information would also help the involved firm limit the scope of any recall, should it be necessary. However, FDA does recognize the diversity of the food chain and has allowed for flexibility in the final rule. For example, the requirement to record lot/code number or other identifier applies only to persons who manufacture, process, or pack food and only to the extent that information exists. Also, the final rule allows covered persons to use existing abbreviations or codes currently used to identify the food. However, if these abbreviations and/or codes are used, they must be readily deciphered for FDA upon request so that an ''adequate description'' of the food is recorded.

(Comment 88) One comment questions the need for the extensive recordkeeping requirements in the regulations and suggests that much of the facility information required in the recordkeeping rule is already required in the registration interim final rule. The comment gives as an example the duplicate requirements that the nontransporter must maintain a record of the responsible individual, fax number, and e-mail address for: (1) The facility that shipped product to your facility, (2) the transportation company that delivered the product, (3) the transportation company that picked up product from your facility, and (4) the facility where your product is being shipped.

(Response) FDA does not agree that much of the information required under this recordkeeping rule is already required under the registration interim final rule. Information required under the registration interim final rule pertains to the facility itself, including information about the general food product categories that the facility manufactures/processes, packs, or holds. Information that this final rule mandates be established and maintained in records is information pertaining to food that will assist FDA in identifying the immediate previous sources and the immediate subsequent recipients of all food that is received and released by a person. In addition, to complete the tracing investigation, the identity of the transporters who transported the food to and from the sources and recipients is required, which is not covered by the facility registration. Moreover, the scope of section 305 of the Bioterrorism Act (registration) is not as broad as section 306 of the Bioterrorism Act (establishment and maintenance of records). Specifically, registration applies only to facilities that manufacture, process, pack, or hold food for consumption for humans or animals in the United States. Recordkeeping applies to these facilities, as well as those who transport, distribute, receive, or import food. Recordkeeping also applies to all food regardless of whether it will be consumed in the United States or exported.

However, FDA has deleted the requirement that persons subject to subpart J of this final rule identify a responsible individual in the records. Instead, for those facilities required to register under part 1, subpart H, FDA will use the emergency contact telephone number provided by those facilities. For other facilities, FDA does not believe requiring such facilities to provide an emergency contact telephone number is needed to assist the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, since that telephone number would be contained in the very records FDA would be seeking assistance in locating.

(Comment 89) One comment states that it is unreasonable to require nontransporters to have a record of the intermediate transporters, i.e., transporters who do not have direct contact with the nontransporters.

(Response) Neither the proposed rule nor the final rule requires nontransporters to establish and maintain records identifying intermediate transporters. With respect to transportation records, § 1.337(a)(6) of this final rule only requires nontransporters to establish and maintain records of the transporter that brought the food to them. Similarly, § 1.345(a)(6) of this final rule only requires nontransporters to establish and maintain records of the transporter that took the food from them. The transporters are required to keep records that identify intermediate transporters.

(Comment 90) One comment states that some firms use carriers such as United Parcel Service, Federal Express, and the United States Postal Service to deliver their products and conduct all their transactions with these carriers via the Internet. The address and fax numbers of these carriers are not relevant. The comment requests that FDA revise the section on identifying information of the transporter to require only ''sufficient identifying information.''

(Response) FDA disagrees with this comment. In the event that FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA would need to determine from the source and recipient records who transported the subject food to complete the tracing investigation. Although the transportation may be arranged over the Internet, companies such as those mentioned in the comment have fixed addresses, such as a corporate headquarters, that would need to be included in the record so that if FDA had to access their existing records under section § 1.361 of this final rule, FDA would know where to go.

(Comment 91) One comment states that wines produced in France are sold by someone other than the producer and that the producer never knows the destination of the wine. The comment states that the recordkeeping requirement is an unnecessary burden on the producer because much of the producer's wine may be sent to destinations other than the United States.

(Response) There is no requirement for a person that manufactures or processes food to know the ultimate destination of its product. A person subject to subpart J of this final rule is only required to establish and maintain records to identify the transporter and nontransporter immediate previous sources and transporter and nontransporter immediate subsequent recipients of food. Further, FDA notes that it has excluded all foreign persons, except foreign persons who transport food in the United States, from all of the regulations in subpart J.

(Comment 92) One comment requests clarification on the records requirements for products produced before the regulations take effect.

(Response) Covered persons are required to establish and maintain records to identify the immediate previous sources and the immediate subsequent recipients of all food as of the compliance date of this final rule, keeping in mind the staggered compliance dates provided in § 1.368 of this final rule. If a food was received before the compliance date of this final rule, then there is no obligation to keep records of the immediate previous sources of that food. If a food is released on or after the compliance date of this final rule, you must establish and maintain records of the immediate

subsequent recipients of the food, regardless of when that food was produced or received.

2. Information Reasonably Available to Identify the Specific Source of Each Ingredient

(Comment 93) A few comments state that the requirement to keep records that identify the specific source of each ingredient to a lot of finished product exceeds the intent of the Bioterrorism Act. One comment adds that the language in the Bioterrorism Act clearly authorizes a regulation to require the maintenance of records that show the person from whom a product is received and the person to whom a product is sent. The comment states that there is nothing in the language of the Bioterrorism Act or in its legislative history that would support including a requirement that products received be directly associated with products that are shipped.

(Response) FDA does not agree with these comments. Section 306(b) of the Bioterrorism Act expressly states that the Secretary

* * * may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, *which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging*, in order to address credible threats of serious adverse health consequences or death to humans or animals'' (emphasis added).* * *

Thus, the Bioterrorism Act clearly gives FDA the authority to determine what records are needed to achieve this objective.

The final rule contains those requirements that FDA has determined are necessary to help FDA identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. If FDA cannot immediately narrow its tracing to a specific source, tracing becomes much more difficult and time-consuming, there is an increased risk to consumers, and some food sources may be unfairly implicated. FDA notes, however, that the final rule (§ 1.345(b)) only requires nontransporters to identify the specific source of each ingredient that was used to make every lot of finished product to the extent such information is reasonably available.

(Comment 94) A few comments state that they are not able to provide information that ties the specific source of each ingredient to a lot of the finished product. Several comments agreed with FDA's decision to require identification of the specific source of an ingredient in a finished product only when the information is ''reasonably available.'' Some comments request that the agency make clear in the final rule that, in many instances, it will be impossible to identify the specific source of a material that is held in bulk and that multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form.

Several other comments state that, because their ingredients are commingled, they are unable to provide FDA with information that ties the specific source of each ingredient to a lot of the finished product. Certain bulk products such as flour, shortening, vegetable oil, fructose syrup, and milk cannot be identified as ingredient lots. Other comments state that the ability to identify specific sources of ingredients will vary based on many factors. One comment states that produce is often commingled to meet marketplace needs. A few comments state that some processors commingle ingredients in their processing operations, which makes it impossible to trace the specific source of ingredients to a lot of finished product. One comment states that most companies would only be able to produce possible sources of ingredients in batches of final products. The comment asserts that companies should only be required to do so in a crisis.

(Response) FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA's intent to mandate reengineering of long-standing existing processes. For this reason, the final rule requires the identification of the specific source of each ingredient that was used to make every lot of finished product only when the food is released and only if this information is reasonably available. With respect to the comment that companies should only be required to produce records during a crisis, the agency notes that FDA will request access to the records under section 306 of the Bioterrorism Act only when it has reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 95) One comment requests that the agency accept testing of each delivery of incoming product as a substitute for the requirement to tie the specific source of each ingredient to a lot of the finished product. The comment asserts that this testing provides the needed safeguards and would ensure that the ingredient is not contaminated chemically, physically, or biologically.

(Response) The agency does not agree with this comment. The comment fails to specify the nature of the chemical, physical, or biological tests being proposed, or what sampling scheme would be conducted to ascertain that the incoming ingredient is not contaminated. Moreover, only nontransporters are required to identify the specific source of each ingredient that was used to make every lot of finished product, and they are required to do so only if this information is reasonably available. FDA also notes that it has deleted this provision from § 1.337(a) of this final rule and instead inserted it in § 1.345(b) of this final rule. The agency believes records are more likely to be reasonably available to persons when they release food made from the ingredients than when the persons receive the ingredients under § 1.337 of this final rule.

(Comment 96) A few comments request that the agency treat processing aids and incidental additives as it does commingled ingredients. The comments state that they are able to identify the source(s) in use in a facility when specific food products were produced, but are not able to identify the source of the processing aid or incidental additive used to produce a specific lot of food.

(Response) The recordkeeping requirements in these regulations apply to all food unless specifically exempted. Processing aids may be food additives or a generally recognized as safe ingredient. In either case, they fall within the definition of food and are subject to these regulations. If the manufacturing process is such that a processing aid was used to make a specific lot of a finished food product, then the specific source of each processing aid should be identified in the records to the extent that information is reasonably available.

(Comment 97) Several comments ask that the agency clarify the term ''reasonably available'' and provide guidance on what the agency considers is ''reasonably available.'' One comment suggests that the agency use hypothetical case studies as guidance.

(Response) What is ''reasonably available'' is going to depend on the particular circumstances. To illustrate this point in the proposed rule, FDA used a hypothetical case of a cookie maker. (See 68 FR 25188 at 25197.) A company that bakes cookies may source

flour from five different companies rather than depend on a single company as its supplier. The flour from the five companies may be stored in one common silo before being used in the manufacture of the cookies. In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were the sources of the flour. Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. The information reasonably available to the manufacturer would be the identity of all of the potential sources of the flour for each finished lot of cookies. However, if the manufacturer had dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product. If we determine that additional guidance is needed, FDA will consider issuing guidance in the future to explain this requirement further. Again, FDA notes that this requirement now appears in § 1.345(b) of this final rule and has been deleted from § 1.337(a) of this final rule.

(Comment 98) One comment states that manufacturers of packaging face the same issues as processors who deal with commingled ingredients. The comment explains that, during the manufacture of multiple-layer packaging products, it is common to use multiple lots of raw material within a master roll of semifinished or finished product. An example of this condition would be a paper/foil lamination where one roll of foil and three to four rolls of paper are used in the same production run. In this situation, the lot numbers of the raw materials and the lot numbers of the finished products may be known, but it cannot be determined with precision which lot of the input materials is in an individual roll of finished product.

(Response) Manufacturers of packaging (the outer packaging of food that bears the label and does not contact the food) are excluded from all requirements of subpart J of this final rule unless such persons also manufacture, process, pack, transport, distribute, receive, hold or import food in the United States, in which case they are subject to §§ 1.361 and 1.363 of this final rule as to the food's packaging. Manufacturers of food contact substances, whether or not the substances are the finished container that directly contacts the food, are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363 of this final rule. Therefore, such manufacturers are not required to know which lot of the input materials is in an individual roll of finished product.

(Comment 99) Several comments request that the agency clarify the term ''ingredient'' with respect to distilled spirits that have innumerable sources of ingredients dependent upon the category and particular brand. The comments state that there is a question of interpretation as to what is meant by ingredients, given that the distilling process changes substantially the character and chemical composition of the raw materials and some of them may even be absent from the final product.

(Response) Alcoholic beverages are within the definition of ''food'' in § 1.328 of this final rule. A manufacturer of alcoholic beverages is required under § 1.337 of this final rule to identify the source of each ingredient that was received to make the alcoholic beverage, regardless of whether it later changes character and chemical composition.

(Comment 100) One comment suggests that the agency reconsider the requirement for immediate previous sources of bottled water. The comment asserts that the detail of records required under the regulations will not exist in many cases because the bottled water source will be directly out of the ground and that the bottler will capture any potential concerns of a serious threat of adverse health consequences. The comment suggests that water be viewed as other primary agricultural food ingredients.

(Response) Bottled water is within the definition of food as defined in § 1.328 of this final rule. If water is obtained from a public water system, then the public water system is the immediate previous source. If ground water is used, then the location where the water was extracted should be provided.

(Comment 101) One comment recommends that, in requiring a record of the raw material of a product, the agency should limit its requirement to that of major ingredients of the product.

(Response) FDA does not agree with the comment. The comment neither explains what distinguishes a major ingredient from a minor one, nor why the agency should limit its requirement to ''major'' ingredients only. Even if an ingredient is present only in small quantities, it may pose a risk and could be the focus of an intentional attack (e.g., the deliberate addition of a chemical toxin or pathogens), which would further contaminate food products to which they are added.

3. Requirement to Record Responsible Individual

(Comment 102) Several comments object to the requirement to name a responsible individual as duplicative of a requirement in the registration interim final rule. The majority of these comments ask that FDA use the emergency contact information required in the registration interim final rule in place of the responsible individual. The comments suggest that using the emergency contact information would give the agency rapid access to the information and provide the industry with flexibility. The comments state that there is no demonstrated need for the record of each commercial transaction involving the distribution of food to contain the name of a responsible individual, and that the requirement for a responsible individual is too rigid, as there is a high turnover of employees in many companies and the naming of a specific person as the responsible individual would require frequent updating.

(Response) FDA agrees with the comments that there is little utility from requiring that the record of each commercial transaction involving the distribution of food contain the name of a responsible individual, due to the fact that individuals change jobs within and among companies very often, making it unlikely that the person named in the record will have responsibility for the food at issue when FDA seeks to effect a traceback. FDA further notes that, for those facilities required to register under part 1, subpart H, FDA already has the emergency contact designated in the registration under §§ 1.232(d) and (e) and 1.233(d) or § 1.233(e). As explained previously, FDA does not believe this information is necessary for those facilities not required to register under 21 CFR part 1, subpart H, because including an emergency contact telephone number in records being kept will not assist the Secretary in locating the records because FDA would not have the emergency number until it had already accessed the records.

(Comment 103) Some comments suggest that, rather than requiring a specific individual, the agency require a department such as a quality assurance department.

(Response) As explained in response to comment 63 of this document, FDA has deleted the proposed requirement that a responsible individual be listed in each record.

4. Adequate Description of Type of Food

(Comment 104) One comment notes that ''specific variety'' is not appropriate

for many food ingredients and should be changed to ''common name.''

(Response) FDA is requiring an adequate description of the type of food received or released to include brand name where applicable and specific variety where applicable (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce). FDA agrees that ''specific variety'' may not apply in all cases, but should be provided where it applies because it will help narrow the investigation and help FDA identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 105) Some comments recommend that the agency allow the use of company specific codes or an existing abbreviation system. One comment states that commercial documents often incorporate code numbers and abbreviations that identify the food products very specifically. The comments add that, as long as these codes and abbreviations can be deciphered readily for FDA in the event of an agency request for records, the product descriptions should be considered sufficient in their present form.

(Response) As discussed in response to comment 103 of this document, in keeping with FDA's intention to ensure these regulations are not unnecessarily burdensome, FDA agrees that covered persons may use existing abbreviation or code systems that identify the food very specifically, provided the abbreviations or codes can be readily deciphered at the time the records are made available to FDA following an agency request.

(Comment 106) Some comments who represent warehouses state that they rely on the customer's description of the product as the food comes to them in shrink-wrapped pallets and cartons and the warehouse is not permitted to open the packaging.

(Response) It is not clear from the comment what the ''customer's description'' entails; however, FDA is requiring an adequate description of the type of food to be able to narrow the scope of the implicated food in the event of a public health emergency. For this reason, each entity within the chain of distribution of the food must establish and maintain records that adequately describe the type of food received and released so that FDA can identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse consequences or death to humans or animals. It is the responsibility of the covered entity to revise its recordkeeping system so that it establishes and maintains records containing all required information. In the previous example, the warehouse may need to require its customers to provide it with a more detailed description when food is delivered or released than it currently receives.

5. Date Food Received or Released

(Comment 107) One comment agrees with the proposed requirement. Another stated that the term ''released'' is ambiguous in a commercial environment and asked for clarification.

(Response) Under §§ 1.337 and 1.345 of this final rule, if you are a nontransporter, you must establish and maintain records to identify the date you received and released food. Food is ''released'' when it moves from one covered activity to another covered activity (unless both activities are conducted by the same person). For example, an article of food is released from the manufacturer when it is given to the transporter. The food is released again when the transporter delivers the food to a grocery store. Where the manufacturer transports its own food to the grocery store, however, the food is not released when the manufacturer loads his trucks, but rather when the manufacturer delivers the food to the grocery store.

6. Lot or Code Number/Other Identifier

(Comment 108) Several comments state that some products do not have lot numbers (e.g., bulk produce and restaurant foods). The comments state that ''character/number string'' on the package may be hard to identify as a lot code; food product with closed lot codes requires deciphering; lot codes may be on nonvisible portions of the packaging or on the invoice; the integrity of the lot code may be compromised or unreadable if the outer packaging is damaged; and this requirement potentially forces the manufacturer either to stop using or to shorten the lot codes, which would be counterproductive to addressing public health concerns in this initiative. Another comment states that the requirement to record lot or code number/other identifier would be time inefficient and time consuming. One comment states the agency should require lot number tracing when information is ''reasonably available.''

(Response) FDA recognizes the difficulties in some situations of recording lot/code number or other identifiers of food. FDA has revised the final rule to only require that persons who manufacture, process, and pack food to record lot/code numbers or other identifiers. *See* §§ 1.337(a)(4) and 1.345(a)(4) of this final rule. Furthermore, this requirement only applies to the extent the information exists. FDA has learned through comments that tracking lot/code numbers or other identifiers throughout the manufacturing/processing and packing of food is not a problem, because in most cases it is currently being done or capable of being done. It is during the transporting, distribution, and holding of food (e.g., from the warehouse distribution centers to the retail store or restaurant) that such tracking becomes a problem. FDA also learned that the food industry is moving in the direction of being able to track the lot or code number or other identifier throughout the entire food chain, but that the current technology has not made such tracking cost efficient.

(Comment 109) Several comments state that the requirement to record lot/code number or other identifier would cost the industry millions of dollars in operational changes. They state that more warehouse space would be required to separate food by lot number, expensive computer system upgrades would be needed to handle lot code information, and the industry would incur significant administrative and labor costs to enter lot code information into the system. Comments further state that bar code tracing/scanning or radio frequency identification (RFID) systems are costly, and the RFID technology is new. The food distribution business will be affected every minute of every day compared to the infrequent costs associated with investigating food safety issues as the need arises. RFID is being studied and involves placing tagging chips in packaging. It may not be necessary to invent an elaborate system of paper recordkeeping if RFID proves to be useful in the future.

(Response) As discussed in response to comment 108 of this document, FDA recognizes the difficulties in tracking lot/code numbers or other identifiers throughout the entire food distribution chain. This final rule accounts for those difficulties. FDA is aware that technology is developing that will enable lot/code number tracking in the future to be cost efficient for all of the food industry.

(Comment 110) One comment states that food is not sorted by lot code identification. One pallet/bin, slot, or stockkeeping unit may contain multiple lot numbers.

(Response) The final rule does not require warehouse distribution facilities

to track lot/code number or other identifiers in these final regulations.

(Comment 111) A comment states that lot numbers are not scannable or machine readable, and manual transcription of these numbers would introduce errors. The comment states that small businesses would be buried in a mountain of paperwork and this would make it impossible for them to track products accurately.

(Response) As explained in response to comment 108, FDA recognizes the difficulties in tracking lot/code numbers or other identifiers. This final rule reflects those considerations. FDA has balanced the need to provide information that would expedite a traceback in a food-related emergency with the ability to record lot numbers. Because food almost always passes through at least one small business in the distribution chain, FDA cannot exempt small businesses entirely from this important requirement. The final rule, however, does give small and very small businesses more time to comply with its requirements. FDA is aware that technology is developing that will enable lot/code number tracking in the future to be cost efficient for all of the food industry.

(Comment 112) Some comments state that if foods are distributed to the store via direct store delivery (DSD) (i.e., baked goods, breads, soda, snack foods, beer/wine, ice, and milk) the vendor provides the food directly to the store and sometimes stocks the shelves. DSD has no system to track the information the FDA will require.

Several comments note that protecting public health does not necessitate the maintenance of records in every step of the distribution process. The comments state that the current recall system is the most efficient and practical way to identify and remove product from distribution. These comments state that consumers typically return all products in a recall with no regard to the lot code, and that this is the most appropriate response in the event of a terrorist attack. In these comments' opinion, complex lot numbers may slow or substantially limit the recall of contaminated food. Additionally, requiring distributors to compromise the integrity of food packaging to determine lot codes defeats the purpose of the proposal. Some comments state that this requirement represents a disproportionate burden to packaged food distributors.

Some comments state that food manufacturers may use independent delivery persons who pick up product from several manufacturers for delivery to retailers. There may be as many as 75 to 100 different products on each truck. The independent delivery person has no capability to capture the lot numbers of the products of several different manufacturers.

(Response) (Response) The final rule does not require distributors to track lot/code numbers or other identifiers. DSD vendors will not be subject to the lot code requirement in § 1.345(a)(4) for activities other than manufacturing, processing, and packing food. Thus, activities such as holding and transportation are not subject to the requirements.

(Comment 113) Many comments request clarifications for the terms ''other identifiers'' and ''to the extent information this information exists.''

(Response) FDA acknowledges that most firms use lot or code numbers to identify specific batches of their products. However, some may use other technologies such as barcodes. The term ''other identifier'' is intended to capture any other methods that the food industry may be using to identify specific lots of product. FDA is mandating that this information be captured in the records, where required, to the extent this information exists. It is conceivable that certain sectors of the industry may not use lot or code numbers, or other identifiers to identify specific lots of products. In this case, the regulations do not specify that these sectors start using such identifiers. The identifiers are required only to the extent that they already exist.

(Comment 114) A number of comments suggest that, in lieu of lot numbers, purchase orders numbers would serve as acceptable identifiers.

(Response) To the extent that a purchase order contains all required identifiers of food received or released, the purchase orders may be used to satisfy the requirement. To the extent that a purchase order only contains some of the required information, those records will need to be supplemented to satisfy all the requirements contained in §§ 1.337 and 1.345 of this final rule.

FDA notes that the final rule only requires that persons who manufacture, process, or pack food maintain lot or code number or other identifier of the food, and only requires this information to the extent that the information exists. Furthermore, FDA is not specifying the form or the format of the information that is required to be established and maintained.

(Comment 115) One comment states the FDA should standardize lot codes.

(Response) FDA does not agree. The agency has determined that the least burdensome way of issuing the recordkeeping requirements mandated by the Bioterrorism Act is to specify the information that must be contained in the records, but not the format in which the records are kept. As indicated by other comments summarized previously, persons subject to this final rule already have various means to identify food, including lot numbers. The final rule allows such persons to use lot numbers or other appropriate identifiers, including abbreviations, provided such information can readily be decoded to identify particular foods if FDA makes an appropriate request to access records.

7. Quantity and How the Food is Packaged

(Comment 116) A few comments recommend that FDA allow quantity of products in bulk containers to be expressed in gross quantity, e.g., 1 to 5,000 gallon (gal) tank load; 5 to 1,000 gal totes.

(Response) FDA agrees with this comment that, when recording quantity of bulk food, the gross quantity, or weight, (e.g., 5,000 gal) is acceptable. To satisfy the requirement to record how the food is packaged, ''tank load'' or ''totes'' is acceptable. FDA has revised §§ 1.337(a)(5) and 1.345(a)(5) of this final rule accordingly.

(Comment 117) One comment representing warehouses recommends that the final rule require that the information relating to quantity and how a food is packaged be maintained by the warehouse customer.

(Response) FDA disagrees with this comment. Warehouses ''hold'' food and are, therefore, subject to all of the regulations in subpart J of this final rule. The comment has not explained why a warehouse would not know or could not obtain information regarding the quantity of food received and how it is packaged. FDA believes it is necessary to maintain this information at each step of the distribution chain to be able to effectively and efficiently conduct a tracing investigation.

8. Name, Responsible Individual, Address, Telephone Number, Fax Number, E-Mail Address of Transporters Who Transported the Food To You and From You

(Comment 118) Several comments state that the identity of the transporter is known to the shipper but is not typically known to the receiver. The comments assert that it is unreasonable to expect the receiver to have, seek, or maintain information on the identity and related contact information for the transporter that delivered the product, especially if multiple transporters may have been involved. The comments state

that such information would be available from the shipper that arranged the transport. One comment states that it is not usual business practice for distributors to keep records about the transporter who delivers food.

(Response) FDA believes that excluding a source from keeping records on the immediate previous source if that immediate previous source is a transporter would hinder a traceback investigation. The proposed and final rule require nontransporters to identify the name of the firm, address, telephone number and, if available, the fax number and e-mail address of the transporter who transported the food to and from them. See §§ 1.337(a)(6) and 1.345(a)(6) of this final rule. These provisions however, do not require the nontransporter to record transactions to which they were not a party, e.g., where multiple transporters are involved.

I. Comments on Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? (Proposed § 1.351)

(Comment 119) Several comments stated that foreign transporters are not included in the definition of ''foreign facilities'' and that the final rule should be applied to foreign transporters as it is to domestic transporters.

(Response) FDA has excluded all foreign persons, except foreign persons who transport food in the United States, from all of the regulations in subpart J of this final rule. Therefore, foreign transporters are subject to the same requirements as ''domestic'' transporters when transporting food in the United States.

(Comment 120) A number of comments noted that many ''nontransporters'' own trucks or other vehicles and transport food or feed as an incidental part of their operations. They express concern that they would be required to keep two sets of records, one as a nontransporter, and the other as a transporter. One comment recommends that the final rule be applicable to both private and ''for-hire'' transporters.

(Response) ''Transporter'' is defined in § 1.328 of this final rule to mean a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that person has possession, custody, or control of that food for the sole purpose of transporting that food. If a person is considered a nontransporter under the rule, then the person is not subject to the transporter provisions when transporting food, but must comply with the requirements applicable to nontransporters. The final rule applies to transporters regardless of their status as private or for-hire. For example, if a U.S. manufacturer hires a company to deliver its food, the delivery company is subject to the transporter provisions whether or not it is private or for-hire.

If a person is considered a nontransporter under the final rule, then the person is not subject to the transporter provisions when transporting food. For example, a U.S. manufacturer that delivers its food to a grocery store must only keep the records required of a nontransporter. In this situation, the immediate previous sources of the manufacturer are the sources and transporters of the ingredients, and the immediate subsequent recipient of the manufacturer is the grocery store.

(Comment 121) A number of comments note that the specific records being required of transporters are duplicative of the information being required of the immediate prior sources and the immediate subsequent recipients with respect to each other and that such redundancy is unnecessary because the agency could get the information from either or both of the immediate prior sources or immediate subsequent recipients.

(Response) The requirements in the final rule ensure that transporters have records that would assist FDA in a tracing investigation. For example, if a manufacturer of a food product sends 300 boxes of that product to its buyer (the immediate subsequent nontransporter recipient), and the recipient only receives 200 boxes, records created by the transporters (or multiple transporter companies if more than one is used to transfer food between the nontransporter immediate previous source and the nontransporter immediate subsequent recipient) will be the only means of enabling FDA to learn how and when the remaining 100 boxes were diverted, and to where. In addition, under a similar scenario where a manufacturer of a food product sends 300 boxes of that product to its buyer and the recipient receives 400 boxes, transportation records will be the only means of enabling FDA to determine when the additional 100 boxes were introduced into the system and where they came from. Further support for requiring transporters to establish and maintain records is provided in response to comment 82 of this document.

J. Comments on What Information is Required in the Transportation Records? (Proposed § 1.352)

(Comment 122) Several comments recommend that FDA exempt transporters from all recordkeeping elements except the immediate source and immediate subsequent recipient. They note that the cost of complying is not proportional to the risk.

(Response) FDA disagrees with this comment. FDA, however, has taken steps to minimize the burden on transporters by including five alternatives to meet their obligations to establish and maintain records under this final rule. FDA notes that transporters also are subject to the records access requirements in §§ 1.361 and 1.363 of this final rule. This will ensure that FDA has access to all applicable records that will enable FDA to perform a tracing investigation quickly and effectively. Additionally, to ensure there are no gaps in transporter coverage in a traceback investigation, the final rule applies to both interstate and intrastate transporters of food.

(Comment 123) Comments arguing for exemption of transporters state that it is difficult or impossible for the crew of the transporter to open each container of food, contaminate it, repackage it, replace seals, and arrive on time without leaving any trace of their intervention. Other comments suggest that a known and trustworthy transport company will not risk their business by doing something of this nature.

(Response) FDA disagrees that the transportation process is any less vulnerable to attacks on the food supply than any other part of the food industry. FDA believes that recordkeeping requirements are necessary for transporters, but, as discussed previously, it has taken steps to minimize the burden on transporters.

(Comment 124) A number of comments state that the transporter has no access to detailed information about the shipment and is dependent on the information listed on the bill of lading provided by the shipper. Therefore, the information required of transporters should be limited to the information on the bill of lading. One comment states that a bulk shipper, for example, has a 5,000 gal shipment of orange juice and has access to only this information, and detailed descriptive information such as brand names, specific variety, and package types are not applicable to bulk loads. Several comments state that transporters are frequently provided with preloaded and/or sealed vehicles for transport, and the transporter does not have knowledge of the contents

other than what is on the bill of lading prepared by the shipper. They argue that they cannot access the sealed cargo to obtain specific information to confirm or supplement the bill of lading information. Similarly, other comments advise that they cannot verify bill of lading information for food contained in shrink-wrapped pallets. These comments believe that the carriers responsibility should be limited to the description provided by the shipper.

(Response) As discussed in response to comment 82 of this document, transporters are not required to establish and maintain the detailed information about a particular shipment of food that nontransporters are required to establish and maintain under §§ 1.337 and 1.345 of this final rule. The final rule provides five alternatives for interstate and intrastate transporters to meet their obligation to establish and maintain required records.

(Comment 125) One comment notes that air transporters may have a record of the consignee (immediate subsequent recipient), but may not have a record of the truck transporter the consignee sent to pick up the freight. The comment believes that the consignee who arranged for the pickup should be responsible for the record, not the air transporter who released the shipment to the agent of the consignee.

(Response) The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. Failure by the immediate previous source or immediate subsequent recipient who enters into an agreement under § 1.352(e) of this final rule to keep such records is a prohibited act. The requirements for transporters in the final rule ensure that FDA has records identifying how a food traveled between a nontransporter supplier and nontransporter recipient when multiple transportation companies or multiple modes of transportation are used. FDA does not believe that the nontransporter will always have this information. For example, if a trucking company that picks up the food from a manufacturer in State A for delivery to a grocery store in State B subcontracts with an airline and subsequent trucking company to deliver the food to the grocery store, the manufacturer may have no knowledge that the food was transported on the airline and subsequent trucking company. Similarly, the grocery store is aware that the second trucking company delivered the food, but may not be aware that before that, the food was transported on an airline and a different trucking company.

In the event that FDA has a reasonable belief that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, such records could be critical to determining whether such adulteration occurred during transportation, and if so, during which leg.

(Comment 126) One comment observes that the Bioterrorism Act does not mention ''transporters'' in providing the Secretary with record access. The comment concludes that Congress chose not to give the Secretary access to the records of transporters and asks why there is a recordkeeping requirement for those transporters.

(Response) FDA disagrees with this comment's assertion that the statute does not provide FDA with access to transporters' records. Section 306 of the Bioterrorism Act amends section 704(a) of the FD&C Act, Factory Inspection, to read:

> * * * In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, *transports*, distributes, holds, or imports foods, the inspection shall extend to all records or other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals * * *. (Emphasis added.)

FDA is imposing a record establishment and maintenance requirement on transporters to ensure that transporters have records that would assist FDA in a tracing investigation in a food-related emergency.

(Comment 127) Numerous comments state that a requirement for specificity as to brand names, specific variety names (e.g., ''romaine lettuce'' rather than ''lettuce''), lot numbers, and the way the food is packaged would require information neither readily available to transporters, nor routinely recorded by transporters. They further state that, if needed, such information could be obtained from both the shipper and receiver. They contend that these requirements are not necessary to effectuate the purposes of the statute. Other comments state that air carriers typically rely on information from those tendering the freight and, in some instances, shipments may not even be identified as containing food, particularly since chewing gum and pet foods are included in the definition of food.

(Response) The final rule does not require transporters to establish and maintain records with brand name or lot numbers. However, FDA believes it is necessary to obtain some information about the shipment of food from transporters to conduct tracing investigations. Transporters are responsible for knowing that they are transporting food.

(Comment 128) Some comments state that requiring brand name descriptions raises cargo security concerns because having more detailed descriptions on paperwork will increase the risk of theft and make it easier for bioterrorists to target certain shipments.

(Response) FDA does not agree with this comment. Interstate transporters are already required to keep similar records under the DOT regulations, and FDA is not aware of these records presenting a security risk; thus, there should not be any increased security risks as a result of this rulemaking. Furthermore, FDA notes that the final rule does not require transporters to establish and maintain records of brand name, specific variety names, or lot numbers.

K. Comments on What are the Record Retention Requirements? (Proposed § 1.360)

(Comment 129) Many comments state that because an infrastructure for long-term record retention does not exist to the extent FDA envisions, more reasonable time requirements for retention of records should be established. Another comment states that, although the proposed record retention periods seem simple and straightforward, in practice, they are difficult and confusing for some companies to apply because of the other record retention requirements of varying lengths with which they also must comply. The comment urges FDA to review the recordkeeping retention periods now in effect for specific food categories (e.g., acidified foods, low acid canned foods, bottled water, juices, seafood, and milk) and work to harmonize the proposed record retention requirements with those periods. A few comments question the value of a 2-year record retention period for a product with a shelflife of 60 days, particularly in light of the additional costs associated with the extended retention requirements for perishables. Another comment states that the proposed timeframes for maintaining records for all food products, based solely on whether a food has a shelflife of 7 days, does not appear to utilize sound risk management principles.

(Response) FDA agrees in part with these comments and has revised the record retention requirements in the final rule. FDA used similar criteria as the NIST definitions for perishable, semiperishable and long shelf-life food. The record retention requirements in § 1.360(b) of this final rule now require record retention of: (1) 6 months for

food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydration, or being placed in a hermetically sealed container.

Transporters, or nontransporters retaining records on behalf of a transporter, are required to retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

(Comment 130) Comments from the transportation industry indicate that FDA should revise the record retention requirements for transporters to be the same for both nonperishable and perishable food shipments, rather than the 1 and 2-year periods FDA proposed, and that the final rule should adopt the FMCSA 1-year retention period required for bills of lading.

(Response) FDA agrees with this comment and has revised the final rule accordingly. Section 1.360(f) of the final rule requires transporters, or nontransporters retaining records on behalf of a transporter, to retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

(Comment 131) One comment suggests that records retention timeframes should be based on a simple partitioning of shelf perishable and shelf stable products, e.g., retain records for products with a shelflife up to 90 days for 1 year and retain records for products with a shelf life greater than 90 days for 2 years from the time of manufacture.

(Response) As stated previously in response to comment 129 of this document, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semi-perishable and long shelf-life food. FDA is convinced such an approach is the most efficient and effective because the food industry already is familiar with classification of foods into these three categories due to existing regulations and practices; and it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage or significant loss of value occurs within 60 days will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

With regard to the comment's statement that records be retained from the time of manufacture, FDA does not agree. The record retention periods begin at the time the food is received and released. Under § 1.360(a) of this final rule, you must create the required records at the times you receive and release food, except to the extent that the information is contained in existing records.

(Comment 132) One comment suggests that retaining records for 6 months after the product expiration date should be more than adequate for investigations for potential threats associated with the food. The comment indicates that expanding system capacity to accommodate much longer record retention is a major cost associated with implementing the proposed regulation and that FDA should either justify the value for longer record retention periods against the increased burden being placed on the industry or substantially decrease the number of records that must be retained for longer duration.

(Response) As previously noted in response to comment number 129, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semiperishable and long shelf-life food. FDA is convinced such an approach is the most efficient and effective because the food industry already is familiar with classification of foods into these three categories due to existing regulations and practices; and it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods.

FDA notes that a traceback may not begin until well past the time the food has been consumed, as explained in the response to the following comments.

(Comment 133) A few comments contend that a shorter record retention time, such as 3 to 6 months, should be sufficient time for retention of records because any harmful effect directly related to a perishable food would be detected well within the life expectancy of the food.

(Response) FDA does not agree that harmful effects directly relating to perishable foods always can be detected within the shelflife of the food. FDA has experienced some situations in which the health hazard was not immediately apparent, but only emerged several months after the food was consumed. Also, FDA recognizes the potential for serious adverse health consequences caused by novel contaminants or novel food sources for known contaminants. In such situations, it may take months to identify the source of contamination, or the contaminant itself.

(Comment 134) Several comments suggest that record retention be based on three categories of food, i.e., perishable, semiperishable, and long shelflife, as defined by NIST. NIST defines perishable food as any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days of the date of packaging. The corresponding time frames for semiperishable and long shelflife food are 60 days to 6 months, and greater than 6 months, respectively. Several comments suggest the record retention time should be 6 months for perishable food; 12 months for semiperishable food and 18 months (or product shelflife plus 12 months or 24 months, whichever is greater) for long shelflife food.

(Response) FDA agrees with this comment. FDA has concluded that this objective can be achieved by inserting language directly in § 1.360(b) of this final rule using similar criteria as the NIST definitions for perishable, semi-

perishable and long shelf-life food. Therefore, FDA has changed the record retention requirements in § 1.360(b) of this final rule to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

Transporters, or nontransporters retaining records on behalf of transporters, are required to retain for 6 months records for food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and for 1-year records for all food having a significant risk of spoilage, loss of value, or loss of palatability after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

(Comment 135) One comment states that records should be retained for 2 years from the date they are created, and not for 2 years from the date of shipment of the product. The comment points out that wine may be shipped several years after it has been manufactured, and that establishing the timeframe from the date of shipment of the product would be an unwarranted burden. One comment suggests that the minimum record retention periods should be stated as time from the date of production, e.g., a minimum of 2 years after the date of production of the food, except perishables, and a minimum of 1 year after the date of production for perishables.

(Response) FDA does not agree with the comment's suggestion, as this will not ensure that FDA has access to the requisite records at the time of a traceback investigation. Often, a traceback begins after consumers become sickened or die. In the comment's example, if the wine was adulterated and presented a threat of serious adverse health consequences or death to humans, FDA may not know this until the wine has been consumed, i.e., after the product was released by the manufacturer into commerce and consumers became seriously ill. If the record retention period began at the time of production, but the wine was aged at the manufacturer's facility 2 years before distribution into commerce, the record retention period would have expired before the wine entered commerce. In the final rule, FDA retains the requirement that records required under subpart J must be established at the time food is received or released and maintained from that time until the end of the time period specified in § 1.360 of this final rule.

(Comment 136) One comment notes that mechanisms for keeping records updated have not been established. The comment asked what should be done if a record's 2-year deadline expires, e.g., is there a requirement to open a new record?

(Response) The final rule does not mandate specific mechanisms, systems, or processes for establishing and maintaining the required records, only the information that must be kept. The record retention period is from the time the food is received or released. Persons are not required to update, modify, or transfer information in a record to a new record after the end of the required retention period.

(Comment 137) One comment expressed concern that, under the proposed regulation, persons who do not know if perishable food is intended for processing into nonperishable food would have to assume it is and maintain records for 2 years. A few comments state that persons, such as distributors, carriers, farms or orchards, roadside stands, and small collection centers generally have no way of knowing whether a perishable food will be processed into a nonperishable food by other parties. A few comments ask FDA to clarify that companies selling perishables can rely on the applicability of the 1-year records retention period unless they have actual knowledge at the time of sale that the perishables will be used for processing into nonperishable foods.

(Response) Section 1.360 of the final rule specifies retention periods based on the type of food being received or released, not on the end use of the food being delivered.

(Comment 138) One comment states that the proposed requirements are more burdensome than is necessary to enable food producers to respond quickly and appropriately to a food safety emergency. The comment further states that the proposal does not take into account the sheer volume that retail grocery stores deal with on a daily basis. According to the comment, the average retail grocery store currently is capable of retaining such records for only approximately 1 week. The comment concludes that the requirement to maintain records for 2 years is completely unworkable and will not serve in the interest of public health in times of crisis.

(Response) FDA has revised the record retention periods for nontransporters to 6, 12, and 24 months as discussed in response to comment number 129. FDA believes that these timeframes are within the period Congress believed appropriate because the Bioterrorism Act gives FDA authority to require records to be retained for up to 2 years. Moreover, Congress did not exempt retailers (e.g., retail grocery stores) from the recordkeeping requirements, as they did in section 305 of the Bioterrorism Act (registration of food facilities). FDA believes that the benefit to FDA and consumers in conducting an efficient and rapid traceback in a public health emergency justifies the burden to industry.

For the final rule, FDA has changed the record retention requirements in § 1.360(b) to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

Transporters or nontransporters retaining records on behalf of a transporter are required to retain 6 months records for food having a significant risk of spoilage, loss of value,

or loss of palatability within 60 days after the date the food is received or released and 1 year all food having a significant risk of spoilage, loss of value, or loss of palatability after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage or significant loss of value occurs within 60 days under normal shipping and storage conditions will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

In addition, FDA has excluded the distribution of food directly to consumers from the requirement to keep records of immediate subsequent recipients of food because FDA can obtain information from consumers and notify them when necessary. Often, consumer illness is the first common indicator that food may be adulterated and present a threat of serious adverse health consequences or death. Requiring retailers to retain records for only weeks or months would greatly impede FDA's ability to conduct a rapid and effective traceback. FDA has selected those timeframes for record retention based on the amount of time perishable and nonperishable food may remain in commerce, and thus, may be the subject of a traceback investigation. FDA further notes its understanding that many retailers currently maintain records for 2 years.

Also, retail food establishments that employ 10 or fewer full-time equivalent employees are now excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 139) A few comments state that the requirement to maintain records for 2 years is very burdensome for those who obtain a variety of fresh produce from a large number of small farmers and commingle lots of produce for distribution.

(Response) FDA notes that these foods for the most part would fall into the category of foods for which a significant risk of spoilage or significant loss of value occurs if held longer than 60 days under normal shipping and storage conditions for the food. As stated previously, the record retention period for this category of foods in this final rule is 6 months.

(Comment 140) A few comments state that, for alcoholic beverages and distilled spirits, retention of records for a period of only 2 years would be inadequate to trace a matured product back to the source. They suggest that FDA should rely on alcoholic beverage importers' and producers' own existing record systems to facilitate tracebacks.

(Response) Although retaining records for 2 years may not be enough for products with long shelflives, the agency notes that the Bioterrorism Act sets the maximum time the agency can mandate record retention at 2 years. FDA further notes, however, that when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the FD&C Act must be readily available for inspection and photocopying or other means of reproduction. Therefore, as a practical matter, FDA may be able to access additional information about food products after the 2-year retention period required by subpart J of this final rule has elapsed.

(Comment 141) Several comments offer suggestions on where the required records should be maintained. One comment recommends that, for intracorporate transfers, companies should be permitted to make all required records accessible at one location. The comment states that this would not delay, and could even enhance, efficiencies in an FDA traceback investigation. Several comments state that companies should have flexibility for determining where to maintain the required records. The comments note that it should be sufficient that the records are maintained and are accessible at some location, including the headquarters office for specific locations within a company. One comment requests clarification on whether records may be stored in separate locations, as long as the combined records adequately provide the required information. The comment notes that confidentiality requirements may cause records that contain part of the required information to be maintained in different locations.

One comment states that, in the context of air transportation of food, the location where the activity occurred may be difficult to determine, and may not be a feasible place to store records or to make them available to FDA at a future date. According to the comment, the option to store records offsite, combined with the flexibility to maintain records in an electronic format, is critical to ensuring prompt access to the records.

(Response) FDA requires in the final rule that the required records must be retained at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. The agency clarifies that the intent of this provision of the regulation is to provide flexibility for a company to determine the most efficient and readily accessible means of storage, consistent with the company's business practices. Access to the records may be provided to FDA electronically, by facsimile, or by other appropriate means consistent with the availability requirements in § 1.361 of this final rule, once FDA makes a written request under section 414(a) or 704(a) of the FD&C Act. Each individual company may determine the appropriate location for maintaining the required records and for ensuring that the record availability requirements can be met.

L. Comments on What Are the Record Availability Requirements? (Proposed § 1.361)

(Comment 142) Some comments state that the proposed time is reasonable for record production if the requested records are onsite and of recent transactions (i.e., within the last 3 months). One comment urges the agency to clarify that, although companies must make the records available within 4 hours, the agency does not expect companies to link the sources of each ingredient with every finished lot of product within that timeframe. Another comment states that, within the 4-hour proposed time, a firm will not be able to make records available that are stored offsite and currently are subject to contracts that allow the vendors to deliver records on the next business day. The comment recommends that FDA consider the possibility of allowing records stored offsite to be produced at locations more convenient than the manufacturing facility, such as FDA offices, headquarters, or other locations mutually agreed upon to expedite record examination.

Some comments also state that the cost of renegotiating record storage contracts would cost thousands of dollars, more than the $151 per firm cost that FDA estimated. They recommend that FDA allow companies to provide records ''within a reasonable period of time'' or that the final rule

give companies 24 hours to make records available to FDA from the time of receipt of FDA's official request. Several comments state that the proposed time does not reasonably reflect the following: The scope of requested records; the accessibility, degree of compatibility and number of recordkeeping systems involved; the limitations on record maintenance of some systems; the limited physical access to nonelectronic records; and the presence or absence of a quality assurance system. Comments further state that, with millions of foods transported annually, many firms utilize various data systems and have implemented records maintenance procedures to meet their specific company needs. Compliance with this new rule requires establishing new protocols and developing new database systems, which would require a substantial capital investment.

Comments also note that the proposed rule does not consider the time required to verify the completeness and accuracy of records, transmission of data to appropriate authorities and the availability of knowledgeable personnel to access specific records. They suggest that FDA should focus on the information contained in the records, rather than on the records themselves. Comments suggest FDA change the proposed language to include: As soon as possible within 24 hours from the time the request is made. Other comments state that the proposed time is not enough, particularly if the request for record is made late during the day, or on Friday, or on a day (Sunday) when the location where records are maintained is closed and insufficient staff is available to retrieve the requested records. Comments urge FDA to allow companies to provide records as quickly as is practicable, given the nature of the recordkeeper's operations.

(Response) FDA agrees with these comments in part and has amended the proposed records availability requirements in this final rule. Section 1.361(a) of this final rule states: ''* * * Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of an official request * * *.'' FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 143) Other comments suggest that records be available within 12 hours regardless of what time of day the FDA request is made or the next business day, in the event the next day falls on a weekend or a holiday. Some suggest a timeframe within 24 hours if the request is made during a working week and within 72 hours if a request is made during a weekend.

Several comments state that the majority of businesses, especially small businesses, store records that are older than 3 weeks ''offsite'' where many storage facilities are not open on weekends and holiday. Comments also state that more than 24 hours is needed to retrieve such records and to impose criminal liability for noncompliance is unworkable and unfair. Comments urge FDA to allow companies to provide records within a reasonable period of time or that the final rule gives companies 24 hours to make records available to FDA from the time of receipt of an official request.

(Response) FDA agrees with these comments in part. In this final rule, FDA is requiring that records be made available as soon as possible, but not more than 24 hours from the time of receipt of an official request. FDA does not agree with the comments' suggestion that more time be made available if a request for records is made outside of the working week. FDA notes that it would only access the records if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Under these circumstances, it is critical for FDA to move as quickly as possible to trace backwards to identify the source of any such adulteration and trace forward from that source to remove all similarly adulterated food from commerce to protect the public health. FDA notes that although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 144) Several comments urge FDA to reconsider its proposed definition of work hours (8 a.m. to 6 p.m.). The comments state that in most ports of entry, the hours of operation of the trade community are established to mirror the hours of the commercial operations of CBP. If FDA requests records outside of those hours of operation, FDA could encounter difficulty in contacting the appropriate parties from whom to request records. Comments suggest that FDA use the phrase ''during times in which a firm is operating'' or ''during a firm's normal business hours.''

(Response) FDA is no longer defining work hours, and has modified its proposed records availability requirement to ''as soon as possible, not to exceed 24 hours from the time of receipt of the official request.''

(Comment 145) Some comments state that the agency has not considered difficulties of compliance in the real world where there are different time zones within the United States and foreign countries. According to these comments, mandating an unattainable compliance time may cause great confusion globally and may actually impede the information gathering process. Comments urge FDA to allow for records to be provided to FDA within a timeframe not to exceed 24 hours or other timeframe appropriate to the scope of records being sought. Others suggest 24 hours for domestic and 36 hours for foreign facilities.

(Response) FDA agrees in part with these comments. FDA has deleted the 4-hour and 8-hour requirements. The final rule requires all records to be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request. With respect to the comments suggestion that foreign facilities be given 36 hours, FDA notes that foreign persons (except for foreign persons who transport food in the United States) are not subject to these final recordkeeping regulations.

(Comment 146) Many foreign governments express concern that FDA does not have authority regarding recordkeeping and record access when a firm is located in a foreign country. One foreign government urges FDA to recognize the role of another competent authority with respect to records access as provided for under the World Trade Organization Agreement on Sanitary and Phytosanitary Measures. Foreign governments request that FDA operate under agreements with these governments so that FDA will convey its request to the competent authority in that country. The competent authority can then carry out investigations on behalf of FDA and provide FDA with any resulting relevant information.

(Response) Foreign persons, except those who transport food in the United States, are not subject to these final recordkeeping regulations. If FDA needs to access food records that are established and maintained by foreign persons, FDA will work with the relevant competent authorities in those countries to do so.

(Comment 147) One comment notes that the proposed rule does not take into account the time required to translate into English records in other languages that are obtained from firms located in foreign countries.

(Response) Foreign persons, except those who transport food in the United States, are not subject to these final recordkeeping regulations. In the event FDA needs to access records kept by foreign persons, FDA intends to work

with the relevant competent authorities in those countries to do so.

(Comment 148) One comment states that, for rurally-located industry, it is difficult for primary agricultural dealers from any location to meet the proposed requirements, because, in some of these small businesses, one person assumes many responsibilities.

(Response) FDA has considered this and other comments and has changed the record availability requirement from the proposed rule. Under this final regulation, records shall be made available as soon as possible, but not to exceed 24 hours after FDA has made the request. In the circumstances in which FDA would access the records, it is critical for FDA to move as quickly as possible to trace backwards to identify the source of any such adulteration and trace forward from that source to remove all similarly adulterated food from commerce to protect the public health. FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 149) One comment states that the proposed time for records access is problematic for small-scale exporters that do not have any representation in the United States; hence, they need special treatment.

(Response) Foreign persons are not subject to these final recordkeeping regulations, except to the extent they transport food in the United States.

(Comment 150) Several comments state that the Bioterrorism Act only provides authority to access and copy records for the purpose of determining whether a food believed to be adulterated is actually so and for conducting a tracing investigation in regard to such an adulterated food. Comments express concern over possible unlawful conduct and abuse of discretion by FDA field inspectors and other officials. They urge FDA to clearly define legal violations concerning recordkeeping and record access requirements so corporate officers can make responsible decisions. They also urge FDA to integrate the constitutionally required safeguards into the regulations.

Comments recommend that FDA establish procedural safeguards to protect manufacturers and their customers by providing the affected company with a reasonable written notice that explains how the ''reasonable belief'' standard is being met and identifies the type of records being requested. According to comments, this would inform the affected company which records are being sought and the legal basis for the request. Several comments also request that FDA develop procedures requiring that the written notice be examined and approved by the District Director in whose district the implicated food is located, or by any FDA official senior to such District Director. They urge FDA to develop guidelines to define ''reasonable belief'' and base a decision to access records on laboratory analyses confirming adulteration and/or on an affidavit sworn under penalty of perjury.

Other comments state that FDA should issue interim final regulations with an opportunity for comment on the procedural protections that will be utilized to implement the record maintenance and inspection provisions of the Bioterrorism Act. Specifically, the comments state that the regulations should at least delineate agency procedures for authorizing the review, those officials who are permitted to review the documents, the standard for when such review may occur, an appellate procedure for those who disagree with the agency's determination, and the reasonable times, limits and circumstances to which the Bioterrorism Act limits FDA's review, as well as the procedures FDA must implement to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by FDA under the Bioterrorism Act. Others urge FDA to incorporate these procedures into regulations and ask that the public be granted an additional 60 days to comment.

(Response) FDA's record access authority under sections 414(a) and 704(a) of the FD&C Act became effective upon enactment of the Bioterrorism Act on June 12, 2002. The record access provisions of the Bioterrorism Act do not require FDA to issue implementing regulations. FDA intends to issue guidance to FDA personnel regarding FDA's exercise of this provision in accordance with FDA's GGPs regulations (§ 10.115). The previously stated comments will be considered as FDA develops the agency's guidance. FDA does not agree that these procedures need to be codified.

(Comment 151) One comment observes that, depending on the length of the distribution chain involved in a contamination event, FDA may need to examine records of numerous food handling facilities. As a result, it could still take FDA several days to obtain needed records. The comment suggests that source labeling could help FDA determine the ultimate source faster.

(Response) The comment's suggestion is outside the scope of the proposed rule. The authority granted in section 306 of the Bioterrorism Act relates to establishing requirements for records to identify immediate previous sources and recipients of food, not establishing labeling requirements.

(Comment 152) One comment requests specific guidelines and an opportunity to object to providing the records for a period before access of the records.

(Response) FDA disagrees. FDA does not currently provide a period of time in which a person subject to an inspection may object prior to that inspection. As discussed in response to comment 171 of this document, FDA plans to issue a guidance document regarding the record access provisions.

M. Comments on What Records Are Excluded From This Subpart? (Proposed § 1.362)

(Comment 153) Several comments express concern that information that FDA would view, copy, or otherwise access could contain confidential information, such as confidential commercial or trade secret information. Two comments ask FDA to permit a person subject to the requirements of section 414 of the FD&C Act to redact what they consider to be nonpublic information from records properly sought by FDA. One comment asks FDA to permit a person to create a separate document containing only that information FDA is entitled to inspect. Examples of confidential information that comments have described include formulas, recipes, information about their businesses, where the product was purchased or sold, product development information, and location and business operations of farms.

One comment requests that FDA allow the affected person to either redact confidential information from the source records (purchase orders, bills of lading, etc.), or create separate records containing the information required by section 414 of the FD&C Act, but not including the information excluded by § 1.362 of this final rule or any other confidential information.

(Response) FDA understands the comments' concerns about protecting the confidentiality of nonpublic information. If a person wishes to create separate records that do not contain certain confidential information, the person may do so, as long as the records are created at the time the food is received or released and the records contain the information required by the regulations. In addition, section 306 of the Bioterrorism Act excludes many types of confidential data from the record requirements: Recipes for food (see § 1.328 for the definition of recipe),

financial data, pricing data, personnel data, research data, and sales data (other than shipment data regarding sales). Section 306 of the Bioterrorism Act, however, does not allow other types of confidential data to be withheld from FDA even if they are confidential. The laws governing FDA's activities, however, require it to protect certain trade secret and confidential information. See responses to comments 74 and 154 of this document.

Further, because timely information is critical to a tracing investigation, records and other information must be made available to FDA as soon as possible, not to exceed 24 hours from the time of a request (§ 1.361 of this final rule). If the provision of information and records to FDA is delayed so that information can be redacted, the information and records may not have been provided ''as soon as possible.''

(Comment 154) Comments ask that FDA take steps to maintain the confidentiality of the information it receives. One comment asks that FDA develop and inform the public of procedural safeguards it will follow to obtain the information needed without jeopardizing the confidentiality of business information. Two comments ask that FDA provide guidance about its information disclosure procedures. Other comments ask how FDA will ensure the confidentiality of sensitive business information.

Comments ask that FDA provide for special procedures to safeguard the confidentiality of the identities of flavors and spices and other secret ingredients in a recipe. Two comments request that FDA issue a regulation and another comment suggests that FDA issue an interim final regulation concerning the statutory requirement under section 414(c) of the FD&C Act to prevent unauthorized disclosure of any trade secret or confidential information.

A comment asks that FDA provide a paragraph in a regulation requiring that FDA maintain the confidentiality of nonpublic information. That comment expresses concern about information FDA might receive from an ''unaffected source,'' ''incorrectly implicated sources'' in the distribution chain, or the identity of a food company that was the victim of ''food contamination in premeditated form.'' A comment asks that FDA amend its public information regulations to provide that information obtained under the records access authority is exempt from disclosure under FOIA.

(Response) As discussed in response to comment 74, several statutes and the agency's information disclosure regulations at parts 20 and 21 govern the agency's ability to disclose information to the public, including information obtained under section 306 of the Bioterrorism Act. For example, section 301 of the FD&C Act prohibits any person from using

> * * * to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts * * *, any information acquired under authority of [section 414 or 704] concerning any method or process which as a trade secret is entitled to protection * * *.

FDA already has procedures in place to ensure that FDA staff follow these laws. See, e.g., FDA Staff Manual Guide sections 2280.10, 3250.15, and 3291.5. Furthermore, the record provisions in the Bioterrorism Act recognize that FDA may obtain trade secret or confidential information, and direct the Secretary to ''* * * take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of [such information] * * *'' (21 U.S.C. 414(c)). FDA is planning to reemphasize in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained.

FDA has previously issued information disclosure regulations applicable to information FDA obtains, and these regulations are applicable to information FDA obtains under the Bioterrorism Act (parts 20 and 21). FDA notes that these regulations are applicable regardless of whether the person supplying the information is ultimately determined to be an ''unaffected source,'' ''incorrectly implicated source,'' or the victim of ''food contaminated in premeditated form.'' Therefore, it is not necessary for FDA to issue additional information disclosure regulations.

Moreover, FDA routinely reviews, evaluates, investigates and maintains confidential, trade secret information that encompasses sophisticated, cutting edge technologies, as well as confidential records that contain formulations and other trade secret information. Based upon FDA's track record of consistently ensuring the confidentiality of this type of information, we have attained the trust of the pharmaceutical, medical device and biologics industries. Moreover, the utilization of such information by an FDA employee for his or her own advantage, or the revelation of such information to outside parties beyond the scope allowed by the FD&C Act, is a prohibited act (21 U.S.C. 331(j)) subject to criminal prosecution.

(Comment 155) One comment asks that FDA not disclose personal details (name of responsible person) about secondary suppliers. The comment notes that disclosure of personal details of secondary supplies might be contrary to international and European privacy regulations. One comment notes that disclosure to the public of the names of the firm and the responsible individual might conflict with foreign confidentiality rules of law. Other comments express concern about protecting personal privacy information. Another comment states that farmers are concerned about the effect of possible information disclosure on the personal and physical security of their farms where they reside with their families.

(Response) Foreign persons, except for those who transport food in the United States, are exempt from all of the requirements in subpart J of this final rule. Farms are also exempt. FDA follows Federal statutes (e.g., FOIA, the Privacy Act) and its regulations (e.g., parts 20 and 21) in determining the proper treatment of information it receives, including personal information. FOIA, for example, contains exemptions that allow FDA to withhold personal information from the public in certain circumstances (5 U.S.C. 552(b)(6) and (b)(7)).

(Comment 156) A few comments ask what assurances FDA can give to a person subject to the Bioterrorism Act that the information will not be subject to unauthorized disclosure. Other comments ask that CBP and FDA guarantee nondisclosure of the information. A comment asks how FDA can guarantee the confidentiality of confidential and secret information such as formulas.

(Response) FDA complies with Federal law (e.g., the FD&C Act, FOIA, Trade Secrets Act) and regulations (e.g., parts 20 and 21) regarding the dissemination of the information it receives. FDA employees are subject to criminal penalties for disclosing information in violation of section 301(j) of the FD&C Act or the Trade Secrets Act. FDA plans to reemphasize to its field personnel the importance of current protections and legal requirements against unauthorized disclosure of any protected information FDA obtains.

(Comment 157) A comment concerned about adverse publicity asks with whom might FDA share information.

(Response) FDA is authorized to share certain nonpublic information with others. For example, FDA may share confidential commercial information with a sister agency within the

Department of Health and Human Services, a State government agency official whom FDA has commissioned to act on its behalf under section 702 of the FD&C Act (21 U.S.C. 372) (§ 20.84), its contractors (§ 20.90), other Federal government agencies (§ 20.85), or foreign government agencies (§ 20.89). Procedural and other safeguards must be followed for FDA to share nonpublic information with other persons. For FDA to share confidential commercial information with CBP under § 20.85, CBP must sign a written agreement that it will not further disclose the information except with FDA's written permission.

(Comment 158) Several comments express concern about the risk of disclosure of information about a formula or recipe. One of these comments noted that, even if the complete formula may not be disclosed, listing the source of each ingredient in a product would reveal the recipe for that product. Other comments ask how FDA would handle commercially sensitive information that might be derived if FDA provides information about a ''one-up'' source nontransporter for each of the ingredients in a recipe.

(Response) As discussed in response to comment 74 of this document, several statutes and the agency's information disclosure regulations at parts 20 and 21 govern the agency's ability to disclose information to the public, including information obtained under section 306 of the Bioterrorism Act. For example, section 301 of the FD&C Act prohibits any person from using

> * * * to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts * * *, any information acquired under authority of [section 414 or 704] concerning any method or process which as a trade secret is entitled to protection * * *.

FDA follows these laws in determining the proper treatment of the information it receives.

N. Comments on What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required by This Subpart?'' (Proposed § 1.363)

(Comment 159) Three comments state that imposition of criminal liability would be inappropriate and excessive if they performed to the best of their abilities. The comments state that taking time beyond 4 hours to locate, compile, and provide records on a detained article's manufacture should not be viewed as a prohibited act.

(Response) As noted previously, FDA has changed the proposed times in § 1.361 of this final rule for responding to a request for access to records to a requirement that all records be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request. Failure to establish or maintain records or refusal to permit access to or verification or copying of any record is a prohibited act under section 301 of the FD&C Act.

(Comment 160) One comment states that the rules on recordkeeping are not enforceable outside the United States. The comment states that any legal proceedings based on failure to comply with the final rule that could result in confiscation of assets held in the United States or action against foreign executives visiting U.S. territory would be considered by a foreign country to be a very grave step. This would be unworkable in practice and problematic in terms of bilateral relations. The comment requests that FDA clarify that no enforcement action will be taken against foreign persons outside the United States.

(Response) Foreign persons, except those who transport food in the United States, are not subject to subpart J of this final rule and thus, for the most part, the concerns raised by the comment are moot. If FDA needs to access records kept by foreign persons, FDA intends to work in cooperation with the relevant competent authorities to do so.

(Comment 161) One comment encourages FDA not to use incidental infractions of its final recordkeeping regulations as a pretext for bringing additional enforcement actions for alleged violations of other agency regulations that are outside the scope of the Bioterrorism Act.

(Response) Nothing in the proposed or final rule suggests that FDA would take such actions.

O. Comments on What Are the Compliance Dates for This Subpart? (Proposed § 1.368)

(Comment 162) Many comments strongly urge FDA to revise the compliance dates in the proposed rule. The comments state that given the scope of the proposed requirements it is not possible for industry to be in compliance within the 6, 12, or 18 months proposed by FDA. The comments state that each of the new requirements imposes programming, training, and business practice adjustments that FDA must take this into account in setting an appropriate effective date for the regulation. The recommendations that FDA received from comments are as follows: 9 to 12 months for larger businesses; 1 year regardless of the size of the business; 18 months regardless of the size of the business; 18 months for large firms and 24 to 30 months for smaller firms, depending on their numbers of employees; an additional 1 year for each entity group; and 2 to 7 additional years.

(Response) FDA has carefully considered these comments and agrees that businesses should be given additional time to comply in view of the programming, training, and business practice adjustments that will be needed. Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance within December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance within June 9, 2005, and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance within December 11, 2006. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment. FDA does not believe that extending more time is appropriate given the need for the regulations to help improve FDA's ability to address credible threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the information will enable FDA to notify more quickly the consumers and/or facilities that might be affected by the outbreak.

Further, the Bioterrorism Act directs FDA to take into account the size of a business in promulgating regulations. Consistent with this provision, FDA has: (1) Provided a full exemption for very small retailers based on the rationale stated previously; (2) provided a partial exemption for small (11 to 500 employees) and large (more than 500 employees) retailers from having to establish and maintain records as to immediate subsequent recipients; and (3) provided extended compliance times for very small businesses and small businesses in all sectors.

(Comment 163) Some comments state that the transportation chain information requirements, by themselves, are so complex they simply cannot be developed in such a short timeframe even if industry were not dealing with several other major security-related regulatory efforts under the Trade Act of 2002 and the Maritime Transportation Security Act of 2002.

The comments ask FDA to require more reasonable timetables that would be less costly and have a more realistic chance of successful compliance.

(Response) As stated in the response to the comment 162, FDA has modified the compliance timeframes proposed. The final rule gives covered persons 12, 18, or 24 months after the date of publication to come into compliance, depending on the size of the business. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment.

(Comment 164) Several comments state that the food distribution chain is comprised of multiple links or components, some of which will qualify as small or very small businesses, such as independent truck operators or some DSD operations. For example, some large national baked goods companies deliver products directly to stores through individuals who function as independent businesses (e.g., they own their own trucks, purchase the food from the vendor and sell it to the store, and hold licenses to the particular delivery routes). The comments state that, if these businesses are covered by the small business exemption, they will not be required to provide the information that larger businesses will be required to retain. The comments recommend that FDA either extend the exemption through all subsequent links in the distribution chain, or else recognize the interconnectedness of the systems and impose a single, more realistic compliance date with which all in the food distribution chain will be able to comply, e.g., establish a universal compliance date for the regulations of June 9, 2005.

(Response) FDA does not agree that all businesses should be subject to a universal compliance date. FDA has considered the interconnectedness of the food distribution system and contractual relationships that exist between very small, small, and large businesses. FDA has determined that large, small, and very small businesses will have 12, 18, and 24 months, respectively, from the date of publication of this final rule, with which to comply. These timeframes represent an extra 6 months over the timeframes in the proposed rule for all business sizes to come into compliance. FDA believes that many large businesses and possibly many small businesses already establish and maintain records that contain most or all of the information required by these regulations, and thus should not require longer than 12 and 18 months, respectively, to come into compliance. Very small firms would have 24 months to comply.

FDA anticipates that the very small and small businesses will be able to lower their compliance costs by learning from the experience of the large businesses. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment.

(Comment 165) One comment notes that small businesses doing business with large businesses would have to comply with the large business timeframe and asks FDA to reconsider this exception, and allow small businesses to comply on the 12 and 18 month schedule.

(Response) FDA has considered the interconnectedness of the food distribution system and contractual relationships that exist between very small, small, and large businesses. FDA has determined that small and very small businesses will have 18 and 24 months, respectively (not the 12 and 18 months that were proposed that the comment alludes to) to comply with the regulations, regardless of whether they are engaged in doing business with large firms.

(Comment 166) Several comments express support for the different implementation dates based on the size of a business. The comments state that the extra time will ensure that small businesses have adequate time to understand the new rules, reorganize their administrative recordkeeping, and spread the costs of the new rules over a greater volume of their (limited) production. In addition, within the first year of implementation, the comments note that the larger companies and FDA will resolve many of the problems that will arise with the new rules. The comments maintain that large companies are better able to adjust to any problems than are small businesses.

(Response) FDA agrees with this comment, and for the reasons stated in the preceding paragraphs, has modified the compliance dates and extended each of the proposed compliance dates by an additional 6 months.

(Comment 167) Several comments request that FDA clarify the method used to determine business size for deciding the timeframe for compliance. The comments ask whether a company's size is determined based on all employees of the parent company, the entire corporation as a whole, or upon each individual enterprise or location or manufacturing facility. The comments also question how full- and part-time employees are counted.

(Response) The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(Comment 198) Some comments state that the criterion used to determine small and very small businesses is the number of employees, whereas in other countries, especially the developing ones, other criteria are used to better reflect the nature of the businesses. The comments ask FDA whether the value of investment and value of assets can be considered as other criteria in determining if a business meets the definition of a small or very small business in order to be allowed extended time to comply with the regulations. The comments also ask FDA to consider factors such as production capacity and production value for labor-dense firms such as in China, where the production rate per person is lower than that in the United States.

(Response) FDA continues to believe it is appropriate to use the number of full-time-equivalent employees as a criterion to differentiate between very small, small, and large businesses. This is consistent with other regulations the agency has issued where staggered compliance dates were utilized, e.g., the juice HACCP regulation (21 CFR 120.1(a)).

(Comment 169) Two comments ask FDA to phase in enforcement of these provisions once the regulations are in effect, especially as to the critical elements of the regulation. One of the comments requests that FDA allow a grace period of 1 year before enforcing any of the rule's requirements against any organization that is taking good faith steps to achieve compliance.

(Response) Rather than phase in enforcement, FDA has extended the compliance dates for all covered persons subject to this final rule. The earliest that covered persons would have to be in compliance is 1 year for large firms, and the latest is as much as 2 years for very small firms.

(Comment 170) Two comments ask whether the staggered timeframes apply to foreign businesses of varying sizes.

(Response) Foreign persons, except for those who transport food in the United States, are not subject to the recordkeeping regulations in this final

rule. For foreign persons who transport food in the United States, the staggered compliance dates based on size of business applies.

(Comment 171) Two comments ask how the proposed rule affects long shelflife products prepared before the introduction of the new rule still in storage when full compliance is required. Is the rule retroactive or does it apply to food manufacturers from the date of full compliance?

(Response) Once applicable compliance dates occur, covered persons must establish and maintain records. As explained previously, records must be created at the times you receive and release the food. Persons do not need to keep records of the immediate previous sources of food if that food is received before the compliance date of the rule. Likewise, persons do not need to keep records of the immediate subsequent recipients if that food is released before the compliance date of subpart J of this final rule.

(Comment 172) One comment states that implementation may prove to be a major barrier to foreign shipments due to the additional strains and demands upon communication systems, port and airport facilities, and on the inspection infrastructure. The comment also states that it may overlap with the beginning of the fresh fruit export season.

(Response) Foreign persons, except those who transport food in the United States, are not subject to this final rule; however, persons that import food from foreign countries are subject to the rule. FDA believes that the compliance timeframes specified in § 1.368 of this final rule give all persons subject to this final rule, including importers, sufficient time to determine what steps are needed to be able to comply with the final rule, and to be in compliance on their respective compliance dates, while allowing FDA to meet its statutory objective of ensuring that persons that manufacture, process, pack, hold, transport, distribute, receive, or import food in the United States establish and maintain records that will significantly improve FDA's ability to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 173) One comment states that the proposed delay in the compliance date for small businesses does not adequately address small business needs. One comment states that FDA should provide businesses with additional assistance with compliance.

(Response) FDA has increased the compliance period for small businesses from 12 months to 18 months, and for very small businesses from 18 months to 24 months. With respect to additional assistance, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), FDA plans to publish a small entities compliance guide to assist small and very small businesses with complying with the recordkeeping requirements. As described previously, FDA also plans to conduct outreach activities to explain the requirements of this final rule to affected entities.

(Comment 174) One comment states that the phase-in for small and very small businesses is not a good idea because if the consequences are as grave as FDA claims, everyone must be required to comply at the earliest possible time, allowing for systems and procedural development and employee training. The comment states that a phase-in of the regulations would pose a threat to public health and safety, should not be part of this regulation, and would be against the public interest.

(Response) The Bioterrorism Act specifically states that, in issuing these regulations, the Secretary shall take the size of a business into account. FDA considered reduced requirements for, or even exempting, small businesses. However, most food products and ingredients pass through at least one small business during commerce. In addition, more than 80 percent of the covered entities are considered very small businesses. If FDA were to exempt small businesses from these regulations, permit shorter record retention periods, or subject them to reduced records requirements, FDA's tracing investigations would be severely compromised. Given the foregoing, FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

(Comment 175) A few comments point out that the burden for maintaining records is proportionately similar for large transporter companies and small independent transporters. Therefore, according to the comments, the relative regulatory burden for small, independent transporters is no greater than for large companies. The comments contend that all carriers, regardless of the size of the company, should be required to comply with the same requirements on the same timetable.

(Response) As stated previously, the Bioterrorism Act specifically states that, in issuing these regulations, the Secretary shall take the size of a business into account. FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

IV. Analysis of Economic Impacts—Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

This final regulatory impact analysis reflects changes made in the regulation from the proposed rule to the final rule, as well as changes in estimates in response to comments. It also includes responses to comments on the preliminary regulatory impact analysis (PRIA) (see 68 FR 25188). Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA for a fuller explanation of the estimates over which there were no significant comments or changes. As noted in the previous section of this preamble, FDA received 212 submissions in response to the proposed rule, which raised over 200 issues. We continue with the discussion of the comments and FDA's responses to those comments using the same presentation as in section III of this document, focusing here on the comments FDA received on the PRIA. Accordingly, the word ''Comment'' again will appear in parenthesis before the description of the comment, and the word ''Response'' will appear in parenthesis before FDA's response.

A. Summary of the Costs and Benefits of the Final Rule

We revised the estimated costs of the final rule in response to comments on the proposed rule and to account for the changes between the proposed and final rules. The final rule will cover more

than 1 million entities at a cost of approximately $1.41 billion in present value with a 7-percent discount rate. With a discount rate of 3 percent, the estimated present value of the costs is approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the rule beginning in the second year for large and small firms, and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The total cost estimate can be computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 1 of this document. The recurring annual costs of the final rule (the sum of additional records maintenance and learning for new firms) are about $123 million. The annualized costs of this final rule are $108,000 using a 3-percent discount rate and $110,000 using a 7-percent discount rate.

TABLE 1.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,200
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.
[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during foodborne outbreaks by reducing the time required for preventive action. Furthermore, the final rule will eliminate the recurrence of outbreaks that may have been prevented had poor records quality not resulted in prematurely terminating the initial traceback investigation. The number of illnesses prevented (excluded those associated with food security will be approximately 1,204. The food safety benefits reported in the table are the values of averted illnesses from increased food safety. Averted illnesses are valued by low, middle, and high cost of illness estimates for both $5 million and $6.5 million values of a statistical life. The estimated annual benefits from enhanced food safety range from $7 million to $25 million. These estimates should be interpreted as the minimum benefits from this final rule because they do not include the benefits from enhanced food security.

TABLE 2.—VALUE OF AVERTED ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

B. Description of Proposed Rule

The proposed rule required the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States and also by certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The proposed regulations would implement section 306 of the Bioterrorism Act. FDA expected that the requirements the agency proposed would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

C. General Comments

(Comment 176) FDA received a number of comments that asserted that the costs of the proposed rule were incorrectly estimated.

(Response) If the comment asserted costs or benefits were incorrectly estimated without specifying which costs or benefits, there was not sufficient information for FDA to respond. Comments that specified which costs or benefits the comments believed were incorrectly estimated are addressed in later sections of this analysis.

(Comment 177) There were several general comments that the costs that result from the rule are too high and would result in the failure of enterprises and small businesses.

(Response) In the PRIA, FDA estimated the impacts of the costs of compliance on small businesses using FDA's small business model using a cash flow metric (Ref. 1). In this

analysis, we use the small business model to calculate the effects on small businesses using the difference between revenue and variable cost as the metric. A finding that firms incur costs greater than revenues as a result of this rule can be interpreted to mean that they may be driven out of business. We incorporated both the annualized value of one-time costs and the recurring costs for computing the effects of this final rule on small firms.

We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes in current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will incur negative cash flows (defined as revenues less than variable costs) as a result of this rule. The percentages of firms predicted to incur negative cash flows range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule.

D. The Tradeoff Between Costs and Risk Reduction

(Comment 178) Many comments argue that the benefits from the rule do not justify the costs to the food industry. Another comment states that it remains doubtful that the benefits from the regulation justify the costs, while another comment expressed the need for a proper model to compare the costs of the recordkeeping provisions with a measure of the risks averted from the provisions.

(Response) FDA agrees that the measure of the net benefits used to justify the regulation remains uncertain. A large portion of the uncertainty arises from FDA's inability to quantify the benefits from the regulation. In the PRIA, we used epidemiological evidence from four outbreaks to suggest qualitative results.

In the final rule, we develop a more comprehensive and detailed model to estimate the food safety benefits using information generated from FDA outbreak investigations (Ref. 2). We use this information to estimate the number of illnesses averted as improved recordkeeping practices lead to faster traceback investigations and higher rates of successful traceback completions. These estimates understate the true expected benefits from the rule, because they are derived solely from food safety data and do not take into account the expected benefits of this rule to food security. The estimate of strictly food security benefits is based on classified data and is not used in this analysis. A qualitative description of the security benefits is provided below under section IV.E.1 of this document, entitled ''Bioterrorism Considerations''.

Although benefit-cost analysis is primarily a quantitative exercise, the existence of non-quantified benefits and costs, as well as uncertainty around the quantified measures, means that assessing whether costs justify benefits entails a qualitative element. Decision aids such as uncertainty analyses are used to help decision makers in these instances.

(Comment 179) There were several comments stating that the costs of compliance for specific sectors, including foreign facilities, food contact suppliers, and transportation facilities, did not justify the benefits of reducing the risks of contamination posed by those sectors.

(Response) In the final analysis that follows, we refine the analysis of the benefits of selected policy options including those expected from foreign firms, food contact substance suppliers, and transportation facilities.

(Comment 180) One comment states the need to measure benefits from the regulation against the existing traceback and recall capability of the industry. This comment questions whether the provisions in the recordkeeping rule would improve response times for removing product from the market, and potentially reduce the number of illnesses from a foodborne outbreak. The comment suggests that FDA should consider what the savings would be in anticipated response times and records recovery times, as well as how this would translate into a reduction in illnesses and enhanced product recovery. Finally, the comment states that the burdensome exercise to produce records could actually slow and hinder the objectives of recalling a suspected product.

(Response) FDA agrees with the comment that a model is needed to determine the savings in investigation traceback times, and the numbers of illnesses that would be avoided from this regulation. FDA has developed a model of the benefits, which is described later in this section. However, FDA does not agree that the benefits should be compared to the current system for recalling products since few investigations result in recalls. Instead, FDA believes that benefits from this final rule will primarily be from faster investigations leading up to preventive actions, including recalls. A recall or other preventive action is made only after a product has been implicated. The benefits from the recordkeeping rule are to improve the accuracy and speed with which a product is implicated. If recalls or other preventive actions are made too quickly and cover too wide a range of products, there is the very real danger of a recurrence of the outbreak if the source is not investigated. For that reason, the benefits from the regulation include not only faster traceback investigation times, but also higher rates of completed traceback investigations, and the commensurate reduction in outbreak recurrences.

(Comment 181) One comment states that the analysis failed to meet Office of Management and Budget (OMB) guidelines for regulatory impact analysis by failing to do the following: (1) Adequately consider the need and consequences of the regulation and (2) show that the benefits outweigh the costs of the regulation. In addition, the comment states that the purpose of the regulation is to expand the agency's jurisdiction, rather than to maximize the net benefits to society, and that alternatives with the highest net benefits (including the alternative not to regulate) were not chosen. Finally, the comment states that the analysis failed to consider the condition of the affected food industries, potential future regulatory actions, and the weak state of the national economy as required.

(Response) In the PRIA, we stated that the need for these regulations is to enable FDA to respond to, and help contain, food for which the agency has a reasonable belief that it is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. In the final rule we bolster the explanation of the need for the regulation by analyzing vulnerabilities due to shortfalls in current recordkeeping practices. These shortfalls are shown to inhibit current outbreak investigation efforts and, by extension, efforts to mitigate serious adverse health consequences or death to humans or animals. The perceived vulnerability of the U.S. food supply to an attack, as articulated by Congressional passage of the

Bioterrorism Act, elevates the importance of addressing these shortfalls.

The analysis of the benefits of the final rule uses characteristics of conventional outbreaks and investigations to more clearly identify and quantify shortfalls in existing recordkeeping practices and how each is addressed by the recordkeeping regulation. We measure the effects in terms of the number of illnesses averted due to reductions in the duration of outbreak investigations and reductions in the number of investigations that are prematurely terminated because of poor records quality. When an investigation is prematurely terminated, there is both a loss of data that might prevent recurrences of the outbreak and a decrease in the effectiveness of any preventive action. The need for this regulation is underscored when the potentially large sizes of outbreaks from intentional attacks on the food supply are considered. Although the probability of such an intentional attack is unknown, the size of the benefits from this regulation are larger, the larger the size of such an outbreak.

We estimate benefits using data from FDA outbreak investigations. We then compared estimated benefits for a number of regulatory options. In this way, the benefits of each regulatory option can be compared to its costs. While the costs and benefits of the policy alternative ''not to regulate'' are not considered in the final rule, they were analyzed in the proposed rule. We did not estimate the effects of potential future regulatory actions because we do not anticipate any such actions that would affect the estimated costs or benefits of this final rule.

In response to the comment that we have not shown that benefits exceed costs, the Executive Order requires that costs must be justified by benefits. We believe we have done so in this analysis. Finally, in the PRIA, FDA addressed the state of the national economy by examining the impact of the final rule on the most vulnerable firms in the industry, through simulations using our small business model (Ref 1.), and also in the Unfunded Mandates section by examining the impact of the rule on all consumers as well as producers in the food economy in general.

In this analysis we use the small business model to calculate the effects of the costs of this final rule on the survival of small businesses. We incorporated both the annualized one-time costs and the recurring costs for computing the effects on cash flows. We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will shut down as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

E. Estimating the Benefits

The benefits from the recordkeeping rule will be from illnesses averted due to faster traceback components of outbreak investigations, and an increased ability to complete investigations that previously would have been prematurely terminated due to poor records quality. Because of this new recordkeeping rule, a greater number of traceback investigations will be completed, and traceback investigations will take less time because of shorter records access times and better records quality.

The benefits estimated in this analysis are realized only in the event of a foodborne outbreak (intentional or unintentional) because the probability of a terrorist attack is unknown. However, the estimated costs are incurred at all times regardless of whether there is an outbreak investigation underway, as well as by all facilities, regardless of whether they are implicated in the outbreak.

1. Bioterrorism Considerations

Interviews with FDA traceback personnel indicate that traceback and source investigations involving fresh produce find that the contamination often occurs at the farm level (Ref. 2). The interviews suggest that bioterrorism scenarios envision possible intentional contaminations on the farm, in distribution, at processing, and at retail. Moreover, fresh products may be more likely targeted for intentional contamination when they are at intermediate levels of processing than when they are at the farm level.

The benefits from the recordkeeping rule are from enhanced food safety and enhanced food security. We can estimate the food safety benefits, but we cannot estimate the food security benefits, as the probability of the occurrence of a deliberate outbreak is unknown. The tangible benefits from the recordkeeping rule occur after an outbreak of food-related illness. With the records required by this rule, the agency can investigate outbreaks more quickly and will not be forced to terminate an investigation because of poor or nonexistent records. The speeding up of investigations generates benefits in some cases because the information from the records will enable the agency to take actions to reduce the size of the outbreak. Both the increased completion rate and faster investigations may reveal more sources of outbreaks and help to prevent recurrences.

The food security benefits of recordkeeping come from mitigating a terrorist attack on the food supply, and preventing unnecessary expense in the event of a hoax or a small terrorist event. While we are unable to estimate the benefits from such scenarios, we can point to investigative speed as a principal mechanism for mitigating their costs. The first benefit—mitigating the effects of an attack—is similar to the food safety benefit. Investigations will be quicker because of better records. Investigation speed may be crucial in the early period after a terrorist attack to more quickly determine the likely scope and scale of the contamination. With quicker investigations, the government can act sooner to reduce the public health and other effects of a terrorist attack on the food supply. These benefits should be qualitatively the same as in the case of an accidental outbreak of food-related illness, but we expect them to be potentially larger for a terrorist attack on the food supply.

The second counterterrorism benefit from recordkeeping is also difficult to quantify but may be important: the ability to identify quickly a potential food security hoax. The hoax could be completely false, or it could be a small event masquerading as a large event. For example, a terrorist could contaminate a single container of some food and send out an Internet message stating that the entire national stock of that food was contaminated. If the goal is to spread terror rather than to cause mass illness, then a small attack or even an Internet announcement with no contaminated products could persuade consumers that the risk is real.

With a sufficiently plausible background story implicating a widely-consumed food, the hoax might lead to

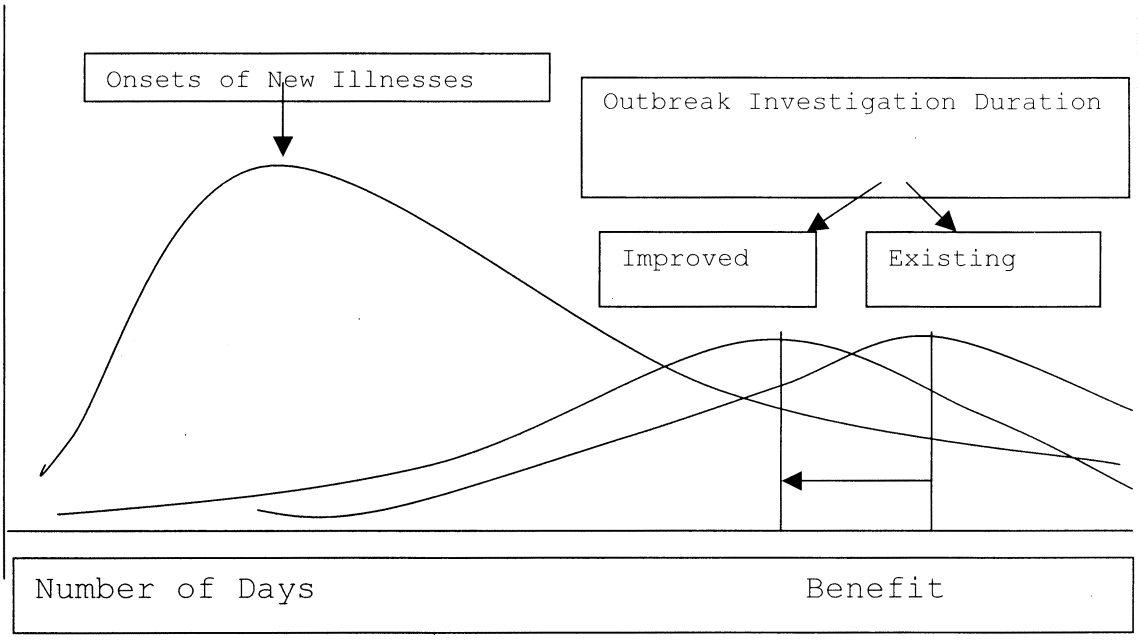
extensive protective efforts by businesses and consumers. Consumers might take costly preventive actions, such as throwing away food, stopping their consumption of the suspect food item, or visiting physicians or emergency rooms to determine if they have been exposed to some hazard. Producers and distributors might destroy inventories of the suspect food as a preventive measure. If there is widespread uncertainty about the extent of contamination, this protective behavior could easily generate high costs. If the terrorist attack on a food is a small-scale event masquerading as a national event, a full system of records will allow the agency to trace the suspect foods through the food chain to determine the extent of contamination. The government could quickly narrow down the range of suspect foods and, if the risk is absent, reassure the public that the suspect foods are indeed free of contamination by terrorists. The ability to move quickly and authoritatively will possibly generate real benefits by preventing costly defensive actions by businesses and consumers.

2. Benefits: Model Framework

The primary food safety benefits from this rule are from the number of illnesses averted due to improved recordkeeping practices. Improved recordkeeping practices result in faster traceback investigations and higher traceback completion rates, which will reduce the expected number of illnesses from intentional and unintentional outbreaks.

The following diagram visually depicts the benefits from faster traceback times from the recordkeeping rule. The number of onsets of new illnesses and outbreak investigation duration curves overlap to estimate the number of days that an investigation is likely to reduce the duration of an outbreak. With faster traceback times, the distribution of the durations of outbreak investigations shifts to the left from ''existing'' to ''improved,'' reducing even further the number of days of an outbreak. This diagram assumes the outbreak is still going on at the time the traceback investigation begins. The reduced number of days of an outbreak can then be translated into a reduced number of illnesses from an outbreak.

Figure 1: The Distributions of the Onsets of New Illnesses Over Time During an Outbreak, and the Duration of an Outbreak Investigation.



There are two ways that the recordkeeping rule speeds up traceback investigations: (1) Higher records quality means that traceback investigators spend less time trying to find and analyze information that might have been missing or incomplete had there been no rule and (2) the rule makes failure to provide records within the required time period a violation, thus increasing cooperation with investigators who need rapid access to records. Greater traceback speeds result in more recalls (if the product is still in the marketplace), administrative detentions (under section 303 of the Bioterrorism Act), import actions, closures, and other preventive actions that reduce the number of illnesses during an outbreak. The following is a description of the model used to measure the benefits from the recordkeeping rule.

i. *Given the speed of the initial recognition and epidemiological investigation of an outbreak, the benefits from the recordkeeping rule*

depend on the following factors: (1) the average duration of a traceback investigation, (2) the average number of traceback investigations prematurely terminated for reasons of poor records quality, and (3) the distributions of outbreak durations and sizes.

ii. *The average duration of a traceback investigation depends on the number of point-of-service and distributor investigative visits per traceback investigation, and the average duration of an investigative visit*. The quantity of records that needs to be reviewed is an important determinant of the duration of a traceback investigation. However, we assume that the change in the quantity of records requested is much smaller than the change in the quality of the records requested as a result of this final rule. We therefore omit the quantity of records reviewed during a traceback investigation as a modeling consideration when measuring the impact of the final rule.

iii. *Because traceability information, such as lot codes, may be readily identified on the label of packaged products but is largely absent for fresh produce, the average number of investigative visits per outbreak may depend on the food category (e.g., fresh and packaged) of the contamination source*.

iv. *The average duration of an investigative visit depends on the following factors*: Average records access times, which depend in part on how records are stored and maintained; average travel times and overnight stays required to complete an investigative visit; and average records analysis times. The time required to analyze records depends on the quality of the records.

v. *The rate that traceback investigations are prematurely terminated due to poor records quality will decline as the average quality of records improves*. This improvement will reduce the number of outbreaks that result from recurring contaminations that may otherwise have been prevented.

vi. *The size, contaminating agent, and duration of an outbreak determines the number of illnesses averted from faster preventive action and higher success rates of traceback completion*. The value of the averted illnesses is the averted medical expenses, and the averted loss in welfare, including pain, suffering, and productivity that would otherwise result from the illness.

Thus, the model may be summarized as the following:

i. *Benefits are determined by*: (1) The sizes of outbreaks, and the nature of contaminating agents, which determine the baseline number and severity of illnesses potentially averted; (2) the reduced time needed to complete a traceback investigation, which reduces the number of illnesses by allowing faster preventive action; and (3) the increased rates of successful traceback completion, which reduce the number of illnesses that result from outbreak recurrences.

ii. Time to complete a traceback investigation is determined by the time needed to complete an investigative visit, and the number of investigative visits.

iii. *Time to complete an investigative visit is determined by the record access times, and the record analysis times*.

iv. *Record analysis times are determined by records quality (we ignore the quantity of records requested on the assumption that the changes in the quantity resulting from this final rule will be negligible compared with changes in the quality)*.

v. *The rate of successfully completed traceback investigations is determined by the quality of the records*.

vi. *The value of the averted illnesses is computed by adding together the estimated value of averted healthy life days lost, and the averted medical expenses due to the illness*.

3. Data on Outbreak Sizes, Durations, and Contaminating Agents

Data used to estimate the numbers of illnesses, contaminating agents, and outbreak durations are taken from FDA information documenting investigations monitored by the agency from 2000-2003 (Ref. 2). The investigation information is drawn from multiple, non-standardized sources that irregularly document different aspects of investigations. The number of investigations reported in the table is not exhaustive; more investigations may be documented elsewhere. Moreover, it is possible that the information does not perfectly reflect the universe of FDA outbreak investigations because the methods for its collection and distribution are non-standardized. Nevertheless, we believe the information is sufficiently accurate, and that the list of outbreaks is sufficiently exhaustive for purposes of estimating the benefits from the recordkeeping final rule.

The outbreak duration is calculated as the time between the first and last illness, and the sizes of the outbreaks are calculated as the numbers of known illnesses attributed to an outbreak. The charts that follow depict the sizes and durations of the outbreaks from 2000 to 2003 as estimated from FDA outbreak investigation data.

Chart 1:

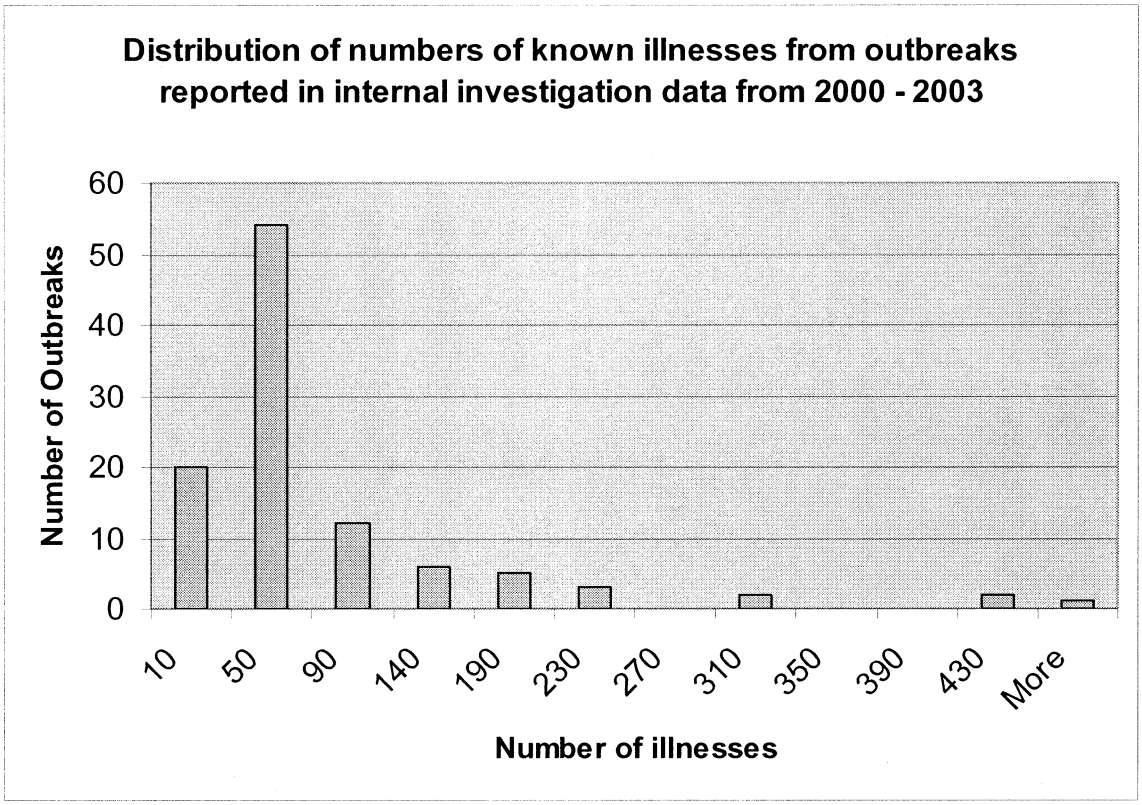
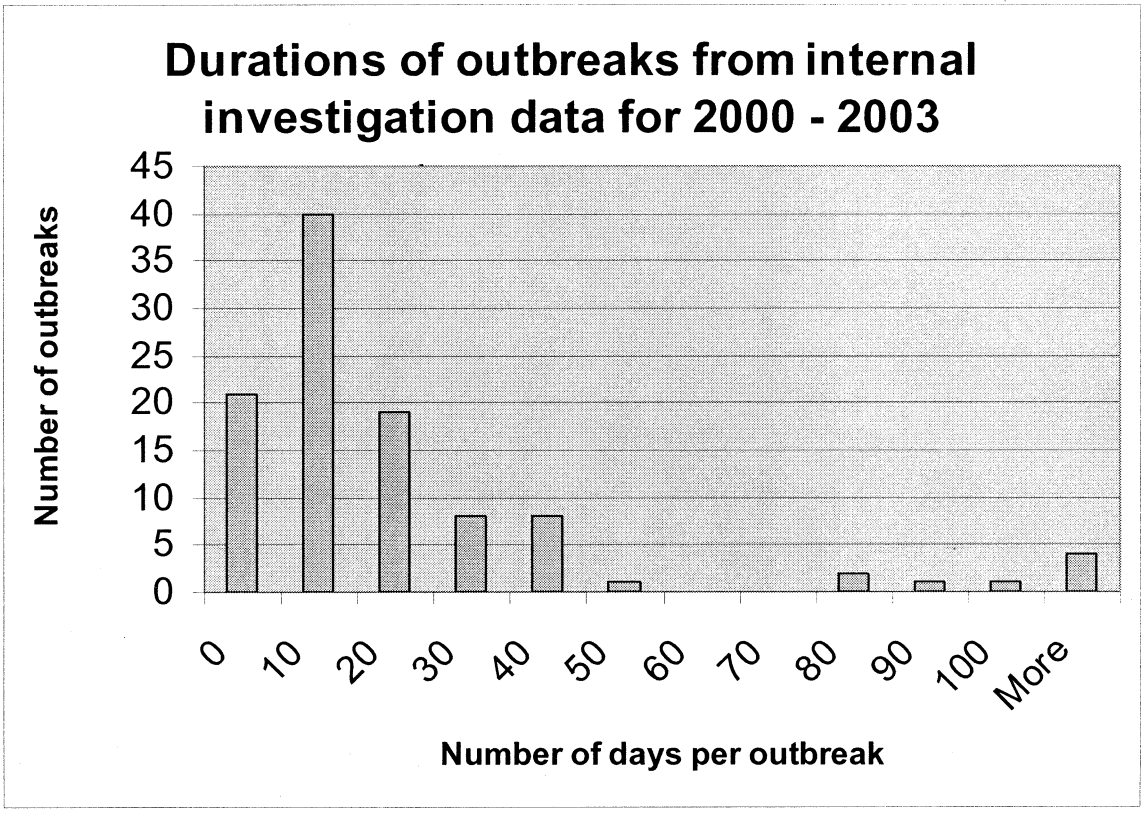
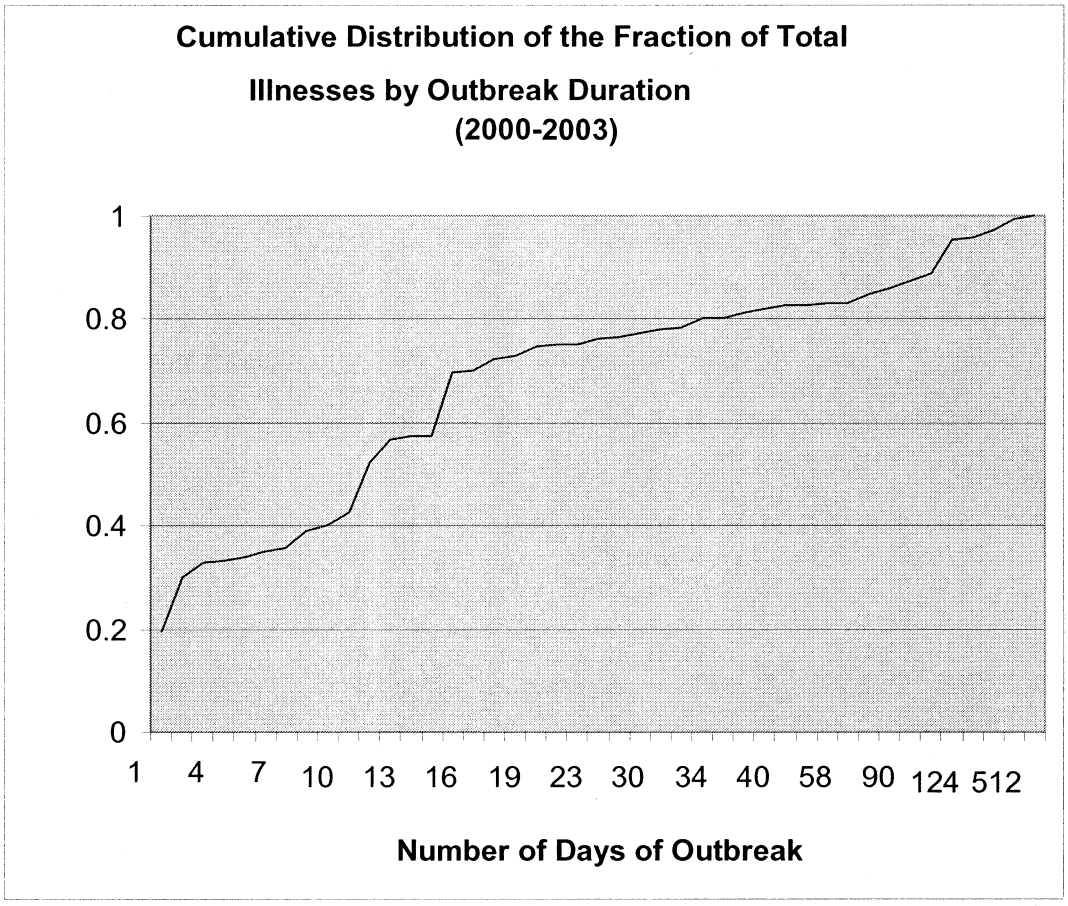

Distribution of numbers of known illnesses from outbreaks reported in internal investigation data from 2000 - 2003
Number of Outbreaks
60
50
40
30
20
10
0
10
50
90
140
190
230
270
310
350
390
430
More
Number of illnesses

Chart 2:



The next diagram combines information from the two preceding diagrams and depicts the cumulative distribution by outbreak duration of the percent of all onsets of illnesses. The horizontal axis in the following diagram gives the number of days that outbreaks lasted, and the vertical axis gives the fraction of all illnesses that occurred during outbreaks of a given duration. The diagram shows that approximately 80 percent of illnesses were from outbreaks that lasted for 33 or fewer days, and 20 percent of all illnesses were from outbreaks that lasted more than 33 days.

Figure 2:



Estimates of the durations and magnitudes of outbreaks based on FDA outbreak investigation information may overestimate the true average outbreak magnitudes and durations. The outbreaks monitored by FDA may be the most difficult to investigate because they involve interstate commerce (so illnesses are geographically dispersed), and may sicken a greater number of people. Consequently, the duration and magnitudes of the outbreaks may be longer and more severe than the average duration and magnitude of all investigations, which includes investigations at the local level in addition to the national level. However, as indicated earlier, the estimates presented here are based on food safety considerations and may understate the benefits of this final rule when the possibility of bioterrorism (food security) is considered.

4. The Total Number of Illnesses

The following table 3 of this document reports agents, illnesses, and deaths taken from the FDA outbreak investigation information. The 129 outbreaks from approximately 21 agents resulted in reports of 8,325 illnesses, 444 hospitalizations, and 21 deaths. The data reported in the table are drawn from multiple, non-standardized, sources that irregularly document different aspects of investigations.

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Bacteria			
Campylobacter	1	20	0
E. coli 0157:H7	13	287	45
Listeria	2	51	10
Salmonella	59	4,411	253
Shigella	3	672	30
Vibrio P.	4	124	0

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003—Continued

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Chemical			
Ammonia	1	141	42
Methomyl	1	26	0
Sodium nitrite	1	5	0
Parasitic			
Cryptosporidium	1	19	0
Cyclospora	4	78	3
Toxin			
Ciguatera or Ciguatoxin	3	26	3
Histamine	3	26	7
Saxotoxin	1	17	0
Scromboid	2	14	4
Star Anise	1	20	0
Toxin	1	78	0
Viral			
Hepatitis A	4	945	18
Norovirus	18	1,246	11
Viral or Vitri	1	35	4
Unknown	5	84	14
Total	129	8,325	444

The number of illnesses reported in table 5 of this document represents only the known cases, cases that have been recorded elsewhere in the public health system. For each reported illness, there are many illnesses that are unreported, so the actual number of illnesses from outbreaks is much larger than the reported number. For example, CDC states that the ratio of total (unreported plus reported) illnesses to reported sporadic illnesses from *Salmonella* is 38 (Ref. 3).

To estimate the number of unreported illnesses from outbreaks that FDA monitors, we assume the same pathogen-specific hospitalization rates as those used in the CDC estimates for the burden of foodborne illness (Ref. 3). For example, CDC assumes a 0.295 hospitalization rate for all illnesses caused by the pathogen *E. coli* 0157:H7. Moreover, CDC assumes that about one-half of hospitalizations related to foodborne illnesses are reported or diagnosed (Ref. 3). Consequently, we estimate that there were 90 hospitalizations due the *E. coli* pathogen from outbreaks monitored by FDA 2000 to 2003 (i.e., twice the number of hospitalizations from *E. coli* 0157:H7 reported in table 3 of this document). Based on the CDC hospitalization rate for *E. coli*, we estimate that the total number of illnesses (reported and unreported) from outbreaks caused by *E. coli* contamination is approximately 305 (i.e., 90 divided by 0.295, the hospitalization rate for illnesses caused by *E. coli* 0157:H7).

In order to characterize uncertainty in the estimates, we assumed that the total number of unreported illnesses from outbreaks for almost all pathogens would be distributed as a negative binomial with the parameters defined by the case hospitalization rates, and twice the reported number of hospitalizations. The estimated total number of illness for each agent is extrapolated from the estimated number of hospitalizations, with two exceptions: Estimates obtained of the total number of illnesses from *Listeria monocytogenes* and *Vibrio parahaemolyticus* were less than the reported total from those pathogens, so we used the reported total instead of the estimated total.

Case hospitalization rates for chemical poisoning and for other toxins are not reported in the CDC report, and (because such cases are unusual and characterized by severe acute distress) we assumed that half of such cases would be hospitalized. Finally, we assumed that the total number of illnesses from unknown agents is the same fraction of the estimated total summed over all pathogens, as the reported total summed over all pathogens. The estimated ratio of the total number of illnesses to reported illnesses was computed by dividing the estimated total by the reported total summed of all pathogens.

The average estimate of the ratio of total illnesses to reported illnesses from all pathogens, as well as the high and low estimates representing the 95 percent and 5 percent levels are reported in the following table. We estimate a total of 71,928 reported and unreported illnesses from outbreaks monitored by FDA from 2000 to 2003. This total reflects 8,325 illnesses that were reported, and approximately 63,603 that were estimated to be unreported.

TABLE 4.—ESTIMATED RATIO OF THE TOTAL NUMBER OF ILLNESSES TO REPORTED NUMBER OF ILLNESSES

Mean	Low (greater than 5% of the range)	High (greater than 95% of the range)
8.64	7.89	9.51

5. The Costs of Each Illness

We estimate the direct medical costs as well as the indirect costs of illnesses from outbreaks monitored by FDA. The direct medical costs include the costs of any doctor visits and hospitalizations that are required. Indirect costs are from the loss in productivity and quality of life as a result of the symptoms and severity of the illness. We estimate the indirect and direct costs of each illness for mild, moderate, and severe cases.

Mild cases are assumed to remain untreated with no direct medical costs. We assume that persons with moderate cases visit a physician and that those with severe cases require hospitalization. The average costs of $64 for a physician visit was obtained from the online source, Medical Economics (Ref. 4), and hospitalization costs were obtained from the Health Cost and Utility Project's (HCUP) Nationwide Inpatient Sample (Ref. 5) by type of illness.

The numbers of days that symptoms persist for each illness and severity were estimated from the FDA-Center for Food Safety and Applied Nutrition (CFSAN) Bad Bug Book (Ref. 6), CDC's National Center for Infectious Diseases, Infectious Disease Information fact sheets (Ref. 7), and from a CFSAN report entitled ''Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act'' (Ref. 8). These estimates were assumed to be uniformly distributed with the means reported in table 5 of this document.

TABLE 5.—DURATION OF THE ILLNESS FOR MILD, MODERATE, AND SEVERE CASES

Mild	Moderate	Severe	
Bacteria			
Campylobacter	4	8	8
E. coli 0157	3	8	18
Listeria	4	30	37
Salmonella	4	12	16
Shigella	3	11	18
Vibrio P.	2	2	3
Chemical			
Ammonia	3	5	7
Methomyl	3	5	7
Sodium nitrite	3	5	7
Parasitic			
Cryptosporidium	17	22	60
Cyclospora	17	22	60
Toxin			
Ciguatera or Ciguatoxin	2	5	19
Histamine	2	5	19
Saxotoxin	2	5	19
Scromboid	2	5	19
Star Anise	2	5	19
Toxin	2	5	19
Viral			
Hepatitis A	22	22	28
Norovirus	2	2	6
Viral or Vitrio	2	2	6

The distributions over mild, moderate, and severe cases for most of the illnesses were estimated from the CDC (Ref. 3), and a CFSAN report entitled ''Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness'' (Ref. 9). The case distributions over mild, moderate, and severe cases were estimated for chemical and marine toxin poisoning from a study by Brevard et al. (Ref. 10), and a study reported by CDC (Ref. 11).

The indirect costs of an illness are the loss in welfare measured as a loss in life quality or, in the extreme case, death from the illness. This loss in quality of life also includes lost worker productivity while ill. Estimates of the indirect costs will vary depending on the symptoms of the illness and their severity. We use a quality of well-being scale for a typical gastrointestinal illness to adjust the well-being of a person with mild, moderate, or severe symptoms (Ref. 12). The well-being scale assumes a value of 1 for a person in good health, and is reduced according to the

symptoms and impaired mobility, reduced physical activity, and reduced social activity that result from the illness.

We compute an index of lost quality adjusted life days (QALD) by subtracting the individual's health status when ill from one and then multiplying that fraction by the number of days the illness lasts. The result represents the number of health days lost from an illness; we estimate the loss for varying severities for each illness. The QALD losses for an average foodborne illness are reported in the following table 6 of this document.

TABLE 6.—LOST QALDS DUE TO AN AVERAGE CASE OF FOODBORNE ILLNESS

Severity of Illness	Symptom	Mobility	Physical	Social	Quality Adjustment	QALDs Lost
Mild	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Moderate	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Severe	-0.29	-0.090	-0.077	-0.061	0.48	0.52

To reflect uncertainty in the literature, FDA uses a range to estimate the values of the health days lost. We use a low estimate of $100,000 for the value of a life year. This is consistent with that proposed by Garber and Phelps, who suggest a value of approximately twice the annual income (Ref. 13). U.S. Census data reports that the median family income in 2001 was approximately $51,000 (Ref. 14).

Middle and high estimates of the value of a health day are derived from estimates reported in the literature of the value of a statistical life. A value of a statistical life of $6.5 million is consistent with the findings of a literature survey of the premium for risk observed in labor markets, reported by Aldy and Viscusi (Ref. 15). We derive middle and high estimates of the value of a health day by annualizing the value of a statistical life of $6.5 million over 35 years at discount rates of 3 percent and 7 percent. These computations yield middle and high estimates for the value of an additional year of life of about $300,000 and $500,000. We estimated the range in values of a health day by dividing each of the estimates of the value of an additional year of health by 365, which yields estimates of $274, $822, and $1,370.

To calculate the indirect costs of mild, moderate, and severe cases of the illnesses, we multiplied the low, middle, and high estimates of the value of a health day by the QALD estimated for each illness and severity. Consistent with OMB's guidance on the use of multiple values for a statistical life, we used values of $5.0 million and $6.5 million to compute the value of a death from an illness.

The estimated range of the average cost of an illness resulting from outbreaks monitored by FDA from 2000 to 2003 is reported in the following table. The averages reported in table 7 of this document are weighted by the total number of reported and unreported illnesses from each agent, as well as the assumed distributions of mild, moderate, and severe cases, including deaths, from those illnesses. As explained earlier, we valued statistical deaths at $5 million and $6.5 million, and the low, medium, and high estimates assume values of a healthy year of $100,000, $300,000, and $500,000.

TABLE 7.—AVERAGE COST OF AN ILLNESS ACROSS OUTBREAKS

	Low	Medium	High
VSL = $5 million	$6,136	$13,209	$20,282
VSL = $6.5 million	$6,810	$13,883	$20,955

6. The Stages of an Outbreak Investigation

There are four stages in an outbreak investigation. The first stage is the preliminary investigation of laboratory results and epidemiological evidence used to determine the parameters of the outbreak, including the following: number ill, food vehicle contaminated, microbial or other agent responsible, potential commercial sources of contamination, as well as the degree of confidence in the information on each of these parameters. The second stage of the outbreak investigation is the decision making part, when FDA determines what resources will be committed to proceed further in the investigation. The third stage is the traceback investigation, which is conducted to do the following: (1) Identify the source and distribution of the implicated food and remove the contaminated food from the marketplace; (2) distinguish between two or more implicated food products; and (3) determine potential routes and sources of contamination in order to prevent future illnesses, or to treat persons sooner for the identified contaminants. The traceback investigation involves investigative visits by FDA inspectors to points of service, which are the facilities where consumers had purchased the contaminated food, and also distribution facilities.

A fourth stage is the source investigation of the specific practices at the farm, transportation, or other facility that may have led to the outbreak. For many outbreaks, the source investigation occurs well after any preventive action can be taken to limit the number of illnesses. This would be true for outbreaks from contaminated foods with short shelf lives that no longer are in circulation at the time of the source investigation, or from contaminations occurring at banquets, parties, or other one-time events where the source investigation cannot limit the size of the outbreak. For these outbreaks, the improved recordkeeping practices specified in the final rule would not improve FDA's current ability to limit the size of the outbreak, or prevent additional illnesses.

However, for certain products such as eggs, sprouts, and other fresh products, additional illnesses due to conditions at the source may continue if shipments from contaminated facilities continue. The same may also be true for perishable foods imported on a frequent basis from contaminated facilities. For these kinds of outbreaks, the ability to more rapidly implicate a contaminated farm or manufacturing source will improve FDA's ability to limit the size of the outbreak, or prevent its recurrence.

7. The Duration of Traceback Investigations, and Numbers of Premature Terminations

FDA outbreak investigation personnel estimate that a full outbreak investigation lasts at least 3 to 5 weeks, with a most likely duration of 2 to 6 months, and a maximum duration of 10 months (Ref. 2). The numbers of outbreak investigations and investigative visits come from internal interviews with investigation personnel and from other data maintained by FDA (Ref. 2).

The annual numbers of outbreaks investigated, investigative visits, and investigations that are prematurely terminated for reasons of poor records quality are reported in table 8 of this document. A traceback is defined to be prematurely terminated for records quality reasons if investigators noted in summarizing information that data quality impeded the investigation which ended before investigators were able to determine the specific cause of the outbreak. We used the simple averages over the 4 years reported in the table to estimate the annual numbers of outbreaks investigated, the annual numbers of investigative visits per outbreak investigated, and the annual rates of investigations prematurely terminated for reasons of poor records quality. We characterized the uncertainty of these estimates as normal distributions with means and standard deviations taken from the data on annual numbers of outbreaks and investigative visits per outbreak. For the annual rate of prematurely terminated investigations, we characterized the uncertainty with a beta pert distribution using the average, low and high values reported in the table 8 of this document.

TABLE 8.—OUTBREAK INVESTIGATION DATA

Year	Number of Outbreaks Investigated	Number of Investigative Visits per outbreak	Rate of records quality related premature terminations
2000	9	12	0.11
2001	9	11	0.33
2002	18	7	0.06
2003	17	6	0.00

The recordkeeping requirements of this final rule will improve the quality of records established and maintained by persons that manufacture, process, pack, transport, distribute, receive, hold, or import food. For options that provide comprehensive coverage of all food facilities, we estimate that the number of investigations prematurely terminated because of poor records would fall to zero. For options that provide less than comprehensive coverage, the reduction in premature terminations is reduced in proportion to the coverage.

Because outbreaks whose investigations are prematurely terminated may recur, the benefits from reducing that number may be high (if many people continue to become ill as a result of the recurrence). Based on FDA outbreak investigation information, the average number of reported illnesses in outbreaks that occurred between the years 2000 and 2003 was approximately 65. However, many illnesses from outbreaks go unreported, so the average total number of illnesses from an outbreak is much larger than the reported number. Using the estimated average ratio of total illnesses to reported illnesses reported earlier, we estimate that by avoiding just one outbreak recurrence, approximately 559 persons would avoid becoming ill.

Traceback durations may be different for processed food sold in packages with labels with identifying barcodes than for fresh food items sold in packages with no labels. Eggs and fresh produce account for 90 percent of all outbreaks investigated by FDA, while labeled packaged foods account for only 10 percent (Ref. 2). To determine the likely length of time it takes to investigate a packaged food product, we use a range that includes the low end, where investigators are able to obtain the exact package that contains the identifying barcodes, and the high end that assumes the package, with the identifying barcodes, is not available. In the latter case, any subsequent recalls would likely include more foods than the implicated lot.

The final rule relaxes the proposed requirement for lot codes to be established and maintained on all records. If FDA were to require all persons, including distributors, transporters, and retailers, to include lot numbers in the records they establish and maintain under this final rule, the traceback durations for many products would be reduced and would be comparable to those currently reported for tracebacks of packaged products that contain barcode information. If all retailers and distributors were required to establish and maintain lot codes for all processed products, then the duration of the traceback component of an outbreak investigation for many products could be reduced to 1 to 14 days. Examples of reported traceback times for fresh products and for packaged products that contain lot code information in bar code format are reported in table 9 of this document.

TABLE 9.—DURATION OF THE TRACEBACK COMPONENT OF AN OUTBREAK INVESTIGATION[1]

	Most Likely	Low	High
Eggs and fresh produce	6 to 8 weeks	2 to 5 weeks	12 weeks

TABLE 9.—DURATION OF THE TRACEBACK COMPONENT OF AN OUTBREAK INVESTIGATION[1]—Continued

	Most Likely	Low	High
Packaged products	3 days	1 day	14 days

[1] Estimates reported in Ref. 2 of this document.

8. The Duration of Investigative Visits

The main delays in traceback investigations are long travel times and overnight stays, slow and poor cooperation from recordkeepers, and inconsistent and incomplete records. Many recordkeepers may not be inclined to devote sufficient labor to providing records to inspectors during business hours because that is a costly time of day to reallocate resources. Furthermore, sometimes companies follow time-consuming procedures before approving FDA's request for records access. The legally binding provision in this rule will expedite cooperation from recordkeepers and reduce access times. When we take into account the requirement in the rule that access be provided on weekends, we estimate a substantial amount of time saved due to the records access provision—especially when there are multiple point of service or distributor visits.

The inconsistency and incompleteness with which some records are maintained are also important causes for delay in an investigative visit. Records from approximately 50 percent of access requests require additional information from the recordkeeper. Examples of information that may be incomplete include supplier contact information, a description of a product received or shipped, or date of receipt or shipment. This information is used by analysts located at headquarters, along with inventory rotation and control information, to determine precisely what was shipped, by whom, and when it was received. Often, many similar products from different suppliers are received during the course of the day by any given receiver.

Frequently, records document transactions from regular suppliers or customers where the identity of the shipper and description of the product can be determined readily based on the regularity and composition of the shipments. Sometimes, an entity will receive an unusual shipment (especially during holiday seasons), or it may receive multiple shipments of similar products from different suppliers, making it difficult to precisely link an incoming product with an outgoing shipment. Other times, descriptions of products received differ from how they are referenced on the shipping documents, making it difficult for the analyst to link the incoming product with an outgoing shipment.

Each category of incidents may result in confusion on the part of the analyst located at central headquarters and require an additional visit by the field inspector to the recordkeeper for further clarification. Because travel times account for a significant amount of time in a traceback investigation, and an estimated 20 percent of all point of service or distributor visits require an overnight stay, we estimated that the final rule would result in substantially reduced traceback durations.

Including travel time, 1 full day is usually required to obtain records after a request. A second full day is required when the records are not available on the first day. Furthermore, although records analysis times are typically only 7 to 10 hours, approximately 50 percent of all investigative visits require a return trip to clarify inconsistencies in the records, or to obtain additional information to compensate for incomplete records. In addition to slow compliance with records access requests, the unavailability of personnel and flight schedules may necessitate an overnight stay and an extra day of travel by an FDA investigator. Approximately 20 percent of all investigative visits require an overnight stay.

The duration of each component of an investigative visit, both inclusive and exclusive of travel times, is reported in the following table. We assume a uniform distribution of between 1 and 3 days including travel times for obtaining requested records. We assume that the times for records analysis are uniformly distributed between 0.8 and 1.6 days, including travel times. The lower bound reflects the time for records analysis when documents are able to be quickly transferred to headquarters. The upper bound reflects 1 full day of travel with 50 percent requiring an additional follow-up and 20 percent requiring an overnight stay.

TABLE 10.—DURATION OF THE COMPONENTS OF AN INVESTIGATIVE VISIT

		Including Travel Time and Overnight Stays
Obtaining requested records	4 to 48 hours	Uniformly distributed between 1 and 3 days
Records analysis	7 to 10 hours	Uniformly distributed between 0.8 to 1.6 days

We estimate the time for a traceback investigation by multiplying the duration of an average investigative visit by the number of investigative visits per traceback investigation. We estimate the duration of an investigative visit by adding the time to comply with a records access request to the time required to analyze those records. If obtaining requested records takes 1 to 3 days (i.e., 1 to 2 days to comply with the access request and 1 day of travel) and records analysis, inclusive of travel, takes between 0.8 and 1.6 days (i.e., 50 percent require return trips and 20 percent of trips require an overnight stay), the duration of an investigative visit is assumed to be uniformly distributed between 1.8 and 4.6 days (i.e., 1 to 3 days plus 0.8 to 1.6 days), with a simple average of 3.2 days.

From annual data we assume that the number of investigative visits per outbreak for the years 2000 to 2003 is normally distributed with a mean of approximately 9 visits and standard deviation of approximately 3 visits per traceback investigation. Using just the mean numbers of visits in a traceback investigation and visit durations, we estimate that the traceback component of an outbreak investigation takes approximately 29 days (the duration of an investigative visit multiplied by the number of investigative visits per outbreak).

9. Adjustments to Account for Records Requests Made on the Weekends

If there are 4 sets of weekends during the 29 day traceback time period in which records are inaccessible, then the estimated calendar duration (including weekends) of a current traceback investigation becomes much longer. To allow more accurate comparison of the time savings between current traceback times with those projected under alternative policy options requiring 4 and 8 hours, and up to 24 hours records access, we adjust the estimate of current traceback times to account for requests that would be made on weekends following issuance of this final rule. Most current records requests are made during the week, because establishments may not be open or key personnel may be absent on weekends. However, this final rule requires records access when requests are made on either weekdays or weekends. Consequently, we assume that there is a 1 in 7 chance of requesting records on a Saturday, and a 1 in 7 chance of requesting records on a Sunday if FDA were conducting a traceback investigation of a food for which it had a reasonable belief the food was adulterated and presented a serious threat of serious adverse health consequences or death to humans or animals.

A 24-hour records access requirement would improve current traceback times by allowing weekend records access requests. We assume that a records access request that would be made on a Saturday or Sunday following issuance of this final rule, would currently not be made until the following Monday. Taking this assumption into account, we estimate that the current time to satisfy a records request made on a Saturday to be 3 to 5 days (i.e., 2 days, plus 1 to 3 days), or an average of 4 days for 1/7 of all access requests (i.e., records requested on a Saturday), and 2 to 4 days (i.e., 1 day, plus 1 to 3 days), or an average of 3 days for 1/7 of all access requests (i.e., records requested on a Sunday).

With the average of 1.2 days for records analysis times, the adjusted estimate of the total time for satisfying a records access request and records analysis is an average of 5.2 days (1.2 days, plus an average of 4 days) for requests made on a Saturday, and 4.2 days (1.2 days, plus an average of 3 days) for requests made on a Sunday. The adjusted estimate of current traceback times is computed as an expectation of traceback times taking into account the probabilities of records requests made on weekdays and weekends. Assuming nine investigative visits per traceback investigation, the adjusted estimate of the current traceback time is approximately 33 days (((3.3 days x 5/7) + (4.2 days x 1/7) + (5.2 days x 1/7)) x 9 visits). The adjusted estimate of the current traceback duration is reasonably consistent with the current traceback durations reported by traceback personnel of between 6 and 8 weeks for eggs and fresh produce, and 3 days for packaged products that contain lot code information on the labeling.

10. Estimate of the Time Required Before Preventive Action

We estimated the time required before taking preventive action using FDA outbreak investigation information. We estimated the time required for a preventive action as the time that elapsed between the onset of the first reported illness and the first action taken by FDA or a commercial or state entity. In 11 of 26 traceback investigations considered from 2000 to 2003, an average of 78 days had elapsed between the time of the onset of the first illness in the outbreak and any initial preventive measure.

The estimate of the time required for a preventive action may be overstated because for those investigations that had entries reporting an initial action, but did not report a specific date of the action, we used the information entry date to approximate the date of the initial action. The information entry date is the date on which the initial action is recorded by FDA. Consequently, this procedure likely overestimates the time to preventive action because the information entry date is later than the date of the initial action it approximates, and in some cases may be significantly later than that date.

Moreover, many investigations do not involve any preventive action that would limit the magnitude of the outbreak, because either the investigation lasts longer than the shelf life of the implicated food product (so that there is no longer any implicated food in circulation), or the implicated source of the outbreak is determined to be an isolated event with no possible preventive action that would limit the size of the outbreak. Because information from such observations is not used in the analysis, the resulting estimate of the investigation duration is likely to be shorter than what would otherwise be obtained.

Based on the outbreak data used to create figure 2 of this document entitled ''Cumulative Distribution of the Fraction of Total Reported Illnesses by Outbreak Duration,'' we estimate that between 15 and 18 percent of all illnesses were from outbreaks that lasted more than 78 days. This implies that, with an average of 2,081 reported illnesses per year, the faster tracebacks could potentially prevent up to a maximum of 312 to 374 (reported) illnesses per year. The average duration of outbreaks that last longer than 78 days is approximately 121 days, for an average net excess of 43 days (121 days minus 78 days). By dividing the maximum number of known illnesses per year, by the average duration of outbreaks that persist beyond 78 days, we estimate a maximum daily average of 8 to 9 illnesses that occur each day after the 78 day threshold.

We characterize the uncertainty in the estimate of the time for preventive action as a Beta-Pert distribution with the most likely value of 78 and the minimum and maximum values (taken from the data) of 6 days and 150 days. The Beta-Pert distribution is a Beta distribution that has been re-scaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 times the most likely) + maximum) divided by 6. We use the Beta-Pert distribution since it is less sensitive to extreme values and generates more outcomes close to the mean than a Triangular distribution. We assume that the average duration of outbreaks that persist beyond the time for preventive action is distributed normally with a mean of 121 minus the time for preventive action, and a standard deviation (computed from the data) of 17. We assume a uniform distribution with a range between 0.15 and 0.18 in the estimate in the portion of annual illnesses that potentially could be averted by faster preventive action.

11. Estimating the Impact on Traceback Performance for Options With Different Coverage

Our framework for estimating the impact on baseline traceback speeds and completion rates for policy options with alternative levels of coverage uses the number of facilities in each sector to weight the sectoral contribution to baseline traceback performance. We adjusted the weights of the transportation, warehouse, and mixed-type facilities sectors to account for special considerations related to their contributions to traceback speeds and completion rates. For options that distinguish between very small and large facility coverage, we also adjusted

the contributions to traceback performance by facility size.

We estimated that options with the most comprehensive coverage will lead to the greatest decrease in times for preventive action, and eliminate the largest number of investigations that are prematurely terminated for reasons of poor records quality or nonexistent records. Options with more limited coverage will have a more limited impact on traceback speeds and completion rates. The factors used to scale baseline traceback speeds and rates of premature terminations are described by the following expression:

Total baseline performance = contribution by grocery outlets, given that contamination occurred further up the supply chain + contribution by wholesalers and importers, given that contamination occurred further up the supply chain + contribution by warehouses, given that contamination occurred further up the supply chain + contribution by manufacturers, given that contamination occurred further up the supply chain + contribution by transporters, given that contamination occurred further up the supply chain + contribution by mixed-type facilities.

The contribution to baseline traceback speeds by each sector is adjusted to reflect the probability that the food was contaminated further up the supply chain. Based on conversations with traceback personnel, we estimated that 10 percent of outbreaks requiring traceback records are from contamination at manufacturing facilities, and 90 percent are from contamination at the farm facilities (which may include mixed-type facilities subject to the recordkeeping requirements of this final rule).

a. *Adjustments to traceback performance for the grocery sector*. The baseline contribution from the retail sector to traceback performance is composed of contributions from both the restaurant and grocery sectors. The contribution to traceback performance from grocery outlets represents only a fraction of the total contribution of the retail sector. We adjust the probability of requiring traceback records from grocery outlets downward to account for the possibility that initial traceback from retail could begin at a restaurant as well as at a grocery outlet. For the adjustment we use the estimated number of restaurant locations of approximately 900,000 reported in a recent survey conducted for the National Restaurant Association (Ref. 16).

b. *Adjustments to traceback performance for transportation and warehouse facilities*. We adjusted estimates of the contributions to traceback performance by warehouse and transportation facilities to reflect the ''checks and balances'' nature of traceback records from these facilities for many investigations. Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. This requirement allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. It is critical that FDA be able to locate and remove from commerce any adulterated food that presents a credible threat of serious adverse health consequences or death to humans or animals.

We assume that there is a uniform likelihood between zero and one that there are more than two transportation or warehouse facilities used in the provision of a transportation or storage service. For these cases there is no adjustment to the value of records from such facilities during a traceback investigation. When two or fewer facilities provide transportation and warehouse services (estimated to be approximately half of the total number of such services) we adjust downward the value of records to acknowledge their role of verifying, rather than identifying, the buyer or seller of the food. For these cases we adjust the value of records to traceback performance by a factor of 0.5.

c. *Adjustments to traceback performance for large and very small facilities*. We adjusted the contributions by large and very small facilities to traceback performance to reflect the substantially different quantities of food each facility size is responsible for. While the number of very small facilities accounts for a large fraction of the total number of facilities, the quantity of food for which these facilities are responsible is relatively small. Consequently, estimates of the contributions to traceback performance should reflect the lower likelihoods of investigative visits at very small businesses.

For options that differentiate between coverage by facility size, we used estimates of the quantities of food passing through very small establishments and the quantities of food passing through all other sized establishments to scale each sector's contribution to traceback performance. In this way we were able to estimate the contribution by very small size establishments and other size establishments to traceback performance for each sector. We used U.S. Census data (Ref. 17) to estimate the percentage of the total number of food establishments that are very small, as well as their revenues, by sector and report them in the chart below. The fraction of the total number of facilities that are very small ranges from an estimated 73 percent of convenience outlets to 90 percent of transporters. In contrast, the percentage of total convenience store revenues from very small facilities is an estimated 18 percent, while very small transporters are responsible for an estimated 16 percent of total revenues from that sector.

TABLE 11.—THE PERCENTAGE OF VERY SMALL FOOD ESTABLISHMENTS THAT MAKE UP EACH SECTOR AND THE PERCENTAGE OF THE TOTAL SECTOR'S FOOD FOR WHICH THEY ARE RESPONSIBLE

Sector	% of Establishments That Are Very Small	% of Food Sector Revenue From Very Small Establishments
Manufacturers	77	15
Wholesalers	81	14
Transporters	90	16
Grocery outlets	88	18
Convenience outlets	73	18

TABLE 11.—THE PERCENTAGE OF VERY SMALL FOOD ESTABLISHMENTS THAT MAKE UP EACH SECTOR AND THE PERCENTAGE OF THE TOTAL SECTOR'S FOOD FOR WHICH THEY ARE RESPONSIBLE—Continued

Sector	% of Establishments That Are Very Small	% of Food Sector Revenue From Very Small Establishments
Importers	82	14
Mixed-type facilities	82	15

Source: U.S. Census, 1997 Economic Census.

In addition to a lower probability of an investigative visit at very small compared with other size facilities, records quality or records access times might also be different for very small and other size facilities. However, conversations with FDA investigative personnel revealed that there are no differences in records quality or records access times across business sizes. Consequently, we estimate the duration of an investigative visit to be the same for very small and other size businesses.

12. Estimating the Benefits When Selected Sectors Are Excluded

In this section we describe the estimated reduction in benefits that would be incurred from excluding certain sectors. We will provide additional quantitative information on this later in the analysis. We selected specific sectors for analysis in this section based on comments received on the proposal. The reduction in benefits from excluding foreign persons, transport persons, and food contact substance persons (including the finished container that contacts the food) from establishing and maintaining records are estimated as affecting traceback performance and the number of outbreak victims. The final rule excludes food contact substance and foreign facilities from recordkeeping maintenance requirements. As stated earlier, these estimates all account for food safety benefits based on traceback investigations currently performed and do not consider food security benefits, which are based on classified information.

a. *Excluding foreign facilities.* One policy option excludes approximately 225,000 foreign persons from all recordkeeping requirements. Although it is impossible to estimate the likelihood of intentional contamination at foreign facilities compared with domestic facilities, in this analysis we assume that there is no difference between the probabilities of foodborne outbreaks originating at foreign and domestic facilities. Consequently, the estimated reduction in benefits from excluding foreign persons is based solely on the number of facilities that are excluded, and the likely importance of their records for traceback performance. Because foreign facilities are close to the beginning of the supply chain for U.S. domestic consumption, the importance of their records during a traceback investigation is moderate while the costs to obtain those records during a traceback investigation are high.

b. *Excluding persons that manufacture, process, pack, hold, transport, distribute, receive, or import food contact substances.* Another policy option excludes food contact substance suppliers, estimated to be 37,000 manufacturers and distributors of the finished container that contacts the food, from the requirement to establish and maintain records. Because of the small number of manufacturers and distributors of the finished container that contacts the food compared with the total number of foreign suppliers, their exclusion from recordkeeping requirements would have a relatively small impact on traceback performance (if we ignore the possibility that excluding packaging suppliers increases their profile as potential targets for terrorist activities). Moreover, because manufacturers and distributors of the finished container that contacts the food occupy up-stream positions along the supply chain relative to foreign entities, we estimate the reduction in benefits from excluding them to be less than that from excluding foreign entities. Finally, if the requirements of section 306(a) of the Bioterrorism Act were satisfied, FDA would have access to existing records at these facilities.

c. *Excluding transporters.* One policy option would exclude all transporters from the requirement to establish and maintain records. FDA determined, however, that the qualitative and quantitative impact on benefits in the classified and unclassified scenarios would greatly eliminate the effectiveness of the rule and FDA's ability to timely and efficiently respond to a threat of serious adverse health consequences or death to humans or animals. As a practical matter, because the final rule's requirements for interstate shipments can be satisfied by compliance with existing requirements for interstate shipments, the final rule only establishes new requirements for the following: (1) Intrastate transporters; and (2) intrastate shipments conveyed by interstate transporters. FDA estimates that there are approximately 115,000 intrastate carriers, and based on DOT data, almost one million commercial drivers report intrastate travel. In reviewing the truck tonnage by commodity, approximately 12 percent of the intrastate shipments are of FDA-regulated food products. The average distance these products are shipped is 231 miles, which means many shipments are intrastate, especially in the larger western states.

For some foods, distribution may be limited primarily to intrastate transportation, depending on the time of year and state. Many businesses have their own delivery trucks that are used intrastate, several use employee vehicles for deliveries, and many rent vehicles to deliver products. These vehicles are used to deliver all types of food products—refrigerated, cooked, as well as fresh food and produce, and grocery items. Some local firms pick up their own merchandise from ''warehouse'' facilities to stock their own locations. Many of these ''warehouses'' (commonly referred to as ''Bin warehouses'') may receive product via interstate transporter and subsequently deliver to a variety of intrastate retail customers via many different intrastate means. Data on the volume of foods that move in intrastate commerce are maintained by individual state Department of Agriculture and by DOT. For example, from CA, LA, and TX alone, DOT reports over 12 percent of intrastate truck tonnage is from FDA-regulated products (ref. 18). Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003, there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with

intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

Most of the seafood consumed in Florida is transported only intrastate, but in Oklahoma most seafood is transported interstate. In 2002, there was an outbreak in New Jersey and Florida linked to fish. Intrastate records assisted us in pinpointing the portion of the Indian River, Florida that was causing the problem. Information on egg tracebacks from 1996–2003 indicates that 35 percent of the tracebacks that resulted in farm investigations were intrastate. This past summer, the State of Oregon was able to stop a sprout-associated outbreak from becoming a serious one by tracing back to a Washington sprouter that was just over the border from Oregon after some initial cases before the Salmonella serotype had been identified. The sprouts were recalled. If the sprouter had been located in Oregon so that the sprouts were not transported interstate, it would have been problematic to a traceback investigation limited solely to interstate transporters.

The North Carolina green onion traceback investigation, which was part of the largest Hepatitis A outbreak that has ever occurred in the U.S., is another example of the importance of intrastate records. There, the amount of time spent on the traceback within that State was twice as long as the other three tracebacks done in other states because the distributor in North Carolina did not have records. Traceback from the Tennessee outbreak took over a month, the Georgia traceback took a month, and Pennsylvania traceback took a week. Because we had no intrastate records in the North Carolina outbreak, the traceback was determined to be inconclusive after two months, which meant that we would not have been able to identify the farms involved if it had not been for the other outbreaks.

This year, there was an *E. coli* O157:H7 outbreak associated with bagged lettuce product in CA that was only in intrastate commerce. That traceback might have been lost had records not have been available. Exempting transporters could significantly impede FDA's ability to rapidly and effectively respond to a public health emergency involving a food transported within a state, particularly if the adulteration occurred during transport and the food was delivered to multiple sources within the State. In scenarios where time is of the essence to prevent serious injuries or death, having records available becomes even more critical. In addition, not only must FDA be able to rapidly obtain records, it is imperative that FDA be assured that those records contain certain essential information to allow FDA to prevent further harm in an efficient and effective manner.

Additional examples of circumstances involving food products that have significant intrastate manufacturing, processing or distribution are provided in the following paragraphs:

- An intrastate sandwich and snack food company that sells to retail outlets for consumption had an outbreak of *Listeriosis* or *Salmonellosis* that was traced back to the sandwiches. The product was completely distributed using the company trucks within the state. FDA was unable to determine which sandwiches caused the outbreak. The sandwiches were delivered to retail customers, and it was impossible to track which sandwiches went to which retailer. The transporter did not track which product was delivered to which location. In this case, the firm had to recall all of its products.
- Retail stores regularly purchase food, especially locally grown produce, from ''truck farmers.'' These farm trucks travel from store to store within a state, sometimes selling an entire truckload to a store, other times a portion. There is no manifest or record other than a bill of sale—e.g., 200 cantaloupes from Farmer Brown. If the contamination occurred on the truck, FDA would not have a record from the truck of all other delivery sites.
- Several days into the investigation of a Hepatitis A outbreak from chicken salad in one city, FDA learned that the chicken was ''cubed'' at another facility in another city within the state, and transported to the ''manufacturing facility.'' The source of the outbreak was the site where the chicken was ''cubed'' by an ill employee; however, there were no records to indicate when the cubed product was shipped or received by the salad manufacturing facility.

Having transporter documents would be critical if there was an intentional or unintentional contamination of the product while en route. Because of our limited experience, we cannot anticipate how much additional time it would add to our investigation, should records not be available.

The probability that a traceback investigation will require records that document the movements and packaging of food items between transportation facilities is uncertain. At least one outbreak involving the contamination of dairy products while inside a truck that had previously carried non-pasteurized eggs is estimated to have infected about 224,000 persons (Ref. 19). This example illustrates only one potential way that food may be contaminated while in the possession of transporters, and suggests that these risks of contamination can be considerable.

13. Options With Different Access and Retention Requirements and With Different Compliance Dates

a. *24 hour and 4- and 8-hour records access requirements.* For options with comprehensive coverage (and using simple average numbers), when compared with current traceback times, we would save an estimated 10 days for the proposed option requiring 4 and 8 hour records access, and 5 days for the option requiring 24 hour records access. When travel times are included, the provisions of the recordkeeping rule will significantly reduce the records access as well as the records analysis times. When travel times are included, the 4 and 8 hour records access times in the proposed rule would reduce the range of records access times to 1 to 2 days. The final rule requires records access within 24 hours of a request, which would reduce records access times by a smaller amount than with the proposed 4 and 8 hour requirement. Because current records access times are between 1 and 3 days including travel times, we assume that relaxing the requirement to 24 hours would only speed up compliance for records requested on the weekends. The proposed records access times of 4 and 8 hours would result in estimated records access times of between 1 and 2 days, and a records analysis time of 1 day (because the improved records quality would preclude the need for return investigative visits).

We assume that a 10-day reduction in the duration of the traceback component of an outbreak investigation would reduce the time required to take an initial preventive action by 10 days as well. A savings of 10 days would reduce the average amount of time required to take a preventive action to 68 days (based on the estimated current time of 78 days), and a savings of 5 days would reduce the time required to take a preventive action to 73 days. From data used to generate the cumulative distribution displayed earlier in this document in figure 2 entitled ''Cumulative Distribution of the Fraction of Total Illnesses by Outbreak Duration (2000–2003),'' we find that between 15 and 18 percent of all outbreak victims became ill from outbreaks that lasted more than 65 days. Consequently, the benefits from

reducing traceback times by either 10 days for the 4-and 8-hour records access requirement, or 5 days for the 24-hour records access requirement can be considerable. We assume that with comprehensive coverage, the number of traceback investigations that are prematurely terminated because of poor records quality will fall to zero under either the 24-hour records access requirement, or under the proposed 4- and 8-hour records access requirement.

The reduced durations of traceback investigations computed in the previous paragraphs are based on the assumed comprehensive coverage of the proposed recordkeeping rule. Excluding certain persons from all or part of the requirements of the regulation results in a reduction in the benefits as measured by reduced times for traceback investigations. The extent of the reduction in benefits from reduced traceback durations depends on the number of persons (and facilities for which the persons are responsible) that may be excluded from the regulation and the position along the supply chain of the excluded facilities. The position along the supply chain influences the probability of contamination, as well as the probability of losing the paper trail. We assess the relative benefits of excluding certain sectors as policy options later in this document.

Finally, if there is a deliberate attack on the food supply, with catastrophic consequences, then the duration of the preliminary and decision making parts of the outbreak investigation will likely be substantially compressed, and the importance of the traceback investigation in preventing additional illnesses from an outbreak will be elevated. If firms fully understand the seriousness of an outbreak, their reaction times may be compressed as well, which would tend to reduce the computed benefits from this rule. However, we expect FDA to be more likely than all firms to fully understand the seriousness of an outbreak.

As an example computing how compressed preliminary investigation and decision making times affect the benefits from faster tracebacks, we estimate the duration of the preliminary and decision making parts of the outbreak investigation to currently be approximately 55 days (i.e., the difference between 78 days for an initial preventive action and 33 days for the traceback investigation). If we assume a 50 percent reduction in the times for the preliminary and decision making components of an outbreak investigation, then a 10-day reduction in traceback times would result in preventive measures taken after approximately 56 days (28 days, rounding up, for the preliminary and decision making investigations plus 28 days for a traceback investigation) compared with the current 78 day duration. For a 75 percent reduction in the duration of the initial parts of an outbreak investigation, a 10-day reduction in traceback times would result in preventive measures being taken after approximately 42 days (14 days for preliminary and decision making investigations plus 28 days for a traceback investigation) compared with the current 78 days.

b. *Records retention requirements of 6 months, 12 months, and 24 months based on three NIST definitions*. Many comments suggested that product shelf lives as defined by the NIST should determine which product records would be subject to retention requirements of 6 months, 12 months, and 24 months. We estimate a negligible reduction in costs (which we estimate to be zero) and benefits associated with reducing retention times in the final rule.

The provision specifying the shorter retention requirements of 6 months, 12 months, and 24 months may result in the destruction of records earlier than would be the case for the longer retention requirements. While we estimate the reduction in benefits from the reduced retention times to be negligible, we explain the logic behind the perverse incentive for the early destruction of records, and its potential impact on traceback performance. The benefits from the records access requirements cannot be realized without the records retention requirements. If records no longer exist, there is nothing for FDA to access.

Given the records access requirement, the records retention requirement in both the proposed and final rules may create a perverse incentive for entities to destroy records, even though we estimate that this incentive will lead to the actual destruction of very few records, and very small reductions in investigative speed. Private firms are quite reluctant to share their private records with outsiders such as federal regulatory agencies. Facilities may choose to destroy records once legal retention requirements have been met rather than risk the possibility of sharing them with FDA. Consequently, there is a nonzero probability that facilities will destroy records subject to the retention requirements shortly after the legal retention requirement has been met, and that those records would not exist in the event of an FDA records access request.

The incentive to destroy records due to the access requirement will likely result in the destruction of a very small fraction of records because of the private utility from retaining records, and also the costs of destroying them. Because of the perverse nature of this incentive, it is informative to estimate its impact on the benefits from final rule—especially since the costs of the 1 and 2 years records retention provisions were estimated to be zero because the retention time periods are the same as or shorter than current business practices.

We used outbreak investigation data to estimate the reduction in benefits when retention requirements are redefined to be 6, 12, and 24 months based on NIST definitions of shelf lives. Investigations that remained open 6 months after initial exposure were considered possible candidates for continued investigative visits. From FDA investigation information, we estimated that about 20 percent of all FDA investigations from 2000 to 2003 remained open 6 months after initial exposure to the pathogen. However, it is likely that most of these investigations did not require access to a firm's records after 6 months.

We assume that a maximum of 20 percent of all traceback investigations are candidates for a records access request 6 months after initial exposure to the pathogen. We assume that half of the investigative visits in one of these candidate investigations requires access to records after 6 months, and that 1/3 of these access requests are for records subject to the 6 month retention period (i.e., a 1/3 probability for 6 months, a 1/3 probability for 12 months and a 1/3 probability for 24 months). Consequently, 3.3 percent of records requests for records subject to the 6 month retention time are estimated to be made after 6 months (20 percent x 1/2 x 1/3).

We assume that the potential records destroyed (after retention requirements have been met) as a result of the access requirement would be from the set of establishments with the poorest food safety practices. To determine the percent of firms with the poorest food safety practices, we obtained information from FDA personnel indicating that inspections of approximately 3 to 4 percent of all FDA-regulated food and cosmetic facilities from 2001 to 2003 were classified as official action indicated (Ref. 20). Based on this information, we assume that the incentive for records destruction will result in approximately 3 to 4 percent of firms destroying their records after 24 months, with destruction taking place shortly after retention commitments have been met.

We assume that the private utility of records decreases over time, and that the rate at which records subject to 6 months retention are destroyed shortly after meeting the retention requirement is half that for records subject to 12 months retention, which is half that for records subject to 24 months retention. Consequently, an estimated 0.5 percent of records subject to the 6 month retention time are assumed to be destroyed shortly after the 6 months have been met (i.e., the solution for ''X'' when solving the algebraic problem, 3.5 percent = X + 2X + 4X, where 3.5 percent is the midpoint between 3 and 4 percent and the rate at which all records are destroyed, X is the rate that records subject to the 6 month retention requirements are destroyed, 2X is the rate that records subject to 12 month retention requirements are destroyed, and 4X is the rate that records subject to the 24 month retention requirements are destroyed.). The destruction of records is estimated to affect about 0.02 percent of access requests (i.e., 0.5 percent records destruction rate x 3.3 percent of records requests made after 6 months). Finally, we assume that records destruction will slow down and terminate traceback investigations at the same rates at which the destruction takes place. Consequently, we estimate that both traceback speeds and rates of successful traceback completions will decline by 0.02 percent because of access requests when the requested records had been destroyed because of retention requirements.

c. *Extending the compliance dates.* Another policy option considers extending each of the proposed compliance dates by 6 months: Large, small, and very small firms would be required to be in compliance with the regulation 12, 18, and 24 months, respectively, after publication of the final rule instead of the proposed 6, 12, and 18 months after publication. The longer compliance dates reduce the time savings for a preventive action for 50 percent of the annual number of traceback investigations, and lead to a 50 percent increase in the annual number of outbreak investigations prematurely terminated for records quality reasons. Unlike the reduction in the benefits from the other policy options considered, these are one-time decreases in the benefits, because the option only extends the initial baseline compliance times by 6 months.

d. *Exemption of all very small entities.* FDA also considered whether it should exempt all entities with ten or fewer employees, not just those in the retail sector as is provided in the final rule; however, this would create a ''Swiss Cheese'' approach to trace back, as there would be a potential failure of entities to keep records throughout the distribution chain. The number of very small entities account for a large fraction of the total number of food establishments.

Moreover, many of our failures in a typical trace back investigation (i.e., unclassified scenarios) have been at the wholesaler (distributor) level. As discussed above, we would have significant concerns if 90 percent of the transporters (as very small entities) would be excluded from the requirements to establish and maintain records, particularly if these are predominantly intrastate transporters that are not currently subject to DOT's requirements. (FDA notes that intrastate shipments carried by interstate transporters also are not subject to DOT's requirements.)

In light of the above, FDA does not believe we would have an effective recordkeeping system if we were to exempt all very small entities from the rule. Unlike the very small retailers who are at the end of the distribution chain only, a full exemption by size would create holes throughout the distribution chain and would not provide FDA adequate assurances that, in the event of a threat of serious adverse health consequences or death to humans or animals, FDA would be able to conduct an efficient and effective traceback investigation.

F. Costs

1. Estimates of the Number of Facilities Affected By the Final Rule

In the PRIA, FDA estimated the number of transporters and packers from data in the 2000 County Business Pattern statistics (Ref. 21) and the 1999 Nonemployer statistics (NES) (Ref. 22). We assumed that local and long distance specialized freight carriers devoted exclusively to transporting food were about 20 percent of the total of the specialized freight category. In the PRIA, FDA requested comments on the assumption that 20 percent was appropriate for this estimate.

(Comment 182) Several comments suggest that the number of trucking entities covered by the rule was substantially underestimated. One comment suggests that while 20 percent of the specialized carriers transport food products at any specific time, most specialized carriers transport food at one time or another. Another comment suggests that FDA's estimate of the number of covered trucking entities was low; the comment cites information obtained from the U.S. DOT that indicated close to 600,000 operating authorities on file, which includes Mexican, Canadian, and domestic carriers. Moreover, the comment suggests that if half of the general carrier population (600,000 carriers) transports food on an occasional basis, then over 300,000 companies would be affected. These numbers suggest an estimate of covered trucking facilities much larger than FDA's estimate. To support the assertion of an underestimate, the comment suggests that FDA-regulated Mexican carriers alone likely account for 12,000 facilities. Another comment states that individual transporters, not only transportation firms, will hold food while it is in transit and that transportation vehicles do not appear to be exempt from the recordkeeping requirements.

(Response) FDA agrees with the concerns underlying many of these comments and revises its estimates of the number of transportation entities in a way that is consistent with the data and framework used in the PRIA. Although FDA does not dispute the comment that most specialized carriers transport food items at one time or another, the ease with which transporters enter and leave the food industry is considered in the PRIA. That analysis already accounts for the additional learning, records access, and planning costs incurred by new entrants. In the PRIA, FDA estimated that there would be approximately a 10 percent rate of entry and exit of new and existing firms for all sectors. FDA calculated the startup costs for these new entrants and added them to the compliance costs incurred by existing facilities.

The County Business Pattern and NES used by FDA in the analysis include all potentially covered transporters (except foreign-based carriers that transport food in the United States), including individual carriers. However, in the PRIA, FDA neglected to include the number of establishments under North American Industry Classification System (NAICS) code 4841 for general freight trucking as well as for NAICS code 488510 for freight transportation arrangement. In the analysis of the final rule, we include entities that fall under both of these categories.

The combined data from the County Business Pattern and NES contain 384,358 establishments under code 4841 for general freight trucking. In addition, the County Business Pattern data contain 15,177 establishments for code number 488510 for freight transportation arrangement. To estimate the number of facilities under code 488510 in the NES data, we calculated

the ratio of the number for code 488510 to the total number for code 488 in the County Business Pattern data, and then applied that ratio to the number of establishments under code 488 in the NES data. We assumed a uniform distribution of food and nonfood carriers under the general freight trucking category and estimated the number of establishments that transport food products under code 4841 to be half of the total for that category. We assumed the number of establishments under code 488510 that arrange freight transportation for food products to be 20 percent of the total for that category. We assumed that the same percentage applies to the total assumed for specialized freight carriers dedicated to the food industry. As a result of these changes, the total number of domestic transportation and packing facilities is revised upward from 16,773 facilities used in the PRIA to 234,980. The numbers of establishments by code are reported in table 12 of this document.

TABLE 12.—NUMBER OF TRANSPORTATION ESTABLISHMENTS BY NAICS CODE

NAICS Code	Description	CBP 2000	NES 99
481112	Scheduled freight air transportation	584	2,413
481212	Nonscheduled chartered freight air transportation	217	
483111	Deep sea freight transportation	485	4,754
483113	Coastal and Great Lakes freight transportation	546	
483211	Inland water freight transportation	402	
4841	General freight trucking	27,937	164,242
48422	Specialized freight (exclusively used) trucking, local	6,499	4,946
48423	Specialized freight (exclusively used) trucking, long distance	2,580	8,189
488320	Marine cargo handling	607	2,415
488510	Freight transportation arrangement	3,035	3,814
488991	Packing and crating	1,315	

Foreign transportation carriers that cross the northern and southern U.S. borders are not counted in the County Business Pattern and NES data, because they are foreign based. All of these carriers are subject to DOT regulations, and the costs of compliance for these facilities are assumed to be zero because the final rule allows a transporter to meet its obligations by keeping the records currently required by DOT. However, foreign transportation carriers that cross the northern and southern U.S. borders are assumed to incur learning costs associated with this final rule.

FDA estimates the number of Mexican carriers that are subject to DOT regulations from a study conducted for DOT by Economic Data Resources under the auspices of the International Association of Chiefs of Police (Ref. 23). Using 1999 U.S. Customs and Border Protection data on the use of annual decals and per-trip payments by commercial vehicles at Southwest border crossings, that study estimated the total number of vehicles that cross the Southwest border to be approximately 76,177. Furthermore, using 1998 data on Mexican interstate commercial vehicle registrations, the DOT study estimated the number of commercial carriers of Mexican origin that use the Southwest border crossings to be approximately 63,000, or approximately 83 percent of the total. If one half of the total number of these trucks carry food items, then approximately 31,500 carriers of Mexican origin are subject to this final rule and would not be counted in the CBP or NES data.

In order to estimate the number of commercial carriers of Canadian origin that would be covered by this final rule, from the DOT study we obtain an estimate of approximately 79,643 carriers that purchase annual decals at the Northern border. We assume the same ratio of the total number of trucks that purchase annual decals for Southwest border crossings as that for northern border crossings (42 percent) and estimate the total number of trucks that cross the northern border to be approximately 191,167. Furthermore, we assume the percentage of these carriers that are of Canadian origin is the same as that used to estimate Southwest border crossings by Mexican carriers (83 percent). This assumption yields a total of 158,099 carriers of Canadian origin that are subject to DOT regulations. If one half of the total number of these trucks carry food items, then approximately 79,050 carriers of Canadian origin are subject to this final rule and would not be counted in the CBP or NES data. The number of transport facilities is revised upward by 110,550 (i.e., 79,050 plus 31,500) to account for the number of foreign based transporters that are subject to the final rule and not counted in the NES or CBP data.

(Comment 183) One comment states that direct selling businesses are clearly not accounted for because there are millions of such entities involved on either a full or part-time basis, while the combined estimate of domestic retailers and wholesalers used in the analysis is only slightly more than 300,000. Furthermore, the comment states that the burden on these retailers would be higher than for other retailers.

(Response) FDA does not agree that there are millions of direct marketers of food in the United States. Nor does FDA agree that the burden on direct marketing retailers would be greater than for other retail establishments. However, FDA does agree that the data sources used in the PRIA may not account for many small direct marketers that may not have filed as a sole proprietorship business with the Internal Revenue Service (IRS). While these direct marketers may have been omitted in the PRIA, they are considered exempt in the final rule and are not included in the cost estimates in this analysis. Nevertheless, in order to respond to comments and to estimate the cost of policy options that include very small retailers, FDA does revise its estimate of the number of retail establishments to account for direct marketers that may not have been included in the PRIA.

FDA found estimates of 10 million (Ref. 24) and 12 million (Ref. 25) direct marketers in the United States, but these estimates included all the direct marketers of both nonfood and food products in the United States. FDA does not have a complete census of the number of marketers of food versus nonfood products. To approximate the percentage of direct marketers selling food, FDA divided the number of direct marketing companies selling food by the number selling all types of products, using data from the directory of companies on the Web site of a large direct selling trade organization (Ref. 25). Of the 141 companies in the directory, approximately 5 market food or beverages, or approximately 3.5 percent of the total.

The number of direct marketing establishments should be captured by the NES, which are generated chiefly from administrative records of the IRS. These data are primarily composed of sole proprietorship businesses filing IRS Form 1040, Schedule C (Ref. 22). Many of the nonemployer businesses are very small, and many are not the primary source of income for their owners. Furthermore, nonemployers account for 75 percent of all businesses.

There is the possibility that direct marketers are included in the estimate of the number of direct marketers cited earlier and excluded in the NES if they are casual market participants, and have temporarily left the industry, or if they do not file as a sole proprietorship business with the IRS. Casual market participants might be included in the estimate of the total number of direct market facilities even if they are not active members. This would tend to inflate the total number of direct marketers to include both active and inactive members. Because of the ease of entry and exit by these firms, casual direct marketers that have temporarily left the industry are assumed to be approximately half of the number of direct marketers of food, or 1.75 percent of all direct marketers. This assumption leaves an estimated 1.75 percent (175,000) of direct marketers that are not counted in the NES statistics because they did not file as a sole proprietorship business with the IRS. We use this estimate of the number of direct food marketers that did not file as a sole proprietorship business with the IRS to revise our estimate of the total number of retail facilities.

Direct marketers that did not file as a sole proprietorship business with the IRS are assumed to be part-time suppliers and to sell mostly at the retail level. Furthermore, because these are very small businesses that only sell food products on a part-time basis, the additional records maintenance costs for these facilities will be considerably less than that for larger, full-time businesses. We estimate the additional records maintenance costs for these part-time facilities to be one half that for other retailers. The learning costs, records redesign costs, and records access planning costs for these facilities are assumed to be the same as for other facilities.

FDA does not agree that the burden of the rule would be higher for direct marketers than for other retailers. In the PRIA, FDA estimated that about 88 percent of retailers classified as very small firms have fewer than 10 employees. FDA believes it is reasonable to assume that compliance costs for direct marketers would be about the same as for other very small firms.

(Comment 184) One comment suggests that FDA underestimated the number of mixed-type facilities that engage in nut farming. The comment states that, in the almond industry, there are about 360 hullers and processors who are also growers, while FDA estimated that there were only 290 mixed-type facilities that engage in all categories of nut farming. Furthermore, because there are about 6,000 almond growers, the comment states that this implies that 6 percent of all almond growers would be classified as mixed-type facilities, compared to FDA's estimate of 2 percent of all nut farms.

(Response) FDA acknowledges considerable uncertainty in the estimates of the numbers of mixed-type facilities that engage in farming and is receptive to comments from industry that can improve them. There is likely to be more uncertainty in the estimates of the number of mixed-type facilities that engage in any individual category of nut farming than that for the estimate of the number of mixed-type facilities that engage in nut farming over all categories of nuts. FDA will use the estimate provided by the comment to revise its estimate of mixed-type facilities that engage in nut farming from 2 percent to 6 percent. The total number of mixed type facilities that engage in farming is revised upward to 31,077 from 30,497 used in the PRIA.

Table 13 of this document is a revised table of mixed-type facilities that engage in farming.

TABLE 13.—MIXED-TYPE FACILITIES ENGAGE IN FARMING

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Farms
Pig farms (feed mixing)	46,353	1.5%	695
Cattle (feed mixing)	785,672	1.0%	7,857
Poultry (feed mixing)	36,944	1.0%	369
Other animal production (feed mixing)	110,580	1.0%	1,106
Dairy	86,022	1.1%	903
Grain, rice, and beans	462,877	1.0%	4,629

TABLE 13.—MIXED-TYPE FACILITIES ENGAGE IN FARMING—Continued

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Farms
Apples	10,872	1.5%	163
Oranges	9,321	1.5%	140
Peaches	14,459	1.5%	217
Cherries	8,423	1.5%	126
Pears	8,062	1.5%	121
Other fruit	29,413	1.5%	441
Nuts	14,500	6.0%	870
Berries	6,807	1.5%	102
Grapes	11,043	10.5%	1,160
Olives	1,363	3.5%	48
Vegetables and melons	31,030	0.5%	155
Organic vegetables	6,206	50.0%	3,103
Honey	7,688	50.0%	3,844
Syrup	4,850	100.0%	4,850
Herbs	1,776	10.0%	178
Total			31,077

(Comment 185) One comment states that FDA mistakenly omitted the number of food grade warehouses that are subject to the regulation included in NAICS code 49311. Consequently, FDA's estimate that a total of 76,952 wholesaler and public warehouse companies are affected by the regulation is too low, and these additional warehouses should be included in the cost calculation of the final rule.

(Response) FDA agrees that public warehouses included in NAICS code number 49311 were omitted from the count of total warehouse facilities. Table 14 of this document describes the primary activities performed by the warehouses included in this classification.

TABLE 14.—DESCRIPTION OF PRIMARY ACTIVITIES PERFORMED BY WAREHOUSES BY NAICS CODE

NAICS	SIC	Corresponding Index Entries
493110	4225	Bonded warehousing, general merchandise
493110	4225	General warehousing and storage
493110	AUX	Private warehousing and storage, general merchandise
493110	4225	Public warehousing and storage (except self storage), general merchandise
493110	4226	Warehousing (including foreign trade zones), general merchandise
493110	4225	Warehousing and storage, general merchandise

There are a total of 4,415 of such facilities listed in the County Business Pattern data. In the NES statistics, there are 4,700 reported for the aggregate NAICS code of 4931. To estimate the number of warehousing facilities that would be included in NAICS code 49311 in the NES statistics, we scaled the aggregate number in the NES statistics by the ratio of the numbers reported for code 49311 to the total of those reported under code 3931 in the County Business Pattern. When the imputed NES numbers for code 49311 are added to the reported County Business Pattern numbers for code 49311, the total number of facilities in the NAICS code is 7,328 facilities. We adjust the total number of warehouses by one half of the total number of facilities reported for code 49311 by assuming that half of the total number of facilities included in that code handle food items. The number of warehouse facilities is revised upward to 6,089 from the 2,425 in the PRIA. The facilities-to-firm adjustment factor used for the facilities listed in NAICS code 49311 is the average of that used for the

other two warehouse codes in the analysis.

(Comment 186) One comment requests clarification as to whether all members of the International Bottled Water Association were included in the number of facilities covered by the regulation.

(Response) The NAICS code 3121 used in the PRIA includes all beverage manufacturers and specifically includes bottled water manufacturers. All other bottled water suppliers are included in the various NAICS codes used to count wholesalers and retailers, and other food suppliers.

Finally, the changes to the costs and benefits of the final rule due to the expanded coverage to include persons that export food for consumption outside of the United States are estimated to be small. We assume that the export of food and feed occurs at the manufacturing and wholesaling levels, with retailers unlikely to engage in export. The U.S. Census Bureau's 1997 Economic Census (Ref.17) indicates that approximately 4 percent of wholesale trade in all grocery and related products (NAICS code 4224) was from export sales. We assume that the same percent also applies to exports in the manufacturing sector and also to the numbers of facilities in those sectors. An estimate of 4 percent likely overstates the true incremental cost of covering exported food and feed since most, if not all of the establishments engaged in export are also likely to be engaged in domestic commerce and consequently would not incur additional learning and records redesign costs. Moreover, firms that export and also engage in domestic commerce are unlikely to incur additional maintenance costs because it is unlikely that they would follow two sets of recordkeeping practices. Consequently, only firms that are exclusively exporters will incur incremental recordkeeping costs as a result of expanded coverage. We assume that half of all wholesale and manufacturing establishments estimated to engage in export, or 2,736 facilities, are exclusively exporters and will incur recordkeeping costs as a result of expanded coverage to include export of food and feed.

The incremental benefits from expanding the coverage to include exported food and feed are from the possibility that some of these shipments may be diverted for domestic consumption, and their coverage may enhance traceback investigations should they be necessary. The food safety (but not food security) benefits from expanded coverage are likely to be negligible since the likelihood of diversion is small, and the likelihood that a diverted shipment is accidentally contaminated is also small. However, the food security benefits, while not quantifiable, include classified scenarios that could include diversion of food and feed. Further, FDA is concerned that exempting foods intended for export from the recordkeeping regulations could lead to such foods being targeted for tampering by terrorists and reintroduction into domestic commerce as they would prove more intractable to tracing investigations. Including the revisions described previously, we estimate that a total of 707,672 facilities will be covered by this final rule. This represents a reduction of 96,642 facilities compared with the number estimated in the analysis of the proposed rule.

2. High Cost of Tracking by Lot Code

(Comment 187) Many comments state that lot codes are not currently used in tracking products at the distributor and retailer levels, and that requiring lot codes to be recorded by these entities would represent a large change in business practice. One comment states that only 10 percent of food distributors currently use lot numbers to track their food products. One comment states that its facility tested the proposed requirement to establish records of lot numbers in its daily operations and concluded that there would be an 80 percent loss in productivity as a result of the requirement. Another comment states that labor costs for unloading a truck at a distributor would increase by a factor of 15 under an exhaustive check of shipper and lot code information. The comment further states that a conservative estimate of the unloading costs would be a threefold increase in current costs if a less exhaustive spot check of the lot codes is required.

Other comments illustrate the dramatic change in current business practices that would result from requiring lot codes to be included in records. However, several comments indicate that although the technology to maintain lot codes in bar code format does not currently exist, the industry is moving in that direction and such a requirement might be feasible in 5 to 7 years.

(Response) In estimating the costs of the rule, FDA assumed that all required information provided for in the regulation represented only small deviations from current business practice. The comments received strongly suggest that the cost estimates for maintaining records on lot codes for distributors and retailers were substantially understated. The results reported by one comment of an experiment that tested the requirement in their daily operations indicated an 80 percent loss in productivity. Other estimates of the increase in labor costs that would result from this requirement ranged from three-fold to fifteen-fold. FDA revises the estimates of the costs to maintain records on lot codes by assuming an 80 percent loss in productivity for retailers and distributors from compliance with this provision. For other policy options included in this analysis as well as in the final rule, the requirement to establish and maintain records containing lot codes is relaxed to be consistent with current feasibility.

3. Records Retention Costs

(Comment 188) Several comments address the costs of records retention. Several comments suggest that records are often stored off site or at corporate headquarters, with a nonzero cost for retrieval. Another comment recommends that we review our estimate of records retention costs of zero. The comment states that firms that handle products not covered by the juice HACCP regulation (part 120) may not have a records retention strategy and may have to implement a new strategy for records retention and recovery. Several comments express uncertainty with regard to the appropriate records retention time of either 1 year or 2 years for the products that they handle. These comments suggest definitions of ''perishable'' that would be more consistent with the terminology used in the trade, which is different from the definition in the proposed rule. Recommended records retention times ranged from a low of 6 months for perishable foods, up to 2 years for other foods.

(Response) In the PRIA, we used information from preliminary outreach to tentatively conclude that requirements for records retention of 1 year for perishable products, and 2 years for all other foods were consistent with current industry norms. The respondents to the outreach were not necessarily subject to the recordkeeping requirement of the juice HACCP rule, and we assume that the understanding of the term ''perishables'' by the respondents to that outreach was based on the conventional use of the term, rather than the definition of the term used in the PRIA.

In response to comments, the record retention requirements for nontransporters in the final rule now provide: (1) 6 months for food for which a significant risk or spoilage or significant loss of value occurs within

60 days under normal shipping and storage conditions for that food; (2) 1 year for food for which a significant risk of spoilage or significant loss of value occurs within 61 days to 6 months under normal shipping and storage conditions for that food; and (3) 2 years for food for which a significant risk of spoilage or significant loss of value occurs greater than 6 months under normal shipping and storage conditions for that food.

(Comment 189) One comment suggests that the estimates of zero storage costs from records retention are too low. The comment estimates that offsite storage and recovery costs range between $2.50 and $3.50 per cubic foot per year.

(Response) The costs for records storage and retrieval are not zero, but the additional storage costs likely to be incurred by covered entities as a result of this regulation are assumed to be zero. We assume that the private benefits from retaining records for the 1 and 2 years time frames required by this rule exceed the private costs of doing so. The range of comments to the proposal suggests that this assumption is reasonable. The private benefits of retaining records include enhancing a firm's ability to do the following: (1) file claims for shortages in quantities or qualities of products received, (2) respond to claims for shortages in quantities or qualities of products shipped, (3) sue suppliers for damages resulting from products received, and (4) respond to suits filed by downstream users for damages resulting from products shipped. FDA also believes that most firms retain these records for at least two years for income tax purposes. Therefore, FDA is not persuaded by the comment that most firms do not currently retain these records.

Evidence gathered from interviews with FDA traceback investigation personnel indicate that current records retention practices in the food industry have not been a major obstacle to successful traceback investigations. In addition, comments suggest that records retention requirements should be linked to the shelf life of the product (which is presumably the current practice), and suggest retention times of 6 months to 2 years, depending on the shelf lives of the products. FDA interprets this evidence to indicate that even in the absence of records retention requirements, the private incentives to retain records would result in records retention times in excess of those required in the regulation.

(Comment 190) One comment draws comparisons of the proposed records retention burden on small and large trucking firms. The comment contains a calculation of the number of records that would be required to be retained by a typical owner and operator of a single truck. The comment states that a 2 year retention requirement would obligate an owner and operator of a single truck to have on hand approximately 598 sets of load documents at any given time. If the average set of documents contained 20 pages, then this person would be required to retain approximately 11,960 pages at any given time. The comment suggests that this amount of documentation could be easily kept inside the truck in a side box and later transferred to an office corner or file cabinet at the owner's convenience. By assuming the number of documents to be retained by a firm is commensurate with the number of trucks owned by the firm, the comment argues that the proposed retention requirement would require large firms to retain an unreasonable amount of paperwork requiring substantially more storage space.

(Response) FDA notes that we computed the retention costs of the proposed rule on a per-facility basis and that we assumed that costs did not differ significantly from those of current business practices. The example documented in the comment illustrates the small amount of storage space that is required per facility. In the PRIA, FDA assumed that all firms keep most of the proposed records so that larger firms with a larger quantity of records may find it necessary to retain off-site records storage. In the final rule, FDA has revised the recordkeeping retention and other requirements for transporters to be consistent with current requirements for interstate transportation. Consequently, the retention requirements from this final rule should impose no extra burden on these facilities.

(Comment 191) One comment from an association of wholesalers states that its members typically retain invoices and shipping records for approximately 6 months and will find it difficult to find the storage space to retain records under the proposed requirements. The comment states that a 2-year retention requirement would constitute a dramatic change in distributors' operations and lead to a substantial increase in data storage costs.

(Response) FDA does not agree that the retention requirements from this final rule will impose a large burden on food businesses. Only a small fraction of information is required to be added to existing records. Furthermore, based on preliminary research, a survey of dietary supplement manufacturers, and our interpretation of most of the comments to the proposed rule, the retention requirements in this final rule do not differ substantially from the industry norm. We believe that any change in practice from wholesalers that generates costs is mostly included in the estimated redesign and other set-up costs.

4. Records Access Costs

(Comment 192) One comment states that a 4 and 8 hour records access cost is an additional cost, because it requires retrieval on the weekends, which may require companies to renegotiate storage contracts to allow for weekend access.

(Response) FDA researched typical records storage contracts and found that at least one company's standard records retention contract explicitly provides that ''unscheduled or emergency delivery of records'' was to be charged on a ''per event'' basis (Ref. 26). FDA assumes this to be the norm in the industry. For both the proposed and final rules, FDA does not estimate the probability of a records access request, and weekend access is assumed to be charged on a per-event basis, which is considered a cost of performing a records access request. Because the records access costs are estimated to be the private costs of planning for a records access request, rather than for performing a records access request, the estimates for planning for a records access request in the analysis of the final rule do not change.

(Comment 193) Many comments assert that the cost estimates for requiring 4 and 8 hour records access were too low or inappropriate. Comments support this assertion by citing factors ranging from the additional staffing requirements necessary to respond to a records request at such short notice, to the burden of a records access request being dependent on the number of records, and to the length of time covered by the records requested. Some comments state that a 48-hour records access requirement would be reasonable, and some comments state that 24 hours would be reasonable.

(Response) FDA acknowledges the difficulties faced by firms complying with the 4 and 8-hour records access requirements. This final rule requires providing access to records as soon as possible, but no later than 24 hours after an FDA request. The costs for 4 and 8 hours and 24 hours are analyzed as policy options later in this document. In the PRIA, we estimated the records access costs as the costs for planning for a records access request. FDA assumed

that the 4-and 8-hour response time required would compel business practices to change as firms developed preemptive emergency plans, while a 24-hour response requirement would not compel firms to modify their current business practices. Interviews with FDA traceback personnel suggest that firms are able to comply with a 24-hour records access request. Many comments support the notion that a 24-hour response time is not an unreasonable requirement given current business practices. Consequently, FDA maintains the assumption that a 24-hour records access requirement is reasonable under current business practices and that a 4 and 8 hour records access requirement would require additional planning for a records request.

Relaxing the records access requirement from 4 and 8 hours to 24 hours leads to an estimated cost savings relative to the PRIA. The access planning cost estimate assumed that 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) would be a one-time requirement for each firm. FDA estimated that new businesses would also have to incur records access costs. As a result of relaxing the records access request time to 24 hours, these costs will no longer be incurred.

5. Additional Records Maintenance and Redesign Costs

The cost estimates assume that the information a covered entity must keep is specified, but that the form or type of system in which those records are maintained is not specified; we expect that firms will collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements in the manner most economically feasible for them, including modifying shipping or purchase records, such as bills of lading, invoices, or purchase orders.

(Comment 194) Several comments question the format for presenting the additional required information and whether existing records could satisfy the requirements. These comments cite specific types of transactions to illustrate the difficulties in maintaining the required information on one form. In addition, several comments state that the required information is typically available. One comment states that it is already standard business practice to maintain all required information on bills of lading in the trucking industry. Several comments state that FDA should maintain flexibility in the information required, as well as the type of forms maintained.

(Response) Neither the proposed nor final rule specifies the form or format in which records are to be established and maintained. There are no restrictions on the kinds of forms maintained. Commercial invoices, bills of lading, packing lists, and other forms commonly used when executing business transactions can all be used to record the information required by the regulation. We assume that most of the required information is already maintained on forms ordinarily used in conducting business. Persons subject to this final rule can choose to record the required information in one record or to use existing and newly created supplemental records to capture the required information.

(Comment 195) One comment requests clarification that ''transportation record'' includes the various documents that may be developed by a company and that it is not necessary to include all of this information in one shipping document. Furthermore, the comment asks us to clarify that existing records can be used to satisfy the requirements, even if they are not in the same location within the manufacturing facility (i.e., all required information is there, but not in the same location).

Others comment that the proposed regulation is not practical or reasonable, and fails to consider the business practices currently in place for food protection.

(Response) FDA believes that most of the information required by this regulation is currently collected as a matter of normal business practices and that any changes to current business practices as a result of this final rule are small. The revised language in the final rule removing the requirement to record lot codes for distributor and retail facilities increases the agency's belief that changes to existing recordkeeping practices will be small.

(Comment 196) One comment states that the need for both manufacturers and third party warehouse or wholesalers to keep the records is redundant.

(Response) Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. It allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. In a traceback investigation, it is critical that FDA be able to locate and remove from commerce any adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 197) Several comments suggest that the information required by the proposed regulation is excessive and that it would require significant changes in business practices to collect and maintain the required information. One comment suggests that requiring records of names, addresses, and telephone numbers of each supplier for each transaction is excessive. A comment suggests that its firm has no way to capture all of the proposed data elements through current sources of transaction documentation.

(Response) FDA assumes, and comments agree, that most of the information required by this regulation is already collected and maintained through currently used transaction documents. The final rule requires lot codes or other identifiers only of persons who manufacture, process, or pack food, and only to the extent this information exists. The final rule also does not require that a responsible individual be identified for the immediate previous source and immediate subsequent recipient for each transaction, as was required by the proposed rule. Accordingly, FDA does not modify its assumptions underlying the estimate of the costs of establishing and maintaining records.

6. Estimates of Additional Records Maintenance Costs Too Low

In the PRIA, FDA assumed that the burden of maintaining and collecting additional information would be shared among more than one facility.

(Comment 198) Comments state that FDA's estimates of recordkeeping burden obtained from the juice HACCP rule are inappropriate. The comments state that using the juice HACCP model substantially underestimates time requirements because most other types of firms would require more resources to achieve the proficiency required under the HACCP rule.

(Response) The juice HACCP cost estimates that we used to estimate costs in the PRIA were published before the juice HACCP rule took effect. The cost estimates for that rule were for firms that were not yet in compliance. FDA continues to believe that those cost estimates are an appropriate reference for this final rule, because they represent a precedent for cost estimates of activities similar to those required in this regulation.

(Comment 199) According to numerous discussions with those who are subject to HACCP regulations, the time and money estimates of the costs FDA provided in the seafood HACCP

rule were about 1/10 the actual values. This represents a big underestimate of the true costs of the regulation.

(Response) The costs estimated in the PRIA use cost estimates of the juice HACCP rule as a reference, not those of the seafood HACCP regulation. FDA has also received information that costs for compliance with the seafood HACCP rule were underestimated. FDA developed the estimates for the juice HACCP rule much later than those for the seafood HACCP rule. In addition, the burden for the additional records maintenance required in this final rule is considerably less than that required by the juice HACCP rule, particularly because FDA has relaxed the requirement for maintaining lot code information in the final rule and removed the requirement to record and maintain contact information for each transaction.

(Comment 200) Some comments state that FDA failed to account for the effect of higher transaction costs (as a result of the regulation) on reducing arbitrage opportunities. Food arbitrage is a line item in most food distributors' and retailers' financial statements. The comments assert that this final rule will result in fewer arbitrage opportunities, because the cost of a transaction will rise, which will cause a substantial reduction in profits, encourage layoffs, and raise consumer prices.

(Response) FDA agrees that the recordkeeping provisions in this regulation may increase the costs of transactions, thereby decreasing the total number of transactions. FDA believes, however, that transactions will be only slightly costlier and the effect on consumer prices and arbitrage opportunities will be small.

(Comment 201) One comment urges FDA to clarify and confirm that it would not consider records identifying producers of coffee cherry for traceback purposes as information that would be considered to be ''information reasonably available.'' The comment states that it would be prohibitively costly to link the identities of individual coffee cherry growers to any processed food item, because the cherries from many growers are typically mixed upon delivery to a processing facility.

(Response) Both the proposed and final rules require incoming ingredients to be linked specifically to outgoing food products only if that information is reasonably available (as discussed previously). What is reasonably available is determined on a case-by-case basis and depends on the operating practices of a specific facility. FDA does not intend the rule to require covered entities to reconfigure their operations. If cherries from many growers are typically mixed (i.e., commingled), then full information linking ingredient source to final product may not be reasonably available. If, however, the cherries are in separate bins based on supplier or easily can be separated and identified, then full information linking source to final product may be reasonably available. In the PRIA, FDA acknowledged the prohibitive cost of a policy option requiring producers to be able to link specific ingredients to specific food products (option 13 in the proposal). That option was ultimately rejected, in part, because of the high cost of identifying the producers of traditionally commingled raw commodities. Instead, both the proposed and final rules required linkage only when the linkage is reasonably available.

7. Labor Cost Estimates

(Comment 202) Several comments suggest that the wage rate used by FDA in the PRIA of $25.10 is too low. One comment suggests that an hourly wage of $33 would be more appropriate for the analysis, because it would reflect the need for higher-level personnel involvement due to complexities in the proposed rule. Another comment suggests that the $25.10 wage is reasonable, but that the hour estimates are too low.

(Response) FDA disagrees with the suggestion to increase the wage rate used in the analysis because the implied annual wage and overhead cost of more than $52,000 seems more than reasonable, as suggested in another comment.

(Comment 203) One comment argues that there is no evidence that the wage of $25.10 used in the analysis has been doubled to account for overhead in any of the calculations.

(Response) The hourly wage of an administrative worker reported by the Bureau of Labor Statistics of about $12.55 was doubled in the computations to account for overhead costs. FDA acknowledges that this was not clearly stated in the PRIA.

8. Learning Costs

(Comment 204) Some comments state that FDA's estimate of 3 hours for learning costs is low. The comments state that access to the Internet and lack of fluency in English are not the only costs. The comments maintain that learning cost estimates did not include the time for an FDA explanatory video and did not include adequate time for evaluating the information in the rule.

(Response) Although the comment states that 3 hours is too low an estimate, the comment did not indicate how the learning cost estimates as a whole, or any of the component cost estimates, can be improved. FDA explicitly incorporates the costs of searching, learning, and comprehending the rule in the PRIA. Learning cost estimates are composed of costs for searching for a copy of the requirements, and reading and understanding them. Because of the approximate nature of the calculation, FDA rounds up to the nearest half hour to 3 1/2 hours for the time required for reading and comprehending the requirements of this final rule for all English reading users. Although the cost of viewing the explanatory video was not explicitly included in the PRIA, such a viewing was assumed to reduce the burden from other searching and learning activities. Consequently, in the analysis of the final rule, FDA maintains the learning costs estimates used in the PRIA.

9. Specific Sector Cost Estimates

a. *Transportation and warehouse sector.* (Comment 205) At least one comment states that trucking companies already maintain the required records to comply with another Federal regulation and therefore additional Federal requirements would be duplicative.

(Response) FDA has included several options in this final rule for transporters to comply with their obligations to establish and maintain records under this final rule. One option is for transporters to keep some of the records currently required by the FMCSA regulations as of the date of publication of this final rule. The FMCSA regulations already require interstate transporters to establish and maintain transportation records, and we assume that interstate transporters who already comply with the FMCSA recordkeeping requirements will choose to comply with this final rule by maintaining such records. However, the FMCSA regulations cover only interstate common carriers, while this regulation covers all persons who transport food, including intrastate carriers. Moreover, domestic air carriers, and interstate transporters of low-value packages may not be required to comply with FMCSA regulations. Consequently, as a result of this final rule, intrastate carriers, intrastate shipments by interstate carriers, domestic air cargo carriers, and transporters of low-value packages may incur recordkeeping costs, in addition to learning costs, as a result of this final rule.

To estimate the costs incurred by intrastate carriers, domestic air cargo carriers, and transporters of low value

packages, we first estimate the number of facilities that engage in only intrastate food transportation. Then, we adjust this number to account for domestic air cargo carriers of food shipments and carriers of low-value food packages. Additional records maintenance costs incurred by interstate carriers of intrastate shipments are estimated to be zero since it is unlikely that a transportation establishment would use two sets of recordkeeping practices.

To determine the number of intrastate carriers subject to this final rule but not subject to FMCSA requirements, we take a weighted average of the ratios of local to total general freight trucking in the CBP data under NAICS code 4841, and the local to total specialized freight trucking in the County Business Pattern data under NAICS code 4842. Weights are applied to reflect the importance of local specialized and local general freight in all local trucking to estimate the overall number of intrastate carriers. This computation estimates that 50 percent of all freight carrying trucks are intrastate carriers. Consequently, we assume that 50 percent of all transportation facilities are not already subject to recordkeeping requirements under FMCSA, and will incur the full records redesign and additional records maintenance costs of this regulation.

The total number of domestic air cargo carriers of food packages is estimated from NAICS code 481112 in the CBP and NES data which was used for estimating the total number of transporters in the PRIA. Since not all of the carriers reported under NAICS code 481112 transport food items, we used a factor of 50 percent to scale data from the CBP and the NES to estimate the number of air cargo carriers that have a significant portion of their business transporting food items. The resulting estimate of the number of air cargo carrier facilities that transport food items is approximately 1,825 or 0.078 percent of the total number of transporters. These facilities will incur records redesign costs and additional records maintenance costs, in addition to learning costs as a result of this final rule.

The number of carriers of low-value food items is estimated using the number of couriers under NAICS code number 49211, which was not included in the PRIA. According to the U.S. Census Bureau, this NAICS includes establishments primarily engaged in providing air, surface, or combined courier delivery services. From the CBP and NES statistics there are approximately 141,931 establishments engaged in courier services. Since this includes courier services that use both air and surface transportation, we reduce this number by 50 percent, under the assumption that only establishments engaged in surface courier services are likely to carry food items, resulting in an estimate of 70,965 surface courier facilities.

Most surface courier services may carry food items as an incidental part of their business and will incur learning costs as a result of this rule. However, only a small fraction will carry food items as a significant part of their business and will incur additional records maintenance and records redesign costs. We estimate that 10 percent of surface couriers services will ve more than an incidental portion of their business transporting food items and will incur records redesign and additional maintenance costs in addition to learning costs. This is consistent with the fraction of restaurants that report retail sales as a secondary activity of their establishment (Ref. 29). The resulting estimated number of surface transporters of low-value packages of food items that would incur additional records maintenance and records redesign costs is 7,097 facilities.

(Comment 206) Several comments suggest that transportation carriers have only a limited knowledge of the contents of the packages that they carry and should not be held liable for much of the information. These comments suggest that transporters have detailed information on sources and recipients of the products that they carry but do not have the capacity to track other details of the contents of the packages, such as lot codes and other details. For example, one comment states that air carriers typically rely on the shippers for information, and shipments may not be identified as containing food. Others comment that because carriers lack knowledge of the contents of packages, the default records retention times for all shipments will be the longer required time of 2 years, even if the contents are perishable products. The comments state that this 2-year default retention time will only add to the records retention burden already faced by many trucking firms.

(Response) FDA acknowledges that, currently, the transporter may have limited knowledge of the contents of the packages that it carries and that an undue records retention burden would result if the default would be the longer retention period. FDA notes, however, that under this final rule transporters must know that they are transporting food and be able to record a description of that food. Nonetheless, FDA has relaxed the records retention requirement for transporters from the proposed rule to this final rule. Transporters, or nontransporters retaining records on behalf of a transporter, are required to retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released. FDA also has codified in this final rule an option for transporters to comply with recordkeeping requirements of this final rule by keeping records already required by the existing bill of lading requirements applicable to interstate transporters.

(Comment 207) One comment expresses concern that differing knowledge of the contents of food packages between transporters and nontransporters would require standards of information exchange to be created to coordinate the contents of records maintained by the two types of entities. The comment suggests that without such standards, the coordination costs may be high, because certain records maintained by nontransporters would need to be exchanged with transporters for them to have the full knowledge of the contents and extent of the packaging. Failure to create these standards would result in elevated costs for transporters.

(Response) FDA acknowledges the limited knowledge that transporters currently may have about the contents of the packages that they carry. FDA has included less detailed information requirements in the final rule to respond to these comments; however, FDA believes the information it is requiring is necessary to allow the FDA to conduct a tracing investigation efficiently and effectively. In addition, FDA included an option whereby transporters can fulfill their recordkeeping requirements by keeping records already required for interstate transporters. Furthermore, the final rule provides an option allowing transporters to enter into a contractual arrangement with the non-transporter immediate previous source located in the United States or with the non-transporter immediate subsequent recipient located in the United States; any contractual arrangements would redistribute the burden of establishing and maintaining transportation records between transporters and non-transporters but would not change the total recordkeeping costs since the same number of records would be established

and maintained under all negotiated arrangements. FDA assumes that current business practices are the low-cost arrangement for the establishment and maintenance of records and does not revise its estimate of recordkeeping costs to account for higher coordination costs between transporters and nontransporters.

(Comment 208) Some comments state that FDA's estimated cost per facility in the public warehousing sector is likely to be incorrect because of the apparent assumption that costs incurred would be similar for both a public warehouse and a wholesaler. The comments argue that, because wholesalers own a product, they are more knowledgeable about its contents and packaging than are warehouse facilities. The comment notes that a warehouse is a third party provider of warehousing, storage, and other value added services; does not have direct knowledge of where a product originates; and may not have full knowledge of the contents and packaging of a product, or of the product's next destination. Another comment states that the information asked for in the proposal is reasonable, but that this information will be difficult, costly, or impossible to obtain for public warehouse facilities.

(Response) FDA acknowledges that warehouse facilities and wholesalers perform different functions. FDA has accounted for the differences in its cost estimates. The NAICS definition of the wholesale trade includes, ''* * * selling merchandise, generally without transformation* * * to other business* * *.'' The definition also characterizes wholesalers as normally operating from a warehouse or office (Ref. 27). In contrast, the NAICS defines the warehousing and storage sector as providing facilities to store goods but not sell the goods that they store. In addition, warehouse facilities may also provide logistical services for the goods that they store (Ref. 27).

Although the warehouse and wholesaler functions are clearly different, FDA assumes that both kinds of facilities would have records giving an immediate previous source and an immediate subsequent recipient of the product. Because warehouse facilities do not take ownership of the products that they handle, they may not have specific information about the products and their packaging.

In the course of their day-to-day business dealings, warehouses may not be privy to a description of the type of food or details of its packaging sufficient to satisfy this regulation. To acquire this knowledge and maintain the required records, warehouses may incur costs in addition to those that would be incurred by the owners of the product. FDA assumes that as part of their normal business practices, warehouse facilities may be required to maintain a limited amount of information on the immediate previous source and immediate subsequent recipient of a comparable magnitude to that of the owners of the products. However, the detailed information on the product and its packaging required by the regulation may be more costly to obtain for warehouse personnel than for the owners of the product. For some products, warehouse facilities are assumed to have the same required knowledge of the required information on the stored product and its packaging as that of the owner of the product. For other products, the warehouse personnel's knowledge of the required information on the stored product and its packaging is less than that of the owner. We estimate that, for half of all food products stored, warehouse personnel have the same amount of the required knowledge of the food and its packaging as the owner of the product, and that the additional records maintenance costs would be comparable to those incurred by the product owners. For products for which warehouses currently lack the required knowledge, we assume that the additional records maintenance costs for warehouse facilities would be approximately 50 percent higher than those for owners of the products. Much of the extra cost may involve contracting with product owners to provide the required information.

b. *Interstate conveyances and catering services sector.* (Comment 209) Several comments suggest that the costs to the interstate conveyance catering industry were greatly underestimated and that this sector should be excluded from the regulation. One comment states that for airline caterers, each flight typically includes hundreds of individual foods from scores of different sources and suppliers. The comment further states that this industry is further complicated by the large number of special meal requests by individual passengers on each flight.

(Response) In the PRIA, we assumed that persons subject to this final rule may be required to add a limited amount of new information to existing transactions records, such as bills of lading, commercial invoices, and other shipping documents. We did not model the costs of compliance for each sector in the food economy, and assumed that the private incentives to maintain most, if not all, of the required information were sufficient. Examples of private incentives to maintain the required records are provided in our response to comment 189. Moreover, we do not require that the information be in any particular form or format, which further reduces the potential costs of compliance.

c. *Pet foods sector.* (Comment 210) Some comments suggest that FDA eliminate requirements for pet food because the risk of exposure through that sector is small. Other comments acknowledge potential targets and impacts from terrorist attacks through the pet food sector and encourage FDA to require all in the pet food sector to be subject to the final rule.

(Response) In the proposed rule, pet food not subject to the BSE rule was excluded from the requirement to establish and maintain records. In this final rule, all animal feed entities, including all pet food entities, are subject to all requirements of the rule, but have a records retention requirement of 1 year. There are approximately 19,600 facilities that were excluded in the proposed rule and that have been included in this final rule. In the PRIA, rather then estimate the cost savings from excluding these facilities from complying with the regulation, we noted that the costs were overestimated because pet food facilities were included in the estimates. In the final rule, pet food entities are subject to the regulation and are included in the cost estimates.

d. *Food contact substances and the packaging sector.* (Comment 211) FDA received many comments that FDA underestimated the number of facilities covered by the definition of substances and components of substances that contact food. One comment states that FDA does not include the ''upstream'' manufacturers that make ingredients and components that go into food packaging who would be required to comply with the recordkeeping provisions of this regulation. The comment further states that there is no logical conclusion to this chain. Some other comments assert that FDA did not account for warehouses that hold articles that can migrate to food from food packaging, or other articles that contact food.

Another comment states that FDA's count of the number of domestic facilities is overly inclusive if FDA's intention is to include only finished packaging and that the Operational and Administrative System for Import Support (OASIS) database used for the count of foreign facilities does not include suppliers of food contact articles. Other comments indicate that FDA understated the number of

facilities covered by the regulation by not identifying transporters of food contact materials, and that the 20 NAICS codes do not cover all food packaging manufacturers and distributors. Several comments state that all packaging firms handle both outer packaging and food contact substances, and for all practical purposes, will have to track all products they produce, because they may not know if a shipment is destined for food or nonfood use. One comment states that FDA's count of foreign facilities from OASIS did not include all imported food contact substances.

(Response) The final rule does not require persons who manufacture, process, pack, transport, distribute, import, receive, or hold packaging (the outer packaging of food that bears the label and does not contact the food) to establish or maintain records. However, these persons are subject to the records access requirements with respect to any existing records if they also engage in another regulated activity with respect to the food in, or to be placed in, such packaging. Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. Moreover, all other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the establishment and maintenance requirements with regard to the finished container, and are only subject to the records access provisions for existing records under §§ 1.361 and 1.363.

In the final rule, records access costs are estimated to be zero and we assume that the only costs incurred by persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are learning costs. Because the economic burden on these facilities in the final rule has been substantially reduced from that estimated in the PRIA, we assume that the impact on costs of any possible underestimation of their numbers will be very small.

e. *Foreign facilities and related impacts.* (Comment 212) There were many comments that state that the expansion of requirements to foreign facilities would have a large impact on international trade by making imports more expensive. Some comments state that costs for compliance by developing countries were underestimated in the PRIA because their labor and technology are so different from those that prevail in developed countries.

(Response) In the final rule, all foreign persons are excluded from all requirements in this rule, except for foreign persons who transport food in the United States. Because all foreign persons who transport food in the United States are currently subject to FMCSA regulations as interstate transporters, and can meet the requirements of transporters in subpart J of this final rule by keeping records already required by FMCSA, the costs of compliance for these facilities, including the costs for the records access requirement, are assumed to be zero.

(Comment 213) One comment questions the implied assumption in the PRIA that foreign transporters share the cost burden with other foreign facilities when foreign transporters are not covered by the rule.

(Response) Foreign persons who transport food in the United States are covered by this final rule. The revised costs of compliance by these facilities to establish and maintain records are assumed to be zero because they will be in compliance with this final rule if they keep the records currently required by FMCSA for interstate transporters.

10. Compliance Dates

Several comments suggest changes in the compliance dates. In the design of the regulation, the compliance dates are used primarily to address regulatory flexibility considerations. Consequently, these comments are treated in the regulatory flexibility section of the final analysis.

G. Summary of the Costs and Benefits of the Final Rule and Policy Options Considered

The revisions to the cost estimates based on comments to the proposed rule and on changes in records requirements between the proposed and final rule result in estimated costs of approximately $1.41 billion expressed in present value terms, using a 7-percent discount rate. Using a discount rate of 3 percent, the estimated costs of the final rule expressed in present value terms are approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the final rule, beginning in the second year for large and small firms and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The details of the assumptions used to estimate the costs are provided in the PRIA. The estimated total cost is computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 15 of this document.

TABLE 15.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,000
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.

[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during a foodborne outbreak by reducing the time required for preventive action. Furthermore, the final rule will reduce the recurrence of outbreaks that may have been prevented had nonexistent or poor records quality not resulted in prematurely terminating the initial traceback investigation. In addition to relaxing elements of the requirement for records to contain lot code information, the reduction in benefits from the final rule compared to the proposal results from excluding foreign facilities except those that transport food in the United States, relaxing recordkeeping requirements for food contact substance facilities, relaxing recordkeeping requirements for very small retail facilities, adopting retention requirements based on the NIST food shelf life definitions, and relaxing the records access requirement from 4 and 8 hours to as soon as possible, not to exceed 24 hours.

The estimated costs and benefits of many policy options considered in this section summarize the details of the analyses based on the comments FDA received and are reported in the following tables. The costs for the options are reported in present value terms for both 7 percent-and 3-percent discount rates. We summed the discounted annual costs over a 20 year horizon to obtain the estimate of the total costs. A 20-year horizon for measuring the costs from the regulation is reasonable, given uncertainty in the regulatory environment and technological change. The reduction in benefits relative to the proposal from each modification is based on the impact that each option would likely have on traceback times and the rates of traceback completions. Again, the benefits are based solely on food safety concerns (i.e., typical traceback scenarios with which FDA has been involved) and do not take into account food security concerns.

In table 16 of this document we compare the costs of the options considered to the baseline option of the proposed rule, with the caveat that the provision requiring all records to contain lot code information, which was included in the proposed rule, is no longer in the baseline. All other provisions included in the proposed rule are in the baseline for this analysis.

All options consider relaxing one provision, or excluding one sector from the recordkeeping requirements. In that way, a comparison of the cost of a policy option with the cost of the baseline yields the marginal cost savings from either relaxing a provision in the baseline, or reducing the coverage by one sector relative to the baseline. The columns containing the absolute amount and percentage cost savings show the savings relative to the baseline. In the final rule reported in table 18 of this document, the provisions requiring lot code information, 4- and 8-hour records access, and short compliance dates are all relaxed to yield cost savings relative to the baseline. Additional cost savings result from excluding the following: (1) Foreign persons, except for foreign persons who transport food in the United States; (2) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances except the finished container that directly contacts the food; and (3) persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished containers that directly contacts food except for those who place food directly in contact with its finished container.

The option to relax the requirements for all records to contain lot code information when feasible saves more costs relative to the baseline than any other option. The cost savings from relaxing the lot code information requirement is approximately $13 billion in present value terms with a 7 percent discount rate, and $18 billion with a 3 percent discount rate. Based on detailed information in the comments, requiring lot code information to be contained in all records by retailers and distributors would result in approximately an 80 percent loss in productivity for distributors and retailers.

Excluding many foreign persons and relaxing the 4- and 8-hour records access requirement also result in significant cost savings. By excluding all foreign persons except those who transport food in the United States, approximately 225,000 facilities would not have to establish and maintain records relative to the baseline. This exclusion results in a cost savings of approximately $770 million, or 19 percent, relative to the baseline in present value terms when a 7-percent discount rate is used, and a savings of $1 billion when a 3 percent discount rate is used. A 24-hour records access requirement results in a cost savings of approximately $260 million relative to the baseline with a 7-percent discount rate, and $318 million with a 3-percent discount rate.

Extending the compliance dates and broadening the scope of foods subject to the limited 1-year records retention period relative to the baseline are all provisions in the final rule. Cost savings from extending the compliance dates by 6 months relative to the baseline result from reductions in inventory losses and discounts in the costs realized when incurred 6 additional months into the future. These cost savings are approximately $271 million relative to the baseline with a 7-percent discount rate, and $163 million with a 3 percent discount rate. Adopting retention requirements based on NIST definitions based on shelf life is not assumed to increase costs, but will reduce the benefits by a negligible amount.

Throughout the analysis, we have estimated costs based on the number of facilities, and assume that this number, whenever used, approximately reflects the number of persons covered by the regulation. The revised number of facilities covered by the final rule is estimated to be 707,672 (including persons who manufacture, process, pack, transport, distribute, receive, hold, or import food, and foreign based transporters that transport food in the United States). Learning costs are assumed to be incurred by all facilities and persons 2 years following enactment of this final rule and are computed by multiplying the number of facilities by the cost of learning per facility. Based on details outlined in the proposed rule, learning costs are computed using a $25.10 wage rate and 4.5 hours spent learning for Internet users (approximately 71 percent, and 5.5 hours spent learning for non-Internet users). The total learning costs are computed to be $85,082,000.

Records redesign costs are assumed to be incurred by approximately 101,153 large and small firms 2 years following issuance of this final rule and by 222,316 very small firms after 3 years following issuance of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food, and foreign based transporters that transport food in the United States are assumed not to incur records redesign costs. In this analysis, FDA assumed that all sizes of firms will bear the $1,365 per-firm records redesign cost estimate that was used in the proposal as the most likely records redesign cost for small and very small firms. The redesign costs are $53,508,000 after the second year and $151,731,000 after the third year following issuance of this regulation.

FDA assumes the additional records maintenance costs to be incurred by 110,081 large and small facilities 2 years following issuance of this final rule and by 379,493 facilities after 3 years and for all subsequent years following issuance of the final rule. Persons who

manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food and foreign based transporters that transport food in the United States are assumed to not incur additional records maintenance costs. FDA assumes the 34,634 convenience store facilities will spend 2.5 hours per year and that persons who directly market food are excluded from the rule. All other facilities (344,859) will spend 13 hours per year on additional records maintenance at an hourly cost of $25.10. The undiscounted total additional records maintenance costs 2 years following enactment of the rule are $70,745,000. After 3 years, and for each subsequent year, the undiscounted additional records maintenance costs are $114,701,000. The annual costs for records access planning and for records retention for all persons are assumed to be zero in the final rule.

The following table includes the estimated reduction in benefits relative to the proposal from policy options that would exclude select sectors from recordkeeping requirements, or that would relax certain provisions, which are considered in detail earlier in this analysis. The benefits from each policy option are ranked by size, so that policy options that would result in large reductions in benefits relative to the proposal are ranked highest, where a ranking of one represents the largest reduction in benefits relative to the proposal.

The reduction in benefits from relaxing the requirement for all persons to establish and maintain records containing lot numbers is very high. With lot codes contained on all records, the duration of a traceback investigation for many products would likely be between 1 and 14 days (estimated current times for many packaged products that contain all lot code information on the package). Relaxing the lot code requirement may increase the traceback times of these products to between 6 to 8 weeks (estimated current times for many fresh products not accompanied by lot code information). Relaxing the requirement for all records to contain lot code information leads to the largest reduction in benefits relative to the baseline.

The reduction in benefits from excluding all foreign persons except those who transport food in the United States is considerable because the large number of excluded entities increases the likelihood of hampering traceback investigations. Moreover, the risk of contamination (unintentional) is generally higher for many products earlier in the supply chain. In addition, enforcement costs for foreign persons would likely be prohibitively high—decreasing the likelihood of obtaining records required for a traceback even if these persons were covered. When compared to the eight other individual options considered for the final rule, the large number of excluded foreign persons ranks third highest of the reductions in benefits relative to the baseline considered. This reduction in benefits, however, is mitigated in one respect: The risk of not being able to complete traceback investigations due to this exclusion is considered low because most of these foreign entities occupy positions early in the supply chain.

The reduction in benefits from relaxing the recordkeeping requirements for persons who manufacture, process, pack, transport, distribute, import, receive, or hold food contact substances other than the finished container that directly contacts the food, and who manufacture or process the finished container that directly contacts the food, as estimated by the number of applicable facilities, is small. Although relaxing requirements for these persons may expose a ''soft target'' for intentional contamination, the probability of foodborne illness from unintentionally contaminated food contact substance and finished container material is low. Furthermore, the likelihood of needing records from food contact substance and finished container facilities during traceback investigations is also low. When compared to the other issues considered for the final rule, relaxing the requirements for these persons ranks only seventh in the reductions in benefits relative to the baseline.

The reduction in benefits from relaxing the requirement to access records within 24 hours from 4- and 8-hour requirement would be substantial. We estimate that relaxing the records access requirement would increase the amount of time for any preventive action to be taken during a traceback investigation by about 5 days relative to the baseline, if all persons subject to an access request took the full 24 hours to respond. The loss of time relative to the baseline would limit the preventive benefits for 15 percent to 18 percent of outbreaks. Relaxing the record access requirement from 4 and 8 hours, to within 24 hours ranks second in reductions in benefits relative to the baseline.

The reduced benefits from extending the compliance period by 6 months for each person subject to the final rule are a twofold increase in the number of outbreak victims relative to the baseline in the first year only. Baseline benefits reduce the impact of 15 percent to 18 percent of outbreaks and eliminate the problem of prematurely terminated investigations because of poor records quality (i.e., about 10 percent of the total number of traceback investigations estimated from FDA outbreak investigation information). Extending the compliance dates by 6 months ranks sixth in the reductions in benefits relative to the baseline.

We estimate that allowing transporters to comply with this final rule by complying with existing requirements (e.g., records already required by FMCSA) will have a negligible impact on the benefits relative to that from the more comprehensive requirements of the proposal. Option 7 in table 16 of this document incorporates a 24-hour access provision, 6, 12, and 24 month retention requirements, extension of the compliance dates, and adjusted recordkeeping requirements for transporters based on existing requirements. In table 18 of this document, the costs and benefits of the final rule are compared with those from the adjusted comprehensive coverage of option 7 in table 16 of this document.

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
Baseline[1]: Proposed rule except requirement for all records to contain lot codes is relaxed.	$4.0 billion	$5.27 billion		

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS—Continued

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
(1) Baseline except existing interstate transporter requirements are sufficient.	$3.78 billion	$4.97 billion	No reduction[2]	1
(2) Baseline except retention of 6, 12, and 24 months per NIST standards	$4.0 billion	$5.27 billion	Negligible reduction	2
(3) Baseline except food contact entities are excluded.[3]	$3.92 billion	$5.16 billion	Exclude 37,000 facilities near the top of supply chain. Low risk of contamination and low risk of loss of the paper trail.	3
(4) Baseline except compliance dates are extended by 6 months.	$3.73 billion	$5.10 billion	An estimated one-time, two-fold increase in the number of victims compared with the baseline in the first year only.	4
(5) Baseline except foreign facilities are excluded.	$3.23 billion	$4.26 billion	Exclude 225,000 facilities near the beginning of the supply chain. Very high cost of enforcement and access.	5
(6) Baseline except relax records access from 4 and 8 hours, to 24 hours.	$3.74 billion	$4.95 billion	Adds a maximum of about 5 days to the time for preventive action during an outbreak.	6
(7) Adjusted comprehensive coverage	$2.59 billion	$3.57 billion	Incorporates all policy options and adjusted numbers of facilities	

[1] Note that option 1 is used as the baseline in the descriptions of all other options. The variation of the proposed rule with the relaxed lot code requirements is used as the baseline in this table because the high cost of requiring lot codes on all records ($16.58 billion) is overwhelming. While the reduction in benefits from relaxing the lot code requirements is also large, we thought that the inclusion of that option in this table would confuse the presentation and add little practical value to the policy analysis.

[2] Because this chart only reflects food safety, it does not include classified food security scenarios which envision intrastate shipments being targeted for tampering.

[3] This option overstates the cost reduction from provisions in the final rule that exclude food contact substance entities since it assumes that they will not have to incur learning, records redesign, and additional records maintenance costs. In the final rule these entities will incur learning costs since they will still be subject to access requirements for records that they keep during the course of normal business activity.

We constructed the policy options reported in the following tables to provide a range of net benefit and cost effectiveness measures for alternative coverage options. The records access, retention, and compliance date provisions, as well as the requirements for transporters for all options reported in the following tables, are the same as those reported for option 7 in the previous table. In addition, coverage for the option entitled ''all entities'' is the same as that for option 7 in the previous table. Persons handling the finished container that contacts food are excluded from all of the following coverage options for the policy reasons stated previously. However, while persons handling the finished container that contacts food other than those who place food directly in contact with the finished container, are not required to establish and maintain records in the final rule, they are required to provide access to FDA to existing records if the conditions for access are satisfied. This requirement is implicit in all of the options with different coverage reported in the following tables.

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
Option						
Adjusted Comprehensive	All	All	All	All	All	All

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS—Continued

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
A		All				
B	All					
C		All	All			
D		All	All	All		
E		All	All	All	All	
F		All	All	All	All	All
G (final rule)	Exclude very small	All	All	All	All	All
H	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small
I	Exclude very small	All	All	All	All	Only interstate

Note: Very small firms are defined as those with fewer than 10 full-time equivalent employees.

In the following table, costs, food safety benefits, and cost effectiveness measures are reported for each of the coverage options described in the above table, and the final rule. Costs are reported in terms of annualized costs and incremental costs using a 7-percent discount rate over a 20-year horizon. Benefits are reported in terms of the annual number of food safety illnesses averted (reported and unreported), and the incremental number of illnesses averted. The estimates of the numbers of averted illnesses should be interpreted as minimum values because they relate to only the food safety benefits; bioterrorism considerations are not incorporated into the estimates. Cost effectiveness measures are in terms of the incremental costs per averted illness, and the average cost per averted illness.

The incremental cost per averted illness is used to measure the relative cost effectiveness of an option when compared with successively more stringent requirements. It is computed by dividing the incremental costs from the option by the incremental benefits. Since option H averts a larger number of illnesses at lower cost then options A through F, option H dominates the other options and they can be eliminated from further consideration in an incremental cost effectiveness analysis. Thus, the cells for computing the incremental costs per averted illness for those options are left blank in table 18 of this document. Similarly, through the principle of weak (or extended) dominance, option I can be eliminated from the incremental cost effectiveness analysis. (For a full discussion of extended dominance in cost-effectiveness analysis, see Gold, M.L., J.E. Siegel, L.B. Russell, and M.C. Weinstein, ''Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine, Oxford University Press,'' New York, p. 286, 1996). Consequently, only options H, the final rule, and the adjusted comprehensive coverage are used to measure the incremental cost effectiveness. We assume that bioterrorism considerations would not alter the relative order of the number of illnesses averted across all options.

The average costs per averted illness reported in table 18 of this document are calculated by dividing the annualized costs by the total number of illnesses averted for each option. The average costs per averted illness is the cost-effectiveness of each option relative to the baseline. For the final rule, the average cost-effectiveness expressed in costs per illness prevented is $110,000 discounted at 7 percent and $108,000 discounted at 3 percent.

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option A	$40,975,852		245			$167,248
Option C	$56,753,102		316			$179,598
Option D	$67,712,296		355			$190,739
Option E	$69,902,094		359			$194,713
Option B	$135,636,340		572			$237,126
Option F	$119,792,995		621			$192,903

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS—Continued

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option H	$30,610,378	$30,610,378	1,067	1,067	$28,688	$28,688
Option I	$106,138,020		1,072			$99,009
Final Rule	$132,750,092	$102,139,714	1,204	137	$745,545	$110,258
Adjusted Comprehensive	$244,134,086	$111,383,994	1,282	78	$1,428,000	$190,432

The distribution of the number of illnesses averted due to faster traceback investigations and more successfully completed traceback investigations for each policy option are also reported in the following tables. Of the 800 annual food safety illnesses averted due to improved recordkeeping practices, about 600 can be attributed to more successfully completed tracebacks, and about 200 from faster tracebacks. The sum of averted illnesses from faster tracebacks, plus that from more successfully completed tracebacks may differ from that reported in the table of totals because of rounding in the computations.

TABLE 19.—ALL AVERTED (REPORTED AND UNREPORTED) FOOD SAFETY ILLNESSES PER YEAR

	Mean	Low	High
Adjusted Comprehensive	1,282	0	6,400
Option A	245	0	1,079
Option B	572	0	2,660
Option C	316	0	1,452
Option D	355	0	1,612
Option E	359	0	1,750
Option F	621	0	2,846
Final Rule	1,204	0	6,061
Option H	1,067	0	5,372
Option I	1,072	0	5,504

TABLE 20.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM FASTER TRACEBACK INVESTIGATIONS

	Mean	Low	High
Adjusted Comprehensive	451	0	2,692
Option A	83	0	513
Option B	206	0	1,278
Option C	111	0	691
Option D	122	0	755
Option E	124	0	763
Option F	184	0	1,078
Final Rule	425	0	2,532
Option H	387	0	2,307
Option I	396	0	2,414

TABLE 21.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM MORE SUCCESSFULLY COMPLETED TRACEBACKS

	Mean	Low	High
Adjusted Comprehensive	826	0	3,024
Option A	161	0	605
Option B	364	0	1,296
Option C	203	0	778
Option D	232	0	864
Option E	234	0	864
Option F	434	0	1,728
Final Rule	775	0	2,592
Option H	676	0	2,592
Option I	673	0	2,592

The next table shows the food safety benefits as the number of averted illnesses valued by the low, middle, and high cost of illness estimates, and for the $5 million and $6.5 million estimates of the value of a statistical life. These are estimated annual food safety benefits and should be interpreted as minimum benefits from this final rule because food security benefits are not included.

TABLE 22.—VALUE OF AVERTED FOOD SAFETY ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

V. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the final rule on small entities. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities.

We estimate that more than 75 percent of all businesses covered by this final rule are small or very small. The undiscounted per-facility costs for small and very small businesses are reported in the following table. Costs for learning and records redesign are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs are incurred each year following publication of the final rule beginning in the second year for large and small firms, and in the third year for very small firms.

TABLE 23.—ESTIMATED PER FACILITY RECORDKEEPING COSTS

21 CFR Section	Costs
1.337, 1.345, and 1.352 (learning)	$120.00
1.337, 1.345, and 1.352 (records redesign)	$411.00
1.337, 1.345, and 1.352 (additional records maintenance)	$219.00

Comments Summary

Comments cover topics such as reasons why staggering compliance dates will not achieve regulatory flexibility objectives, suggestions of regulatory alternatives that would achieve regulatory flexibility objectives, appeals to consider the cumulative costs of all four bioterrorism regulations together when considering the impact on small businesses, appeals for exclusion of certain categories of small businesses, as well as other general topics. The different categories of comments are summarized in the following paragraphs.

(Comment 214) One comment finds the definition of ''small business'' uncertain and asks whether it is based on either the number of employees at a

firm or the number of employees at a facility.

(Response) The U.S. Small Business Administration (SBA) establishes small business definitions (or size standards) by industry (Ref. 28). The most common SBA size standard applicable to manufacturers covered by this final rule is 500 employees. Other pertinent SBA size standards include 100 employees for wholesale distributors, $21.5 million in receipts for transporters, and $6 million or $23 million in receipts for retailers, depending on the type of store. After discussions with the SBA, we define a small business in the food industry as having more than 10 and fewer than 500 full-time equivalent employees, and we define very small firms as having 10 or fewer full-time equivalent employees.

Firm size, rather than facility size, is used in the cost estimates for regulatory flexibility purposes whenever the data permit. For purpose of the compliance dates, the firm size governs. For purpose of the retail exclusion, the number of employees at the facility applies.

(Comment 215) Several comments suggest that the recordkeeping requirements are so onerous that compliance periods should be extended to as many as 7 years.

(Response) In the PRIA, FDA assumed that the recordkeeping provisions required a limited amount of additional information over current business practices. Comments suggest that this may not be true for certain provisions. In the final rule, we have relaxed some of the more costly provisions, such as the requirement for records to contain lot code information for all persons subject to the final rule, and we have relaxed the records access requirement to 24 hours. We have also revised the requirements applicable to transporters so that they have multiple options for complying with the final rule. These modifications should reduce the costs of compliance for small businesses. In addition, we have extended the compliance dates of the final rule by 6 months to 12, 18, and 24 months for large, small, and very small businesses. The extension should further reduce the costs of compliance with the final rule because the costs of the required changes in records quality and records access fall as compliance time increases. Moreover, given the purpose of the Bioterrorism Act, FDA believes a 7-year compliance period is excessive.

(Comment 216) One comment states that large carriers account for only 0.28 percent of all carriers and that 0.28 percent of all carriers should not be unfairly burdened to comply with regulations 1 year before the rest. Another comment states that across-the-board compliance dates of 18 months better serves the purposes of the Bioterrorism Act, because it reflects the large volume of food that moves through big business.

(Response) The Regulatory Flexibility Act requires that special consideration be given to small businesses when such flexibility does not compromise the efficacy of the regulation. In the PRIA, FDA considered several other potential flexibility options and found that the policy of staggering the compliance dates and exempting very small retailers were the only ones that did not appreciably compromise the effectiveness of the regulation.

(Comment 217) Several comments state that large businesses would likely pass the costs of the regulation on to smaller firms. In addition, the proposed regulatory flexibility from staggered compliance dates would largely be ineffective, because large businesses will require their small suppliers to comply with the regulation to ensure their own compliance. Another comment suggests extending the compliance dates to 18 months for large businesses and 36 months to small businesses but acknowledged that staggering compliance dates would complicate business practices.

(Response) FDA acknowledges the difficulties in addressing regulatory flexibility considerations with staggered compliance dates. Nevertheless, FDA has decided that staggering the compliance dates is a viable mechanism to address regulatory flexibility considerations without compromising the effectiveness of the regulation as intended by Congress when it enacted section 306 of the Bioterrorism Act. However, to address the concerns expressed by these comments without compromising the effectiveness of the regulation, in the final rule compliance dates for all size businesses have been extended by 6 months to 12 months for large, 18 months for small, and 24 months for very small businesses. FDA further notes that small and very small businesses are not required by FDA to comply earlier than these timeframes even if they are doing business with larger businesses that have earlier compliance dates.

(Comment 218) At least one comment suggests that requiring the same compliance date for all firms and excluding small businesses from complying with the regulation compromises the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations. Such a compromise is contrary to the intent of the Regulatory Flexibility Act.

(Response) In the PRIA, FDA considered three regulatory flexibility options: (1) Exempting small business from all regulatory requirements, (2) offering small business exemptions from parts of the regulation, and (3) specifying longer effective compliance dates for small businesses. We found that specifying longer compliance dates for small businesses was one option that would not appreciably compromise the purpose of the regulation.

(Comment 219) Several comments state that the 4 and 8 hour provision for records access is more onerous for small businesses and suggest either flexibility in the extent of the records to be made available in that time period for small businesses, or extending the records access time requirements for small businesses. One comment suggests that the rule requires firms to keep more records than is necessary and that FDA should consider relaxing the level of detail in the small business records required to be made available in the 4 and 8-hour records access times. One comment states that the burden on a small firm from devoting a single employee, who generally performs multiple tasks, to accessing requested records is greater than that on a large firm devoting an employee who may generally perform only one task.

(Response) The proposed rule required large and small firms to provide access to records up to 4 hours after a request made during business hours, and up to 8 hours after a request made after business hours. FDA's current experience is that access to records generally takes 2 to 3 days and the requirements in the regulation will considerably increase the speed of traceback investigations. To acknowledge the concerns addressed by these comments, FDA has relaxed the records access requirement to as soon as possible, but within 24 hours. This longer requirement should provide regulatory relief to small businesses; however, FDA reiterates that it expects all businesses to provide access as soon as possible, given that an access request would only be made in a food-related emergency.

(Comment 220) Several comments request an exemption for some specific categories of small business, because they believe the estimated costs of compliance for small businesses are inadequate. Furthermore, one comment states that the regulatory flexibility provisions in the proposed rule did not satisfy SBREFA obligations.

(Response) FDA addresses SBREFA's regulatory flexibility issues by

exempting very small retailers, and by staggering compliance dates so that small and very small businesses would have 18 and 24 months to comply with the regulation. Because food in commerce generally passes through at least one small business before reaching consumers, excluding small businesses in every sector from compliance with the regulation would risk severely compromising the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations.

(Comment 221) Some comments argue that FDA should address the relatively large burden on small businesses due to the cumulative cost of the four bioterrorism regulations when considered together. The comments state that the proposed registration rule estimated that approximately 16 percent of foreign businesses might cease to export to the United States as a result of that rule. The comments note that this figure was used in the sensitivity analysis in the proposed recordkeeping rule to estimate the costs of the rule with 16 percent fewer foreign facilities. However, the comments stated that FDA did not consider the costs of all the bioterrorism regulations combined on small (or other) businesses.

(Response) The cumulative costs of multiple regulations are rarely considered in regulatory impact analyses. However, costs of the other three regulations were analyzed in their respective regulatory impact analyses. To estimate the cumulative costs of the regulation one could add together the costs determined for all four regulations.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule will include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this final rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates have been fulfilled in the Executive Order 12866 analysis in the PRIA. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future Costs

The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after promulgation of the final rule. These costs will be incurred by all domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food except very small retail facilities.

Recurring costs from collecting new information as well as the learning costs for new entrants will be incurred in each future year. An hourly burden of 30 minutes a week was estimated for the additional monitoring and recordkeeping that will be required from this final rule. This hourly burden estimate was modified for convenience stores to allow for structural differences assumed in their operations. Refer to the PRIA for a fuller illustration of the future costs of the final rule.

TABLE 24.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	$123,209,200	$121,980,000	$125,788,000

Particular Regions, Communities, or Industrial Sectors

The costs of the establishment and maintenance of records will be shared among all domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, except very small retail facilities that are exempted from the final rule. The higher costs incurred by domestic suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Because consumer demand for food is highly inelastic, almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports

This rule requires additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs will increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of United States exports could reduce the quantity of United States exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the final rule, the increases in the price of United States exports (and resulting decreases in quantity demanded) will be quite small.

VII. SBREFA

SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirement are shown below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Establishment and Maintenance of Records

Description: The Bioterrorism Act contains a provision authorizing the Secretary to establish requirements regarding the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food which are needed to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequence or death to humans or animals.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce. FDA received several comments about the hourly burden imposed by the rule on respondents.

(Comment 222) One comment states that the cumulative effect of the regulation is a staggering amount of required paperwork that needs to be organized and made available.

(Response) This comment is not directly responding to any specific request for comments but is a general comment. The duplication of records is unnecessary as long as existing records contain all of the required information. In this analysis we use the FDA small business model to calculate the effects on small businesses using the difference between revenues and variable costs as the metric. We incorporated both the one-time costs and the recurring costs to compute the effects on small businesses. The effects were computed for firms in the dietary supplements industry, candy manufacturing, and the ready-to-eat food manufacturing industry, including firms that manufacture breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will incur negative cash flows as a result of this rule. The percentages of firms predicted to incur negative cash flows are range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

(Comment 223) One comment states that the PRA was adopted to prevent the burden of collecting unnecessary information that has little practical utility or benefit. The comment further states that FDA needs to realign the benefits with the costs of the regulation.

(Response) This is a response to the request for comments on whether the information required in the proposal would have any practical utility. Compared with the description of the costs in the proposal, the benefits were not as well defined. In the final rule, the benefits of each provision are more clearly identified, which facilitates greater realignment of costs with the benefits of the regulation. As stated previously, however, the benefits are underestimated because they only consider food safety concerns and do not address food security concerns, which are based on classified information.

(Comment 224) One comment suggests that FDA should reduce the paperwork burden by integrating the paperwork requirements from this regulation with current U.S. CBP process so that only one form needs to be completed.

(Response) The final recordkeeping regulation excludes all foreign persons, except for foreign persons who transport food in the United States so that many foreign persons do not have to establish or maintain records. Moreover, neither the proposed nor final rules specify the form or format of required records. Accordingly, existing records used for U.S. CBP purposes may be used if they contain all of the information required by this final rule and are retained for the required time period.

Burden: FDA estimates that the paperwork burden of this final rule will be incurred by approximately 707,672 facilities owned by 581,943 firms. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food as well as foreign persons who transport food in the United States. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 of this final rule includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the registration interim final rule (68 FR 58894). The learning burden presented in table 25 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following issuance of the final rule.

The records redesign burden presented in table 25 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 25 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning in each subsequent year following enactment of the final rule. These burdens for new

firms are reported in table 26 of this document.

TABLE 25.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—FIRST AND SECOND YEARS[1]

21 CFR Section	No. of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352 (learning)	707,672	1	707,672	4.790		3,390,000
1.337, 1.345, and 1.352 (redesign)	150,358	1	150,358	29.084	$70,409,000	4,373,000
Total						7,763,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 26.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Record Keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (additional records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	70,767	1	70,767	4.790	339,000
Total					5,359,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

IX. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies 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. Accordingly, the agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Eastern Research Group, Small Business Model, 2003.

2. Estrin, A., Memo to Docket Summarizing Conversations Held Between May 15, 2003, and August 7, 2003, With Experts Jack Guzewich and Sarah Pichette; Also a Description of Data Obtained From FDA's Outbreak Investigations, February 6, 2004.

3. Mead, P.S., L. Slutaker, V. Dietz, et al., ''Food-Related Illness and Death in the United States,'' *Emerging Infectious Diseases*, Center for Disease Control and Prevention (CDC), vol. 5, no. 5, September-October 1999.

4. Finger, Anne L., Senior Editor, ''Primary Care: Where Do You Stand on the Pay Scale?'' Medical Economics, (*http://www.memag.com/*), March 19, 2001.

5. Healthcare Cost and Utilization Project, Nation Inpatient Sample (NIS)—2001, Washington, DC, Agency for Healthcare Research and Quality, 2003.

6. FDA/CFSAN Bad Bug Book, accessed at *http://www.cfsan.fda.gov/~mow/intro.html* on May 3. 2004.

7. National Center for Infectious Diseases, Infectious Disease Information, CDC, accessed at *http://www.cdc.gov/ncidod/diseases/index.htm* on May 3, 2004.

8. ''Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act,'' Research Triangle Institute (RTI), vol. II, Final Report, September 1988.

9. ''Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness,'' Final Report Contract No. 223–01–2466, Task Order 1, With FDA Performed by RTI International, April 2003.

10. Brevard, Theresa A., et al, ''Acute Occupational Disinfectant-Related Illness Among Youth, 1993–1998,'' Environmental Health Perspectives, vol. 111, no. 13, 2003.

11. ''Surveillance for Acute Insecticide-Related Illness Associated with Mosquito-Control Efforts—Nine States, 1999–2002,'' Morbidity and Mortality Weekly Report, vol. 52, no. 27, pp. 629–634, July 11, 2003.

12. Kaplan, et al., ''The Quality of Well-Being Scale: Rationale for a Single Quality of Life Index,'' *Quality of Life Assessment: Key Issues in the 1990s*, ed. Stuart R. Walker and Rachel M. Rosser, 1993.

13. Garber, A.M. and C.E. Phelps, Economic Foundations of Cost-Effectiveness Analysis,'' Journal of Health Economics, vol. 16, pp. 1–31, 1997.

14. U.S. Census Bureau, USA Statistics in Brief, *http://www.census.gov/statab/www/*

part3.html#income, accessed on November 29, 2004.

15. Viscusi, W., Joseph E. Kip and Aldy, ''The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World,'' February 2003, NBER Working Paper No. W9487, accessed at *http://ssrn.com/abstract=379270* on May 3, 2004.

16. National Restaurant Association, 2004 Restaurant Industry Forecast, 2004.

17. U.S. Census, American FactFinder, 1997 Economic Census, accessed at (*http://factfinder.census.gov/servlet/DatasetMainPageServlet?_program=ECN&_lang=en&_t=*) on March 31, 2004.

18. U.S. Department of Transportation, available at *http://www.transtats.bts.gov*, accessed on April 6, 2004.

19. Hennessy, T.W., C.W. Hedberg, L. Slutsker, et al., ''A National Outbreak of *Salmonella Enteriditis* Infections from Ice Cream,'' *New England Journal of Medicine*, vol. 334, pp. 1281–1286, 1996.

20. Lee, Judy O., E-Mail Correspondence, October 27, 2004 at 1:33 p.m.

21. United States Census Bureau, 2000 County Business Patterns, available at *http://www.census.gov/epcd/cbp/view/cbpview.html*, accessed on March 30, 2004.

22. United States Census Bureau, 1999 Nonemployer Statistics, available at *http://www.census.gov/epcd/nonemployer/index.html*, accessed on March 30, 2004.

23. Economic Data Resources, Estimates of Commercial Motor Vehicles Using the Southwest Border Crossings, Under the Auspices of the International Association of Chiefs of Police for U.S. Department of Transportation, September 20, 2000.

24. Direct Sales World, Facts and Figures and Comment of the World of Direct Sales, accessed at *http://www.nmworld.com/pages/Countries/USA/index.html* on July 10, 2003.

25. Direct Selling Association, Direct Selling By the Numbers, accessed at *http://www.dsa.org/research/numbers.htm#DISTTYPE* on July 10, 2003.

26. University of Pennsylvania Center Rate Schedule, Internet address: *http://www.archives.upenn.edu/urc/rates04.html* accessed on September 15, 2003.

27. United States Census Bureau, 2002 NAICS Definitions accessed at *http://www.census.gov/epcd/naics02/def/ND488510.HTM* on September 15, 2003.

28. United States Small Business Administration, Small Business Size Regulations, 13 CFR 121.201, available at *http://www.sba.gov/size/indextableofsize.html*, accessed on February 27, 2004.

29. Memorandum on the Number of Restaurants Selling Retail Food, dated December 15, 2003.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. New subpart J (§§ 1.326 through 1.368) is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

Requirements for Transporters to Establish and Maintain Records

General Requirements

Compliance Dates

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, ''processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term ''farm'' includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

Requirements for Transporters to Establish and Maintain Records

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following

records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

(11) Trailer initials/number;

(12) Container initials/number;

(13) No. packages; and

(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

(1) Shipper's name and address;

(2) Consignee's name and address;

(3) Customs reference/status;

(4) Airport of departure and destination;

(5) First carrier; and

(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in § 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) Description of the records to be established and/or maintained;

(4) Provision for the records to be maintained in compliance with § 1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by § 1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under § 1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(c) to establish, maintain, or establish and maintain, records required under § 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2004, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (f) to read as follows:

§ 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: November 30, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Dated: December 2, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04–26929 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–0277]

Final Regulation Implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—Establishment and Maintenance of Records for Foods; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; public meeting on final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic public meetings to discuss the final regulation implementing section 306 (Maintenance and Inspection of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which is publishing in this issue of **Federal Register**. The purpose of these public meetings is to provide information on the rule to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1584, FAX: 301–436–2605, e-mail: *marion.allen@fda.hhs.gov*, for general questions only about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002.

In this issue of the **Federal Register**, FDA is publishing the final rule implementing section 306 of the Bioterrorism Act and a draft guidance on records access under the Bioterrorism Act. During the public meetings, FDA will explain this rule and the draft guidance and answer questions of clarification.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

II. Final Rule and Draft Guidance

Section 306 of the Bioterrorism Act directs the Secretary of Health and Human Services (the Secretary) to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

In addition, the Bioterrorism Act provides records inspection authority to FDA such that if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and the records are necessary to assist FDA in making such a determination, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records.

III. Registration for the Public Meetings

Please submit your registration information (including name, title, firm name, address, telephone number, e-

mail address, and fax number) at least 5 working days before the public meeting date. For specific site locations, we encourage you to register online at *http://www.cfsan.fda.gov/~dms/fsbtac23.html* or fax directly to Sharon Barcellos at 202–479–4970. We will accept registration onsite. Space is limited and registration will be closed at each site when maximum seating capacity for that site is reached (between 100 to 200 persons per site). If you need special accommodations due to a disability, please notify the contact person as listed under **FOR FURTHER INFORMATION CONTACT** in this document at least 7 working days in advance of the meeting. All participants must present valid photo identification when entering a Federal building and parking facility.

IV. Dates, Times, and Addresses of Public Meetings

TABLE 1.—PUBLIC MEETING—SECTION 306: ESTABLISHMENT AND MAINTENANCE OF RECORDS FOR FOODS

DATES	LOCATION
Thursday, January 13, 2005	Harvey W. Wiley Federal Bldg. 5100 Paint Branch Pkwy. College Park, MD 20740 Time: 9 a.m. to 1 p.m. EST
Tuesday, January 25, 2005	Courtyard by Marriott Chicago 165 E. Ontario St. Chicago, IL 60611 312–573–0800 Time: 9 a.m. to 1 p.m. CST Renaissance Seattle Hotel 515 Madison St. Seattle, WA 98104 800–546–9184 Time: 9 a.m. to 1 p.m. PST
Thursday, January 27, 2005	San Francisco Downtown Courtyard 299 Second St. San Francisco, CA 94105 415–947–0700 Time: 9 a.m. to 1 p.m. PST Wyndham Orlando Resort 8001 International Dr. Orlando, FL 32819 407–351–2420 Time: 9 a.m. to 1 p.m. EST
Tuesday, February 1,2005	Renaissance Philadelphia Airport Hotel 500 Stevens Dr. Philadelphia, PA 19113 610–521–5900 Time: 1 p.m. to 5 p.m. Hilton Boston Back Bay 40 Dalton St. Boston, MA 02115 617–236–1100 Time: 9 a.m. to 1 p.m.

IV. Transcripts

A transcript will be made of the proceedings of each meeting. You may request a copy of a meeting transcript in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the public meetings at a cost of 10 cents per page. The transcript of each public meeting will be available for public examination at the Division of Dockets Management, (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26930 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004G–0381]

Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The draft guidance is intended to clarify the circumstances under which FDA may access and copy records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2003 (Bioterrorism Act) and establishes procedures to exercise its authority.

DATES: Submit written or electronic comments on the draft guidance by January 24, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' to Rudaina Alrefai (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Rudaina Alrefai, Division of Compliance Information and Quality Assurance (HFC–240), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6815, e-mail: *rudaina.alrefai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The Bioterrorism Act created a new section 414 (21 U.S.C. 350c) entitled ''Maintenance and Inspection of Records,'' in the Federal Food, Drug, and Cosmetic Act. Under this new authority, the Secretary of Health and Human Services (the Secretary) may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records. In addition, sections 414(a) and 704(a) (21 U.S.C. 374(a)) authorize FDA to access and copy all records related to an article of food if the following occurs: (1) The Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist FDA in making such a determination.

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' in which the agency is establishing requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records.

The purpose of this draft guidance is to describe the procedure that FDA intends to follow to exercise its new authority, and clarify the circumstances under which FDA may access and copy records under the Bioterrorism Act.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as a level 1 guidance consistent with GGPs. The draft guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the draft guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.cfsan.fda.gov/guidance.html.*

Dated: November 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26931 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Thursday,

December 9, 2004

Part V

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Part 354

User Fees for Agricultural Quarantine and Inspection Services; Interim Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 354

[Docket No. 04–042–1]

RIN 0579–AB88

User Fees for Agricultural Quarantine and Inspection Services

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the user fee regulations by adjusting the fees charged for certain agricultural quarantine and inspection (AQI) services that are provided in connection with certain commercial vessels, commercial trucks, commercial railroad cars, commercial aircraft, and international airline passengers arriving at ports in the customs territory of the United States. Existing user fees have not been adjusted since October 1, 2001. Due to the events of September 11, 2001, and the resulting increased security concerns, a greater volume and variety of cargo entering the United States is being inspected. The fee adjustments are needed to recover the costs of this increased inspection activity and to account for routine inflationary increases in the cost of doing business. The adjusted AQI user fees will cover fiscal years 2005 through 2010.

DATES: This interim rule is effective January 1, 2005. We will consider all comments that we receive on or before February 7, 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. 04–042–1, 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. 04–042–1.
- *E-mail:* Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–042–1'' on the subject line.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

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, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information concerning program operations, contact Ms. Jennifer Lemly, Staff Officer, Quarantine Policy, Analysis and Support Staff, PPQ, APHIS, 4700 River Road Unit 60, Riverdale, MD 20737–1236; (301) 734–8372. For information concerning rate development, contact Ms. Donna Ford, Branch Chief, Financial Services Branch, FMD, MRPBS, APHIS, 4700 River Road, Unit 55, Riverdale, MD 20737–1232, (301) 734–5901.

SUPPLEMENTARY INFORMATION:

Background

Section 2509(a) of the Food, Agriculture, Conservation, and Trade Act of 1990 (21 U.S.C. 136a), referred to below as the FACT Act, authorizes the Animal and Plant Health Inspection Service (APHIS) to collect user fees for agricultural quarantine and inspection (AQI) services. The FACT Act was amended on April 4, 1996, and May 13, 2002.

The FACT Act, as amended, authorizes APHIS to collect user fees for AQI services provided in connection with the arrival, at a port in the customs territory of the United States, of:

- Commercial vessels,
- Commercial trucks,
- Commercial railroad cars,
- Commercial aircraft, and
- International airline passengers.

According to the FACT Act, as amended, these user fees should recover the costs of:

- Providing the AQI services for the conveyances and the passengers listed above,
- Providing preclearance or preinspection at a site outside the customs territory of the United States to international airline passengers, commercial vessels, commercial trucks, commercial railroad cars, and commercial aircraft, and
- Administering the user fee program.

Introduction

On November 16, 1999, we published in the **Federal Register** (64 FR 62089–62096, Docket No. 98–073–2) a final rule that amended the user fee regulations in § 354.3 by adjusting the fees charged for certain AQI services we provide in connection with certain commercial vessels, commercial trucks, commercial railroad cars, commercial aircraft, and international airline passengers arriving at ports in the customs territory of the United States. We did this to ensure that we recovered the anticipated actual cost of providing these services. That rulemaking established the user fees for these services for fiscal years (FYs) 2000 through 2002.

Subsequent rulemaking, culminating in a final rule published in the **Federal Register** on January 24, 2003 (68 FR 3375, Docket No. 02–085–2), extended those adjusted user fees beyond FY 2002 until the fees could be revised again.

Subsequently, in an interim rule that was published in the **Federal Register** and effective on September 3, 2002 (67 FR 56217–56218, Docket No. 02–085–1), we extended those adjusted user fees beyond FY 2002 until the fees could be revised again.

In addition to the routine increases in the cost of providing AQI services, due to inflation, replacement of equipment, etc., the events of September 11, 2001, have had a profound impact on costs and revenues. Following the attacks, there was a sharp drop in the number of international passengers entering the United States. While international air traffic has rebounded, it has not returned to its pre-September 11 levels. We estimate that due to the decreases in the volume of passenger and cargo traffic entering the United States since September 11, 2001, revenues generated through AQI user fees are more than $135 million lower than they otherwise would have been. Despite the drop in traffic, we have had to step up our AQI inspection activities, rather than curtail them, due to increased post-September 11 security concerns, which include the threat of bioterrorism. Since FY 2001, AQI staffing has increased by approximately one-third. Inspectors are

now inspecting a greater volume of cargo entering the United States and a greater variety of types of cargo than they did before September 11, 2001. Such operations are very personnel-intensive and costly.

Following the terrorist attacks of September 11, 2001, certain AQI functions, but not the laws or regulations upon which they are premised, were transferred from APHIS to the Customs and Border Protection (CBP) bureau of the Department of Homeland Security (DHS). Together with certain U.S. Customs Service and Immigration and Naturalization Service employees, APHIS agricultural inspectors were brought into the newly created CBP bureau in an effort to secure our borders and ports of entry while still facilitating the movement of legitimate trade and travelers. The creation of a consolidated border inspection organization has allowed for unprecedented information sharing, cross-training among specialists, and the use of innovative techniques that were not possible when border inspection functions were spread across three separate agencies.

Because our AQI programs are funded solely through user fee collections, it is imperative that we adjust the fees upward to cover our increased program costs. We estimate that, absent the necessary fee adjustments, the AQI account would be in deficit status by July 19, 2005, meaning that APHIS and CBP could be forced to lay off significant numbers of employees and cut back on services. Such cutbacks would increase the potential for animal and plant pests and diseases to enter the United States and could disrupt trade if inspectors were not available to inspect and clear cargo on a timely basis.

In this interim rule, therefore, we are amending our AQI user fee regulations in order to cover our increased costs. Specifically, we are establishing fees to be charged for FYs 2005 through 2010 for each of the types of conveyances or persons to whom AQI services are provided: Commercial vessels, commercial trucks, commercial railroad cars, commercial aircraft, and international airline passengers. However, because commercial truck inspection has separate fees for trucks with and without decals, we are actually adjusting a total of six fees. These adjustments are designed to recover our full costs for providing these AQI services and are based on an analysis of our costs for providing services in recent years, as well as our best projections of what it will cost us to provide these services in FYs 2005 through 2010.

These user fee adjustments are necessary to prevent plant and animal diseases and pests from entering the United States and to protect against the growing threat of bioterrorism.

By projecting our flat-rate AQI user fees 6 years into the future, we are allowing our customers to make necessary business plans. We will review our fees annually and, if necessary, undertake rulemaking to amend them if the published fees do not properly recover our costs. We also plan to publish a notice in the **Federal Register** prior to the beginning of each fiscal year to remind or notify the public of the user fees for that particular fiscal year.

AQI User Fee Accounting

In FY 1992, APHIS established accounting procedures to segregate AQI user fee program costs from all other costs. We published a detailed description of these procedures in the **Federal Register** on December 31, 1992 (57 FR 62469–62471, Docket No. 92–148–1), as part of an interim rule amending some of our user fees. We maintain all AQI fees we collect in distinct accounts, carefully monitor the balances in these accounts, and only use these funds to pay for our actual costs for providing these distinct services. Any surplus in these accounts carries forward from year to year, is not subject to appropriation by Congress, and is available until expended to fund AQI activities.

Types of AQI Program Costs

As part of our accounting procedures, we maintain separate accounting codes to record costs that can be directly related to an inspection activity. These are referred to as ''direct-charge costs.'' At the State (*i.e.*, field) level and below, we direct-charge the following costs to the AQI account: Salaries and benefits for inspectors and canine officers, supervisors (such as officers-in-charge), and clerical staff; equipment used only in connection with services subject to user fees; contracts; and large supply items such as x-ray equipment and uniforms.

Other program-delivery-related costs, at the State level and below, that cannot be directly charged to individual accounts are charged to ''distributable'' accounts established at the State level and are referred to as ''distributable costs.'' The following types of costs are charged to distributable accounts: Utilities, rent, telephone, vehicles, office supplies, etc. The costs in these distributable accounts are prorated (or distributed) among all the activities that benefit from the expense, based on a formula under which the costs that are directly charged to each activity are divided by the total costs directly charged to each account at the field level. For example, if a work unit performs work on domestic programs, AQI user fee programs, and AQI-appropriated programs, the costs are distributed among each of these programs, based on the percentage of the direct costs for that activity at the field level that is charged to that activity.

AQI program costs also include program direction and support costs we incur at the regional and headquarters level, as well as Agency-level support costs. Headquarters-level costs include salaries and benefits for employees of APHIS' Plant Protection and Quarantine and International Services programs who are based at the programs' headquarters in Riverdale, MD, and Washington, DC. We incur Agency-level support costs through activities that support the Agencies (*i.e.*, APHIS and CBP), such as recruitment and development; legislative and public affairs; regulation development; regulatory enforcement; and budget, accounting, payroll, purchasing, billing, and collection services.

Departmental charges are assessed for various AQI program costs including Federal telephone service, mail, processing of payroll and money management, unemployment compensation, Office of Workers Compensation Programs, and central supply for storing and issuing commonly used supplies and forms.

In order to identify properly our actual total AQI program costs in prior fiscal years, we first identified the direct-charge costs. We then added to this the pro-rata share costs of the distributable accounts maintained at the State, regional, headquarters, Agency, and departmental levels.

Cost Projections for FY 2005 Through FY 2010

We used the prior year (FY 2004) costs of $327 million and added inflationary factors to project our costs for FY 2005 through FY 2010. Based on the 2005 Mid-Session Review—Economic Assumptions, a factor of 1.5 percent has been added for pay increases and general inflation cost increases (*i.e.*, all of the AQI costs other than pay increases) for FYs 2005 through 2010. Since the percentage increase was the same for both factors, a flat 1.5 percent has been applied to all costs. We then added a reasonable amount (25 percent of AQI program costs) to contribute to a reserve in the AQI account to identify our total

anticipated costs for those years. We split our total costs for each fiscal year into six AQI service categories (costs for the inspection of trucks with and without prepaid decals were calculated separately), performed extensive volume analyses to project volumes of use for each fee category in the out-years, divided our projected costs per fee category by our projected volumes of users per fee category, and rounded each projected fee to obtain the final fees we are establishing. More detailed information about each of these steps follows.

Projected AQI Program Costs for Fiscal Years 2005 Through 2010

Table 1 shows the total projected costs of administering the AQI program for FYs 2005 through 2010. In projecting these costs, we began with a FY 2004 base need of $133 million for APHIS' AQI work and $194 million for CBP's AQI work, for a total FY 2004 AQI cost of $327 million. This figure takes into account only the cost of providing AQI services for FY 2004 and does not include a reserve component. Similarly, the projected annual program costs for FYs 2005 through 2010 reflect only the costs we anticipate for providing AQI services for each of those fiscal years. The reserve-building component for each is shown separately.

BILLING CODE 3410–34–P

Table 1.–Total projected cost of administering the AQI program, FYs 2005 to 2010

Basis for calculating funding need	FY 2004	FY 2005	FY 2006	FY 2007	FY2008	FY2009	2010
APHIS program needs	$133,000,000	$134,995,000	$137,019,925	$139,075,224	$141,161,352	$143,278,773	$145,427,954
CBP program needs	194,000,000	196,910,000	199,863,650	202,861,605	205,904,529	208,993,097	212,127,993
Total program costs	327,000,000	331,905,000	336,883,575	341,936,829	347,065,881	352,271,870	357,555,947
Reserve component	---	23,733,753	23,733,753	23,733,753	23,733,753	23,733,753	23,733,753
Total costs	327,000,000	355,638,753	360,617,328	365,670,582	370,799,634	376,005,623	381,289,700

Reserve Fund

We need to maintain a reasonable reserve balance in the AQI account of 25 percent of the AQI program costs. We are including a reserve-building component in the user fees for each activity for FYs 2005 through 2010. Each fee contributes to the reserve proportionately.

The reserve fund provides us with a means to ensure the continuity of AQI services in cases of fluctuations in activity volumes, bad debt, carrier insolvency, or other unforseen events, such as those of September 11, 2001, which, as noted earlier, resulted in substantial cost increases for the AQI programs and lower-than-anticipated revenues. Maintaining an adequate reserve fund is, therefore, essential for the AQI program. We intend to monitor the reserve balance closely and propose adjustments in our fees as necessary to ensure a reasonable balance. If we determine that any fees are too high and are contributing to unreasonably high reserve levels, we will undertake rulemaking to lower the fees as quickly as possible. Conversely, if it becomes necessary to increase any fees because reserve levels are being drawn too low, we will undertake rulemaking to increase the fees.

Volumes

In order to calculate our costs and fees, we needed to estimate the annual number of users in each category of AQI services that would be subject to inspection in FYs 2005 through 2010. These estimates are based on our review of actual volumes for each service category shown in our FY 1999 through FY 2003 collection history, as well as factors that have affected these volumes in recent years, such as changes in airline passenger volumes as a result of the terrorist attacks on the United States on September 11, 2001. We calculated our projected changes in volumes in the out-years for each of the six AQI user fee categories (commercial trucks with decals and without decals are listed as separate categories) based on an individual analysis of each user fee service category.

Commercial Vessel Volumes

We reviewed actual commercial vessel volumes for FYs 1999 through 2003, as well as year-to-date data for FY 2004. The volumes for all 5 fiscal years fluctuated between 51,007 and 53,421 commercial vessels, with no statistically significant trends identified. The year-to-date data for FY 2004 suggest that the volume for the year will fall within the same range. Based on our assumption of general trade increases each fiscal year, we anticipate a slight increase in commercial vessel volumes of 1 percent per year for FYs 2005 through 2010. We used this percentage to estimate volumes for FYs 2005 through 2010.

Commercial Truck Volumes (Individual Crossings and Decals)

We reviewed actual commercial truck and commercial truck decal volumes in FYs 1999 through 2003, as well as year-to-date data for FY 2004. The volumes of individual truck crossings for all 5 fiscal years fluctuated between 534,586 and 726,677 commercial truck crossings, with no statistically significant trends identified. The numbers of truck decals distributed in FYs 1999 through 2003 fluctuated between 23,094 and 45,607, with no statistically significant trends identified. The year-to-date data for FY 2004 suggest that individual truck crossing and truck decal volumes will remain within these ranges. Using the average percentage change in the past 3 fiscal years, we detected slight increases in the individual commercial truck crossing volumes of 0.55 percent and in the truck decal volumes of 1 percent. These slight increases in volumes are consistent with our assumption of general trade increases each fiscal year. We used these percentages to estimate the respective volumes for individual crossings and decals for FYs 2005 through 2010, as shown in table 2. Projected volumes are one component we use in the calculation of user fees. In estimating the commercial truck user fees for FYs 2005 through 2010, we relied only on the 0.55 percent figure associated with individual crossings because the truck decal fee is not calculated separately but is set at 20 times the individual crossing fee.

Commercial Railroad Car Volumes

We reviewed actual commercial railroad car volumes in FYs 1999 through 2003, as well as year-to-date data for FY 2004. The volumes for the 5 fiscal years fluctuated between 146,809 and 224,269 loaded commercial railroad car crossings, with no statistically significant trends identified. The year-to-date data for FY 2004 suggest that FY 2004 volumes will remain within this range. Based upon the average percentage change in the past 3 fiscal years, we detected a slight increase in loaded commercial railroad car volumes of 1.35 percent per year, and we used this percentage to estimate the volumes for FYs 2005 through 2010. This small increase in volumes is consistent with our assumption of general trade increases each fiscal year.

Commercial Aircraft Volumes

We reviewed actual commercial aircraft volumes for FYs 1999 through 2003, as well as year-to-date data for FY 2004. The volumes in these years ranged between 317,240 and 439,618 commercial aircraft. Although there was a decrease in volumes in FY 2002, the fiscal year following the September 11, 2001, attacks, the commercial aircraft volumes started to rebound in FY 2003, but they did not return to their pre-September 11 levels. Year-to-date data for FY 2004 indicate that the commercial aircraft volumes continue to increase at a rate of about 1.18 percent, which has been the average volume increase for the last 5 fiscal years (FYs 1999 through 2003). Based on this figure, we used an estimated percentage increase in volumes of 1.18 percent per year to project commercial aircraft volumes in FYs 2005 through 2010.

International Airline Passenger Volumes

We reviewed actual international airline passenger volumes for FYs 1999 through 2003, as well as year-to-date data for FY 2004. The volumes in these years ranged between 44,552,311 and 66,609,081 passengers. Although there was a decrease in passenger volumes in FY 2002, the fiscal year following the attacks of September 11, 2001, the passenger volumes began to rebound in FY 2003 but did not return to pre-September 11 levels. The year-to-date data for FY 2004 indicate that passenger volumes continue to increase at a rate of about 1.18 percent, which has been the average volume increase for the last 5 fiscal years (FYs 1999 through 2003). Based on this figure, we used an estimated percentage increase in volumes of 1.18 percent per year to project international airline passenger volumes for FYs 2005 through 2010.

Estimated volumes for each category of AQI services for FY 2004 and projected estimated volumes for FYs 2005 through 2010 are shown in table 2. Estimated costs for each category of AQI services for FYs 2005 through 2010 are shown in tables 3 through 8.

BILLING CODE 3410–34–P

Table 2.--Volumes by AQI service category for FYs 2004 through 2010

Service category	Est. 2004 volume	Est. 2005 volume	Est. 2006 volume	Est. 2007 volume	Est. 2008 volume	Est. 2009 volume	Est. 2010 volume
Commercial vessels (Increase over prior year)	51,007	51,517 (1%)	52,032 (1%)	52,553 (1%)	53,078 (1%)	53,609 (1%)	54,145 (1%)
Commercial trucks (Increase over previous year)	573,760	576,915 (0.55%)	580,087 (0.55%)	583,277 (0.55%)	586,484 (0.55%)	589,709 (0.55%)	592,951 (0.55%)
Commercial truck decals (Increase over prior year)	24,188	24,430 (1%)	24,674 (1%)	24,921 (1%)	25,170 (1%)	25,422 (1%)	25,676 (1%)
Commercial railroad cars (Increase over prior year)	177,375	179,763 (1.35%)	182,183 (1.35%)	184,635 (1.35%)	187,120 (1.35%)	189,639 (1.35%)	192,192 (1.35%)
Commercial aircraft (Increase over prior year)	421,493	426,467 (1.18%)	431,499 (1.18%)	436,591 (1.18%)	441,742 (1.18%)	446,955 (1.18%)	452,229 (1.18%)
International airline passengers (Increase over prior year)	58,748,166	59,441,394 (1.18%)	60,142,803 (1.18%)	60,852,488 (1.18%)	61,570,547 (1.18%)	62,297,080 (1.18%)	63,032,185 (1.18%)

Calculation and Rounding of User Fees

Once we established the total annual costs to administer the AQI program, including the amount necessary to maintain the AQI account reserve at a reasonable level, we began the calculation of our fees. In calculating the user fees, we divided the sum of the costs of providing each service by the projected number of users subject to inspection (*i.e.*, the volume of use), thereby arriving at ''raw'' fees. We then rounded the raw fees. As in the past, we rounded raw fees up, rather than down, to ensure that we collect enough revenue to cover the costs of providing services and to maintain a reasonable reserve balance. Any excess collections due to rounding are added to the reserve balance for each individual fee category. If an increase in volume results in additional revenue from user fees, this revenue would not necessarily increase the reserve because the additional money would be used to service the increased volume. We rounded all user fees up to the nearest quarter, except for the international airline passenger user fee. Given the sheer volume of passengers, if we rounded up to the nearest quarter we would recover far more than is necessary. Therefore, we rounded these passenger user fees up to the nearest nickel. Tables 3 through 8 contain data on projected costs, including the amounts necessary to maintain reasonable reserve levels; volumes of use; raw and rounded fees; and projected revenues for FYs 2005 through 2010.

BILLING CODE 3410–34–P

Table 3.--AQI user fee rates–FY 2005

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$25,036,968	51,517	$485.99	$486.00	$25,037,262
Commercial trucks[1]	2,880,674	576,915	4.99	5.00	2,884,575
Commercial truck decals	2,442,883	24,430	99.99	100.00[1]	2,443,000
Loaded railroad cars	1,347,871	179,763	7.49	7.50	1,348,223
Commercial aircraft	29,838,091	426,467	69.96	70.00	29,852,690
Airline passengers	294,092,266	59,441,394	4.94	4.95	294,234,900
Total	355,638,753	.....	.....	.....	355,800,650[2]

[1]Decals may be purchased at 20 times the individual crossing rate, or $100 per decal.

[2]The figure of $355.8 million represents the revenue that would be collected if the adjusted fee were in effect for the entire fiscal year. It is likely, however, that the adjusted fee will only be in effect for three-fourths of the fiscal year, in which case the projected revenue is $327.6 million. The reserve fund will be used to cover the anticipated shortfall.

Table 4.--AQI user fee rates–FY 2006

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$25,387,460	52,032	$487.92	$488.00	$25,391,616
Commercial trucks[1]	2,921,000	580,087	5.03	5.25	3,045,457
Commercial truck decals	2,477,080	24,674	100.39	105.00[1]	2,590,770
Loaded railroad cars	1,366,740	182,183	7.50	7.50	1,366,373
Commercial aircraft	30,255,794	431,499	70.11	70.25	30,312,805
Airline passengers	298,209,254	60,142,803	4.96	5.00	300,714,015
Total	360,617,328	.....	.....	.....	363,421,036

[1]Decals may be purchased at 20 times the individual crossing rate, or $105 per decal.

Table 5.--AQI user fee rates–FY 2007

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$25,743,209	52,553	$489.85	$490.00	$25,750,970
Commercial trucks[1]	2,961,932	583,277	5.07	5.25	3,062,204
Commercial truck decals	2,511,791	24,921	100.79	105.00[1]	2,616,705
Loaded railroad cars	1,385,892	184,635	7.51	7.75	1,430,921
Commercial aircraft	30,679,762	436,591	70.27	70.50	30,779,666
Airline passengers	302,387,996	60,852,488	4.96	5.00	304,262,440
Total	365,670,582	.....	.....	.....	367,902,906

[1]Decals may be purchased at 20 times the individual crossing rate, or $105 per decal.

Table 6.--AQI user fee rates–FY 2008

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$26,104,294	53,078	$491.81	$492.00	$26,114,376
Commercial trucks[1]	3,003,477	586,484	5.12	5.25	3,079,041
Commercial truck decals	2,547,023	25,170	101.19	105.00[1]	2,642,850
Loaded railroad cars	1,405,331	187,120	7.51	7.75	1,450,180
Commercial aircraft	31,110,089	441,742	70.42	70.50	31,142,811
Airline passengers	306,629,420	61,570,547	4.98	5.00	307,852,735
Total	370,799,634	.....	.....	.....	372,281,993

[1]Decals may be purchased at 20 times the individual crossing rate, or $105 per decal.

Table 7.--AQI user fee rates–FY 2009

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$26,470,796	53,609	$493.77	$494.00	$26,482,846
Commercial trucks[1]	3,045,646	589,709	5.16	5.25	3,095,972
Commercial truck decals	2,582,783	25,422	101.59	105.00[1]	2,669,310
Loaded railroad cars	1,425,061	189,639	7.51	7.75	1,469,702
Commercial aircraft	31,546,872	446,955	70.58	70.75	31,622,066
Airline passengers	310,934,465	62,297,080	4.99	5.00	311,485,400
Total	376,005,623	.....	.....	.....	376,825,296

[1]Decals may be purchased at 20 times the individual crossing rate, or $105 per decal.

BILLING CODE 3410-34-C

Table 8.--AQI user fee rates–FY 2010

AQI activity	Est. total costs	Projected volume	Raw fee	Rounded fee	Projected revenue
Commercial vessels	$26,842,795	54,145	$495.76	$496.00	$26,855,920
Commercial trucks[1]	3,088,447	592,951	5.20	5.25	3,112,993
Commercial truck decals	2,619,079	25,676	102.00	105.00[1]	2,695,980
Loaded railroad cars	1,445,088	192,192	7.51	7.75	1,489,488
Commercial aircraft	31,990,206	452,229	70.73	70.75	31,995,202
Airline passengers	315,304,086	63,032,185	5.00	5.00	315,160,925
Total	381,289,701	.....	.....	.....	381,310,508

[1]Decals may be purchased at 20 times the individual crossing rate, or $105 per decal.

Table 9 shows the AQI user fees in effect prior to the effective date of this interim rule and the projected user fees for FYs 2005 through 2010. Also, below, we describe each AQI service and explain additional activities and costs as they pertain to each service individually.

Table 9.--Rounded AQI user fees–FYs 2004-2010

Service	Previous user fee	FY 2005 user fee	FY 2006 user fee	FY 2007 user fee	FY 2008 user fee	FY 2009 user fee	FY 2010 user fee
Commercial vessels	$480.50	$486.00	$488.00	$490.00	$492.00	$494.00	$496.00
Commercial trucks	4.75	5.00	5.25	5.25	5.25	5.25	5.25
Commercial truck decals[1]	95.00	100.00	105.00	105.00	105.00	105.00	105.00
Commercial railroad cars	7.00	7.50	7.50	7.75	7.75	7.75	7.75
Commercial aircraft	65.25	70.00	70.25	70.50	70.50	70.75	70.75
International airline passengers	3.10	4.95	5.00	5.00	5.00	5.00	5.00

[1]Commercial truck decals are issued on a calendar year basis. Decal rates will be effective on January 1 of each year.

Commercial Vessel User Fee

We inspect commercial vessels of 100 net tons or more arriving at ports of entry in the customs territory of the United States. Vessel owners/operators pay a user fee for the first 15 arrivals at ports. CBP collects this user fee on our behalf.

The AQI user fee for commercial vessel inspection prior to this interim rule was $480.50. That fee became effective on October 1, 2001, and had not been adjusted prior to this rulemaking. The user fee from the effective date of this interim rule until the end of FY 2005 is $486.00. User fees for subsequent years are as follows: $488 in FY 2006, $490 in FY 2007, $492 in FY 2008, $494 in FY 2009, and $496 in FY 2010.

Commercial Truck and Truck Decal User Fees

We inspect commercial trucks arriving at land ports in the customs territory of the United States from Mexico. CBP collects these user fees on our behalf.

Commercial trucks crossing at land border ports are also required to pay CBP user fees; therefore, our regulations provide that commercial truck owners/operators must prepay our user fee if they are prepaying the CBP user fee. In this case, our required prepaid user (decal) fee is 20 times the user fee for each single arrival. This fee covers an unlimited number of entries during the calendar year. Upon payment, the truck owner or operator receives a decal to place on his or her truck windshield. This is a joint decal that indicates that both the Customs (now part of DHS) and APHIS user fees for the truck have been paid for that calendar year.

Prior to this rulemaking, the commercial truck user fee was $4.75 for a single crossing and $95 for a decal. This interim rule raises the fee to $5 for a single crossing and $100 for a decal until the end of FY 2005. User fees for FYs 2006 through 2010 are $5.25 for a single crossing and $105 for a decal.

Commercial Railroad Car User Fee

We inspect loaded commercial railroad cars arriving at land ports in the customs territory of the United States. The fees for this service are calculated and remitted by the individual railroad companies within 60 days after the end of each calendar month. If a railroad company chooses to prepay our fees, the fee is 20 times the individual arrival fee for each loaded rail car. This prepaid user fee covers 1 calendar year's worth of AQI inspections. Our user fee prior to this interim rule was $7 per commercial loaded railcar. The fee from the effective date of this interim rule until the end of FY 2005 is $7.50. User fees for subsequent years are as follows: $7.50 in FY 2006 and $7.75 in FYs 2007 through 2010.

Commercial Aircraft User Fee

We inspect international commercial aircraft arriving at airports in the customs territory of the United States. The fees for this service are calculated and remitted by the individual airline companies within 31 days after the end of each calendar quarter. The user fee for commercial aircraft inspection prior to this interim rule was $65.25. This interim rule raises the fee for commercial aircraft inspection to $70 from the effective date of the rule until the end of FY 2005. User fees for subsequent years are as follows: $70.25 in FY 2006, $70.50 in FYs 2007 and 2008, and $70.75 in FYs 2009 and 2010.

International Airline Passenger User Fee

We inspect international airline passengers arriving at airports in the customs territory of the United States. Millions of travelers pass through U.S. airports daily. Our overall goal, keeping in mind airport security, is a timely, seamless inspection process that is integrated with the clearance processes of other Federal agencies with inspection responsibilities, that will ensure the fastest passenger clearance time while at the same time safeguard against the introduction of pests and diseases of animals and plants. Our joint goal is to enhance security and improve enforcement and regulatory processes in order that international air passengers are cleared through the entire Federal inspection process as quickly as possible without jeopardizing our security requirements. In partnership with the airline industry, we obtain advance information on international air passengers through the use of an Advance Passenger Information System to expedite the overall processing of passengers with no loss in enforcement of security requirements.

Prior to this interim rule, the user fee for international airline passenger clearance was $3.10 per passenger; the fee from the effective date of this interim rule until the end of FY 2005 will be $4.95 per passenger. The user fee for FYs 2006 through 2010 will be $5 per passenger. We wish to point out that, under the regulations, it is the user fee in effect at the time the fee is collected—in most cases, at the time the ticket is purchased—that applies; therefore, passengers who purchased a ticket and paid a user fee prior to the effective date of this rule would not have to pay an additional $1.85 if their date of departure came after the effective date of this rule.

Miscellaneous

In addition to the substantive changes described above, we are making a number of editorial changes to § 354.3. Previously, there were various addresses given for remittances of AQI user fees and for the submission of statements and other information. This interim rule provides a single new address for these purposes. The new address is as follows: U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181. Where reference was made in § 354.3 to ''APHIS user fees'' and ''APHIS permits,'' we now refer to ''AQI user fees'' and ''AQI permits.'' We have also updated the definition of *Customs* to read as follows: ''The Bureau of Customs and Border Protection, U.S. Department of Homeland Security.'' In § 354.3(b)(2)(vi), we have updated a reference to an obsolete Customs form. The amended paragraph refers to ''the Vessel Entrance or Clearance Statement, CBP Form 1300.'' Additionally, for the sake of clarity, we have made an editorial change to the introductory text that precedes the table in § 354.3(b), changed the paragraph heading of § 354.3(d)(4) from *Remittance and statement procedures* to *Statement procedures*, and added the heading *Remittance procedures* to § 354.3(d)(5). Further, in § 354.3(e)(3)(i), we have replaced the word ''vessel'' with the word ''aircraft,'' also for the purpose of clarification. Though there are some paragraphs of § 354.3 that remain unchanged, in the rule portion of this document, we have reprinted the section in its entirety so that it will be available to users of the regulations when this interim rule is published.

Emergency Action

This rulemaking, which adjusts our flat-rate AQI user fees, is necessary on an emergency basis to ensure the adequate funding and continued operation at necessary levels of CBP and APHIS activities vital to preventing the introduction of plant and animal pests and diseases into the United States. Under these circumstances, the Administrator has determined that there is good cause under 5 U.S.C. 553 for issuing this rule as an interim rule rather than by publishing it as a notice of proposed rulemaking. We are making this rule effective on January 1, 2005, to provide adequate notice of our adjusted fees.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this interim rule on small entities, as required under the Regulatory Flexibility Act. The economic analysis is summarized below. The full analysis is available on the EDOCKET Web site (see **ADDRESSES** above). Copies of the full analysis may also be obtained by contacting Ms. Donna Ford, Branch Chief, Financial Services Branch, FMD, MRPBS, APHIS, 4700 River Road Unit 55, Riverdale, MD 20737–1232, (301) 734–5901.

In this interim rule, we are amending the user fee regulations by adjusting the fees charged for certain AQI services we provide in connection with certain commercial vessels, commercial trucks, commercial railroad cars, commercial aircraft, and international airline passengers arriving at ports in the customs territory of the United States. The fees are being updated to enable us to recover the cost of providing those services.

The volume and intensity of inspection activities have increased dramatically in recent years, particularly since the events of September 11, 2001. Consequently, the cost of providing AQI services has increased, significantly outpacing user fee collections. In addition, the funding required to maintain even the current level of services has increased as well, due to pay raises and inflation.

Increasingly open and more extensive international trade brings with it the need for increased vigilance against threats to the agricultural resources of the United States. In addition, bioterrorism is a new and serious threat. Therefore, the need exists for more cargo inspection, both in the sheer number of inspections and in the range of commodities inspected. Broader and more intensive passenger screening has also become necessary. As shown in table 10, had APHIS continued to collect user fees in FY 2005 through FY 2010 at the rates in effect prior to this interim rule, total collections would have amounted to approximately $1.502 billion. Program costs are expected to be about $2.210 billion over the same period. This $708 million difference demonstrates the magnitude of the shortfall in cost recovery that would have occurred absent the changes.

BILLING CODE 3410–34–P

BILLING CODE 3410-34-C

Table 10.--Comparison of FY 2004 and new AQI user fee revenues (in millions of dollars)

Fiscal year	2005	2006	2007	2008	2009	2010
Estimated total program costs (including reserve component)	$355.6	$360.6	$365.7	$370.8	$376.0	$381.3
Projected revenues from FY2004 user fees	243.2	246.0	248.8	251.7	254.6	257.5
Projected shortfall with 2004 user fees	(112.5)	(114.6)	(116.9)	(119.1)	(121.4)	(123.8)
Projected revenues from new user fees	327.6[1]	363.4	367.9	372.3	376.8	381.3

[1]The figure of $327.6 million in projected revenues for FY 2005 is based on our assumption that the new fees will only be in effect for three-fourths of that fiscal year. Since we are projecting that the total program costs in FY 2005 will be $355.7 million, we anticipate that there will be a shortfall that will have to be covered by the AQI reserve fund. Were the new fees to be in effect for all of FY 2005, however, projected revenue would total $355.8 million.

Benefits

The chief benefit associated with AQI services is the prevention of losses that could be incurred as a result of plant and animal pests and diseases entering the United States. Such potential losses include reductions in yield and productivity of affected hosts, costs to governmental and private entities of pest or disease control and eradication, and losses in export revenues due to trade embargoes. The harm to American agriculture associated with the introduction of plant and animal pests and diseases can be immense. For example, the eradication efforts associated with an outbreak of exotic Newcastle disease in the western United States that began in October of 2002 cost U.S. taxpayers, both State and Federal, in excess of $180 million. In addition, the total direct value of the export restrictions which were in place from October 2002 though December 2003 has been estimated at $167 million.[1]

The primary benefit of increasing AQI user fees is to assure that the program operates at a level considered sufficient to minimize the risk of introduction of agricultural pests and diseases. If the AQI user fees do not accurately reflect costs, services cannot be adequately provided. Without the fee increases, the reserve fund would be depleted, and the program would be in a deficit status, potentially forcing layoffs of significant numbers of employees and cutbacks in services. As a result, the potential for foreign pests and diseases to enter the United States could be increased. In addition, trade could be disrupted if inspectors were not available to inspect and clear cargo on a timely basis.

While the expected benefits of this interim rule are not quantified, they are likely to exceed the costs.

Costs

International airline passengers and the operators of commercial aircraft, commercial vessels, commercial trucks, and commercial railroad cars will be affected by this rule. Taken collectively, the changes in user fees contained in this rule appear very large, amounting to more than $100 million per fiscal year in increased revenues. Estimates of changes in demand for commercial vessel, aircraft, truck, and railroad car inspections attributable to the changes in user fees are hindered by the difficulty in choosing appropriate prices and elasticities of demand; however, the fee increases represent very small portions of the overall costs related to the AQI activities in all categories, so the economic impacts on passengers and conveyances affected by this interim rule are likely to be very small. These impacts are discussed in greater detail in the paragraphs that follow.

Impact on International Air Passengers

AQI fees are charged for the inspection of passengers on commercial aircraft upon arrival from outside the United States, with certain limited exceptions. International air passenger user fees will increase by $1.85, or 60 percent, in FY 2005, and by an additional $0.05 in FY 2006, with no further increases projected through FY 2010. The total increase, therefore, is $1.90, or 61 percent. These revised fees are expected to generate a substantial increase in program revenues—an additional $120 million by 2010—because of the volume of international air travel. In fact, the bulk of increased program revenues from the fee revisions—more than 80 percent—will come from this category.

The increases in the AQI user fees for this category are larger, in percentage terms, than those for the other service categories. As noted earlier, due to the events of September 11, 2001, and the resulting increased security concerns, we are inspecting a greater volume of international airline passengers arriving in the United States than we did before. Additional personnel and additional inspection measures have been needed to clear passengers through the Federal inspection process in a timely manner while at the same time ensuring that post-September 11 security concerns, which include the threat of bioterrorism, are addressed. These increased inspection operations are very personnel-intensive and costly, but a very necessary part of the process.

The individual fee increases, while high in percentage terms, are very small relative to international airfares. In 2002, overseas visitors[2] to the United States paid an average of $1,317 in international airfare, and U.S. residents visiting overseas destinations paid an average of $1,409 in international airfare.[3] The FY 2005 user fee of $4.95 amounts to less than 0.4 percent of the average international air fare, and the overall increase is less than 0.1 percent.

Fare increases can affect passenger demand and, therefore, affect the airlines. The impact of increased user fees on the volume of international air passengers will depend on the price elasticity of demand for international air travel. Because there are no close substitutes for international air travel, it can be assumed that demand is relatively inelastic. When demand is relatively inelastic, the percentage decrease in quantity of trips demanded will be less than the percentage increase in price attributable to increased user fees. This, combined with the fact that the user fee increase is very small relative to the price of an international air ticket, should make the impact very small.

Impact on Commercial Aircraft

Certain international scheduled and unscheduled (chartered) air passenger, air cargo, and air courier carriers arriving at U.S. customs ports are subject to AQI inspections. AQI user fees are charged for these inspections. These regulations affect international flights, many of which are operated by foreign-owned firms. Agency records show that about 43 percent of the aircraft clearance user fees collected in FY 2003 were from foreign airlines. More than 2,000 domestic firms operate in air transportation; however, the vast majority do not operate international flights and, therefore, are not subject to the fees. According to Agency records, 15 major air carriers, 20 national carriers, and 18 large regional carriers[4] were responsible for about 87 percent of the aircraft clearance fee collections in FY 2003.

Commercial aircraft user fees increase by $4.75, or 7 percent, in FY 2005 and by $0.25 in FYs 2006, 2007, and 2009, respectively, for a total increase of $5.50, or 8 percent, over the period covered by this interim rule. Based on the expected volume, the increase in user fees generates additional revenues ranging from $1.5 million in FY 2005, when the adjusted fee is expected to be in effect for only three-fourths of the fiscal year, to $2.5 million in FY 2010. We anticipate that there will be more than 400,000 aircraft needing clearance annually during the period covered by this interim rule.

The impact of the increases in this user fee should be small. The fee increases are very small relative to the overall operating costs of air carriers. About 57 percent of the aircraft cleared are owned by U.S. carriers, and about 87 percent of those aircraft are owned by

[1] *Economic Impact of Poultry Export Restrictions.* USDA–APHIS, CEAH.

[2] ''Overseas'' refers to all countries except Canada and Mexico.

[3] Survey of International Air Travelers. Office of Travel and Tourism Industries, International Trade Administration, U.S. Department of Commerce.

[4] Department of Transportation (DOT), Bureau of Transportation Statistics (BTS), Office of Airline Information, Air Carrier Groupings. Carriers are grouped according to operating revenue boundaries: Major air carriers—over $1 billion; national air carriers—over $100 million to $1 billion; large regional air carriers—$20 million to $100 million; and medium regional air carriers—under $20 million.

major carriers, national carriers, or large regional carriers. In 2002, 13 domestic major air carriers had operating expenses of $79 billion, 30 domestic national air carriers had operating expenses of $6 billion, and domestic large regional air carriers had operating expenses of $670 million.[5] The total increase in the fee over the entire period covered by this rule, applied to all annual inspections, will represent an increase in operating expenses of 0.007 percent on average for a major carrier, 0.01 percent on average for a national carrier, and 0.6 percent on average for a large regional carrier.[6]

Impact on Commercial Vessels

The user fee for inspecting commercial vessels increases by $5.50, or 1 percent, per vessel inspected in FY 2005 and by a total of $15.50, or 3 percent, over the period covered in this interim rule. The additional revenues collected are estimated to be $0.2 million in FY 2005 and $0.8 million in FY 2010. The impact of the increases in this user fee should be small. The fee increases represent an extremely small proportion of the operating costs of bulk vessels. The total daily operating costs of dry bulk vessels in the year 2001 averaged $14,769,[7] placing the total increase in this user fee at 0.1 percent of a single day's operating expenses.

Impact on Commercial Trucks

AQI user fees are charged for the inspection of commercial trucks arriving in the United States. The fee for single truck inspections increases by $0.25, or 5 percent, in FY 2005 and by $0.50, or 11 percent, in total over the period covered in this interim rule. The truck decal user fee, which is set at a level equal to 20 times the single crossing fee, increases by $5 in FY 2005 and by $10 in total. Additional collections from both commercial truck sources (single entry user fees and multiple entry truck decals) will be $0.3 million in FY 2005. In FY 2010, additional collections from single-entry fees and multiple-entry decals will total an estimated $0.6 million.

If we assume that any U.S. trucking firm that regularly transports freight across the U.S./Mexican border will purchase an APHIS decal, which is good for an unlimited number of entries during the calendar year, the proposed increase in user fees in FY 2005 could cost a firm, at most, an additional $5 per truck decal or an estimated $325 for a firm operating 65 trucks.[8] This increase is insignificant when compared to the annual receipts of the typical trucking firm, representing only 0.02 percent of the average U.S. trucking firm's year 2000 operating revenues of $1.8 million.

Impact on Loaded Railroad Cars

AQI user fees are charged for the inspection of loaded railroad cars entering the United States from Mexico. Loaded railcar user fees will increase by $0.50, or 7 percent, in FY2005, and by a total of $0.75, or 11 percent, over the period covered in this interim rule. The annual volume of loaded railroad cars arriving in the United States from Mexico is estimated at about 200,000. The additional revenues from the increases in this user fee are expected to be $0.1 million in FY 2005 and to total $0.7 million over the period covered in the rule.

The impact of the increase in fees should be small. The total increase in this user fee over the entire time frame covered in this rule of $0.75 per railcar represents only about 0.06 percent of the average freight revenue per carload for Class I railroads (those with 2002 operating revenue of at least $272 million) in 2003.[9] Even the full fee in FY 2005 of $7.50 represents only 0.6 percent of the average freight revenue per carload.

Administrative Cost Estimates

Additional reporting costs to private airlines associated with revising user fees are likely to be very small because mechanisms are already in place for collecting fees. There should be no additional recordkeeping costs for ticketing agents and tour operators who are not involved in remitting fees and are not expected to remit fees in the future. Similarly, additional reporting burdens associated with cargo inspection fees on vessel, aircraft, railcar, and truck operators resulting from a revision of user fees are likely to be very small as mechanisms are already in place for collecting fees.

Alternatives

One alternative to this interim rule would have been to leave the regulations unchanged. In that case, the fees would have remained unchanged. However, in addition to routine increases in the cost of providing AQI services due to inflation, replacement of equipment, and mandated increases in pay costs, the events of September 11, 2001, have had a profound impact on costs and revenues. Revenues have diminished due, in large part, to reduced passenger loads, conveyance arrivals, and cargo volumes. On the other hand, new security concerns regarding international travel have led us to adopt an inspection process that is much more extensive than before and is very personnel-intensive. Therefore, AQI program costs have not declined, but rather have increased considerably. In fact, the program's cost has significantly outpaced user fee collections. If APHIS were to continue to collect user fees at the rates in effect prior to this interim rule during the period from FY 2005 through FY 2010, total collections would be more than $708 million short of projected program costs. As noted earlier, such a shortfall could result in AQI service cutbacks, which would increase the potential for animal and plant pests and diseases to enter the United States and could disrupt trade if inspectors were not available to inspect and clear cargo on a timely basis. Therefore, this alternative was rejected.

Another alternative to this rule would have been to leave the AQI user fees unchanged and request that Congress cover the additional AQI program costs through appropriations. Since FY 1992, however, APHIS has received no directly appropriated funds to provide AQI services. The shift to funding AQI programs through user fees rather than through appropriations provided a more equitable way of matching program costs to program users or beneficiaries. The implementation of user fees is based on the premise that the beneficiaries or users of a public system should pay for its operation, rather than the public at large. The use of appropriations to cover the growth in the cost of AQI activities would shift some of the burden of paying for the AQI system back to U.S. taxpayers and away from the users of that system. Therefore, this alternative was rejected.

A third alternative to this rule would have been to simplify the fee increases by using a set percentage increase for the out-years of the proposal. This approach would have involved increasing the fees to cover the cost

[5] Air Carrier Profile. National Transportation Statistics 2003. DOT/BTS.

[6] Based on the number of inspections in FY 2003 (APHIS records) and operating expenses for air carriers for 2002 (DOT/BTS).

[7] Ruth K. DeVelbis, Transportation Industry Analyst, Office of Financial and Rate Approvals, Maritime Administration, personal communication May 2004.

[8] This estimate is based on the assumption that a firm owns 65 trucks, the average number of truck registrations per trucking establishment. (DOT/BTS).

[9] Based on data from *Class I Railroad Statistics*. Association of American Railroads, Policy and Economics Department. Freight revenue per ton-mile ($0.02283 in 2003) × average length of haul (862.4 miles in 2003) = freight revenue per haul ($19.70). Freight revenue per haul × average tons per carload (62.3 in 2003) = average freight revenue per carload ($1,226.60).

increases in FY 2005, followed by fee increases of 1.5 percent per year in FYs 2006 through 2010.[10] However, the annual number of users in each category of service and trends in those numbers affect the level at which each fee should be set to properly recover the cost of providing the corresponding service. These volumes fluctuate over time, and those fluctuations also vary by user fee service category. While developing the needed fee increases, APHIS performed a review of factors affecting volumes for each service category shown in our collection history. This review showed that a set percentage increase in the fees would eventually result in an excess of revenues flowing into the reserve fund because we do anticipate general volume increases. A 1.5 percent across-the-board fee increase, which does not take into account volume fluctuations and variations between categories, would result in additional reserve contributions of $26 million in 2010, exceeding our planned reserve level. Moreover, a single rate of increase for all service categories would have users of one service subsidizing fees paid by users of another service. Therefore, we rejected this alternative.

Impact on Small Entities

The Regulatory Flexibility Act requires that the Agency specifically consider the economic impact of its rules on small entities. The fee changes will directly affect commercial maritime vessels of 100 net tons or more, commercial trucks, commercial railroad cars, and commercial aircraft arriving at ports in the customs territory of the United States. Some of the firms affected will be foreign-owned firms, and some will be U.S.-owned firms. The fee changes will also affect international airline passengers arriving in the customs territory of the United States, but passengers are not included in the discussion here because the Regulatory Flexibility Act does not cover individuals.

The Small Business Administration (SBA) has established guidelines for determining which establishments are to be considered small. For air transportation, the SBA defines a small business entity as having 1,500 or fewer employees. For water transportation, a small business entity is defined as having 500 or fewer employees. The definition for small business entity in truck transportation is one having $18.5 million or less in annual receipts. For railroad transportation, the SBA defines a small business entity as having 500 or fewer employees.

According to 1997 Economic Census data for air transportation (North American Industry Classification System [NAICS] code 481; not including large certificated passenger carriers),[11] only 13 of the 1,868 firms that operated for the entire year employed more than 1,000 workers. Thus approximately 99 percent (1,855 firms) of these air transportation firms employed fewer than 1,500 workers. However, the vast majority of these firms are not operating internationally and are therefore not affected by this rule. In 2002, approximately 65 percent of the 72 major, national, and large and medium regional air carriers would have been considered small by SBA standards. All of the major air carriers, and 12 of 30 nationals, would be considered large. In FY 2003, those large air carriers accounted for more than 78 percent of the aircraft clearance inspections for which user fees were collected.

Data on deep-sea coastal water transportation (NAICS code 4831) from the 1997 Economic Census show that of the 487 firms that operated for the entire year, 40 firms employed 100 or more workers. Thus, at least 92 percent of affected water transportation firms would be considered small. Data on truck transportation (NAICS code 484) from the 1997 Economic Census show that of the 70,044 firms that operated for the entire year, 1,614 firms had annual receipts in excess of $10 million. Thus, approximately 97.7 percent (68,830 firms) of all truck transportation firms had less than $10 million in annual receipts. Based on information from the Association of American Railroads (AAR),[12] of the 571 firms that operated for all of 2001 in railroad transportation (NAICS code 4011), only 18 firms employed more than 500 workers. Thus approximately 97 percent (553 firms) of all line-haul railroads employed fewer than 500 workers.

From the above it can be expected that a considerable number of those entities affected by this rule can be considered small. However, as we have noted in our discussions of the individual transportation sectors, the impacts of the user fee changes represent a small portion of overall operating costs on transportation entities, whether small or large, and should therefore have a small impact.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, 5 U.S.C. 801–808). Under SBREFA, major rules, in general, cannot take effect until 60 days after the rule is published in the **Federal Register**. However, section 808(2) of SBREFA states that agencies may waive this effective date requirement for ''good cause'' and establish an earlier effective date. As explained above, this rule is necessary on an emergency basis to ensure the adequate funding and continued operation at necessary levels of CBP and APHIS activities vital to preventing the introduction of plant and animal pests and diseases into the United States, and the Administrator has determined that there is good cause for issuing this rule as an interim rule rather than by publishing it as a notice of proposed rulemaking. For these same reasons, there is ''good cause'' under section 808(2) of SBREFA to make this rule effective on a date earlier than would otherwise be required under that Act.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork

[10] As a policy, USDA is using an inflation factor of 1.5 percent when estimating increases in salaries and other economic factors, in accordance with the Mid-Session Review—Economic Assumptions.

[11] U.S. Census Bureau, U.S. Department of Commerce. The Economic Census does not cover large certificated passenger carriers that report to the DOT's Office of Airline Statistics. Data from the 2002 Economic Census are not yet fully available, and data from the *National Transportation Statistics 2003*, DOT/BTS do not contain information on firm size.

[12] The Economic Census does not cover railroads.

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 354

Animal diseases, Exports, Government employees, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Travel and transportation expenses.

■ Accordingly, we are amending 7 CFR part 354 as follows:

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

■ 1. The authority citation for part 354 is revised to read as follows:

Authority: 7 U.S.C. 7701–7772 and 8301–8317; 21 U.S.C. 136 and 136a; 49 U.S.C. 80503; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 354.3 is revised to read as follows:

§ 354.3 User fees for certain international services.

(a) *Definitions.* Whenever in this section the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

APHIS. The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Arrival. Arrival at a port of entry in the customs territory of the United States, or at any place served by a port of entry as specified in 19 CFR 101.3.

Calendar year. The period from January 1 to December 31, inclusive, of any particular year.

Commercial aircraft. Any aircraft used to transport persons or property for compensation or hire.

Commercial purpose. The intention of receiving compensation, or making a gain or profit.

Commercial railroad car. A railroad car used or capable of being used for transporting property for compensation or hire.

Commercial shipment. A shipment for gain or profit.

Commercial truck. A self-propelled vehicle, designed and used for transporting property for compensation or hire. Empty trucks and truck cabs without trailers fitting this description are included.

Commercial vessel. Any watercraft or other contrivance used or capable of being used as a means of transportation on water to transport property for compensation or hire, with the exception of any aircraft or ferry.

Customs. The Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

Customs territory of the United States. The 50 States, the District of Columbia, and Puerto Rico.

Designated State or county inspector. A State or county plant regulatory official designated by the Secretary of Agriculture to inspect and certify to shippers and other interested parties as to the phytosanitary condition of plant products inspected under the Plant Protection Act.

Export certificate for processed plant products. A certificate (PPQ Form 578) issued by an inspector, describing the plant health condition of processed or manufactured plant products based on inspection of submitted samples and/or by virtue of the processing received.

Person. An individual, corporation, partnership, trust, association, or any other public or private entity, or any officer, employee, or agent thereof.

Phytosanitary certificate. A certificate (PPQ Form 577) issued by an inspector, giving the phytosanitary condition of domestic plants or unprocessed or unmanufactured plant products based on inspection of the entire lot or representative samples drawn by a Federal or State employee authorized to conduct such sampling.

Phytosanitary certificate for reexport. A certificate (PPQ Form 579) issued by an inspector, giving the phytosanitary condition of foreign plants and plant products legally imported into the United States and subsequently offered for reexport. The certificate certifies that, based on the original foreign phytosanitary certificate and/or additional inspection or treatment in the United States, the plants and plant products are considered to conform to the current phytosanitary regulations of the receiving country and have not been subjected to the risk of infestation or infection during storage in the United States. Plants and plant products which transit the United States under Customs bond are not eligible to receive the phytosanitary certificate for reexport.

(b) *Fee for inspection of commercial vessels of 100 net tons or more.* (1) Except as provided in paragraph (b)(2) of this section, the master, licensed deck officer, or purser of any commercial vessel which is subject to inspection under part 330 of this chapter or 9 CFR chapter I, subchapter D, and which is either required to make entry at the customs house under 19 CFR 4.3 or is a United States-flag vessel proceeding coastwise under 19 CFR 4.85, shall, upon arrival, proceed to Customs and pay an agricultural quarantine and inspection (AQI) user fee. The AQI user fee for each arrival, not to exceed 15 payments in a calendar year (i.e., no additional fee will be charged for a 16th or subsequent arrival in a calendar year), is shown in the following table. The AQI user fee shall be collected at each port of arrival.

Effective dates	Amount
January 1, 2005, through September 30, 2005	$486.00
October 1, 2005, through September 30, 2006	488.00
October 1, 2006, through September 30, 2007	490.00
October 1, 2007, through September 30, 2008	492.00
October 1, 2008, through September 30, 2009	494.00
October 1, 2009, through September 30, 2010	496.00

(2) The following categories of commercial vessels are exempt from paying an AQI user fee:

(i) Foreign passenger vessels making at least three trips a week from a port in the United States to the high seas (including ''cruises to nowhere'') and returning to the same port in the United States, not having touched any foreign port or place other than in Canada, or taken on any stores other than in Canada;

(ii) Any vessel which, at the time of arrival, is being used solely as a tugboat;

(iii) Vessels used exclusively in the governmental service of the United States or a foreign government, including any agency or political subdivision of the United States or a foreign government, so long as the vessel is not carrying persons or merchandise for commercial purposes;

(iv) Vessels arriving in distress or to take on bunkers, sea stores, or ship's stores;

(v) Tugboats towing vessels on the Great Lakes; and

(vi) Any vessel which sails only between United States and Canadian ports, when the Master of such vessel arriving from Canada certifies, in the ''Particulars of Voyage'' block of the Vessel Entrance or Clearance Statement, CBP Form 1300, that the vessel has sailed solely between the United States and Canada for the previous 2 years.

(c) *Fee for inspection of commercial trucks.* (1) Except as provided in paragraph (c)(2) of this section, the driver or other person in charge of a commercial truck that is entering the customs territory of the United States and that is subject to inspection under part 330 of this chapter or under 9 CFR, chapter I, subchapter D, must, upon arrival, proceed to Customs and pay an AQI user fee for each arrival, as shown in the following table:

Effective dates	Amount
January 1, 2005, through September 30, 2005	$5.00
October 1, 2005, through September 30, 2006	5.25
October 1, 2006, through September 30, 2007	5.25
October 1, 2007, through September 30, 2008	5.25
October 1, 2008, through September 30, 2009	5.25
October 1, 2009, through September 30, 2010	5.25

(2) The following categories of commercial trucks are exempt from paying an AQI user fee:

(i) Trucks entering the customs territory of the United States from Canada.

(ii) [*Reserved*]

(3) Prepayment.

(i) The owner or operator of a commercial truck, *if* entering the customs territory of the United States from Mexico *and* applying for a prepaid Customs permit for a calendar year, must apply for a prepaid AQI permit for the same calendar year. Applicants must apply to Customs for prepaid AQI permits.[1] The following information must be provided, together with payment of an amount 20 times the AQI user fee for each arrival:

(A) Vehicle make, model, and model year.

(B) Vehicle Identification Number (VIN).

(C) License numbers issued by State, Province, or country.

(D) Owner's name and address.

(ii) No credit toward the prepaid AQI permit will be given for user fees paid for individual arrivals.

(d) *Fee for inspection of commercial railroad cars.* (1) Except as provided in paragraph (d)(2) of this section, an AQI user fee will be charged for each loaded commercial railroad car which is subject to inspection under part 330 of this chapter or under 9 CFR chapter I, subchapter D, upon each arrival. The railroad company receiving a commercial railroad car in interchange at a port of entry or, barring interchange, the railroad company moving a commercial railroad car in line haul service into the customs territory of the United States, is responsible for paying the AQI user fee. The AQI user fee for each arrival of a loaded railroad car is shown in the following table. If the AQI user fee is prepaid for all arrivals of a commercial railroad car during a calendar year, the AQI user fee is an amount 20 times the AQI user fee for each arrival.

Effective dates	Amount
January 1, 2005, through September 30, 2005	$7.50
October 1, 2005, through September 30, 2006	7.50
October 1, 2006, through September 30, 2007	7.75
October 1, 2007, through September 30, 2008	7.75
October 1, 2008, through September 30, 2009	7.75
October 1, 2009, through September 30, 2010	7.75

(2) The following categories of commercial railroad cars are exempt from paying an AQI user fee:

(i) Commercial railroad cars entering the customs territory of the United States from Canada;

(ii) Any commercial railroad car that is part of a train whose journey originates and terminates in the United States, if—

(A) The commercial railroad car is part of the train when the train departs the United States; and

(B) No passengers board or disembark from the commercial railroad car, and no cargo is loaded or unloaded from the commercial railroad car, while the train is within any country other than the United States; and

(iii) Locomotives and cabooses.

(3) Prepayment.

(i) Railroad companies may, at their option, prepay the AQI user fee for each commercial railroad car for a calendar year. This payment must be remitted in accordance with paragraph (d)(5) of this section.

(ii) No credit toward the calendar year AQI user fee will be given for AQI user fees paid for individual arrivals.

(4) Statement procedures. The Association of American Railroads (AAR), and the National Railroad Passenger Corporation (AMTRAK), shall file monthly statements with the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, within 60 days after the end of each calendar month. Each statement shall indicate:

(i) The number of loaded commercial railroad cars entering the customs territory of the United States from Mexico during the relevant period;

(ii) The number of those commercial railroad cars pulled by each railroad company; and

(iii) The total monthly AQI user fee due from each railroad company.

(5) Remittance procedures. Individual railroad companies shall remit the AQI user fees calculated by AAR, and AMTRAK shall remit the AQI user fees it has calculated, within 60 days after the end of each calendar month in which commercial railroad cars entered the customs territory of the United States. AQI user fees, together with monthly statements, must be remitted to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181.

(6) Compliance. AAR, AMTRAK, and each railroad company responsible for making AQI user fee payments must allow APHIS personnel to verify the accuracy of AQI user fees collected and remitted and otherwise determine compliance with 21 U.S.C. 136a and this paragraph. The AAR, AMTRAK, and each railroad company responsible for making AQI user fee payments must advise the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, of the name, address, and telephone number of a responsible officer who is authorized to verify AQI user fee calculations, collections, and remittances, as well as any changes in the identifying information submitted.

(e) *Fee for inspection of commercial aircraft.* (1) Except as provided in paragraph (e)(2) of this section, an AQI user fee will be charged for each commercial aircraft which is arriving, or which has arrived and is proceeding from one United States airport to another under a Bureau of Customs and Border Protection ''Permit to Proceed,'' as specified in 19 CFR 122.81 through 122.85, or an ''Agricultural Clearance or Safeguard Order'' (PPQ Form 250), used pursuant to § 330.400 of this chapter and 9 CFR 94.5, and which is subject to inspection under part 330 of this chapter or 9 CFR chapter I, subchapter D. Each carrier is responsible for paying the AQI user fee. The AQI user fee for each arrival is shown in the following table:

Effective dates	Amount
January 1, 2005, through September 30, 2005	$70.00
October 1, 2005, through September 30, 2006	70.25
October 1, 2006, through September 30, 2007	70.50
October 1, 2007, through September 30, 2008	70.50
October 1, 2008, through September 30, 2009	70.75
October 1, 2009, through September 30, 2010	70.75

(2) The following categories of commercial aircraft are exempt from paying an AQI user fee:

[1] Applicants should refer to Customs and Border Protection regulations (19 CFR part 24) for specific instructions.

(i) Any aircraft moving solely between the United States and Canada;

(ii) Any aircraft used exclusively in the governmental services of the United States or a foreign government, including any Agency or political subdivision of the United States or a foreign government, as long as the aircraft is not carrying persons or merchandise for commercial purposes;

(iii) Any aircraft making an emergency or forced landing when the original destination of the aircraft was a foreign port;

(iv) Any passenger aircraft with 64 or fewer seats, which is not carrying the following cargo: Fresh fruits, fresh vegetables, plants, unprocessed plant products, cotton or covers, sugarcane, or fresh or processed meats; and which does not offer meal service other than beverages and prepackaged snacks that do not contain meats derived from ruminants, swine, or poultry or fresh fruits and fresh vegetables. Aircraft exempt from the user fee under this paragraph would still be subject to the garbage handling requirements found in § 330.400 of this chapter and 9 CFR 94.5;

(v) Any aircraft moving from the United States Virgin Islands to Puerto Rico; and

(vi) Any aircraft making an intransit stop at a port of entry, during which the aircraft does not proceed through any portion of the Federal clearance process, such as inspection or clearance by APHIS or the Bureau of Customs and Border Protection, no cargo is removed from or placed on the aircraft, no passengers get on or off the aircraft, no crew members get on or off the aircraft, no food is placed on the aircraft, and no garbage is removed from the aircraft.

(3) Remittance and statement procedures. (i) Each carrier must remit the appropriate fees to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, for receipt no later than 31 days after the close of the calendar quarter in which the aircraft arrivals occurred. Late payments will be subject to interest, penalty, and handling charges as provided in the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3717).

(ii) The remitter must mail with the remittance a written statement to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181. The statement must include the following information:

(A) Name and address of the person remitting payment;

(B) Taxpayer identification number of the person remitting payment;

(C) Calendar quarter covered by the payment;

(D) Ports of entry at which inspections occurred;

(E) Number of arrivals at each port; and

(F) Amount remitted.

(iii) Remittances must be made by check or money order, payable in United States dollars, through a United States bank, to ''The Animal and Plant Health Inspection Service.''

(4) Compliance. Each carrier subject to this section must allow APHIS personnel to verify the accuracy of the AQI user fees remitted and to otherwise determine compliance with 21 U.S.C. 136a and this paragraph. Each carrier must advise the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, of the name, address, and telephone number of a responsible officer who is authorized to verify AQI user fee calculations and remittances, as well as any changes in the identifying information submitted.

(5) Limitations on charges. (i) Airlines will not be charged reimbursable overtime for inspection of aircraft if the aircraft is subject to the AQI user fee for arriving aircraft as prescribed by this section.

(ii) Airlines will not be charged reimbursable overtime for inspection of cargo from an aircraft if:

(A) The aircraft is subject to the AQI user fee for arriving aircraft as prescribed by this section; and

(B) The cargo is inspected between 8 a.m. and 4:30 p.m., Monday through Friday; or

(C) The cargo is inspected concurrently with the aircraft.

(f) *Fee for inspection of international passengers.* (1) Except as specified in paragraph (f)(2) of this section, each passenger aboard a commercial aircraft who is subject to inspection under part 330 of this chapter or 9 CFR, chapter I, subchapter D, upon arrival from a place outside of the customs territory of the United States, must pay an AQI user fee. The AQI user fee for each arrival is shown in the following table:

Effective dates[1]	Amount
January 1, 2005, through September 30, 2005	$4.95
October 1, 2005, through September 30, 2006	5.00
October 1, 2006, through September 30, 2007	5.00
October 1, 2007, through September 30, 2008	5.00
October 1, 2008, through September 30, 2009	5.00
October 1, 2009, through September 30, 2010	5.00

[1] Persons who issue international airline tickets or travel documents are responsible for collecting the AQI international airline passenger user fee from ticket purchasers. Issuers must collect the fee applicable at the time tickets are sold. In the event that ticket sellers do not collect the AQI user fee when tickets are sold, the air carrier must collect the user fee from the passenger upon departure. Carriers must collect the fee applicable at the time of departure from the traveler.

(2) The following categories of passengers are exempt from paying an AQI user fee:

(i) Passengers arriving from Canada whose journey originates in Canada;

(ii) Crew members who are on duty on a commercial aircraft;

(iii) Airline employees, including ''deadheading'' crew members, who are traveling on official airline business;

(iv) Diplomats, except for United States diplomats, who can show that their names appear on the accreditation listing maintained by the United States Department of State. In lieu of the accreditation listing, an individual diplomat may present appropriate proof of diplomatic status to include possession of a diplomatic passport or visa, or diplomatic identification card issued by a foreign government;

(v) Passengers departing and returning to the United States without having touched a foreign port or place other than Canada;

(vi) Passengers arriving on any commercial aircraft used exclusively in the governmental service of the United States or a foreign government, including any agency or political subdivision of the United States or a foreign government, so long as the aircraft is not carrying persons or merchandise for commercial purposes. Passengers on commercial aircraft under contract to the United States Department of Defense (DOD) are exempted if they have been precleared abroad under the joint DOD/APHIS Military Inspection Program;

(vii) Passengers arriving on an aircraft due to an emergency or forced landing when the original destination of the aircraft was a foreign port;

(viii) Passengers transiting the United States and not subject to inspection; and

(ix) Passengers moving from the United States Virgin Islands to Puerto Rico.

(3) AQI user fees shall be collected under the following circumstances:

(i) When through tickets or travel documents are issued indicating travel to the customs territory of the United

States which originates in any location other than Canada;

(ii) When through tickets or travel documents are issued in Canada indicating an arrival in the customs territory of the United States following a stopover (layover) in a location other than Canada; and

(iii) When passengers arrive in the customs territory of the United States in transit from a location other than Canada and are inspected by APHIS or Customs.

(4) *Collection of fees.* (i) Any person who issues tickets or travel documents on or after May 13, 1991, is responsible for collecting the AQI user fee from all passengers transported into the customs territory of the United States to whom the AQI user fee applies.

(A) Tickets or travel documents must be marked by the person who collects the AQI user fee to indicate that the required AQI user fee has been collected from the passenger.

(B) If the AQI user fee applies to a passenger departing from the United States and if the passenger's tickets or travel documents were issued on or after May 13, 1991, but do not reflect collection of the AQI user fee at the time of issuance, then the carrier transporting the passenger from the United States must collect the AQI user fee upon departure.

(C) AQI user fees collected from international passengers pursuant to paragraph (f) of this section shall be held in trust for the United States by the person collecting such fees, by any person holding such fees, or by the person who is ultimately responsible for remittance of such fees to APHIS. AQI user fees collected from international passengers shall be accounted for separately and shall be regarded as trust funds held by the person possessing such fees as agents, for the beneficial interest of the United States. All such user fees held by any person shall be property in which the person holds only a possessory interest and not an equitable interest. As compensation for collecting, handling, and remitting the AQI user fees for international passengers, the person holding such user fees shall be entitled to any interest or other investment return earned on the user fees between the time of collection and the time the user fees are due to be remitted to APHIS under this section. Nothing in this section shall affect APHIS' right to collect interest for late remittance.

(5) *Remittance and statement procedures.* (i) The carrier whose ticket stock or travel document reflects collection of the AQI user fee must remit the fee to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181. The travel agent, United States-based tour wholesaler, or other entity, which issues its own non-carrier related ticket or travel document to a passenger who is subject to an AQI user fee under this part, must remit the fee to APHIS, unless by contract the carrier will remit the fee.

(ii) AQI user fees must be remitted to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, for receipt no later than 31 days after the close of the calendar quarter in which the AQI user fees were collected. Late payments will be subject to interest, penalty, and handling charges as provided in the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3717). Refunds by a remitter of AQI user fees collected in conjunction with unused tickets or travel documents shall be netted against the next subsequent remittance.

(iii) The remitter must mail with the remittance a written statement to the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181. The statement must include the following information:

(A) Name and address of the person remitting payment;

(B) Taxpayer identification number of the person remitting payment;

(C) Calendar quarter covered by the payment; and

(D) Amount collected and remitted.

(iv) Remittances must be made by check or money order, payable in United States dollars, through a United States bank, to ''The Animal and Plant Health Inspection Service.''

(6) Carriers contracting with United States-based tour wholesalers are responsible for notifying the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, of all flights contracted, the number of spaces contracted for, and the name, address, and taxpayer identification number of the United States-based tour wholesaler, within 31 days after the close of the calendar quarter in which such a flight occurred; *except that,* carriers are not required to make notification if tickets, marked to show collection of the AQI user fee, are issued for the individual contracted spaces.

(7) *Compliance.* Each carrier, travel agent, United States-based tour wholesaler, or other entity subject to this section must allow APHIS personnel to verify the accuracy of the AQI user fees collected and remitted and to otherwise determine compliance with 21 U.S.C. 136a and this paragraph. Each carrier, travel agent, United States-based tour wholesaler, or other entity must advise the U.S. Bank, United States Department of Agriculture (USDA), APHIS, AQI, P.O. Box 952181, St. Louis, MO 63195–2181, of the name, address, and telephone number of a responsible officer who is authorized to verify AQI user fee calculations, collections, and remittances, as well as any changes in the identifying information submitted.

(8) *Limitation on charges.* Airlines will not be charged reimbursable overtime for passenger inspection services required for any aircraft on which a passenger arrived who has paid the airline passenger AQI user fee for that flight.

(g) *Fees for export certification of plants and plant products.* (1) For each certificate issued by APHIS personnel, the recipient must pay the applicable AQI user fee at the time and place the certificate is issued, or, in the case of a block of certificates, at the time the certificates are given to the shipper.

(2) There is no AQI user fee for a certificate issued by a designated State or county inspector.

(3) If a designated State inspector issues a certificate, the State where the certificate is issued may charge for inspection services provided in that State.

(4) Any State which wishes to charge a fee for services it provides to issue certificates must establish fees in accordance with one of the following guidelines:

(i) *Calculation of a ''cost-per-certificate'' fee.* The State must:

(A) Estimate the annual number of certificates to be issued;

(B) Determine the total cost of issuing certificates by adding together delivery,[2] support,[3] and administrative [4] costs; and

---

[2] Delivery costs are costs such as employee salary and benefits, transportation, per diem, travel, purchase of specialized equipment, and user fee costs associated with maintaining field offices. Delivery hours are similar hours taken by inspectors, including travel time, inspection time, and time taken to complete paperwork.

[3] Support costs are costs at supervisory levels which are similar to delivery costs, and user fee costs such as training, automated data processing, public affairs, enforcement, legal services, communications, postage, budget and accounting services, and payroll, purchasing, billing, and collecting services. Support hours are similar hours taken at supervisory levels, as well as hours taken in training, automated data processing, enforcement, legal services, communication, budgeting and accounting, payroll purchasing, billing, and collecting.

[4] Administrative costs are costs incurred as a direct result of collecting and monitoring Federal phytosanitary certificates. Administrative hours are

(C) Divide the cost of issuing certificates by the estimated number of certificates to be issued to obtain a ''raw'' fee. The State may round the ''raw'' fee up to the nearest quarter, if necessary for ease of calculation, collection, or billing; or

(ii) *Calculation of a ''cost-per-hour'' fee.* The State must:

(A) Estimate the annual number of hours taken to issue certificates by adding together delivery,[2] support,[3] and administrative [4] hours;

(B) Determine the total cost of issuing certificates by adding together delivery, support, and administrative costs; and

(C) Divide the cost of issuing certificates by the estimated number of hours taken to issue certificates to obtain a ''cost-per-hour'' fee. The State may round the ''cost-per-hour'' fee up to the nearest quarter, if necessary for ease of calculation, collection, or billing.

(5) The AQI user fees are:

(i)(A) $50 for a certificate for a commercial shipment; or

(B) $23 for a certificate for a low-value commercial shipment, if the following criteria are met:

(*1*) The items being shipped are identical to those identified on the phytosanitary certificate;

(*2*) The shipment is accompanied by an invoice which states that the items being shipped are worth less than $1,250; and

(*3*) The shipper requests that user fee charged be based on the low value of the shipment;

(ii) $23 for a certificate for a noncommercial shipment;

(iii)(A) $50 for a certificate for reexport of a commercial shipment; or

(B) $23 for a certificate for reexport of a low value commercial shipment, if the following criteria are met:

(*1*) The items being shipped are identical to those identified on the phytosanitary certificate;

(*2*) The shipment is accompanied by an invoice which states that the items being shipped are worth less than $1,250; and

(*3*) The shipper requests that the user fee charged be based on the low value of the shipment;

(iv) $50 for a processed product certificate for a commercial shipment; and

(v) $7 for reissuing any certificate or certificate for reexport.

(h) *Refunds of AQI user fees.* (1) A shipper who pays for a block of certificates to cover commercial shipments may obtain a refund or a credit against future AQI user fees under the following circumstances:

(i) If a certificate from the block is voided;

(ii) If a certificate from the block is returned unused;

(iii) If the shipper pays for inspection outside of normal business hours (8 a.m. to 4:30 p.m.) under § 354.1 of this part.

(iv) If a certificate from the block is used for a noncommercial shipment; or

(v) If a certificate from the block is used to reissue another certificate.

(2) The amount of any refund or credit will be the amount overcharged, less $7 to cover APHIS administrative expenses.

(i) *Payment methods.* For payment of any of the AQI user fees required in paragraph (g) of this section, we will accept personal checks for amounts less than $100, and checks drawn on commercial accounts, cashier's checks, certified checks, traveler's checks, and money orders for any amount. All payments must be for the exact amount due.

(j) The person for whom the service is provided and the person requesting the service are jointly and severally liable for payment of user fees for any import or entry services listed below, of $56 per hour, or $14 per quarter hour, with a minimum fee of $14 for each employee required to perform the following services. If the services must be conducted on a Sunday or holiday or at any other time outside the normal tour of duty of the employee, then the premium user fee rate as listed below applies, as well as the 2-hour minimum charge and a commuted traveltime period required by § 354.1(a)(2). If the services requested are performed on a Sunday, the hourly user fee rate will be $74, or $18.50 per quarter hour, with a $18.50 minimum. If the services requested are performed on a day other than Sunday outside the normal tour of duty of the employee providing the service, the hourly user fee rate will be $65, or $16.25 per quarter hour, with a $16.25 minimum:

(1) Conducting inspections, on vessels or in storage areas, of solid wood packing material or cargo when a shipment arrives without a certificate or exporter statement required under § 319.40–5(g) or § 319.40–5(h) of this chapter, or with an incomplete certificate or exporter statement; and

(2) Supervising the separation of cargo from solid wood packing material denied entry under this subpart and the destruction or reexportation of the solid wood packing material. (Approved by the Office of Management and Budget under control numbers 1651–0019, 0579–0094, or 0579–0052).

Done in Washington, DC, this 6th day of December 2004.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 04–27053 Filed 12–8–04; 8:45 am]

BILLING CODE 3410–34–P

hours taken as a direct result of collecting and monitoring Federal phytosanitary certificates.

Federal Register

Thursday,
December 9, 2004

Part VI

Department of Health and Human Services

Centers for Disease Control and Prevention

Change in Date of Publication of Final HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC School-based, Regional, State, Territorial, Local, and Community Assistance Programs; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Change in Date of Publication of Final HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC Regional, State, Territorial, Local, and Community Assistance Programs

AGENCY: Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC).

ACTION: General notice.

SUMMARY: On June 16, 2004, CDC published a notice in the **Federal Register** entitled ''Proposed Revision of Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Educational Sessions in CDC Regional, State, Territorial, Local, and Community Assistance Programs.'' The purpose of the notice was to request public comment on proposed revisions to the Guidelines last published in 1992. Also in the notice, CDC stated that it anticipated publishing a Final Guidance document within 120 days of the close of the public comment period.

The purpose of this notice is to announce a revised publication date of the Final Guidance document. CDC anticipated receiving approximately 500 public comments but received nearly 5,000 comments to both notices published on June 16, 2004. CDC is working to appropriately consider each of the comments it received. Because of the increased time that it will take to adequately review the nearly 5,000 comments, CDC now intends to publish the ''Final HIV Content Guidelines for AIDS-related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC Regional, State, Territorial, Local, and Community Assistance Programs'' by spring, 2005.

On June 16, 2004, CDC also published another notice in the **Federal Register** entitled ''Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Educational Sessions in CDC School-based Assistance Programs.'' Like the notice for Community-based assistance programs, this notice requested public comment on the Interim HIV Guidelines for School-based assistance programs and stated that CDC anticipated publishing a Final Guidance document within 120 days of the close of the public comment period. CDC now also intends to publish the Final ''HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Educational Sessions in CDC School-based Assistance Programs'' by spring 2005.

FOR FURTHER INFORMATION CONTACT: David Hale, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333. Telephone: (404) 639–8008.

Dated: December 1, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 04–27020 Filed 12–8–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Change in Date of Publication of Final HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Educational Sessions in CDC School-Based Assistance Programs

AGENCY: Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC).

ACTION: General notice.

SUMMARY: On June 16, 2004, CDC published a notice in the **Federal Register** entitled ''Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Educational Sessions in CDC School-based Assistance Programs.'' The purpose of the notice was to request public comment on the Interim Guidelines. Also in the notice, CDC stated that it anticipated publishing a Final Guidance document within 120 days of the close of the public comment period.

The purpose of this notice is to announce a revised publication date of the Final Guidance document. CDC anticipated receiving approximately 500 public comments but received nearly 5,000 comments to both notices published on June 16, 2004. CDC is working to appropriately consider each of the comments it received. Because of the increased time that it will take to adequately review the nearly 5,000 comments, CDC now intends to publish the ''Final HIV Content Guidelines for AIDS-related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising and Web Site Materials, and Education Sessions in CDC Regional, State, Territorial, Local and Community Assistance Programs'' by spring, 2005.

On June 16, 2004, CDC also published another notice in the **Federal Register** entitled ''Proposed Revision of Interim HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Educational Sessions in CDC Regional, State, Territorial, Local, and Community Assistance Programs''. Like the notice for School-based assistance programs, this notice requested public comment on proposed revisions of the Interim HIV Content Guidelines first published in 1992 and stated that CDC anticipated publishing a Final Guidance document within 120 days of the close of the public comment period. CDC now also intends to publish the ''Final HIV Content Guidelines for AIDS-Related Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, Marketing, Advertising, and Web Site Materials, and Education Sessions in CDC Regional, State, Territorial, Local and Community Assistance Programs'' by spring, 2005.

FOR FURTHER INFORMATION CONTACT: Tim Hack, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1600 Clifton Road, NE., Mailstop K29, Atlanta, Georgia 30333. Telephone: (770) 488–3249.

Dated: December 1, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 04–27019 Filed 12–8–04; 8:45 am]

BILLING CODE 4163–18–P

Federal Register

Thursday,
December 9, 2004

Part VII

The President

Proclamation 7852—National Pearl Harbor Remembrance Day, 2004

Federal Register
Vol. 69, No. 236
Thursday, December 9, 2004

Presidential Documents

Title 3—

The President

Proclamation 7852 of December 6, 2004

National Pearl Harbor Remembrance Day, 2004

By the President of the United States of America

A Proclamation

On a quiet Sunday morning, December 7, 1941, more than 2,400 Americans were killed in the attack on Pearl Harbor. On that day, life changed in America, and the course of history was altered forever.

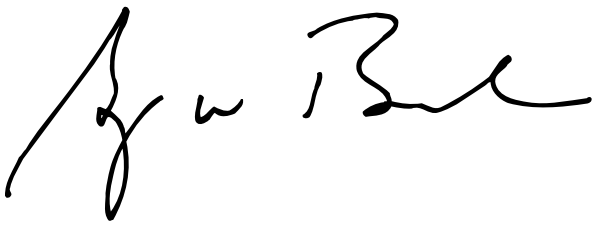
Our citizens reacted to the attack with firm determination to defeat tyranny and secure our Nation. This enterprise required the commitment and effort of our entire country. At the height of the conflict, the United States had ships on every ocean and troops on five continents. In all, more than 16 million Americans wore the uniform of our Nation. They came from all walks of life. They served honorably and fought fiercely. At home, millions more contributed to the war effort, laboring for victory in our factories, on farms, and across America.

Today, we honor those who fought and died at Pearl Harbor, and we pay special tribute to the veterans of World War II. These heroes hold a cherished place in our history. Through their courage, sacrifice, and selfless dedication, they saved our country and preserved freedom. As we fight the war on terror, their patriotism continues to inspire a new generation of Americans who have been called to defend the blessings of liberty. Like those who have gone before them throughout our history, our troops fighting the war on terror are defending America from danger and liberating the oppressed.

The Congress, by Public Law 103–308, as amended, has designated December 7 of each year as ''National Pearl Harbor Remembrance Day.''

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, do hereby proclaim December 7, 2004, as National Pearl Harbor Remembrance Day. I encourage all Americans to observe this solemn occasion with appropriate ceremonies and activities. I urge all Federal agencies, interested organizations, groups, and individuals to fly the flag of the United States at half-staff this December 7 in honor of those who died as a result of their service at Pearl Harbor.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of December, in the year of our Lord two thousand four, and of the Independence of the United States of America the two hundred and twenty-ninth.



[FR Doc. 04–27241
Filed 12–8–04; 9:21 am]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 69, No. 236

Thursday, December 9, 2004

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives.gov/federal_register/**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, DECEMBER

69805–70050	1
70051–70178	2
70179–70350	3
70351–70536	6
70537–70870	7
70871–71338	8
71339–71690	9

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
7850 70351
7851 70353
7852 71689

Executive Orders:
12473 (Amended by EO 13365) 71333
13286 (See EO 13362) 70173
13289 (See EO 13363) 70175
13303 (Amended by EO 13364) 70177
13315 (See EO 13364) 70177
13350 (See EO 13364) 70177
13362 70173
13363 70175
13364 70177
13365 71333

Administrative Orders:
Memorandums:
Memorandum of October 21, 2004 70349

5 CFR

317 70355
352 70355
359 70355
451 70355
530 70355
531 70355
534 70355
575 70355
841 69805
842 69805
843 69805

6 CFR

Proposed Rules:
5 70402

7 CFR

210 ..... 70871, 70872
220 70872
354 71660
905 70874
1464 70367
1775 70877
1951 70883

Proposed Rules:
929 69996

9 CFR

166 70179
430 70051

11 CFR

Proposed Rules:
300 71388

12 CFR

Proposed Rules:
226 70925

13 CFR

121 70180

Proposed Rules:
121 70197

14 CFR

23 70885
39 ..... 69807, 69810, 70368, 70537, 70539, 71339, 71340, 71342, 71344, 71347, 71349, 71351, 71353
71 ..... 70053, 70185, 70371, 70372, 70541, 70542
73 70887

Proposed Rules:
39 ..... 69829, 69832, 69834, 69836, 69838, 69842, 69844, 70202, 70204, 70564, 70566, 70568, 70571, 70574, 70936, 70938
71 70208

15 CFR

732 71356
734 71356
740 71356
742 71356
744 71356
750 69814
772 71356
806 70543

Proposed Rules:
710 70754
711 70754
712 70754
713 70754
714 70754
715 70754
716 70754
717 70754
718 70754
719 70754
720 70754
721 70754
722 70754
723 70754
724 70754
725 70754
726 70754
727 70754
728 70754
729 70754

17 CFR

240 70852
248 71322

Proposed Rules:
240 ..... 71126, 71256

242.....71126
249.....71126

18 CFR

11.....71364

Proposed Rules:

Ch. 1.....70077

21 CFR

1.....71562, 71655
11.....71562
510.....70053
520.....70053
522.....70054, 70055
558.....70056

Proposed Rules:

165.....70082
1301.....70576

22 CFR

122.....70888
129.....70888

23 CFR

655.....69815

24 CFR

570.....70864

Proposed Rules:

206.....70244
2004.....70868
3280.....70016

25 CFR

Proposed Rules:

542.....69847

26 CFR

1.....70547, 70550
25.....70547
31.....69819, 70547
53.....70547
55.....70547
156.....70547
301.....70547
602.....70547, 70550

Proposed Rules:

1.....70578
26.....70404

27 CFR

9.....70889, 71372

29 CFR

1926.....70373
4011.....69820
4022.....69820
4044.....69821

30 CFR

18.....70752
938.....71528, 71551

33 CFR

100.....70551, 70552
117.....70057, 70059, 70373
165.....70374

Proposed Rules:

100.....70578
117.....70091, 70209
165.....70211

35 CFR

Ch. I.....71375

36 CFR

13.....70061
242.....70074

Proposed Rules:

242.....70940

37 CFR

201.....70377
253.....69822

40 CFR

9.....70552
52.....69823, 70893, 70895, 71375
180.....70897
271.....70898
712.....70552

Proposed Rules:

52.....69863, 70944, 70945, 71390
60.....69864, 71472
63.....69864
271.....70946
272.....71391
721.....70404

41 CFR

Proposed Rules:

51-2.....70214
51-3.....70214
51-4.....70214

43 CFR

44.....70557
1880.....70557

44 CFR

64.....70377
65.....70185
67.....70191, 70192

45 CFR

Proposed Rules:

650.....71395

47 CFR

0.....70316
1.....70378
2.....71380
4.....70316
15.....71380
18.....70562
27.....70378
63.....70316
64.....71383
73.....71384, 71385, 71386, 71387
74.....70378
90.....70378
101.....70378

Proposed Rules:

73.....71396

49 CFR

171.....70902
173.....70902
174.....70902
175.....70902
176.....70902
177.....70902
178.....70902
571.....70904
585.....70904
586.....70904
589.....70904
590.....70904
596.....70904
597.....70904

Proposed Rules:

572.....70947

50 CFR

14.....70379
17.....70382
100.....70074
222.....69826
223.....69826
622.....70196
635.....70396
648.....70919, 70923
679.....69828, 70924

Proposed Rules:

17.....69878, 70412, 70580, 70971, 71284
100.....70940
229.....70094
648.....70414
660.....70973
679.....70589, 70605, 70974

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT DECEMBER 9, 2004

AGRICULTURE DEPARTMENT
Farm Service Agency
Special programs:
Farm Security and Rural Investment Act of 2002; implementation—
Business and industry loans; published 11-9-04

AGRICULTURE DEPARTMENT
Rural Business-Cooperative Service
Special programs:
Farm Security and Rural Investment Act of 2002; implementation—
Business and industry loans; published 11-9-04

AGRICULTURE DEPARTMENT
Rural Housing Service
Special programs:
Farm Security and Rural Investment Act of 2002; implementation—
Business and industry loans; published 11-9-04

AGRICULTURE DEPARTMENT
Rural Utilities Service
Special programs:
Farm Security and Rural Investment Act of 2002; implementation—
Business and industry loans; published 11-9-04

COMMERCE DEPARTMENT
Industry and Security Bureau
Export administration regulations:
Encryption export and reexport controls revisions; published 12-9-04

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Human drugs:
Antiperspirant drug products (OTC); final mongraph; published 6-9-03
Antiperspirant products (OTC); final monograph; partial stay; published 10-15-04

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Housing programs:
Data Universal Numbering System; identifier use requirement; published 11-9-04

INTERIOR DEPARTMENT
Surface Mining Reclamation and Enforcement Office
Permanent program and abandoned mine land reclamation plan submissions:
Pennsylvania; published 12-9-04

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Boeing; published 11-4-04

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Beef promotion and research; comments due by 12-13-04; published 11-12-04 [FR 04-25198]
Cotton classing, testing and standards:
Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]

AGRICULTURE DEPARTMENT
Rural Business-Cooperative Service
Special programs:
Farm Security and Rural Investment Act of 2002; implementation—
Renewable Energy Systems and Energy Efficiency Improvements, Grant, Guaranteed Loan, and Direct Loan Program; comments due by 12-15-04; published 11-15-04 [FR 04-25239]

COMMERCE DEPARTMENT
Industry and Security Bureau
Export administration regulations:
Knowledge and red flags; definition and guidance revisions; safe harbor; comments due by 12-15-04; published 11-15-04 [FR 04-25309]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Civil procedures; comments due by 12-13-04; published 10-12-04 [FR 04-22598]
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Bering Sea and Aleutian Islands king and tanner crab; comments due by 12-13-04; published 10-29-04 [FR 04-24103]
Caribbean, Gulf, and South Atlantic fisheries—
Gulf of Mexico reef fish; comments due by 12-16-04; published 11-16-04 [FR 04-25429]
Magnuson-Stevens Act provisions—
Pacific Coast groundfish; fishing capacity reduction program; comments due by 12-16-04; published 11-16-04 [FR 04-25428]
Marine mammals:
Taking and importation—
Kodiak Island, AK; rocket launches at Kodiak Launch Complex; pinnipeds; comments due by 12-13-04; published 10-29-04 [FR 04-24234]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA
Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

ENERGY DEPARTMENT
Meetings:
Environmental Management Site-Specific Advisory Board—
Oak Ridge Reservation, TN; Open for comments until further notice; published 11-19-04 [FR 04-25693]

ENERGY DEPARTMENT
Energy Efficiency and Renewable Energy Office
Commercial and industrial equipment; energy efficiency program:
Test procedures and efficiency standards—
Commercial packaged boilers; Open for comments until further notice; published 10-21-04 [FR 04-17730]

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Alaska Natural Gas Pipeline Act:
Conduct of open seasons for natural gas transportation projects; comments due by 12-17-04; published 11-23-04 [FR 04-25933]
Electric rate and corporate regulation filings:
Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]

ENVIRONMENTAL PROTECTION AGENCY
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 12-16-04; published 11-16-04 [FR 04-25301]
Illinois; comments due by 12-13-04; published 11-12-04 [FR 04-24916]
Iowa; comments due by 12-13-04; published 11-12-04 [FR 04-24918]
Environmental statements; availability, etc.:
Coastal nonpoint pollution control program—
Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Mepanipyrim; comments due by 12-13-04; published 10-13-04 [FR 04-22963]
Toxic substances:
Enzymes and proteins; nomenclature inventory; comments due by 12-15-04; published 11-15-04 [FR 04-25307]
Water pollution control:
National Pollutant Discharge Elimination System—
Concentrated animal feeding operations in New Mexico and Oklahoma; general permit for discharges; Open for comments until further notice; published 12-7-04 [FR 04-26817]
Water pollution; effluent guidelines for point source categories:

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 1047/P.L. 108–429

Miscellaneous Trade and Technical Corrections Act of 2004 (Dec. 3, 2004; 118 Stat. 2434)

H.R. 1630/P.L. 108–430

Petrified Forest National Park Expansion Act of 2004 (Dec. 3, 2004; 118 Stat. 2606)

H.R. 2912/P.L. 108–431

To reaffirm the inherent sovereign rights of the Osage Tribe to determine its membership and form of government. (Dec. 3, 2004; 118 Stat. 2609)

H.J. Res. 110/P.L. 108–432

Recognizing the 60th anniversary of the Battle of the Bulge during World War II. (Dec. 3, 2004; 118 Stat. 2611)

H.J. Res. 111/P.L. 108–433

Appointing the day for the convening of the first session of the One Hundred Ninth Congress. (Dec. 3, 2004; 118 Stat. 2613)

H.J. Res. 115/P.L. 108–434

Making further continuing appropriations for the fiscal year 2005, and for other purposes. (Dec. 3, 2004; 118 Stat. 2614)

S. 150/P.L. 108–435

Internet Tax Nondiscrimination Act (Dec. 3, 2004; 118 Stat. 2615)

S. 434/P.L. 108–436

Idaho Panhandle National Forest Improvement Act of 2004 (Dec. 3, 2004; 118 Stat. 2620)

S. 1146/P.L. 108–437

Three Affiliated Tribes Health Facility Compensation Act (Dec. 3, 2004; 118 Stat. 2623)

S. 1241/P.L. 108–438

Kate Mullany National Historic Site Act (Dec. 3, 2004; 118 Stat. 2625)

S. 1727/P.L. 108–439

To authorize additional appropriations for the Reclamation Safety of Dams Act of 1978. (Dec. 3, 2004; 118 Stat. 2627)

S. 2214/P.L. 108–440

To designate the facility of the United States Postal Service located at 3150 Great Northern Avenue in Missoula, Montana, as the ''Mike Mansfield Post Office''. (Dec. 3, 2004; 118 Stat. 2629)

S. 2302/P.L. 108–441

To improve access to physicians in medically underserved areas. (Dec. 3, 2004; 118 Stat. 2630)

S. 2640/P.L. 108–442

To designate the facility of the United States Postal Service located at 1050 North Hills Boulevard in Reno, Nevada, as the ''Guardians of Freedom Memorial Post Office Building'' and to authorize the installation of a plaque at such site, and for other purposes. (Dec. 3, 2004; 118 Stat. 2632)

S. 2693/P.L. 108–443

To designate the facility of the United States Postal Service located at 1475 Western Avenue, Suite 45, in Albany, New York, as the ''Lieutenant John F. Finn Post Office''. (Dec. 3, 2004; 118 Stat. 2634)

S. 2965/P.L. 108–444

To amend the Livestock Mandatory Price Reporting Act of 1999 to modify the termination date for mandatory price reporting. (Dec. 3, 2004; 118 Stat. 2635)

S. 2484/P.L. 108–445

Department of Veterans Affairs Health Care Personnel Enhancement Act of 2004 (Dec. 3, 2004; 118 Stat. 2636)

Last List December 2, 2004

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.