



Federal Register

~~8-4-09~~

Vol. 74 No. 148

Tuesday

August 4, 2009

Pages 38503–38884



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.federalregister.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: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; 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: 74 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

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, September 15, 2009
9:00 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741-6008



Contents

Federal Register

Vol. 74, No. 148

Tuesday, August 4, 2009

Agricultural Marketing Service

RULES

Irish Potatoes Grown in Colorado:

Modification of the Handling Regulation for Area No. 2,
38504–38505

Onions Grown in South Texas:

Decreased Assessment Rate, 38505–38508

Agriculture Department

See Agricultural Marketing Service

See Food and Nutrition Service

See Rural Business-Cooperative Service

See Rural Housing Service

See Rural Utilities Service

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38577–38578

Centers for Disease Control and Prevention

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38634–38635

Centers for Medicare & Medicaid Services

NOTICES

Statement of Organization, Functions, and Delegations of
Authority, 38663

Children and Families Administration

NOTICES

Award Five Program Expansion Supplements to Wilson-
Fish Projects, 38654–38655

Coast Guard

RULES

District Eight Safety Zones and Special Local Regulations,
38524–38529

Safety Zone:

Hornblower Cruises Fleet Week Fireworks Display, San
Francisco Bay, CA, 38530–38532

NOTICES

Environmental Impact Statements; Availability, etc.:

Application for the Tank Ship S/R AMERICAN
PROGRESS, Review for the Inclusion in the
Shipboard Technology Evaluation Program, 38666

Meetings:

National Maritime Security Advisory Committee, 38667

Commerce Department

See International Trade Administration

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

See Patent and Trademark Office

Copyright Royalty Board

RULES

Proceedings of the Copyright Royalty Board; Remand,
38532–38533

Education Department

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38591–38592

Applications for New Awards for Fiscal Year (FY) 2009:
Teacher Quality Partnership Grants Program, 38592–
38605

Privacy Act; Systems of Records, 38882–38884

Energy Department

See Energy Information Administration

See Federal Energy Regulatory Commission

Energy Information Administration

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38605–38606

Environmental Protection Agency

RULES

Approval and Promulgation of Air Quality Implementation
Plans:

West Virginia; Clean Air Interstate Rule, 38536–38544

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38613–38615

Final NPDES General Permit for Discharges From
Concentrated Animal Feeding Operations in New
Mexico, 38615–38616

Sixty-Fourth Report of the TSCA Interagency Testing
Committee to the Administrator of the Environmental
Protection Agency:

Receipt of Report and Request for Comments, 38878–
38880

Farm Credit Administration

NOTICES

Privacy Act; Systems of Records, 38616–38617

Federal Aviation Administration

RULES

Manual Requirements, 38522–38523

NOTICES

Fuel Drain Valves, 38680–38681

Petition for Exemption; Summary of Petition Received,
38682

Federal Election Commission

NOTICES

Agency Procedure for Notice to Respondents in Non-
Complaint Generated Matters, 38617–38618

Federal Energy Regulatory Commission

NOTICES

Applications:

Columbia Gulf Transmission Co., 38606

Consolidated Hydro New Hampshire, Inc., et al., 38607

Combined Notice of Filings, 38607–38611

Environmental Impact Statements; Availability, etc.:
Northwest Pipeline GP, 38611–38613

Federal Highway Administration

NOTICES

Buy America Waiver Notification, 38679–38680

Federal Housing Enterprise Oversight Office**PROPOSED RULES**

Record Retention, 38559–38564

Federal Housing Finance Agency**RULES**

Affordable Housing Program Amendments:

Federal Home Loan Bank Mortgage Refinancing

Authority, 38514–38522

Capital Classifications and Critical Capital Levels for the

Federal Home Loan Banks, 38508–38514

PROPOSED RULES

Board of Directors of Federal Home Loan Bank System

Office of Finance, 38564–38572

Duty to Serve Underserved Markets for Enterprises, 38572–38576

Record Retention, 38559–38564

NOTICES

Federal Home Loan Bank Collateral for Advances and Interagency Guidance on Nontraditional Mortgage Products, 38618–38626

Federal Housing Finance Board**PROPOSED RULES**

Board of Directors of Federal Home Loan Bank System

Office of Finance, 38564–38572

Record Retention, 38559–38564

Federal Maritime Commission**NOTICES**

Application of Leonardo Ortiz to Practice Before the Federal Maritime Commission, 38627–38628

Federal Mediation and Conciliation Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38626–38627

Federal Reserve System**NOTICES**

Meetings; Sunshine Act, 38627

Fiscal Service**NOTICES**

Surety Companies Acceptable on Federal Bonds: StarNet Insurance Co., 38683–38684

Fish and Wildlife Service**NOTICES**

Availability of Draft Environmental Assessment, etc.:

Limiting Mountain Lion Predation on Desert Bighorn

Sheep on Kofa National Wildlife Refuge, etc., 38667–38668

Draft Comprehensive Conservation Plan/Environmental Assessment:

Klamath Marsh National Wildlife Refuge, Klamath County, OR, 38668–38669

Food and Drug Administration**RULES**

Dental Devices:

Classification of Dental Amalgam, Reclassification of

Dental Mercury, Designation of Special Controls for

Dental Amalgam, Mercury, and Amalgam Alloy, 38686–38714

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38634

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability, 38636–38644

Authorization of Emergency Use of Certain Personal Respiratory Protection Devices; Availability, 38644–38648

Authorizations of Emergency Use of Certain Antiviral Drugs:

Zanamivir and Oseltamivir Phosphate, 38648–38654

Cooperative Agreement Between the Food and Drug Administration and the Dauphin Island Sea Lab, 38655–38656

Debarment Order:

Kim C. Hendrick, 38656–38657

Paul H. Kornak, 38657–38658

Determination of Regulatory Review Period for Purposes of Patent Extension:

EOVIST, 38660–38661

RECOTHROM, 38658–38659

XIENCE V EECSS, 38659–38660

Guidance for Industry and Food and Drug Administration Staff:

Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy, 38661–38662

Food and Nutrition Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38578–38579

Health and Human Services Department

See Centers for Disease Control and Prevention

See Centers for Medicare & Medicaid Services

See Children and Families Administration

See Food and Drug Administration

See Health Resources and Services Administration

NOTICES

2009-H1N1 influenza; Determination and Declarations:

Emergency Use of Certain In vitro Diagnostic, Antiviral, and Personal Respiratory Products Accompanied by Emergency Use Information, 38628–38630

Delegation of Authority, 38630

Implementation of Section 5001 of the American Recovery and Reinvestment Act of 2009:

Federal Medical Assistance Percentage Rates for Federal Matching Shares for Medicaid and Foster Care and Adoption Assistance, 38630–38633

Renewal of Charter for the Presidential Advisory Council on HIV/AIDS, 38633–38634

Health Resources and Services Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38635–38636

Meetings:

Advisory Committee on Heritable Disorders in Newborns and Children, 38662

Homeland Security Department

See Coast Guard

See U.S. Customs and Border Protection

See U.S. Immigration and Customs Enforcement

Housing and Urban Development Department

See Federal Housing Enterprise Oversight Office

NOTICES

Proposed Fair Market Rents for the Housing Choice

Voucher Program, etc. (Fiscal Year 2010), 38716–38828

Interior Department

See Fish and Wildlife Service
See Reclamation Bureau

Internal Revenue Service**RULES**

Treatment of Services Under Section 482:
Allocation of Income and Deductions from Intangible
Property Stewardship Expense, 38830–38876

International Trade Administration**NOTICES**

Countervailing Duties:
Dynamic Random Access Memory Semiconductors from
the Republic of Korea, 38579–38584
Countervailing Duties:
Prestressed Concrete Steel Wire Strand from the People's
Republic of China; Correction, 38584–38585

Justice Department**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38672

Labor Department

See Labor Statistics Bureau

Labor Statistics Bureau**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38672–38673

Library of Congress

See Copyright Royalty Board

National Highway Traffic Safety Administration**NOTICES**

Insurer Reporting Requirements; Reports under 49 U.S.C.
on Section 33112(c), 38681–38682

National Institute of Standards and Technology**NOTICES**

Request for nominations for members to serve on National
Institute of Standards and Technology Federal
Advisory Committees, 38586–38591

National Oceanic and Atmospheric Administration**RULES**

Fisheries of the Exclusive Economic Zone Off Alaska:
Pacific Ocean Perch in the West Yakutat District of the
Gulf of Alaska, 38558
International Fisheries; Western and Central Pacific
Fisheries for Highly Migratory Species:
Fishing Restrictions and Observer Requirements in Purse
Seine Fisheries for 2009–2011, etc., 38544–38558

NOTICES

Endangered Species:
File No. 1596–02; Issuance of Permit Modification, 38585
Meetings:
South Atlantic Fishery Management Council, 38586

Nuclear Regulatory Commission**NOTICES**

Draft Interim Staff Guidance Document for Fuel Cycle
Facilities; Availability, 38673–38674

Office of Federal Housing Enterprise Oversight

See Federal Housing Enterprise Oversight Office

Patent and Trademark Office**NOTICES**

Grant of Interim Extension of the Term of U.S. Patent No.
5,135,759:
MicroSort Sperm Separation Technology, 38585

Postal Regulatory Commission**RULES**

Express Mail and Priority Mail Contract, 38533–38536

Public Debt Bureau

See Fiscal Service

Reclamation Bureau**NOTICES**

Quarterly Status Report of Water Service, Repayment, and
Other Water-Related Contract Negotiations, 38669–
38672

Recovery Accountability and Transparency Board**RULES**

Official Seal, 38503–38504

Rural Business-Cooperative Service**NOTICES**

Funds Availability Under the American Recovery and
Reinvestment Act, 2009; Correction, 38579

Rural Housing Service**NOTICES**

Funds Availability Under the American Recovery and
Reinvestment Act, 2009; Correction, 38579

Rural Utilities Service**NOTICES**

Funds Availability Under the American Recovery and
Reinvestment Act, 2009; Correction, 38579

Securities and Exchange Commission**RULES**

Adoption of Updated EDGAR Filer Manual, 38523–38524

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 38675–38676
Order of Suspension of Trading:
Gulf Alternative Energy Corp., 38676–38677
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Stock Exchange, Inc., 38678–38679
Depository Trust Co., 38677–38678

Small Business Administration**NOTICES**

Small Business Size Standards:
Waiver of the Nonmanufacturer Rule, 38674–38675

Transportation Department

See Federal Aviation Administration

See Federal Highway Administration

See National Highway Traffic Safety Administration

Treasury Department

See Fiscal Service

See Internal Revenue Service

NOTICES

Privacy Act of 1974; Computer Matching Program, 38682–
38683

U.S. Customs and Border Protection**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38663–38664

U.S. Immigration and Customs Enforcement**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38664–38666

Veterans Affairs Department**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 38684

Separate Parts In This Issue**Part II**

Health and Human Services Department, Food and Drug Administration, 38686–38714

Part III

Housing and Urban Development Department, 38716–38828

Part IV

Treasury Department, Internal Revenue Service, 38830–38876

Part V

Environmental Protection Agency, 38878–38880

Part VI

Education Department, 38882–38884

Reader Aids

Consult the Reader Aids section at the end of this page 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.

4 CFR

202.....38503

7 CFR

948.....38504

959.....38505

12 CFR

1229.....38508

1291.....38514

Proposed Rules:

914.....38559

985.....38564

989.....38564

1235.....38559

1273.....38564

1274.....38564

1282.....38572

1732.....38559

14 CFR

135.....38522

17 CFR

232.....38523

21 CFR

872.....38686

26 CFR

1.....38830

31.....38830

602.....38830

33 CFR

100.....38524

147.....38524

165 (2 documents)38524,
38530

37 CFR

351.....38532

39 CFR

3020.....38533

40 CFR

52.....38536

50 CFR

300.....38544

679.....38558

Rules and Regulations

Federal Register

Vol. 74, No. 148

Tuesday, August 4, 2009

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD

4 CFR Part 202

RIN 0430-AA02

Official Seal

AGENCY: Recovery Accountability and Transparency Board.

ACTION: Direct final rule.

SUMMARY: The Recovery Accountability and Transparency Board (Board) is adopting regulations to establish its chapter and to adopt requirements on the use of its official seal. Use by any person or organization may be made only with the Board's prior written approval. Wrongful use of an official seal is subject to administrative action and/or criminal penalty.

The Board believes that this rule is non-controversial, and the Board anticipates no significant adverse comment. If the Board receives a significant adverse comment, it will withdraw the rule.

DATES: This rule is effective September 3, 2009 without further action, unless adverse comment is received by August 24, 2009. If adverse comment is received, the Board will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments by Mail/Hand Delivery/Courier: Jennifer Dure, Office of General Counsel, Recovery Accountability and Transparency Board, 1717 Pennsylvania Avenue, NW., Suite 700, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Kristen Fernandez, Records Manager, telephone (202) 254-7900.

SUPPLEMENTARY INFORMATION: The Board is adopting regulations (4 CFR part 202) on the use of its official seal. The Board has developed a seal that signifies the authoritativeness of the item or document to which it is affixed as an official endorsement of the Board. The seal is to be used for official Board business or as approved under the Board's regulations.

The Board believes there is good cause to bypass notice and comment and proceed to a direct final rule pursuant to 5 U.S.C. 553(b). The rule is non-controversial and merely provides who may use the Board's official seal and for what purpose. Because this rule only impacts Board procedure and practice, notice and comment is unnecessary. Although the Board believes this direct final rule will not elicit any significant adverse comments, if such comments are received, the Board will publish a timely notice of withdrawal in the **Federal Register**.

Executive Order No. 12866

This rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, review by the Office of Management and Budget is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided by the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

This rule imposes no additional reporting and recordkeeping requirements. Therefore, clearance by the Office of Management and Budget is not required.

List of Subjects in 4 CFR Part 202

Official seal.

■ Therefore, under the authority at Public Law 111-5, 123 Stat. 115 (2009), the Board amends Title 4 of the Code of Federal Regulations by establishing a new Chapter II, consisting of Part 202 to read as follows:

CHAPTER II—RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD

PART 202—OFFICIAL SEAL

Sec.

202.1 Description.

202.2 Authority to affix seal.

202.3 Prohibitions against misuse of seal.

Authority: 5 U.S.C. 301, 18 U.S.C. 506.

§ 202.1 Description.

(a) The official seal of the Recovery Accountability and Transparency Board (Board) is described as follows: The American Eagle, right facing, with left wing outstretched and pointing forward with right wing partially shown, is superimposed over a background suggesting the American Flag; upon a blue field, which fills background space above the Eagle's outstretched wing, are thirteen gold, five-pointed stars; the lower half of the background, filling the space beneath the Eagle's outstretched wing, is vertically striped in alternating colors of red and gold. The entire image is circumscribed by a gold boundary with 18 equally spaced "gear" teeth; that image is further encircled by a ring bearing the gold-colored words "RECOVERY ACCOUNTABILITY AND TRANSPARENCY" centered at its top, and the word "BOARD" is centered at its bottom and separated from the top-centered words by two laurel branches to its left and right.

(b) The Board also has developed an alternate, monochromatic version of the seal in which the above-described blue field and red-and-gold stripes are replaced by a white field and white-and-gold stripes. A reproduction of the official seal in black and white appears as follows:



§ 202.2 Authority to affix seal.

(a) The following officials of the Board are authorized to affix the official seal (including reproductions) to appropriate documents, certifications, and other materials of the Board: The Chairman and all Members, the Executive Director, the General Counsel, and the Directors.

(b) The officials named in paragraph (a) of this section may delegate this authority as appropriate.

§ 202.3 Prohibitions against misuse of seal.

(a) Falsely making, forging, counterfeiting, mutilating, or altering the Board seal or reproduction, or knowingly using or possessing with fraudulent intent an altered Board seal or reproduction is punishable under 18 U.S.C. 506.

(b) Any person using the Board seal or reproduction in a manner inconsistent with the provisions of this part is subject to the provisions of 18 U.S.C. 1017, which states penalties for the wrongful use of an official seal, and other provisions of law as applicable.

Ivan J. Flores,

Paralegal Specialist, Recovery Accountability and Transparency Board.

[FR Doc. E9-18509 Filed 8-3-09; 8:45 am]

BILLING CODE 6820-GA-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 948

[Doc. No. AMS-FV-08-0094; FV09-948-1 FIR]

Irish Potatoes Grown in Colorado; Modification of the Handling Regulation for Area No. 2

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim final rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim final rule that modified the minimum size requirement under the Colorado potato marketing order, Area No. 2. For most long potato varieties, the interim final rule changed the minimum size requirement from 2 inches in diameter to 1⁷/₈ inches in diameter and removed the minimum weight requirement. The change is expected to improve the marketing of Colorado Area No. 2 potatoes while increasing returns to producers and potato supplies to consumers.

DATES: *Effective Date:* Effective August 5, 2009.

FOR FURTHER INFORMATION CONTACT:

Teresa Hutchinson or Gary Olson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Telephone: (503) 326-2724, Fax: (503) 326-7440, or E-mail: Teresa.Hutchinson@ams.usda.gov or GaryD.Olson@ams.usda.gov.

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide>; or by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Jay.Guerber@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 97 and Marketing Order No. 948, both as amended (7 CFR part 948), regulating the handling of Irish potatoes

grown in Colorado, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

An interim final rule was published in the **Federal Register** on April 16, 2009, and was effective on April 17, 2009 (74 FR 17589, Doc. No AMS-FV-0094, FV09-948-1 IFR). The interim final rule amended § 948.386 by modifying the minimum size requirement for most long varieties of potatoes handled under the marketing order. The exceptions to these requirements are for potatoes handled under the size designations referred to in the U.S. Standards as "Size B" and "creamers." The revisions described in the interim final rule were made to the handling regulations for all regulated potatoes except those potatoes considered "Size B" or "creamers." The current size requirements for "Size B" and "creamers" remain unchanged.

Except as explained above, for long potato varieties, the interim final rule changed the minimum size requirement from 2 inches in diameter to 1⁷/₈ inches in diameter and removed the minimum weight requirement.

This action did not impact imported potatoes covered by section 608(e) of the Act.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly

or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

Industry Information

There are approximately 73 handlers of Colorado Area No. 2 potatoes subject to regulation under the order and approximately 180 producers in the regulated production area. The order is administered locally by the Colorado Potato Administrative Committee, Area No. 2 (Committee). Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$7,000,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000.

During the 2007–2008 marketing year, approximately 14,225,568 hundredweight of Colorado Area No. 2 potatoes were inspected under the order and sold into the fresh market. Based on an estimated average f.o.b. price of \$12.05 per hundredweight, the Committee estimates that 62 Area No. 2 handlers, or about 85 percent, had annual receipts of less than \$7,000,000. In view of the foregoing, the majority of Colorado Area No. 2 potato handlers may be classified as small entities.

In addition, based on information provided by the National Agricultural Statistics Service (NASS), the average producer price for Colorado potatoes for 2007 was \$9.85 per hundredweight. The average annual fresh potato revenue for the Colorado Area No. 2 potato producers is therefore calculated to be approximately \$778,455. Consequently, on average, the majority of the Area No. 2 Colorado potato producers may not be classified as small entities.

Section 948.22 authorizes the issuance of grade, size, quality, maturity, pack, and container regulations for potatoes grown in the production area. Section 948.21 further authorizes the modification, suspension, or termination of requirements issued pursuant to § 948.22.

Section 948.386 of the marketing order's rules and regulations establishes minimum sizes for various varieties of potatoes. This rule continues in effect the action that changed the minimum size requirement from 2 inches in diameter to 1 $\frac{7}{8}$ inches in diameter and removed the minimum weight requirement for long potatoes that are considered neither "Size B" nor "creamer" size potatoes.

In 2007, handlers were unable to adequately supply the fresh market because of low yields due to poor weather conditions and because of more restrictive regulations. Adverse weather conditions contributed to lower yields and short supplies of potatoes for the market again in the 2008–2009 season. The Committee believes that relaxing the minimum size and weight requirements on long potato varieties allows handlers to market a larger portion of the crop in fresh market outlets, and thus better meet demand. This action is expected to foster increased consumption and have a positive impact on the Colorado potato industry.

This change is expected to improve returns to producers. The interim final rule was a relaxation of the minimum size regulation and, as such, should have a positive impact on industry participants. The Committee believes that this change should not negatively impact either handlers or producers.

The Committee discussed alternatives to this change, including not taking any action. However, for the reasons discussed earlier, the Committee believes this action best meets the needs of buyers and is most beneficial to the industry.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large Colorado Area No. 2 potato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

In addition, as noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the Colorado Area No. 2 potato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 21, 2008, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

This action also affirms information contained in the interim final rule concerning the authority for marketing orders under the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. 601–674), as well as information regarding Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E-Gov Act (44 U.S.C. 101).

Comments on the interim final rule were required to be received on or before June 15, 2009. No comments were received. Therefore, for reasons given in the interim final rule, USDA is adopting the interim final rule as a final rule, without change.

To view the interim final rule, go to: <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AMS-FV-08-0094>.

After consideration of all relevant material presented, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** (74 FR 17589, April 16, 2009) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 948

Marketing Agreements, Potatoes, Reporting and recordkeeping requirements.

PART 948—IRISH POTATOES GROWN IN COLORADO

■ Accordingly, the interim final rule that amended 7 CFR part 948 and that was published at 74 FR 17589 on April 16, 2009, is adopted as a final rule, without change.

Dated: July 29, 2009.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. E9–18539 Filed 8–3–09; 8:45 am]

BILLING CODE

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 959

[Doc. No. AMS–FV–09–0044; FV09–959–2 IFR]

Onions Grown in South Texas; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule decreases the assessment rate established for the South Texas Onion Committee (Committee) for the 2009–10 and subsequent fiscal periods from \$0.03 to \$0.025 per 50-pound equivalent of onions handled. The Committee locally administers the marketing order which regulates the handling of onions grown in South Texas. Assessments upon onion handlers are used by the Committee to fund reasonable and necessary expenses of the program. The

fiscal period begins August 1 and ends July 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective August 5, 2009.

Comments received by October 5, 2009, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; *Fax:* (202) 720-8938; or *Internet:* <http://www.regulations.gov>. Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT:

Belinda G. Garza, Regional Manager, Texas Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (956) 682-2833, *Fax:* (956) 682-5942, or *E-mail:*

Belinda.Garza@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; *Telephone:* (202) 720-2491, *Fax:* (202) 720-8938, or *E-mail:* Jay.Guerber@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 959, as amended (7 CFR part 959), regulating the handling of onions grown in South Texas, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, South Texas onion handlers

are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable onions beginning August 1, 2009, and continue until amended, suspended, or terminated. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate established for the Committee for the 2009-10 and subsequent fiscal periods from \$0.03 to \$0.025 per 50-pound equivalent of onions.

The South Texas onion marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of South Texas onions. They are familiar with the Committee's needs and with the costs for goods and services in their local area, and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2007-08 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on June 9, 2009, and unanimously recommended 2009-10 expenditures of \$184,705.12 and an

assessment rate of \$0.025 per 50-pound equivalent of onions. In comparison, last year's budgeted expenditures were \$185,095.12. The assessment rate of \$0.025 is \$0.005 lower than the rate currently in effect. The Committee recommended a lower assessment rate in order to reduce its reserve fund.

The major expenditures recommended by the Committee for the 2009-10 fiscal period include \$73,705 for management, administrative, and rent expenses; \$45,000 for promotion expenses; and \$44,000 for compliance. Budgeted expenses for these items in 2008-09 were \$66,695, \$45,000, and \$48,000 for compliance, respectively.

The assessment rate recommended by the Committee was derived by considering anticipated expenses and production levels of South Texas onions. In its recommendation, the Committee utilized an estimate of 6 million 50-pound equivalents of assessable onions for the 2009-10 fiscal period. If realized, this will provide estimated assessment revenue of \$150,000 from all handlers. In addition, it is anticipated that \$34,705 will be provided by interest income and reserve funds. When combined, revenue from these sources will be adequate to cover budgeted expenses. Funds in the reserve (currently \$214,770) will be kept within the maximum of approximately two fiscal periods' expenses as required by § 959.43 of the order.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate is effective for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2009-10 budget and those for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 84 producers of onions in the production area and approximately 31 handlers subject to regulation under the order. Small agricultural producers are defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,000,000.

Most of the South Texas handlers are vertically integrated corporations involved in producing, shipping, and marketing onions. For the 2007–08 marketing year, the industry's 31 handlers shipped onions produced on 10,978 acres with the average and median volume handled being 202,245 and 176,551 fifty-pound equivalents, respectively. In terms of production value, total revenues for the 31 handlers were estimated to be \$174.7 million, with average and median revenues being \$5.64 million and \$4.92 million, respectively.

The South Texas onion industry is characterized by producers and handlers whose farming operations generally involve more than one commodity, and whose income from farming operations is not exclusively dependent on the production of onions. Alternative crops provide an opportunity to utilize many of the same facilities and equipment not in use when the onion production season is complete. For this reason, typical onion producers and handlers either produce multiple crops or alternate crops within a single year.

Based on the SBA's definition of small entities, the Committee estimates that all of the 31 handlers regulated by the order would be considered small entities if only their onion revenues are considered. However, revenues from other farming enterprises could result in

a number of these handlers being above the \$7,000,000 annual receipt threshold. All of the 84 producers may be classified as small entities based on the SBA definition if only their revenue from onions is considered.

This rule decreases the assessment rate established for the Committee and collected from handlers for the 2009–10 and subsequent fiscal periods from \$0.03 to \$0.025 per 50-pound equivalent of onions handled. The Committee unanimously recommended 2009–10 expenditures of \$184,705.12 and an assessment rate of \$0.025 per 50-pound equivalent. The recommended assessment rate is \$0.005 lower than the rate currently in effect. The quantity of assessable onions for the 2009–10 fiscal period is estimated at 6 million 50-pound equivalents. Thus, the \$0.025 rate should provide \$150,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve will be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2009–10 fiscal period include \$73,705 for management, administrative, and rent expenses; \$45,000 for promotion expenses; and \$44,000 for compliance. Budgeted expenses for these items in 2008–09 (previous year) were \$66,695, \$45,000, and \$48,000, respectively.

The Committee reviewed and unanimously recommended 2009–10 expenditures of \$184,705.12, which include a decrease in compliance expenses due to a shortened regulatory period. The assessment rate of \$0.025 per 50-pound equivalent of assessable onions recommended by the Committee was determined by considering anticipated expenses and production levels of South Texas onions. As stated earlier, the Committee utilized an estimate of 6 million 50-pound equivalents of assessable onions for the 2009–10 fiscal period, which, if realized, will provide estimated assessment revenue of \$150,000 from all handlers. In addition, it is anticipated that \$34,705 will be provided by interest income and reserve funds. When combined, revenue from these sources will be adequate to cover budgeted expenses.

The Committee discussed alternative expenditure levels, but determined that the recommended expenses were reasonable and necessary to adequately cover program operations. Other assessment rates were not considered because the Committee believed decreasing the rate by \$0.005 was sufficient to reduce their current reserve fund to a desirable level.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the season average f.o.b. price for the 2009–10 fiscal period could range between \$10.00 and \$28.00 per 50-pound equivalent of onions. Therefore, the estimated assessment revenue for the 2009–10 fiscal period as a percentage of total f.o.b. revenue could range between 0.1 and 0.25 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee's meeting was widely publicized throughout the South Texas onion industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the June 9, 2009, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this interim final rule, including the regulatory and informational impacts of this action on small businesses.

This action imposes no additional reporting or recordkeeping requirements on either small or large South Texas onion handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/AMSV1.0/ams:fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other

available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2009–10 fiscal period begins on August 1, 2009, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable onions handled during such fiscal period; (2) this action decreases the assessment rate for assessable onions beginning with the 2009–10 fiscal period; (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim final rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 959

Marketing agreements, Onions, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 959 is amended as follows:

PART 959—ONIONS GROWN IN SOUTH TEXAS

■ 1. The authority citation for 7 CFR part 959 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 959.237 is revised to read as follows:

§ 959.237 Assessment rate.

On and after August 1, 2009, an assessment rate of \$0.025 per 50-pound equivalent is established for South Texas onions.

Dated: July 29, 2009.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. E9–18540 Filed 8–3–09; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1229

RIN 2590–AA21

Capital Classifications and Critical Capital Levels for the Federal Home Loan Banks

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Regulatory Reform Act, Division A of the Housing and Economic Recovery Act of 2008 (HERA), requires the Director of the Federal Housing Finance Agency (FHFA) to establish criteria based on the amount and type of capital held by a Federal Home Loan Bank (Bank) for each of the following capital classifications: Adequately capitalized; Undercapitalized; Significantly undercapitalized; and Critically undercapitalized. In addition, HERA provides that the critical capital level for each Bank shall be the amount of capital that the Director by regulation shall require. HERA also sets forth prompt corrective action (PCA) authority that the Director has for the Banks. To implement these new provisions, FHFA published in the **Federal Register** on January 30, 2009 an interim final rule to define critical capital for the Banks, establish the criteria for each of the capital classifications identified in HERA and delineate its PCA authority over the Banks. FHFA requested comments on all aspects of the regulation. It also sought comment on whether it should establish a “well-capitalized” classification and on what criteria may be appropriate to define such a new category. After considering the comments received on the interim final rule, FHFA is adopting the interim final rule as a final regulation, subject to amendments meant to clarify certain provisions.

DATES: The final regulation is effective August 4, 2009.

FOR FURTHER INFORMATION CONTACT: Julie Paller, Senior Financial Analyst, (202) 408–2842, and Anthony G. Cornyn, Senior Associate Director, (202) 408–2522, Division of Federal Home Loan Bank Regulation, Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006; or Thomas E. Joseph, Senior Attorney-Advisor, (202) 414–3095, Office of General Counsel, Federal Housing Finance Agency, 1700 G St., NW., Washington, DC 20552. The telephone number for the

Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

A. Federal Housing Finance Agency and Recent Legislation

Effective July 30, 2008, HERA, Public Law 110–289, 122 Stat. 2654 (2008), transferred the supervisory and oversight responsibilities of the Office of Federal Housing Enterprise Oversight (OFHEO) over the Federal National Mortgage Association (Fannie Mae), and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises) and the oversight responsibilities of the Federal Housing Finance Board (Finance Board) over the Banks and the Office of Finance (which acts as the Banks’ fiscal agent) to a new independent executive branch agency, FHFA. FHFA is responsible for ensuring that the Enterprises and the Banks operate in a safe and sound manner, including that they maintain adequate capital and internal controls, that their activities foster liquid, efficient, competitive and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See id.* at § 1102, 122 Stat. 2663–64.

Section 1141 of HERA states that the Director shall adopt regulations specifying the critical capital level for each Bank no later than the expiration of the 180 day period from the date that HERA was enacted. *See id.* at § 1141, 122 Stat. 2730 (adopting 12 U.S.C. 4613(b)). In establishing this requirement, HERA provides that the Director shall take due consideration of the critical capital levels established for the Enterprises, with such modifications as the Director determines to be appropriate to reflect the difference in operations between the Banks and the Enterprises.

In addition, section 1142 of HERA requires that the Director, no later than 180 days from its enactment, establish for the Banks criteria for each of the four following capital classifications:

Adequately capitalized; Undercapitalized; Significantly undercapitalized; and Critically undercapitalized. *See id.* at § 1142, 122 Stat. 2730–32. HERA specifies that the criteria should be based on the amount and types of capital held by a Bank and the risk-based, minimum and critical capital levels for the Banks, taking due consideration of the capital classifications established for the Enterprises, with such modifications as the Director determines to be appropriate to reflect the difference in

operations between the Banks and the Enterprises. HERA also provides FHFA prompt corrective action (PCA) authority over the Banks and amends the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) so that specific mandatory or discretionary supervisory actions and restrictions under that statute would apply to any Bank determined to be undercapitalized, significantly undercapitalized or critically undercapitalized. *See id.* at §§ 1143–1145, 122 Stat. 2732–34. The general purpose for the PCA framework is to supplement the FHFA's other regulatory and supervisory authority and provide for timely and, in some situations, mandatory intervention by the regulator.

B. The Bank System Generally

The twelve Banks are instrumentalities of the United States organized under the Federal Home Loan Bank Act (Bank Act).¹ *See* 12 U.S.C. 1423, 1432(a). The Banks are cooperatives. Only members of a Bank may purchase the capital stock of a Bank, and only members or certain eligible housing associates (such as state housing finance agencies) may obtain access to secured loans, known as advances or other products provided by a Bank. *See* 12 U.S.C. 1426(a)(4), 1430(a), 1430b. Each Bank is managed by its own board of directors and serves the public interest by enhancing the availability of residential mortgage and community lending credit through its member institutions. *See* 12 U.S.C. 1427. Any eligible institution (generally a federally-insured depository institution or state-regulated insurance company) may become a member of a Bank if it satisfies certain criteria and purchases a specified amount of the Bank's capital stock. *See* 12 U.S.C. 1424; 12 CFR part 925. The Banks also require members to purchase certain amounts of stock to become a member of the Bank and to undertake specific activities and transactions with the Bank. These stock purchase requirements are set forth in a Bank's capital structure plan as required by amendments to the Bank Act made by the Gramm Leach Bliley Act (GLB Act) in 1999.²

¹ Each Bank is generally referred to by the name of the city in which it is located. The twelve Banks are located in: Boston, New York, Pittsburgh, Atlanta, Cincinnati, Indianapolis, Chicago, Des Moines, Dallas, Topeka, San Francisco, and Seattle.

² All the Banks but the Chicago Bank operate pursuant to a capital structure plan required under the GLB Act. The Chicago Bank, which has not yet implemented its capital structure plan, still operates in accordance with stock purchase requirements set forth in the Bank Act prior to its

C. Interim Final Rule

On January 30, 2009, the FHFA published in the **Federal Register** an interim final rule with requests for comments, which added new subpart A of part 1229 to 12 CFR chapter XII, subchapter B. *See* 74 FR 5595. The comment period for the interim final rule originally was scheduled to close on April 30, 2009, but on March 26, 2009, the FHFA published a notice extending the comment period for an additional 15 days. *See* 74 FR 13083. FHFA received 14 comments on the interim final rule, including comments from all twelve of the Banks. Two industry associations that represent many Bank members also commented. Comments are available at the FHFA Web site, <http://www.fhfa.gov>.

The interim final rule implemented the PCA provisions set forth in sections 1363 through 1369D of the Safety and Soundness Act, as these provisions had been amended and made applicable to the Banks by HERA. The interim final rule also incorporated certain restrictions on capital distributions that are imposed on the Banks by the Bank Act and its implementing regulations, and made clear that those restrictions will continue to apply to any Banks that do not meet their capital requirements or that incur charges against their capital, and that they will apply, in addition to the new PCA restrictions made applicable to the Banks by the Safety and Soundness Act. *See e.g.*, 12 U.S.C. 1426(f) and (h)(3); 12 CFR 917.9(b).

As required by HERA, the interim final rule established the critical capital level for the Banks. The interim final rule also defined the criteria for the four capital classification categories that HERA applied to the Banks. It set forth the process that govern the Director's required quarterly determination of each Bank's capital classification as well as the mandatory and discretionary restrictions and requirements that must or can be imposed on a Bank that the Director determines is less than adequately capitalized.

FHFA asked for comments on all aspects of the interim final rule. It specifically requested comments on whether consideration of the differences between the Enterprises and the Banks with regard to the Banks' cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability should

amendment by the GLB Act. *See* 12 U.S.C. 1426(a)(6).

result in revision to the interim final rule.

FHFA also sought comment on whether it should adopt a fifth capital classification of "well-capitalized" as part of the regulation, although the interim final rule did not adopt such a category. Among the questions posed by FHFA with regard to a potential well-capitalized classification were:

(1) What criteria would be appropriate to define a "well-capitalized" category?

(2) Whether a retained earnings or a market value of equity to par value of capital stock (MVE/PVCS) target would be useful or appropriate for defining a well-capitalized category? and

(3) What restrictions on an adequately capitalized Bank would be appropriate to create an incentive for a Bank to achieve a well-capitalized rating?

The FHFA also asked whether it should adopt a retained earnings or MVE/PVCS target as part of the Banks' risk-based capital regulations or as a requirement that would be separate and distinct from the risk-based capital regulations.

II. Discussion of Comments and Changes to the Interim Final Rule

A. Overview of Comments

Most commenters provided suggestions for changes to the published text of the interim final rule or asked that clarifications be made to certain provisions. Specifically, the comment letters urged FHFA to exempt advances from limits on asset growth applicable to Banks that are not adequately capitalized, alter the definition of executive officer to narrow the scope of persons covered, extend the time period for submission of a capital restoration plan, and clarify the scope of certain mandatory restrictions on Bank acquisitions and on payment of executive compensation or bonuses that become applicable once a Bank is deemed to be undercapitalized or significantly undercapitalized. Each of the suggested changes is addressed more fully below.

Commenters also responded to FHFA questions about different aspects of instituting a fifth capital classification of well-capitalized. Nine of the comment letters expressed at least mild support or did not affirmatively oppose adopting the fifth capital classification, although most of these commenters did not support any approach that would effectively raise current minimum capital standards. Five commenters stated that such a classification was unnecessary or inappropriate. To the extent that they specifically addressed the issue, commenters also believed that

FHFA should not impose restrictions on an adequately capitalized Bank if a well-capitalized category were adopted. A number of commenters suggested specific positive regulatory incentives that FHFA could adopt to encourage Banks to achieve a well-capitalized rating.

Generally, commenters believed that if a well-capitalized category were adopted, the defining criteria should focus on the composition of Bank capital (*i.e.*, retained earnings) rather than the level of capital. All but one of the commenters specifically opposed using an MVE/PVCS measure as part of the defining criteria or as a separate capital requirement. The one commenter that did not specifically oppose the MVE criteria, however, thought that an MVE/PVCS requirement should be adopted only after a separate rulemaking in which FHFA provided a more thorough analysis of the matter.

FHFA has determined that it will not adopt the well-capitalized category as part of this final regulation. Instead, it will consider the comments and suggestions in developing any proposed future amendments to the PCA regulation concerning a well-capitalized category, including any proposals related to the criteria for defining, and for creating an incentive structure for the Banks to achieve, a well-capitalized rating. In developing any amendments, FHFA also would consider any changes that it may propose to the Banks' risk-based capital requirements. FHFA also will continue to weigh whether it would be appropriate to propose a separate target for retained earnings and/or MVE/PVCS, either as a stand-alone regulation or as part of any risk-based capital proposal.

B. Specific Suggestions for Changing the Interim Final Rule

Commenters addressed a number of different provisions and suggested a number of changes to the interim final rule. FHFA has carefully considered these comments. As is discussed below, while FHFA has adopted some changes to the interim final rule in response to the comments, it did not feel that all the suggested amendments were appropriate in light of statutory requirements and policy considerations.

Definition of Executive Officer (§ 1229.1). A number of commenters asked for specific changes to the definition of "Executive Officer" set forth in the regulation. This definition is needed to implement the provision limiting bonuses and compensation paid to executive officers of significantly undercapitalized Banks under § 1229.8(f) of the regulation.

Commenters requested three principal changes be made to the definition in § 1229.1 to provide more clarity as to which employees were executive officers and establish a more appropriate scope for the definition.

First, they asked that the regulation require FHFA to inform the Banks, in advance, which persons in charge of a principal business unit, division or function would be considered an executive officer. This approach, the commenters argued, would be consistent with the treatment provided the Enterprises. Second, they asked, without providing further explanation, that the reference to chief operating officer in the regulation be changed to chief executive officer. Finally, commenters asked that the regulation clarify that administrative or support staff that answer directly to the president or chief operating officer of the Bank or the chairman or vice-chairman of the Bank's board of directors not be considered executive officers. One commenter further stated that the regulation should specify that positions or persons identified by functional area would be within the scope of the definition only if they truly performed the duties of an executive officer.

The Safety and Soundness Act, as amended by HERA, refers to executive officers of a regulated entity in various provisions including the PCA provision and a provision providing the Director with oversight and approval authority for compensation paid to executive officers. It does not, however, specifically define the term. Given that the statute does not differentiate between the term "executive officer" as used in the PCA provision and as used in the provision addressing executive compensation and the two provisions deal with the question of limiting compensation or bonus to certain Bank employees, FHFA believes the definition used in the two regulations ultimately should be the same.

The definition of executive officer in § 1229.1 is similar to the definition of executive officer with respect to a Bank that was proposed for comment as part of the executive compensation regulation on June 5, 2009. *See* Proposed Rule: Executive Compensation, 74 FR 26989. While there are some wording differences between the definition adopted in the PCA regulation and that being proposed in the executive compensation regulation (and the proposed definition in the executive compensation regulation may provide the Director with less discretion to remove persons from coverage than does the definition

in § 1229.1), the definitions remain substantively the same. FHFA also expects that the definition in the PCA regulation will be amended in the future to conform to what is ultimately adopted in the executive compensation regulation. In the meantime, FHFA believes that the current definition of executive officer in § 1229.1 sufficiently identifies the persons that are subject to the PCA regulation restrictions and provides the Director with sufficient flexibility to add or remove specific persons from the list of Bank executive officers so that the concerns raised in the comments can be addressed on a case-by-case basis, if needed. Therefore, FHFA is not revising the definition of executive officer in the PCA regulation at this time.

Advances and Limitations on Asset Growth (§ 1229.6(a)(4)). Most of the commenters requested that the mandatory limitation on asset growth applicable to an undercapitalized Bank and set forth in § 1229.6(a)(4) of the interim final rule be modified to exclude advances from its coverage. This provision prevents the average total assets of a Bank, that was less than adequately capitalized, from exceeding its average total assets of the previous quarter, unless the Director determines the increase is consistent with an approved capital restoration plan and meets other requirements. The commenters argued that in light of the safety and low-risk profile of advances, the self-capitalizing nature of the product and the centrality of advances to the Bank's mission, limits should not be put on advance growth even if the Bank were less than adequately capitalized.

The regulatory language in the interim final rule, however, closely follows the statutory provision that was added to section 1365(a)(4) of the Safety and Soundness Act by section 1143 of HERA. The statutory language appears straightforward and contains no exception for advances or other mission assets of either the Banks or the Enterprises. Instead, the statute allows the Director to waive the limit on asset growth when certain conditions are met. These conditions are carried over to the regulation and include that the growth be consistent with the capital restoration plan and that the ratio of the Bank's tangible equity to total assets is increasing at a rate that will allow the Bank to become adequately capitalized in a reasonable period of time. Thus, it is not clear that the language of the statute provides flexibility to implement this suggested change.

Moreover, § 1229.6(a)(4) imposes a limit on total assets and not on

advances, specifically, so that an undercapitalized Bank would not face a barrier to continued advances growth as long as it reduces its investment portfolio or other asset holdings. In addition, despite commenters' claims, nothing assures that new advances will be self-capitalizing, since a number of the Banks' capital structure plans provide them discretion to set the advances stock purchase requirement below the level of their minimum capital requirements. Further, Bank members often do not have to buy additional stock to take down new advances, as they may have excess stock that can be applied to meeting the stock purchase requirement, or otherwise may not have to buy additional stock, to cover the new advances.³ Thus, a Bank that did not meet its capital requirements, unless it took some other action (e.g., reduce other assets), could become more highly leveraged if it were allowed unconditionally to expand advances. Arguably, the restrictions in the PCA provisions are designed to make sure the Bank has a plan of action that has been reviewed by FHFA to prevent this outcome from occurring.

Given these considerations FHFA has decided not to adopt the changes to § 1229.6(a)(4) suggested by commenters.

Clarify Prohibition on Acquisition of Assets (§ 1229.6(a)(5)). A number of commenters asked that FHFA clarify the scope of the restriction in § 1229.6(a)(5) that prohibits a Bank that is not adequately capitalized from acquiring directly or indirectly, any interest in any entity. They asked especially for FHFA to confirm that this restriction would not prevent the Banks from undertaking authorized activities in the ordinary course of business, such as making otherwise authorized investments in financial instruments. One commenter also noted that existing regulations would likely already require a Bank to receive FHFA approval before making an acquisition in another entity. After considering these comments, FHFA agrees that the language used in the provision is vague, especially in light of other restrictions placed on Bank activities, and that some clarification would be useful.

The regulatory language that is the subject to these comments closely follows the language that was added to section 1365(a)(5) of the Safety and Soundness Act by section 1143 of

HERA. The restriction on the acquisition of an interest in an entity is one of a series of restrictions imposed on regulated entities that are not adequately capitalized, which includes limits on asset growth, new business activities and capital distributions. The Director is allowed under the statute and the regulation to waive this restriction if the Bank has an approved capital restoration plan, the Bank is implementing that plan, the acquisition of the interest is consistent with the plan and with the Bank's safe and sound operations, and will further its compliance with its capital requirements.

There appears to be little or no legislative history as to what Congress intended by this restriction. Given that the statute separately limits the ability of a Bank that is less than adequately capitalized to expand its activity through asset growth or undertaking new business activities, it would be reasonable that this particular restriction is meant to limit a Bank's expansion through acquisition of other operating businesses or lines of business in which the Bank already may be involved. FHFA therefore has decided to clarify the meaning of § 1229.6(a)(5) by revising the restriction to apply to the acquisition of any equity interest in another operating entity.⁴ The revised language also makes clear that the restriction is not meant to prevent a Bank from enforcing any security interest granted to it or otherwise taking possession of collateral in the normal course of business.

FHFA recognizes that under current regulations the Banks would have few if any opportunities to take equity positions in other operating entities without first receiving FHFA's approval. Nevertheless, it is important to carry over into the regulation all the statutory restrictions even if such restrictions may have limited practical effect at this time. The revised language should clarify, however, FHFA's intent that the restriction on the acquisition of interests in any entity was not meant to restrict a Bank's investment in authorized investments such as mortgage backed securities or acquired member assets or otherwise restrict the Bank's ability to accept pledges of security as part of its business.

⁴ Such an interpretation also would appear to bring the meaning of this provision close to that of a similar PCA restriction imposed on insured depository institutions by § 38(e)(4) of the Federal Deposit Insurance Act (FDI Act)(12 U.S.C. § 1831o(e)(4)). The FDI Act provision restricts an undercapitalized institution's acquisition of any interest in any company or in another insured depository institution and limits the right to establish or acquire any additional branch offices.

Submission of Capital Restoration Plan (§ 1229.11(b)). Most of the commenters supported extending the period in which a Bank has to submit a capital restoration plan from the 10 calendar-days required under § 1229.11(b) of the interim final rule. The commenters recognized that the 10 day period was based on requirements currently applicable to the Enterprises but believed the difference in capital structures between the Banks and the Enterprises justified a longer period for the Banks to prepare and submit their capital restoration plans. In this respect, a number of the commenters stated that the Banks would need to amend their GLB Act capital structure plans and take other actions that would not be applicable to the Enterprises to implement the capital restoration plan.⁵ After consideration of these comments, FHFA has decided there is merit to the suggestions and is extending the period of time for submitting a capital restoration plan by a Bank to 15 business-days after a Bank receives written notification that such a plan is required.

The Safety and Soundness Act, as amended by HERA, allows up to 45 days after the date of notification for a regulated entity to submit a capital restoration plan. While the majority of the commenters suggested a 30 calendar-day period for submission of the plan, FHFA believes that 30 calendar-days is too long a period given that a Bank needs to begin taking action immediately to restore capital when a capital deficiency is identified. Moreover, having an approved capital restoration plan in place is a necessary pre-condition imposed by the statute for the Director's granting an exception to many of the restrictions that are imposed on the activities of an undercapitalized or a significantly undercapitalized Bank. Given that the Banks, in their comments, to other regulation provisions have suggested that some of these restrictions may be problematic, FHFA does not want to draw out the period for submission and approval of a capital restoration plan more than necessary. Moreover, Banks will be aware of the likelihood that they will be classified as less than adequately capitalized before the Director issues a

⁵ This comment suggests that some Banks may believe that they have to complete any contemplated amendments to their GLB Act capital structure plan prior to the submission of the capital restoration plan. This is not the case, however. Under § 1229.11 of the final rule, a Bank would need to identify in its capital restoration plan any changes to its stock purchase requirements that it intends to make but it does not necessarily need to have those changes in place at the time it submits its capital restoration plan for approval.

³ All of the stock outstanding, including excess stock, however, would already have been counted as part of the Bank's capital. Thus, in these cases the new advances would increase the Bank's assets without necessarily increasing its capital from the level which was already determined to be insufficient to meet regulatory requirements.

final notification, so a Bank could begin work on its capital restoration plan prior to receiving the final notification.⁶ Thus, FHFA believes that 15 business-days should generally be sufficient for a Bank to prepare its capital restoration plan.

Executive Officers Bonuses and Compensation (§§ 1229.8(e) and (f)). A number of the commenters asked FHA to clarify “whether, in light of contractual and constitutional concerns,” employment agreements entered into prior to the effective date of the regulation are subject to the mandatory limits in §§ 1229.8(e) and (f) on bonuses and compensation paid to an executive officer of a significantly undercapitalized Bank. The comments do not further describe what these concerns are or provide any arguments addressing the constitutional issues. The cited provisions prohibit a Bank that is significantly undercapitalized either from paying a bonus to any executive officer without the prior written approval of the Director or from compensating an executive officer at a rate exceeding the average rate of compensation of that officer during the 12 months preceding the calendar month in which the Bank became significantly undercapitalized, without the prior written approval of the Director.

The regulatory language in §§ 1229.8(e) and (f) closely corresponds to the language in section 1366(c) the Safety and Soundness Act as the provision was amended by section 1144 of HERA. The statute does not provide an exception for employment agreements entered into before a certain date or outstanding as of HERA’s effective date. More importantly, this restriction is triggered only if a Bank becomes significantly undercapitalized—a future event that is unrelated to the date in which an executive officer signed his or her employment agreement. As a general matter, the point of the provision seems to be to preserve resources expended on compensation and prevent executives from benefiting from increased compensation when their behavior, decisions or leadership resulted in (or failed to prevent) a Bank’s becoming significantly undercapitalized. Thus,

⁶For example, under the regulations, Banks first will receive a preliminary notification that the Director proposes to classify them at a level other than adequately capitalized, prior to the final classification. In addition, Banks are required to notify the Director if their capital decreases to the extent that they would expect to be reclassified at a level lower than their previous preliminary or final classification, so that Banks should monitor and be aware of negative changes in their capital levels at all times.

looking to the date of when employment began seems irrelevant to the purpose of the provision, which appears to be to address a future capital deficiency and discourage behavior that may cause such capital problems.⁷

The regulation also allows the Director to authorize a Bank to pay compensation and/or bonuses in excess of the limits established by the provisions. This means that under the regulation, a Bank has the right to make a case once it receives notice of its preliminary classification, or thereafter, that the Director should approve higher compensation or bonuses for executive officers, and allows a Bank to present all relevant information as to why the compensation and bonus restrictions are not appropriate in a particular case.⁸ Thus, FHFA sees no reason to provide a blanket exemption from this restriction in the regulation itself, and believes that such a revision would contradict both the plain language of the statute and would undermine the policy concerns that this provision addresses.

Other comments. One commenter asked FHFA to incorporate into its regulations previous Finance Board guidance that Other Comprehensive Income (OCI) is not included in calculations of permanent and total capital. The referenced guidance was

⁷The provision related to executive officer compensation and bonuses is similar to restrictions on compensation in the FDI Act which become applicable to senior executive officers of an insured financial institution that becomes significantly undercapitalized. See 12 U.S.C. 1831o(f)(4). When federal banking regulators adopted rules implementing this provision of the FDI Act, those rules did not provide an exception for employment agreements entered into prior to its effective date. See 57 FR 44866 (Sept. 29, 1992).

⁸The issue of whether the statutory language is itself constitutionally flawed, as suggested by the commenters, is difficult to address since the comments fail to provide any specific arguments or theory on this point. The constitutional argument that usually arises in these types of cases is that the parties have some fundamental right or protected interest recognized by law so that the loss of that right is subject to due process protection under the Fifth Amendment. In this respect, the Supreme Court has noted that the “fundamental requirement of due process is the opportunity to be heard ‘at a meaningful time and in a meaningful manner.’” *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (citations omitted). The Court has identified three factors that should be balanced in deciding the dictates of due process generally. See *id.* at 335. These are: (i) The private interest that will be affected by the official action; (ii) The risk of an erroneous deprivation of such interest through the procedures used and the value, if any, of additional or substitute procedure; and (iii) The government’s interests, including the function at issue and the fiscal and administrative burdens of additional or substitute procedures. See *id.* (citations omitted). The fact that the Banks can seek the Director’s review of the restriction and provide information as to why the restrictions should not be applied in a particular instance provides an opportunity to be heard that should address the commenters’ concerns.

provided by the Finance Board when it was proposing amendments to its capital regulation based on an Advanced Notice of Proposed Rulemaking (ANPR), as well as responding to some of the comments received as part of that ANPR. See Proposed Rules: Capital Requirements for the Federal Home Loan Banks, 66 FR 41462, 41471–72 (Aug. 8, 2001). Specifically, the Finance Board’s guidance responded to comments that the definitions of permanent and total capital be clarified to exclude certain elements of OCI. The Finance Board noted, however, that there was no need to change the definitions and clarified that OCI was not included in retained earnings as used in the calculation of total and permanent capital. *Id.* Given that this guidance was provided as part of the rulemaking for the capital regulation and addressed definitions in that provision, FHFA is not going to alter those regulations at this time as part of its adoption of the final PCA regulation. It will, however, affirm the Finance Board’s prior interpretation that OCI is not an element of the Bank’s regulatory capital.

C. Other Changes in the Final Regulation

In addition to making the changes described above in response to the comments submitted on the interim final rule, FHFA is also making certain clarifying changes to the regulation. First, FHFA is adding new paragraphs (g) and (h) to § 1229.8 to clarify its view as to what mandatory or discretionary restrictions or obligations that apply to an undercapitalized Bank continue to apply to a Bank found to be significantly undercapitalized.

FHFA is also revising § 1229.10(d) to make clear that restrictions and obligations previously imposed on a significantly undercapitalized Bank continue to apply to a critically undercapitalized Bank for which FHFA has not yet been named conservator or receiver. As originally adopted, this provision only referred to “restrictions” on a significantly undercapitalized Bank but FHFA recognizes that a Bank may also be obligated to take positive actions under the PCA provisions.

Finally, FHFA modified § 1229.11(a) to clarify the type of information it intends a Bank to submit in its capital restoration plan. These changes make clear that the Bank should describe, if appropriate, any actions that it would take to address any long term or structural problems that led to its becoming less than adequately capitalized and that the Bank should provide in its capital restoration plan

projections indicating how each component of total and permanent capital (including retained earnings) and the major components of income, assets and liabilities are expected to change over the term of the plan. FHFA believes that this information is the type of information it would generally request under § 1229.11(a)(5) and is necessary for it to judge the adequacy of the plan and to monitor the plan effectively over time. Thus, § 1229.11(a) is being updated to make clear that this information should be submitted as part of a capital restoration plan.

III. Paperwork Reduction Act

The regulation does not contain any collections of information pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Therefore, FHFA has not submitted any information to the Office of Management and Budget for review.

IV. Regulatory Flexibility Act

The regulation applies only to the Banks, which do not come within the meaning of small entities as defined in the Regulatory Flexibility Act (RFA). *See* 5 U.S.C. 601(6). Therefore, in accordance with section 605(b) of the RFA, 5 U.S.C. 605(b), FHFA, hereby, certifies that the regulation will not have a significant economic impact on a substantial number of small entities.

V. Effective Date

The Administrative Procedure Act provides that the required publication of a substantive regulation shall be made not less than 30 days before its effective date except for: A substantive regulation that grants or recognizes an exemption or relieves a restriction; An interpretative regulation or statement of policy; or As otherwise provided by the agency for good cause found and published with the regulation. *See* 5 U.S.C. 553(d). In publishing the interim final rule, FHFA found that it had good cause for the regulation to become effective immediately. *See* 74 FR at 5604. These reasons are still true with regard to the final rule and the changes made to it. In addition, the changes made to the interim final rule clarify the scope of the provisions of the regulation or ease requirements that had been established in the interim final rule, as in the case of the longer period for submitting a capital restoration plan, rather than add new requirements. Thus, FHFA finds that there is good cause for the regulation to become effective on August 4, 2009.

List of Subjects in 12 CFR Part 1229

Capital, Federal home loan banks, Government-sponsored enterprises, Reporting and recordkeeping requirements.

■ For the reasons stated in the preamble, the Interim Final Rule at subpart A of part 1229 of Title 12 CFR chapter XII, subchapter B, which was published at 74 FR 5595 on January 30, 2009, is being adopted by FHFA as a final regulation with the following changes:

PART 1229—CAPITAL CLASSIFICATIONS AND PROMPT CORRECTIVE ACTION

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

Authority: 12 U.S.C. 1426, 4513, 4526, 4613–4618, 4622, 4623.

■ 2. Amend § 1229.6 by revising paragraph (a)(5) to read as follows:

§ 1229.6 Mandatory actions applicable to undercapitalized Banks.

(a) * * *

(5) Not acquire, directly or indirectly, an equity interest in any operating entity (other than as necessary to enforce a security interest granted to the Bank) nor engage in any new business activity unless:

(i) The Director has approved the Bank's capital restoration plan, the Bank is implementing the capital restoration plan and the Director determines that proposed acquisition or activity will further achievement of the goals set forth in that plan; or

(ii) The Director determines that the proposed acquisition or activity will be consistent with the safe and sound operation of the Bank and will further the Bank's compliance with its risk-based and minimum capital requirements in a reasonable period of time.

* * * * *

■ 3. Amend § 1229.8 by removing the word “and” at the end of paragraph (e), removing the period at the end of paragraph (f) and adding a semi-colon in its place, and adding new paragraphs (g) and (h) to read as follows:

§ 1229.8 Mandatory actions applicable to significantly undercapitalized Banks.

* * * * *

(g) Comply with § 1229.6(a)(4) and (a)(5) of this subpart; and

(h) Comply with any on-going restrictions or obligations that were imposed on the Bank by the Director under § 1229.7 of this subpart.

■ 4. Amend § 1229.10 by revising paragraph (d) to read as follows:

§ 1229.10 Actions applicable to critically undercapitalized Banks.

* * * * *

(d) *Other applicable actions.* Until such time as FHFA is appointed as conservator or receiver for a critically undercapitalized Bank, a critically undercapitalized Bank shall be subject to all mandatory restrictions or obligations applicable to a significantly undercapitalized Bank under § 1229.8 of this subpart and will remain subject to any on-going restrictions or obligations that the Director imposed on the Bank under § 1229.7 or § 1229.9 of this subpart, or any restrictions or obligations that are applicable to the Bank under the terms of an approved capital restoration plan.

■ 5. Amend § 1229.11 by revising paragraphs (a) and (b) to read as follows:

§ 1229.11 Capital restoration plans.

(a) *Contents.* Each capital restoration plan submitted by a Bank shall set forth a plan to restore its permanent and total capital to levels sufficient to fulfill its risk-based and minimum capital requirements within a reasonable period of time. Such plan must be feasible given general market conditions and the conditions of the Bank and, at a minimum, shall:

(1) Describe the actions the Bank will take, including any changes that the Bank will make to member stock purchase requirements, to assure that it will become adequately capitalized within the meaning of § 1229.3(a) of this subpart and, if appropriate, to resolve any structural or long term causes for the capital deficiency;

(2) Specify the level of permanent and total capital the Bank will achieve and maintain and provide quarterly projections indicating how each component of total and permanent capital and the major components of income, assets and liabilities are expected to change over the term of the plan;

(3) Specify the types and levels of activities in which the Bank will engage during the term of the plan, including any new business activities that it intends to begin during such term;

(4) Describe any other actions the Bank intends to take to comply with any other requirements imposed on it under this subpart A of part 1229;

(5) Provide a schedule which sets forth dates for meeting specific goals and benchmarks and taking other actions described in the proposed capital restoration plan, including setting forth a schedule for it to restore its permanent and total capital to levels necessary for meeting its risk-based and minimum capital requirements; and

(6) Address such other items that the Director shall provide in writing in advance of such submission.

(b) *Deadline for submission.* A Bank must submit a proposed capital restoration plan no later than 15 business-days after it receives written notification that such a plan is required either because the notice specifically states that the Director has required the submission of a plan or the notice indicates that the Bank's capital classification or reclassification is to a category for which a capital restoration plan is a mandatory action required of the Bank. The Director may extend this deadline if the Director determines that such extension is necessary. Any such extension shall be in writing and provide a specific date by which the Bank must submit its proposed capital restoration plan.

* * * * *

Dated: July 29, 2009.

James B. Lockhart, III,

Director, Federal Housing Finance Agency.

[FR Doc. E9-18581 Filed 8-3-09; 8:45 am]

BILLING CODE P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1291

RIN 2590-AA04

Affordable Housing Program Amendments: Federal Home Loan Bank Mortgage Refinancing Authority

AGENCY: Federal Housing Finance Agency.

ACTION: Interim final rule with request for comments.

SUMMARY: Section 1218 of the Housing and Economic Recovery Act of 2008 (HERA) requires the Federal Housing Finance Agency (FHFA) to permit the Federal Home Loan Banks (Banks) until July 30, 2010, to use Affordable Housing Program (AHP) homeownership set-aside funds to refinance low- or moderate-income households' mortgage loans. On October 17, 2008, FHFA amended its AHP regulation to authorize the Banks to provide AHP direct subsidies under their homeownership set-aside programs to low- or moderate-income households who qualify for refinancing assistance under the Hope for Homeowners Program established by the Federal Housing Administration (FHA) under Title IV of HERA. Based on the comments received on the amendments and continuing adverse conditions of the mortgage market, FHFA has

determined that in order for the AHP set-aside refinancing program to be implemented successfully for the benefit of the intended households, the scope of the program authority should be broadened and the Banks should have greater flexibility in implementing the program. Accordingly, FHFA is issuing and seeking comment on an interim final rule that authorizes the Banks to provide AHP subsidy through their members to assist in the refinancing of eligible households' mortgages under eligible Federal, State and local programs for targeted refinancing in addition to the Hope for Homeowners Program. These programs would include the Administration's Making Home Affordable Refinancing program. The interim final rule permits the Banks to provide AHP direct subsidy to members and to use the subsidy for principal reduction and for loan closing costs, and requires that households obtain counseling for qualification for refinancing and foreclosure mitigation.

In addition, the interim final rule enhances the ability of the Banks to respond to the mortgage crisis by providing greater flexibility to accelerate their future annual statutory AHP contributions for use in their AHP homeownership set-aside programs in the current year. The interim final rule also permits the Banks to adopt multiple housing needs under their Second District Priority scoring criterion under the AHP competitive application program.

DATES: The interim final rule is effective on August 4, 2009. FHFA will accept written comments on the interim final rule on or before October 5, 2009.

ADDRESSES: Submit comments, identified by regulatory information number (RIN) 2590-AA04, by any of the following methods:

- *Mail/Hand Delivery:* Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552, Attention: Public Comments/RIN 2590-AA04.

- *E-mail:* regcomments@fhfa.gov. Please include "RIN 2590-AA04" in the subject line of the message.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by e-mail to FHFA at regcomments@fhfa.gov to ensure timely receipt by the agency. Include the following information in the subject line of your submission "Affordable Housing Program Amendments: Federal Home

Loan Bank Mortgage Refinancing Authority; RIN 2590-AA04."

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, on the FHFA Web site at <http://www.fhfa.gov>.

FOR FURTHER INFORMATION CONTACT:

Nelson Hernandez, Senior Associate Director, Housing Mission and Goals, 202-408-2819, Nelson.Hernandez@fhfa.gov; Charles E. McLean, Jr., Acting Manager, Housing Mission and Goals, 202-408-2537, Charles.McLean@fhfa.gov; or Melissa L. Allen, Senior Policy Analyst, 202-408-2524, Melissa.Allen@fhfa.gov, Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006; or Sharon B. Like, Associate General Counsel, 202-414-8950, Sharon.Like@fhfa.gov, Federal Housing Finance Agency, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Hearing Impaired is 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Comments

FHFA invites comments on all aspects of the interim final rule, and will revise the rule as appropriate after taking all comments into consideration. Copies of all comments will be posted on the FHFA Internet Web site at <http://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at 202-414-6924.

II. Background

A. HERA

Effective July 30, 2008, Division A of HERA, Public Law 110-289, 122 Stat. 2654 (2008), created FHFA as an independent agency of the Federal Government. HERA transferred the supervisory and oversight responsibilities over the Federal National Mortgage Association (Fannie Mae), Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, Enterprises), the Banks, and the Bank System's Office of Finance, from the Office of Federal Housing Enterprise Oversight (OFHEO) and the Federal Housing Finance Board (FHFB) to FHFA. HERA provides for the abolishment of OFHEO and FHFB one year after the date of enactment. FHFA is responsible for ensuring that the

Enterprises and the Banks operate in a safe and sound manner, including being capitalized adequately, and carry out their public policy missions, including fostering liquid, efficient, competitive, and resilient national housing finance markets. The Enterprises and the Banks continue to operate under regulations promulgated by OFHEO and FHFB until FHFA issues its own regulations. See HERA at § 1302, 122 Stat. 2795.

B. The Banks' Affordable Housing Program

Section 10(j) of the Federal Home Loan Bank Act (Bank Act) requires each Bank to establish an affordable housing program, the purpose of which is to enable a Bank's members to finance homeownership by households with incomes at or below 80% of the area median income (low- or moderate-income households), and to finance the purchase, construction, or rehabilitation of rental projects in which at least 20% of the units will be occupied by and affordable for households earning 50% or less of the area median income (very low-income households). See 12 U.S.C. 1430(j)(1) and (2). The Bank Act requires each Bank to contribute 10% of its previous year's net earnings to its AHP annually, subject to a minimum annual combined contribution by the 12 Banks of \$100 million. See 12 U.S.C. 1430(j)(5)(C). Section 1218 of HERA amended section 10(j) by adding a new paragraph (2)(C) which requires FHFA to allow the Banks until July 30, 2010, to use AHP homeownership set-aside funds to refinance low- or moderate-income households' first mortgage loans on their primary residences. See 12 U.S.C. 1430(j)(2)(C). The Director of FHFA must establish the percentage of set-aside funds eligible for this use by regulation.

The AHP regulation authorizes a Bank, in its discretion, to set aside a portion of its annual required AHP contribution to establish homeownership set-aside programs for the purpose of promoting homeownership for low- or moderate-income households. See 12 CFR 1291.6. Under the homeownership set-aside programs, a Bank may provide AHP direct subsidy (grants) to members to pay for down payment assistance, closing costs, and counseling costs in connection with a household's purchase of its primary residence, and for rehabilitation assistance in connection with a household's rehabilitation of an owner-occupied residence. See 12 CFR 1291.6(c)(4). Currently, a Bank may allocate up to the greater of \$4.5 million or 35% of its annual required AHP

contribution to homeownership set-aside programs in that year.

C. AHP Refinancing Initiative and Proposed Rule

In January 2008, FHFB waived certain homeownership set-aside program provisions of the AHP regulation to allow the Federal Home Loan Bank of San Francisco (San Francisco Bank) to establish a temporary pilot program to provide AHP direct subsidy to enable eligible households with subprime or nontraditional loans held by a San Francisco Bank member or its affiliate to refinance or restructure the loans into affordable, long-term fixed-rate mortgages. See FHFB Resolution No. 2008-01 (Jan. 15, 2008). The authority will expire on December 31, 2009.

In April 2008, FHFB published a proposed rule that would have extended the temporary authority to use AHP set-aside funds for mortgage refinancing or restructuring to all 12 Banks. See 73 FR 20552 (Apr. 16, 2008). FHFB received 36 comments on the proposal. Commenters who supported use of AHP funds for refinancing, recommended flexibility in the rules governing use of the funds so that the Banks and their members would be able to assist a greater number of borrowers in distress, including allowing the use of AHP set-aside funds in conjunction with other Federal, State or local mortgage refinancing programs.

D. October Interim Final Rule

Before FHFB took final action on the proposed amendments to the AHP regulation, section 1218 of HERA added section 10(j)(2)(C) to the Bank Act. Title IV of HERA also required establishment of the Hope for Homeowners Program, a temporary mortgage refinancing program under the FHA, which will expire on September 30, 2011. To implement the requirements of section 1218 of HERA, on October 17, 2008, FHFA published an interim final rule ("October amendments"), which added new § 1291.6(f) to the AHP homeownership set-aside regulation authorizing the Banks, in their discretion, to temporarily establish an AHP set-aside refinancing program. See 73 FR 61660 (Oct. 17, 2008). Specifically, § 1291.6(f) authorized the Banks to provide AHP direct subsidy to their members to assist in the refinancing of low- or moderate-income homeowners' mortgage loans under the Hope for Homeowners Program through the use of AHP subsidy to reduce loan principal and pay FHA-approved closing costs. By linking the use of the AHP subsidy with the Hope for Homeowners Program, FHFA intended

to leverage and enhance the effectiveness of each program, ensure that the full range of Federal assistance to affected homeowners was available quickly, and provide the flexibility that the Banks and their members need to make the AHP refinancing program successful.

FHFA received 38 comment letters on the October amendments, representing 40 commenters.¹ Commenters included: 8 Banks; 2 Bank Advisory Councils; 3 trade associations; 2 housing advocacy and assistance organizations; and 25 individuals. Thirteen of the 40 commenters supported the use of AHP subsidies for refinancing households with unaffordable mortgages. The other 27 commenters opposed the use of AHP subsidies for refinancing, citing the ongoing, critical need for AHP homeownership set-aside subsidies to assist home purchases.

E. HERA Section 1201

Section 1201 of HERA requires the FHFA Director to consider the differences between the Banks and the Enterprises in rulemakings that affect the Banks with respect to the Banks' cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure and joint and several liability. See 12 U.S.C. 4513(f). In preparing the interim final rule, the Director considered these factors and determined that the rule is appropriate, particularly because the rule implements a statutory provision of the Bank Act that applies only to the Banks. See 12 U.S.C. 1430(j). Nonetheless, FHFA requests comment on whether these factors should result in a revision of the rule as it relates to the Banks.

III. Analysis of the Interim Final Rule

A. Definition of Eligible Targeted Refinancing Program: § 1291.1

The October amendments provided that a household's loan is eligible to be refinanced with AHP direct subsidy if the loan is secured by a first mortgage on an owner-occupied unit that is the primary residence of the household, and the loan is refinanced under the Hope for Homeowners Program. FHFA specifically requested comment on whether the Banks should be permitted to use AHP set-aside funds to assist homeowners refinancing under other programs intended to aid distressed homeowners, such as those offered by the Enterprises, FHASecure, or any

¹ Letters from two of the Banks also incorporate the comments of those Banks' respective Affordable Housing Advisory Councils (Advisory Councils).

State housing finance agency programs. *See* 73 FR 61660, 61662 (Oct. 17, 2008). Thirteen commenters supported AHP refinancing authority for the Banks but opposed limiting the authority to assistance under the Hope for Homeowners Program. The commenters stated that the Hope for Homeowners Program is too narrowly tailored to assist a large number of households and has attracted little lender interest. The commenters pointed out that there are other, successful Federal and State programs targeted to assisting households refinance their unaffordable mortgages, and that the Banks should be permitted to provide AHP subsidy in conjunction with these programs. Twelve of the 13 commenters specifically supported use of AHP subsidy with the FHASecure Program, U.S. Department of Agriculture (USDA) programs, and State and local housing finance agency programs. Ten commenters recommended that the Banks be permitted to provide AHP subsidy in conjunction with targeted refinancing or restructuring programs of Fannie Mae and Freddie Mac, which had established the Streamlined Modification Program at the time of the October amendments. Since then, the Administration has superseded the Streamlined Modification Program with the Making Home Affordable Refinance and Modification programs for mortgages owned or guaranteed by the Enterprises. The commenters stated that each Bank should have discretion and flexibility to determine which programs in its district would make best use of AHP subsidy.

In the past year or so, a number of State housing finance agencies established taxable bond programs to refinance households with unaffordable mortgages. To help State and local housing finance agencies address the need for refinancing households into affordable mortgages, HERA authorized the temporary use of tax-exempt mortgage-revenue bonds for refinancing at-risk households with subprime mortgages. *See* HERA, § 3021. Housing finance agencies are likely to increase their refinancing activity in light of this new authority. Most of the Banks work closely with the housing finance agencies in their districts, some of which are also housing associates of the Banks, and many Bank members are participating lenders in existing housing finance agency mortgage-revenue bond programs for home purchasers.

In addition, as part of the Administration's Homeowner Affordability and Stability Plan, Fannie Mae and Freddie Mac are now responsible for implementing the

Making Home Affordable programs, which include the Home Affordable Refinance program for first mortgage loans owned or guaranteed by these agencies. Many Bank members are also Fannie Mae and Freddie Mac approved seller/servicers that already participate in Fannie Mae and Freddie Mac homeownership mortgage programs.

Based on the comments and FHFA's review of Federal, State and local refinancing programs, FHFA has determined that the Hope for Homeowners Program has experienced limited usage due to statutory and regulatory restrictions and market conditions, rendering the current AHP refinancing authority of limited utility.² To date, no Bank has implemented an AHP refinancing program pursuant to the current AHP regulatory refinancing authority. However, other Federal, State and local targeted mortgage refinancing programs could be used in conjunction with the AHP set-aside refinancing authority. Accordingly, the interim final rule provides that loans are eligible for refinancing with AHP subsidy if they are refinanced under an "eligible targeted refinancing program," which is defined in § 1291.1 as a program offered by the Department of Housing and Urban Development (HUD), USDA, Fannie Mae, Freddie Mac, a State or local government, or a State or local housing finance agency for the limited purpose of refinancing first mortgages on primary residences for households that cannot afford or are at risk of not being able to afford their monthly payments, as defined by the program, in order to prevent foreclosure. The Hope for Homeowners Program, as a HUD program, continues to be an eligible program that may be used in conjunction with the AHP set-aside refinancing program. Making the AHP subsidy available for State and local housing finance agency refinancing programs is consistent with the provision in HERA authorizing housing finance agencies to issue Federal tax-exempt mortgage-revenue bonds through the end of 2010 in order to refinance households that have subprime mortgages and are at risk of financial hardship. Including additional eligible targeted refinancing programs of other Federal, State and local agencies is also consistent with the requirement in section 10(j)(9)(G) of the Bank Act that the AHP regulation coordinate AHP activities with other Federal or federally-subsidized affordable housing

activities to the maximum extent possible. *See* 12 U.S.C. 1430(j)(9)(G).

FHFA believes that there should be sufficient demand among these eligible targeted refinancing programs to absorb the limited amount of AHP subsidy that will be available for refinancing. Eligible targeted refinancing programs do not include programs that permit households to refinance for any reason, programs that provide the full amount of subsidy or other financing concessions needed for a household to achieve an affordable mortgage in accordance with the program's terms (see discussion under the Eligible Uses of Subsidy section below), or programs that involve the modification or restructuring of the loans, rather than refinancing (*i.e.*, paying off the original mortgage with the proceeds of a new loan).

The interim final rule does not limit eligible targeted refinancing programs to those in existence as of the effective date of the rule. Federal, State and local agencies and housing authorities are likely to add or replace refinancing programs during the period of AHP set-aside refinancing authorization, based on refinancing needs and housing market conditions, and FHFA does not wish to preclude the use of AHP subsidy with such programs that are consistent with the purposes of this rule. USDA is a primary source of Federal funding for owner-occupied housing primarily in rural areas, and although it has not announced a targeted refinancing program to date, it may do so in the future. A number of State housing finance agencies are also expected to implement targeted refinancing programs under their new tax-exempt mortgage-revenue bond authority in the near future. The FHASecure Program, which ended in December 2008 and assisted thousands of households in troubled mortgages, may be revived, or a program of a similar nature may be established.

Several commenters suggested that FHFA permit AHP subsidy to be used in conjunction with private targeted refinancing programs including not-for-profit programs. One commenter recommended limiting the AHP refinancing set-aside program to assisting in the refinancing of loans originated by Bank members. Three commenters also supported the use of AHP subsidy to restructure or refinance mortgages originated by members and purchased by the Banks for their Mortgage Partnership Finance (MPF) and Mortgage Purchase Program (MPP) portfolios, as consistent with efforts by the Federal Deposit Insurance Corporation to promote lender

² Recent changes to the Hope for Homeowners Program enacted by Congress may expand its usage.

modifications. The interim final rule does not authorize the use of AHP subsidy in conjunction with private refinancing programs, Bank-sponsored targeted advances programs for refinancing, Bank member loan refinancing programs such as the San Francisco Bank AHP refinancing pilot program, or refinancing of MPF or MPP loans. Authorizing the use of AHP subsidy in conjunction with such private refinancing sources would require the establishment of minimum program standards for eligible refinancing, including affordability requirements for the refinanced loan, loan-to-value ratios and other lending terms. If AHP subsidy were permitted to be used in conjunction with refinancing member loans, the interim final rule would need to establish member contribution requirements to ensure that the subsidy was not rewarding members or the Banks for poor underwriting or investment decisions. The comments on the April 2008 AHP refinancing proposal, which was based largely on the San Francisco Bank AHP refinancing pilot program and which included explicit program loan underwriting and member contribution requirements, indicated that the circumstances of the pilot program were not applicable outside of the San Francisco Bank district.

B. Funding Allocation: § 1291.2(b)(2)(i)

The AHP regulation permits a Bank, in its discretion, to set aside annually, in the aggregate, a maximum of the greater of \$4.5 million or 35% of its annual required AHP contribution to provide funds to members participating in homeownership set-aside programs, including mortgage refinancing programs established under § 1291.6(f). See 12 CFR 1291.2(b)(2). Prior to the October amendments, the AHP regulation also required that at least one-third of a Bank's aggregate annual set-aside allocation to such programs be targeted for first-time homebuyers. The October amendments changed this requirement by allowing a Bank to allocate the maximum permissible homeownership set-aside allocation entirely to a mortgage refinancing program established under § 1291.6(f). See 12 CFR 1291.2(b)(2)(i)(A). The October amendments also provided that if a Bank sets aside funds solely for homeownership set-aside programs other than a mortgage refinancing program established under § 1291.6(f), at least one-third of the Bank's aggregate annual set-aside allocation to such programs shall be to assist first-time homebuyers. See 12 CFR 1291.2(b)(2)(i)(B).

All 27 commenters that opposed the October amendments opposed using AHP subsidies for refinancing at the expense of assisting new home purchases, especially at a time when there are fewer sources of purchase assistance and the decline in home prices is making homeownership possible for more low- or moderate-income households. Two of these commenters expressed concern that refinancing often does not prevent a household from losing its home due to factors other than the terms of the original mortgage and, therefore, does not constitute a better use of AHP subsidy than purchase assistance. Three commenters stated that the regulation should retain the existing homeownership set-aside requirement that a minimum one-third of the total set-aside allocation be allocated for first-time homebuyers in order to ensure that some minimum amount of AHP home purchase assistance is available.

FHFA finds these comments to be persuasive. In the current market where many existing homeowners are unable to sell their homes and purchase move-up homes because their mortgages exceed their homes' value, efforts to promote new home purchases could contribute to recovery and stabilization of the housing market. Ensuring that at least some portion of AHP set-aside subsidies is available for home purchase assistance is also consistent with HERA's establishment of Federal funding for what is commonly referred to as the Neighborhood Stabilization Program (NSP). See HERA, §§ 2301 through 2305. The NSP provides funding to State and local government programs for purchasing, rehabilitating and renting or selling foreclosed properties in order to mitigate the blight on communities resulting from the housing crisis. A number of State housing finance agencies are using NSP and mortgage-revenue bond funds to assist first-time homebuyers in purchasing these foreclosed properties.

Consequently, the interim final rule reinstates in § 1291.2(b)(2)(i) the requirement that at least one-third of a Bank's total annual set-aside allocation shall be targeted to assist first-time homebuyers, regardless of whether the set-aside allocation is being used for homeownership or refinancing assistance, or both. Thus, a Bank may use up to two-thirds of its annual set-aside allocation for the AHP set-aside refinancing program. If a Bank wants to increase the amount of AHP subsidy dollars available for refinancing assistance, the Bank may increase its total AHP set-aside allocation, and thereby its refinancing set-aside amount,

by accelerating additional funding from subsequent years' AHP contributions as permitted under § 1291.2(b)(3) and discussed further below. In addition, the first-time homebuyers provision requires that the Bank allocate one-third of the Bank's set-aside funding for first-time homebuyers but does not require the Bank to commit or use the amount of the allocation for first-time homebuyers. If there is not sufficient demand for the first-time homebuyers allocation and the Bank does not commit the entire allocation to first-time homebuyers, then the Bank may ultimately carry over the unused portion of the first-time homebuyers allocation to other AHP set-aside uses, including refinancing.

C. Acceleration of Future AHP Contributions: § 1291.2(b)(3)

Under the Bank Act, a Bank is required to contribute at least 10% of its prior year's net earnings to its current year's AHP. See 12 U.S.C. 1430(j)(5)(C). Section 1291.2(b)(3) of the current AHP regulation permits a Bank, in its discretion, to reallocate (*i.e.*, accelerate), from the subsequent year's required annual AHP contribution for use in the current year, an amount up to the greater of \$2 million or 20% of its required annual AHP contribution for the current year. See 12 CFR 1291.2(b)(3). Prior to amendment in 2007, the AHP regulation based the percentage amount on the Bank's estimated amount of its required AHP contribution for the subsequent year, rather than on its required contribution for the current year.

The current housing and financial crises have created unprecedented financial conditions not contemplated by the AHP regulation. Bank earnings declined in 2008, and the Banks' earnings potential in the near future is uncertain and more unpredictable than in previous years because of market instability. In this environment, a Bank that accelerates AHP funds from the subsequent year's required contribution may find that the subsequent year's actual required AHP contribution is less than the amount accelerated. At the same time, a Bank may have no required current year AHP contribution on which to base a percentage calculation, or even expectation of a required subsequent year AHP contribution. In 2009, two Banks with no 2008 earnings have no required AHP contributions, while several other Banks have very small required AHP contributions. The ability to accelerate funds from future required AHP contributions would enable these Banks to make some level of AHP funding available in 2009.

Consequently, the interim final rule amends § 1291.2(b)(3) to increase the maximum amount that a Bank may accelerate in any one year to the greater of \$5 million (an increase from \$2 million) or 20% of the Bank's required annual AHP contribution for the current year. In addition, because of the uncertainty of future earnings and the possibility that a Bank may find itself in the same situation of having little or no required AHP contribution in the subsequent year, the interim final rule allows a Bank to credit the amount of the accelerated contribution against required AHP contributions over one or more of the subsequent five years. This is consistent with FHFA's policy for treatment of excess AHP annual contributions, under which a Bank that restates its earnings with the result that its annual AHP contribution exceeded the statutorily required amount, may credit the excess contributions against required AHP contributions in future periods. *See* Advisory Bulletin 06-01, "AHP and REFCORP Contributions" (Jan. 25, 2006). FHFA specifically requests comment on the revised acceleration provision in the interim final rule, including whether it provides sufficient flexibility to enable the Banks to maintain adequate AHP contributions during the current housing market and economic crisis.

As a technical matter, FHFA has found that use of the term "allot" in the current AHP regulation to describe the acceleration process has been confused with the process of allocating AHP funding between the homeownership set-aside and competitive application programs, and may also be confused with the process of allocating AHP set-aside funds between the homeownership set-aside and refinancing set-aside programs. Accordingly, the interim final rule uses the term "acceleration," which was used prior to 2007, in lieu of the term "allot" to describe the process of using future required AHP contributions in the current year.

D. General AHP Refinancing Program Authority; Retention Agreements: § 1291.6(f)(1)

Section 1291.6(f)(1) authorizes a Bank, in its discretion, to establish a homeownership set-aside program for the use of AHP direct subsidy by its members to assist in the refinancing of a household's mortgage loan that meets the requirements in § 1291.6, except for certain specified provisions, as well as with the requirements of part 1291. The October amendments exempted the AHP set-aside refinancing program from the provisions in § 1291.6 governing

five-year retention agreements on AHP-assisted household's units. *See* 12 CFR 1291.6(c)(5). Thus, an AHP-assisted household under the refinancing program would not repay AHP subsidy in the event of a subsequent sale or refinancing of the unit during the five-year retention period. *See* 12 CFR 1291.6(c)(5) and 1291.9(a)(7). This exemption from the AHP retention requirements was considered in light of the equity and appreciation sharing requirements of the Hope for Homeowners Program. *See* HERA, § 1402(a) (National Housing Act sec. 257(e)(4)(B), and (k)); 73 FR 61660, 61663 (Oct. 17, 2008).

Three commenters recommended that the Banks be able to require AHP retention agreements for repayment of the AHP subsidy in the event of a sale or refinancing during the five-year retention period. Four commenters stated that there could be cases where households receive AHP subsidy but subsequently fail to qualify under the Hope for Homeowners Program because they fail to make the first payment on their newly refinanced loan, and the Bank could not recover the AHP subsidy in such cases if the household subsequently sold or refinanced the home.

Under the Banks' current AHP competitive application and home purchase set-aside programs, AHP retention agreements, which may be subordinate liens or other forms of legally enforceable agreements, are used in conjunction with all types of mortgage financing provided by all Federal, State and local agencies, including other FHA programs. Because the AHP regulation requires that AHP subsidy only be repaid from any net gain from the sale or refinancing, the AHP repayment requirement should not interfere with any appreciation or equity sharing requirements of the eligible targeted refinancing programs. Requiring AHP retention agreements for the AHP set-aside refinancing program would also maintain consistency between the refinancing program and all other AHP programs, which are subject to the retention agreement requirement. Accordingly, the interim final rule requires that a household assisted under the AHP set-aside refinancing program be subject to an AHP five-year retention agreement in accordance with § 1291.6(c)(5).

E. Eligible Loans: § 1291.6(f)(2)

As discussed above, the interim final rule amends § 1291.6(f)(2) to make loans refinanced under other eligible targeted refinancing programs in addition to the Hope for Homeowners Program eligible

for AHP refinancing subsidy. To be eligible for AHP refinancing assistance, a household must meet the terms of refinancing established by the eligible targeted refinancing program, such as the mortgage debt-to-income ratio, loan-to-value ratio, payment history, type of original loan (*e.g.*, subprime or nontraditional), and reasons for delinquency. In addition, pursuant to HERA, the household must have an income at or below 80% of the area median income (AMI), and the household's loan being refinanced must be a first mortgage on an owner-occupied unit that is the household's primary residence. Two commenters recommended that FHFA establish parameters or details for eligibility and underwriting standards under which other programs' requirements would fall. In the October amendments, FHFA noted that it was not necessary to establish underwriting and other household and loan eligibility requirements for the AHP set-aside refinancing program, because the requirements and standards of the Hope for Homeowners Program provide adequate protections to borrowers whose loans will be refinanced and protect the integrity of the AHP. *See* 73 FR at 61662. The requirements and standards of the other eligible targeted refinancing programs included in the interim final rule similarly protect borrowers and the integrity of the AHP. Reliance on the requirements and standards of other lenders is also consistent with the AHP home purchase set-aside program, which does not establish specific requirements for underwriting a household's mortgage, leaving the establishment of such requirements to the individual lender. Five commenters supported this approach, and several commenters stated that FHFA should not limit eligible loans to subprime and nontraditional mortgages, or require that a household be delinquent in order to receive assistance.

Consistent with the October amendments, for purposes of determining whether a household is at or below 80% of AMI under the AHP set-aside refinancing program, the interim final rule does not establish specific requirements for how a Bank should calculate a household's income. Thus, a Bank may make its own calculation of total household income, or may use the eligible targeted refinancing program's calculation of total household income for purposes of determining whether a household meets the 80% of AMI income limit. This is also consistent with the AHP home

purchase set-aside program, under which each Bank establishes requirements for how to calculate household income, which may include relying on the member's calculation of household income determined in the process of underwriting the mortgage. The Hope for Homeowners Program and the Home Affordable Refinance program do not require households to meet certain income limits in order to be eligible for the program, but do calculate total household income for purposes of determining loan underwriting ratios. State housing finance agency refinancing programs have specific household income limits under their mortgage-revenue bond programs (generally 100% of AMI), and calculate total household income for purposes of determining compliance with those income limits as well as for purposes of determining underwriting ratios. The housing finance agency refinancing programs vary in how they calculate total household income with regard to the income time period (past income or current income) and the income sources (only the mortgage borrowers or all adult household members) used. Ten commenters recommended that the Banks rely on the calculation of total household income determined by other programs providing the refinancing assistance where such programs calculate income.

Section 1291.6(c)(2)(i) of the existing AHP regulation requires a Bank or member to determine a household's income eligibility at the time the member enrolls the household in the AHP homeownership set-aside program. Consistent with this requirement, the Bank or member must determine that the household is at or below 80% of AMI at the time of enrollment in the AHP set-aside refinancing program. However, a Bank or member may use the total household income provided by the eligible targeted refinancing program regardless of when that program calculated the amount.

F. Eligible Uses of AHP Subsidy: *§ 1291.6(f)(3)*

1. Reduction in Outstanding Loan Principal Balance

The October amendments provided that AHP subsidy may pay to reduce the outstanding principal balance of the household's loan below the maximum loan-to-value ratio required under the Hope for Homeowners Program in order for the household to also meet that program's maximum debt-to-income ratio. 12 CFR 1291.6(f)(3)(i). However, there may also be cases where the household meets the program's maximum mortgage debt-to-income

ratio but the outstanding principal balance of the loan exceeds the program's maximum loan-to-value ratio. To take into account such cases, the interim final rule amends the AHP regulation to permit use of the AHP subsidy to reduce the outstanding loan principal balance to the eligible targeted refinancing program's maximum loan-to-value ratio even if this results in the household having a mortgage debt-to-income ratio below the program's maximum mortgage debt-to-income ratio. The maximum amount of AHP subsidy that may be provided for the refinancing is the least amount that results in the loan meeting both the program's maximum loan-to-value ratio and maximum mortgage debt-to-income ratio. Consequently, there is no need for any AHP subsidy where a refinancing program already provides concessions and subsidy sufficient for a household to achieve an affordable mortgage in accordance with the program's terms. For example, the Fannie Mae and Freddie Mac Home Affordable Refinance program, with certain exceptions, does not require maximum mortgage debt-to-income ratios, so, generally, the AHP subsidy could be used only to reduce loan principal to achieve that program's maximum loan-to-value ratio. The interim final rule also clarifies that the applicable program underwriting debt-to-income ratio is the mortgage debt-to-income ratio.

2. Loan Closing Costs

The October amendments also authorized a member to use the AHP subsidy to pay only FHA-approved loan closing costs in connection with the refinancing of an eligible loan under the Hope for Homeowners Program. 12 CFR 1291.6(f)(3)(ii). One commenter opposed restricting the use of AHP subsidy for loan closing costs that are FHA-approved, noting that this is inconsistent with the provision in the AHP regulation that does not specify that AHP subsidy may pay only for FHA-approved closing costs in connection with the purchase of a home under the homeownership set-aside program or under the competitive application program. See 12 CFR 1291.6(c)(4) and (8). To maintain consistency between the AHP homeownership and refinancing set-aside programs, the interim final rule removes the language restricting eligible closing costs to FHA-approved closing costs.

Two commenters requested clarification that AHP subsidy may be used to pay FHA up-front insurance premiums under the AHP set-aside

refinancing program. Because they are required for the mortgage financing, FHA up-front insurance premiums are eligible costs under the AHP homeownership set-aside and competitive application programs. Consequently, AHP subsidy may pay for such insurance premiums under the AHP set-aside refinancing program.

The October amendments excluded the current requirement of the AHP homeownership set-aside program that the rate of interest, points, fees and any other charges for all loans made in conjunction with the AHP subsidy cannot exceed a reasonable market rate of interest, points, fees and other charges for loans of similar maturity, terms and risk. 12 CFR 1291.6(c)(7). As part of the goal to achieve consistency, where applicable, between the requirements of the AHP homeownership set-aside and the refinancing set-aside programs, the interim final rule applies § 1291.6(c)(7) to the refinancing set-aside program.

G. Eligible Lender Participants: *§ 1291.6(f)(4)*

The October amendments stated that a Bank may provide AHP direct subsidy to members that are FHA-approved lenders for the purpose of refinancing an eligible loan with an FHA-insured loan by the member under the Hope for Homeowners Program. The October amendments also stated that a Bank may, in its discretion, provide the AHP subsidy to members that will provide the subsidy to FHA-approved lenders that are not members of the Bank for the purpose of refinancing an eligible loan if, after consulting with the Bank's Advisory Council, the Bank determines that such action would be in the best interests of borrowers in the Bank's district. 12 CFR 1291.6(f)(4). All 13 commenters supporting refinancing, opposed limiting participants in the AHP set-aside refinancing program to FHA-approved lenders, noting that relatively few Bank members are FHA-approved lenders and many Bank members participate in housing finance agency mortgage-revenue bond programs and are Fannie Mae and Freddie Mac approved seller/servicers. Several commenters also stated that assistance should be available to households based on their qualifications, regardless of whether the member providing the AHP subsidy is FHA-approved. In addition, the requirement that members be FHA-approved is too restrictive since the interim final rule permits the use of the AHP subsidy with other eligible targeted refinancing programs in addition to the FHA's Hope for Homeowners Program.

Accordingly, the interim final rule eliminates the FHA-approved lender requirement.

Under the current AHP home purchase set-aside program, the Banks have discretionary authority to decide whether to permit a household to obtain a purchase-money mortgage from any lender or to require the household to obtain its mortgage from the member providing the AHP assistance.³ Consistent with this authority, § 1291.6(f)(4) of the interim final rule permits a Bank, in its discretion, to require a household to obtain its refinancing loan through a member participating in the eligible targeted refinancing program that is providing the new mortgage to the household. The interim final rule also removes the requirement that a Bank must consult with its Advisory Council before determining that a household may use a lender other than a member of the Bank. This requirement is not specified in § 1291.6(c)(2)(iii) with respect to the adoption of other optional household eligibility requirements under the home purchase set-aside program and, in any case, is redundant with the general regulatory requirement that the Banks consult with their Advisory Councils in adopting their AHP Implementation Plans. 12 CFR 1291.3(a) and (b).

H. Household Counseling: § 1291.6(f)(5)

Section 1291.6(c)(2)(iii) of the current AHP regulation permits a Bank, in its discretion, to require homebuyers who are not first-time homebuyers to obtain homeownership counseling under the AHP home purchase set-aside program. *See* 12 CFR 1291.6(c)(2)(iii). The October amendments did not make the discretionary authority to adopt additional household eligibility requirements, such as counseling, applicable to the AHP set-aside refinancing program. Several commenters objected to the exclusion of counseling as an optional household eligibility requirement, noting the importance of counseling for households with troubled loans. The 2008 Consolidated Appropriations Bill recognized the importance of homeowner counseling by establishing and funding the National Foreclosure Mitigation Counseling (NFMC) program to assist households seeking refinancing or restructuring of their mortgages in order to avoid foreclosure. *See* Public Law 110–161. The NFMC program, under the auspices of NeighborWorks

America, is comprised of an array of counseling groups including NeighborWorks' partner organizations, the Homeownership Preservation Foundation, HUD's HOPE NOW counseling coalition, the National Urban League, USA Cares (military assistance), and State and local housing finance agency counseling programs. Most, if not all, of the State housing finance agency refinancing programs require households to be reviewed and vetted by these counseling organizations before applying to their programs. The Home Affordable Refinance program encourages households to seek counseling assistance to determine if they qualify for the Fannie Mae/Freddie Mac refinance program. The NFMC program is playing an important role in counseling households to help them determine their options and qualifications for refinancing assistance under these Fannie Mae, Freddie Mac and State housing finance agency eligible targeted refinancing programs.

FHFA agrees that counseling is an important component of successful refinancing, and should be provided by competent and reputable counseling programs, such as the NFMC program or other counseling programs used by State or local government or housing finance agencies that may not be part of the NFMC program. These counseling programs can also serve as an efficient and effective means of identifying for households the assistance programs for which they may qualify. Accordingly, § 1291.6(f)(5) of the interim final rule requires that a household seeking AHP assistance must obtain counseling for foreclosure mitigation and qualification for refinancing by an eligible targeted refinancing program, through the NFMC program or other counseling program used by a State or local government or housing finance agency. Bank members would refer interested households to an NFMC program participant, or to a State or local government or housing finance agency counseling program, which would determine whether the households are eligible to have their loans refinanced through an eligible targeted refinancing program. Households determined by a counseling organization to qualify for refinancing under an eligible targeted refinancing program would then be referred to participating Bank members, who would enroll the households in the AHP set-aside refinancing program upon determination of their AHP income eligibility.

Under the interim final rule, the NFMC program and other permissible counseling organizations would thereby act as a gateway for households seeking

refinancing assistance. The interim final rule does not establish a requirement for the type of educational counseling that may take a period of time that could delay the closing on the refinancing. Rather, the interim final rule requires the household to go to an NFMC program principally to determine if its loan can be refinanced by one of the eligible targeted refinancing programs and whether AHP subsidy will be needed in order for the household to obtain the refinancing. Although the household will benefit from accompanying foreclosure mitigation and credit counseling, the primary purpose of the interim final rule requirement is to ensure that the household receives counseling on a variety of available refinancing options that are suitable for that household. For example, a lender, such as an FHA lender or Fannie Mae/Freddie Mac seller/servicer, may be able to determine if a household is eligible for a specific program involving that lender, but is not likely to know if the household has other options if it is not eligible for the lender's specific program. Consequently, under the interim final rule, when a household contacts a member directly, the member would refer the household to the NFMC program or other State or local government or housing finance agency counseling program, to determine the household's eligibility before enrolling the household in the AHP refinancing program and committing AHP subsidy.

All NFMC program counseling is free to households; therefore, the interim final rule does not authorize the use of AHP subsidy to pay for such counseling costs. FHFA specifically requests comment on whether households should be required to obtain counseling for foreclosure mitigation and qualification for refinancing by an eligible targeted refinancing program prior to enrollment in the AHP set-aside refinancing program.

I. Sunset Date: § 1291.6(f)(6)

The October amendments included a provision terminating the Banks' authority to commit AHP subsidy for refinancing after July 30, 2010, which is the expiration date of the two-year period in section 1218 of HERA. 12 CFR 1291.6(f)(5). FHFA specifically requested comment on whether the sunset date should be extended to be co-extensive with the sunset date of the Hope for Homeowners Program on September 30, 2011. *See* 73 FR at 61663. Two commenters supported an extension of this sunset date to coincide with the sunset date for the Hope for Homeowners Program. *See* HERA,

³ Requiring a household to obtain a new mortgage through the member is one of several types of optional household eligibility requirements that a Bank may establish under § 1291.6(c)(2)(iii).

§ 1402(a) (National Housing Act sec. 257(r)). One commenter recommended that FHFA consider adopting the sunset dates of other refinancing programs. The interim final rule retains the sunset date of July 30, 2010 in redesignated § 1291.6(f)(6). FHFA may reconsider an extension of the sunset date based on program performance as the sunset date approaches.

J. Competitive Application Program; Second District Priority Scoring Criterion: § 1291.5(d)(5)(vii)

Under the Banks' AHP competitive application program, the Second District Priority is the only one of nine scoring criteria in the AHP regulation for which a Bank may select a housing need that is not prescribed in the regulation. Unlike the First District Priority scoring criterion, the Second District Priority permits a Bank to establish only one housing need in its district. 12 CFR 1291.5(d)(5)(vi), (d)(5)(vii). The current housing crisis has led to acute housing needs that the AHP regulation does not contemplate. These needs reflect a number of interconnected factors related to foreclosures and declining home values, which adversely affect all participants in the housing industry. The hardest hit areas must contend with blighted properties and declining communities where there is a critical need for sustainable and affordable homeownership and assistance to rental sponsors to absorb properties being sold to avoid foreclosure or that are in foreclosure. At the same time, there is an increased demand for affordable rental housing in the wake of households losing their homes, compounded by a significant decline in investors for low-income housing tax credits and housing finance agency bonds for rental production.

FHFA believes that these housing market conditions have generated an urgent need for more flexibility in the Banks' capacity to respond under the AHP. The current scoring system in the AHP regulation can address foreclosed properties only marginally within the context of other, more general housing needs. Permitting the Banks to establish one or more housing needs under the Second District Priority scoring criterion would allow the AHP competitive application program to complement the efforts of the AHP refinancing set-aside and other targeted refinancing programs for foreclosure prevention and HERA's NSP for the disposition of foreclosed properties. Accordingly, the interim final rule amends § 1291.5(d)(5)(vii) of the AHP regulation to permit a Bank to establish one or more housing needs in

the Bank's district under the Second District Priority scoring criterion.

FHFA believes that the severity of the housing market and the urgent need for housing assistance create exigent circumstances for amending the Second District Priority scoring criterion through an interim final rule. An immediate change is also necessary to allow the Banks and their Advisory Councils the opportunity to make any scoring revisions in this regard to their AHP Implementation Plans that would be applicable to their 2009 AHP competitive application funding rounds. FHFA specifically requests comment on whether this scoring change benefits the AHP competitive application program.

IV. Notice and Public Participation

FHFA for good cause finds that the notice and comment procedure required by the Administrative Procedure Act is impracticable or contrary to the public interest in this instance. See 5 U.S.C. 553(b)(B). Section 1218 of HERA requires that FHFA's regulations authorize the use of AHP set-aside subsidy for mortgage refinancing for a two-year period commencing on July 30, 2008. Issuance of an interim final rule will enable the Banks to expedite implementation of AHP set-aside refinancing programs pursuant to § 1218. In addition, as discussed above, exigent circumstances exist for amending the Second District Priority scoring criterion through an interim final rule. The delay that would ensue during a proposed notice and comment rulemaking would significantly curtail the available period of time for implementation and operation by the Banks of AHP mortgage refinancing programs and revised Second District Priorities. In view of the number and nature of the changes being made by this rule, FHFA is requesting comments and will consider all comments received on or before October 5, 2009 in promulgating a final rule.

V. Effective Date

For the reasons stated in part IV. above, FHFA for good cause finds that the interim final rule should become effective on August 4, 2009. See 5 U.S.C. 553(d)(3).

VI. Paperwork Reduction Act

The information collection contained in the current AHP regulation, entitled "Affordable Housing Program (AHP)," has been assigned control number 3069-0006 by the Office of Management and Budget (OMB). The interim final rule does not substantively or materially modify the approved information collection. Consequently, FHFA has not

submitted any information to OMB for review under the Paperwork Reduction Act of 1995. See 44 U.S.C. 3501 *et seq.*

VII. Regulatory Flexibility Act

FHFA is issuing this regulation in the form of an interim final rule and not as a proposed rule. Therefore, the provisions of the Regulatory Flexibility Act do not apply. See 5 U.S.C. 601(2) and 603(a).

List of Subjects in 12 CFR Part 1291

Community development, Credit, Federal home loan banks, Housing, Reporting and recordkeeping requirements.

■ For the reasons stated in the preamble, FHFA hereby amends chapter XII of title 12 of the Code of Federal Regulations as follows:

PART 1291—FEDERAL HOME LOAN BANKS' AFFORDABLE HOUSING PROGRAM

■ 1. The authority citation for part 1291 continues to read as follows:

Authority: 12 U.S.C. 1430(j).

■ 2. In § 1291.1, add the following definition in alphabetical order:

§ 1291.1 Definitions

* * * * *

Eligible targeted refinancing program means a program offered by the U.S. Department of Housing and Urban Development (HUD), the U.S. Department of Agriculture (USDA), the Federal National Mortgage Association (Fannie Mae), the Federal Home Loan Mortgage Corporation (Freddie Mac), a State or local government, or a State or local housing finance agency for the limited purpose of refinancing (*i.e.*, paying off) first mortgages on primary residences for households that cannot afford or are at risk of not being able to afford their monthly payments, as defined by the program, in order to prevent foreclosure.

* * * * *

■ 3. Amend § 1291.2(b)(2)(i) and (b)(3) to read as follows:

§ 1291.2 Required annual AHP contributions; allocation of contributions.

* * * * *

(b) * * *

(2) *Homeownership set-aside programs.*—(i) *Allocation amount; first-time homebuyers.* A Bank, in its discretion, may set aside annually, in the aggregate, up to the greater of \$4.5 million or 35% of the Bank's annual required AHP contribution to provide funds to members participating in homeownership set-aside programs,

including a mortgage refinancing set-aside program established under paragraph (f) of this section, provided that at least one-third of the Bank's aggregate annual set-aside allocation to such programs shall be to assist first-time homebuyers, pursuant to the requirements of this part.

* * * * *

(3) *Additional funding.* A Bank may accelerate to its current year's program from future annual required AHP contributions an amount up to the greater of \$5 million or 20% of its annual required AHP contribution for the current year. The Bank may credit the amount of the accelerated contribution against required AHP contributions under this part 1291 over one or more of the subsequent five years.

■ 4. Amend § 1291.5(d)(5)(vii) to read as follows:

§ 1291.5 Competitive application program.

* * * * *

(d) * * *

(5) * * *

(vii) *Second District priority: Defined housing needs in the District.* The satisfaction of one or more housing needs in the Bank's District, as defined by the Bank in its AHP Implementation Plan. The Bank may, but is not required to, use one of the criteria listed in paragraph (d)(5)(vi) of this section, provided it is different from the criterion or criteria adopted by the Bank under such paragraph.

* * * * *

■ 5. Amend § 1291.6(f) to read as follows:

§ 1291.6 Homeownership set-aside programs.

* * * * *

(f) *Mortgage refinancing program.*—

(1) *General.* A Bank may establish a homeownership set-aside program for the use of AHP direct subsidy by its members to assist in the refinancing of a household's mortgage loan, provided such program meets the requirements of this paragraph (f) and otherwise meets the requirements of regulations in this part. The provisions of paragraphs (c)(2)(ii), (c)(2)(iii), (c)(4), (c)(6) and (c)(8) of this section, shall not apply to such program.

(2) *Eligible loans.* A loan is eligible to be refinanced with AHP direct subsidy if the loan is secured by a first mortgage on an owner-occupied unit that is the primary residence of the household, and the loan is refinanced under an eligible targeted refinancing program.

(3) *Eligible uses of AHP direct subsidy.* Members may provide the AHP direct subsidy to:

(i) Reduce the outstanding principal balance of the loan by no more than the amount necessary for the new loan to qualify under both the maximum loan-to-value ratio and the maximum household mortgage debt-to-income ratio required by the eligible targeted refinancing program; or

(ii) Pay loan closing costs.

(4) *Eligible lender participants.* A Bank, in its discretion, may require that a household obtain its refinancing loan through a member participating in an eligible targeted refinancing program.

(5) *Counseling.* Prior to enrollment in an AHP set-aside refinancing program established under this paragraph (f), a household must obtain counseling for foreclosure mitigation and for qualification for refinancing by an eligible targeted refinancing program through the National Foreclosure Mitigation Counseling program or other counseling program used by a State or local government or housing finance agency.

(6) *Sunset.*—(i) This paragraph (f) shall expire on July 30, 2010, and a Bank may not commit AHP subsidy to households under its AHP set-aside refinancing program after such date.

(ii) A lender may use the AHP subsidy committed by such date for a loan submitted to the eligible targeted refinancing program for approval on or before July 30, 2010 that is approved for refinancing under such program after such date.

Dated: July 28, 2009.

James B. Lockhart, III,

Director, Federal Housing Finance Agency.

[FR Doc. E9-18484 Filed 8-3-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 135

[Docket No. FAA-1999-5401; Amendment No. 135-118]

Manual Requirements

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; technical amendment.

SUMMARY: The Federal Aviation Administration (FAA) is making a minor technical change to a final rule published in the **Federal Register** on February 2, 2005. This final rule established new manual requirements for aging aircraft under 14 CFR part 135. In the final rule, the FAA inadvertently

changed one of the regulatory references in § 135.427(a).

DATES: *Effective Dates:* Effective on August 4, 2009.

FOR FURTHER INFORMATION CONTACT: Kim A. Barnette, Flight Standards Service (AFS-320), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC; phone (202) 385-6403; e-mail Kim.A.Barnette@faa.gov.

SUPPLEMENTARY INFORMATION: On February 2, 2005, the FAA published a final rule in the **Federal Register** (70 FR 5533), better known as 'Aging Airplane Safety', clarifying the content requirements in the maintenance manual. In the process, this final rule re-designated 14 CFR 135.424 to § 135.423, and failed to revise § 135.427(a), which still referenced § 135.424.

Technical Amendment

This technical amendment will correct § 135.427(a) to properly reference § 135.423.

List of Subjects

14 CFR Part 135

Air taxis, Aircraft, Airmen, Alcohol abuse, Aviation safety, Drug abuse, Drug testing, Reporting and recordkeeping requirements.

■ Accordingly, Title 14 of the Code of Federal Regulations (CFR) part 135 is amended as follows:

PART 135—OPERATING REQUIREMENTS; COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 41706, 44113, 44101, 44701-44702, 44705, 44709, 44711-44713, 44715-44717, 44722.

■ 2. Amend § 135.427 by revising paragraph (a) to read as follows:

§ 135.427 Manual requirements.

(a) Each certificate holder shall put in its manual the chart or description of the certificate holder's organization required by § 135.423 and a list of persons with whom it has arranged for the performance of any of its required inspections, other maintenance, preventive maintenance, or alterations, including a general description of that work.

* * * * *

Issued in Washington, DC, on July 30, 2009.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E9-18602 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-13-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33-9058; 34-60390; 39-2466; IC-28838]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Filer Manual to reflect updates to the EDGAR system. The revisions were made primarily to support the 2009 US GAAP Taxonomy, the Schedule of Investments (SOI) Taxonomy and to communicate a change in the Filer Support hours to 9 a.m. to 5:30 p.m. The revisions to the Filer Manual reflect changes within Volume I entitled EDGAR Filer Manual, Volume I: "General Information," Version 7 (July 2009) and Volume II entitled EDGAR Filer Manual, Volume II: "EDGAR Filing," Version 12 (July 2009). The updated manual will be incorporated by reference into the Code of Federal Regulations.

DATES: *Effective Date:* August 4, 2009. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of August 4, 2009.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, contact Rick Heroux, at (202) 551-8800; in the Office of Interactive Disclosure for questions concerning the 2009 US GAAP Taxonomy and the Schedule of Investments Taxonomy contact Jeffrey Naumann, Assistant Director of the Office of Interactive Disclosure, at (202) 551-5352; in the Division of Corporation Finance, for questions on the change in filer support hours of operation, the Form D entity type description requirement or the requirement to provide additional information on the authentication documentation for Update Passphrase and Convert Paper Filer to Electronic Filer requests contact Cecile Peters, Chief, Office of Information Technology,

at (202) 551-3600; and in the Division of Investment Management for questions on changing investment company type contact Ruth Armfield Sanders, Senior Special Counsel, Office of Legal and Disclosure, at (202) 551-6989.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I and Volume II. The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.¹ It also describes the requirements for filing using EDGARLink² and the Online Forms/XML Web site.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.³ Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.⁴

The EDGAR system will be upgraded to Release 9.16 on July 20, 2009 and will introduce the following changes: *Interactive Data/XBRL Changes:* The existing US GAAP Taxonomy will be upgraded to the 2009 US GAAP Taxonomy; the US GAAP Beta 2.0 Taxonomy will no longer be supported; and, the system will support the Schedule of Investments Taxonomy 2008. Taxonomy details can be found on the SEC public Web site's "EDGAR Standard Taxonomies" Web page (<http://www.sec.gov/info/edgar/edgartaxonomies.shtml>). Chapter 6 (Interactive Data) of the EDGAR Filer Manual, Volume II: "EDGAR Filing" has been updated to make minor clarifications to the instructions on XBRL/Interactive Data Tagging.

New Filer Support Hours: The updated EDGAR Filer Manual makes the business hours for all EDGAR Filer Support branches uniform and conforms them to the Commission's official business hours of 9 a.m. to 5:30 p.m. Eastern Time. The manual notes that for

the first time filers may leave voice mail for calls placed outside of the official business hours.

Filer Management: Filers will be required to provide the printed name and title or position of the authorized person signing on both the Update Passphrase and Convert Paper Only Filer to Electronic Filer requests, which are faxed to the SEC.

A new fax line will be added for submitting Form ID notarized authentication documentation. The new fax line number will be (703) 813-6961.

The EDGAR Filing Web site will be updated to allow filers to change their investment company type (ICT) from the "Enter Series and Classes (Contracts) Information" option under the Retrieve/Edit Data menu.

Minor description changes were made to submission form types DEFM14A and PREM14A.

Along with adoption of the Filer Manual, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. 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.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1520, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. We will post electronic format copies on the Commission's Web site; the address for the Filer Manual is <http://www.sec.gov/info/edgar.shtml>.

Since the Filer Manual relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).⁵ It follows that the requirements of the Regulatory Flexibility Act⁶ do not apply.

The effective date for the updated Filer Manual and the rule amendments is August 4, 2009. In accordance with the APA,⁷ we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 9.16 is scheduled to be available on July 20, 2009. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the system upgrade.

¹ We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33-6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on April 23, 2009. See Release No. 33-9027 (April 16, 2009) [74 FR 18465].

² This is the filer assistance software we provide filers filing on the EDGAR system.

³ See Rule 301 of Regulation S-T (17 CFR 232.301).

⁴ See Release No. 33-9027 (April 16, 2009) [74 FR 18465] in which we implemented EDGAR Release 9.15.1. For a complete history of Filer Manual rules, please see the cites therein.

⁵ 5 U.S.C. 553(b).

⁶ 5 U.S.C. 601-612.

⁷ 5 U.S.C. 553(d)(3).

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,⁸ Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,⁹ Section 319 of the Trust Indenture Act of 1939,¹⁰ and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.¹¹

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

■ In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: “General Information,” Version 7 (July 2009). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 12 (July 2009). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: “N–SAR Supplement,” Version 1 (September 2005). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. You must comply with these requirements in

order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1520, Washington, DC 20549, or call (202) 551–5850, on official business days between the hours of 10 a.m. and 3 p.m. Electronic copies are available on the Commission’s Web site. The address for the Filer Manual is <http://www.sec.gov/info/edgar.shtml>. You can also inspect the document 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.

By the Commission.

Dated: July 28, 2009.

Elizabeth M. Murphy,
Secretary.

[FR Doc. E9–18434 Filed 8–3–09; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100, 147 and 165

[USCG–2009–0677]

District Eight Safety Zones and Special Local Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notice of expired temporary rules issued.

SUMMARY: This document provides required notice of substantive rules issued by the Coast Guard and temporarily effective between May 2006 and January 2009, that expired before they could be published in the **Federal Register**. This notice lists safety zones and special local regulations issued in the Eighth Coast Guard District, all of very limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This document lists temporary Coast Guard rules that became effective and were terminated between May 15, 2006 and January 9, 2009.

ADDRESSES: Documents listed in this preamble under the USCG–200#–#### format are available for electronic viewing under their individual docket numbers at <http://www.regulations.gov>. All other document formats are available for viewing online under

Notice USCG–2009–0677 at <http://www.regulations.gov>. These documents are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: For questions on this notice contact Yeoman First Class Denise Johnson, Office of Regulations and Administrative Law, telephone (202) 372–3862. For questions on viewing, or on submitting material to the docket, contact Ms. Angie Ames, Docket Operations, telephone 202–366–5115.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. Safety zones may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. Special local regulations are issued to enhance the safety of participants and spectators at regattas and other marine events. Timely publication of these rules in the **Federal Register** is often precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Because **Federal Register** publication was not possible before the beginning of the effective period, mariners were personally notified of the contents of these safety zones by Coast Guard officials’ on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard is publishing a list of expired temporary regulations pertaining to the Eighth Coast Guard District, which is headquartered in New Orleans, Louisiana. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if

⁸ 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

⁹ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w, and 78ll.

¹⁰ 15 U.S.C. 77sss.

¹¹ 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

sufficient time is available to do so before they are placed in effect or terminated. The temporary rules listed in this notice have been exempted from review under Executive Order 12866, Regulatory Planning and Review,

because of their emergency nature, or limited scope and temporary effectiveness.

The following rules were placed in effect temporarily during the period between May 2006 and January 2009, unless otherwise indicated.

Dated: July 28, 2009.

S.G. Venckus,

Chief, Office of Regulations and Administrative Law.

BILLING CODE 4910-15-P

DIST08 Expired Temporary Listing

Docket Number	Location	Type	Effective Date
CGD05-09-114	Pender County, NC	Safety Zones (Parts 147 and 165)	11/25/2006
COTP Houston-Galveston-06-007	Houston, TX	Safety Zones (Parts 147 and 165)	5/15/2006
COTP Houston-Galveston-06-0010	Galveston, TX	Safety Zones (Parts 147 and 165)	6/15/2006
COTP Houston-Galveston-06-0032	Galveston, TX	Safety Zones (Parts 147 and 165)	10/20/2006
COTP Houston-Galveston-06-0033	Galveston, TX	Safety Zones (Parts 147 and 165)	10/23/2006
COTP Houston-Galveston-06-0034	Galveston, TX	Safety Zones (Parts 147 and 165)	10/24/2006
COTP Houston-Galveston-06-0035	Galveston, TX	Safety Zones (Parts 147 and 165)	10/25/2006
COTP Houston-Galveston-07-001	Galveston, TX	Safety Zones (Parts 147 and 165)	11/29/2006
COTP Houston-Galveston-07-002	Galveston, TX	Safety Zones (Parts 147 and 165)	11/30/2006
COTP Houston-Galveston-07-012	Galveston, TX	Safety Zones (Parts 147 and 165)	4/16/2007
COTP Houston-Galveston-07-017	Houston, TX	Safety Zones (Parts 147 and 165)	8/3/2007
COTP Houston-Galveston-07-019	Galveston, TX	Safety Zones (Parts 147 and 165)	8/27/2007
COTP Houston-Galveston-07-020	Galveston, TX	Safety Zones (Parts 147 and 165)	9/21/2007
COTP Houston-Galveston-07-024	Galveston, TX	Safety Zones (Parts 147 and 165)	10/30/2007
COTP Houston-Galveston-07-025	Galveston, TX	Safety Zones (Parts 147 and 165)	11/9/2007
COTP Houston-Galveston-07-027	Galveston, TX	Safety Zones (Parts 147 and 165)	11/28/2007
COTP Houston-Galveston-07-028	Sargent, TX	Safety Zones (Parts 147 and 165)	11/28/2007
COTP Houston-Galveston-08-001	Galveston, TX	Safety Zones (Parts 147 and 165)	1/5/2008
COTP Houston-Galveston-08-002	Galveston, TX	Safety Zones (Parts 147 and 165)	1/11/2008
COTP Houston-Galveston-08-003	Galveston, TX	Safety Zones (Parts 147 and 165)	1/16/2008
COTP Houston-Galveston-08-004	Galveston, TX	Safety Zones (Parts 147 and 165)	1/23/2008
COTP Houston-Galveston-08-005	Galveston, TX	Safety Zones (Parts 147 and 165)	1/25/2008
COTP Houston-Galveston-08-006	Galveston, TX	Safety Zones (Parts 147 and 165)	2/6/2008
COTP Houston-Galveston-08-007	Galveston, TX	Safety Zones (Parts 147 and 165)	2/10/2008
COTP Houston-Galveston-08-008	Galveston, TX	Safety Zones (Parts 147 and 165)	2/19/2008
COTP Houston-Galveston-08-009	Galveston, TX	Safety Zones (Parts 147 and 165)	2/28/2008
COTP Houston-Galveston-08-010	Galveston, TX	Safety Zones (Parts 147 and 165)	3/11/2008
COTP Houston-Galveston-08-010	Galveston, TX	Safety Zones (Parts 147 and 165)	3/13/2008
COTP Houston-Galveston-08-013	Galveston, TX	Safety Zones (Parts 147 and 165)	3/21/2008
COTP Houston-Galveston-08-014	Galveston, TX	Safety Zones (Parts 147 and 165)	3/27/2008

COTP Houston-Galveston-08-015	Galveston, TX	Safety Zones (Parts 147 and 165)	4/18/2008
COTP Houston-Galveston-08-016	Galveston, TX	Safety Zones (Parts 147 and 165)	4/22/2008
COTP Houston-Galveston-08-017	Rollover Bay, TX	Safety Zones (Parts 147 and 165)	5/28/2008
COTP Houston-Galveston-08-018	Galveston, TX	Safety Zones (Parts 147 and 165)	6/4/2008
COTP Houston-Galveston-08-019	Galveston, TX	Safety Zones (Parts 147 and 165)	6/16/2008
COTP Lower Mississippi River 08-010	Memphis, TN	Safety Zones (Parts 147 and 165)	10/11/2008
COTP Lower Mississippi River 08-019	Memphis, TN	Safety Zones (Parts 147 and 165)	11/26/2008
COTP Lower Mississippi River-08-011	Memphis, TN	Safety Zones (Parts 147 and 165)	10/20/2008
COTP Lower Mississippi River-08-012	Memphis, TN	Safety Zones (Parts 147 and 165)	10/29/2008
COTP Lower Mississippi River-08-020	Greenville, MS	Safety Zones (Parts 147 and 165)	12/12/2008
COTP Mobile-08-008	Chattahoochee, FL	Safety Zones (Parts 147 and 165)	4/19/2008
COTP Morgan City-07-009	New Iberia, LA	Safety Zones (Parts 147 and 165)	9/10/2007
COTP Morgan City-07-017	New Iberia, LA	Safety Zones (Parts 147 and 165)	10/22/2007
COTP Morgan City-08-002	Morgan City, LA	Safety Zones (Parts 147 and 165)	1/27/2008
COTP Morgan City-08-006	Morgan City, LA	Safety Zones (Parts 147 and 165)	4/18/2008
COTP New Orleans-07-012	New Orleans, LA	Safety Zones (Parts 147 and 165)	7/3/2007
COTP New Orleans-07-013	Donaldsonville, LA	Safety Zones (Parts 147 and 165)	7/3/2007
COTP New Orleans-07-016	Harvey, LA	Safety Zones (Parts 147 and 165)	7/4/2007
COTP New Orleans-07-017	Baton Rouge, LA	Safety Zones (Parts 147 and 165)	7/4/2007
COTP New Orleans-07-018	Baton Rouge, LA	Safety Zones (Parts 147 and 165)	7/4/2007
COTP New Orleans-08-012	Jefferson Parish, LA	Safety Zones (Parts 147 and 165)	3/18/2008
COTP Ohio Valley-07-045	Troy, IN	Safety Zones (Parts 147 and 165)	9/25/2007
COTP Ohio Valley-08-001	Parkersburg, WV	Safety Zones (Parts 147 and 165)	5/17/2008
COTP Ohio Valley-08-002	Pickwick, TN	Safety Zones (Parts 147 and 165)	5/4/2008
COTP Ohio Valley-08-003	Charleston, WV	Safety Zones (Parts 147 and 165)	4/26/2008
COTP Ohio Valley-08-004	Louisville, KY	Safety Zones (Parts 147 and 165)	4/11/2008
COTP Ohio Valley-08-005	J. T. Myers Locke and Dam, IN	Safety Zones (Parts 147 and 165)	3/22/2008
COTP Ohio Valley-08-006	Louisville, KY	Safety Zones (Parts 147 and 165)	4/12/2008
COTP Ohio Valley-08-008	Louisville, KY	Safety Zones (Parts 147 and 165)	5/7/2008
COTP Ohio Valley-08-009	Louisville, KY	Safety Zones (Parts 147 and 165)	5/24/2008
COTP Port Arthur-07-014	Orange, TX	Safety Zones (Parts 147 and 165)	9/20/2007
COTP Port Arthur-07-015	Orange, TX	Safety Zones (Parts 147 and 165)	11/1/2007

COTP Port Arthur-08-001	Orange, TX	Safety Zones (Parts 147 and 165)	1/9/2008
COTP Port Arthur-08-002	Port Arthur, TX	Safety Zones (Parts 147 and 165)	1/30/2008
COTP Port Arthur-08-003	Sabine, TX	Safety Zones (Parts 147 and 165)	2/5/2008
COTP Port Arthur-08-004	Port Arthur, TX	Safety Zones (Parts 147 and 165)	2/23/2008
COTP Port Arthur-08-005	Port Arthur, TX	Safety Zones (Parts 147 and 165)	3/5/2008
COTP Port Arthur-08-008	Port Arthur, TX	Safety Zones (Parts 147 and 165)	4/1/2008
COTP Port Arthur-08-009	Port Arthur, TX	Safety Zones (Parts 147 and 165)	4/23/2008
COTP Port Arthur-08-011	Port Arthur, TX	Safety Zones (Parts 147 and 165)	5/6/2008
COTP Port Arthur-08-014	Sabine, TX	Safety Zones (Parts 147 and 165)	6/22/2008
COTP Port Arthur-08-015	Sabine, TX	Safety Zones (Parts 147 and 165)	6/24/2008
COTP Upper Mississippi River-07-036	Louis, MO	Safety Zones (Parts 147 and 165)	10/6/2007
COTP Upper Mississippi River-08-001	St. Louis, MO	Safety Zones (Parts 147 and 165)	1/26/2008
COTP Upper Mississippi River-08-004	Louis, MO	Safety Zones (Parts 147 and 165)	7/4/2008
COTP Upper Mississippi River-08-006	Louis, MO	Safety Zones (Parts 147 and 165)	6/15/2008
COTP Upper Mississippi River-08-007	Louis, MO	Safety Zones (Parts 147 and 165)	7/12/2008
COTP Upper Mississippi River-08-008	Louis, MO	Safety Zones (Parts 147 and 165)	7/4/2008
COTP Upper Mississippi River-08-014	Louis, MO	Safety Zones (Parts 147 and 165)	7/2/2008
COTP Upper Mississippi River-08-020	Louis, MO	Safety Zones (Parts 147 and 165)	7/19/2008
COTP Upper Mississippi River-08-036	Louis, MO	Safety Zones (Parts 147 and 165)	10/5/2008
COTP Upper Mississippi River-08-09	Louis, MO	Safety Zones (Parts 147 and 165)	8/31/2008
COTP Upper Mississippi River-08-10	Louis, MO	Safety Zones (Parts 147 and 165)	7/4/2008
COTP Upper Mississippi River-08-11	Louis, MO	Safety Zones (Parts 147 and 165)	5/25/2008
COTP Upper Mississippi River-08-12	Louis, MO	Safety Zones (Parts 147 and 165)	7/4/2008
COTP Upper Mississippi River-08-13	Louis, MO	Safety Zones (Parts 147 and 165)	5/25/2008
COTP Upper Mississippi River-08-40	Louis, MO	Safety Zones (Parts 147 and 165)	12/5/2008
COTP Upper Mississippi River-08-41	Louis, MO	Safety Zones (Parts 147 and 165)	12/7/2008
USCG-2008-0518	Cincinnati, OH	Safety Zones (Parts 147 and 165)	7/12/2008
USCG-2008-0528	Saint Albans, WV	Safety Zones (Parts 147 and 165)	6/28/2008
USCG-2008-0567	Kingston, TN	Safety Zones (Parts 147 and 165)	7/4/2008
USCG-2008-0577	Charleston, WV	Safety Zones (Parts 147 and 165)	6/22/2008
USCG-2008-0767	Cincinnati, OH	Safety Zones (Parts 147 and 165)	7/27/2008
USCG-2008-0797	Nashville, TN	Safety Zones (Parts 147 and 165)	8/23/2008

USCG-2008-0868	Louisville, KY	Safety Zones (Parts 147 and 165)	8/29/2008
USCG-2008-0980	Charleston, WV	Safety Zones (Parts 147 and 165)	10/4/2008
USCG-2008-0994	Ohio Valley, OH	Safety Zones (Parts 147 and 165)	9/16/2008
USCG-2008-1025	Galveston, TX	Safety Zones (Parts 147 and 165)	10/2/2008
USCG-2008-1027	Galveston, TX	Safety Zones (Parts 147 and 165)	10/3/2008
USCG-2008-1047	Memphis, TN	Safety Zones (Parts 147 and 165)	10/11/2008
USCG-2008-1160	Monroe, LA	Safety Zones (Parts 147 and 165)	12/6/2008
USCG-2008-1269	Orange, TX	Safety Zones (Parts 147 and 165)	1/7/2009
USCG-2008-1271	Chattanooga, TN	Safety Zones (Parts 147 and 165)	1/9/2009
USCG-2009-0012	Hull, MA	Special Local Regulations (Part 100)	2/1/2008

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG–2009–0631]

RIN 1625–AA00

Safety Zone; Hornblower Cruises Fleet Week Fireworks Display, San Francisco Bay, CA**AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of San Francisco Bay near San Francisco, CA in support of a Fleet Week fireworks display. This safety zone is necessary to ensure the safety of participants and spectators from the dangers associated with the pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zones without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from 8:45 a.m. through 10 p.m., each day, on October 9 and 10, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0631 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0631 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Lieutenant Junior Grade Christopher Hartley, U.S. Coast Guard Sector San Francisco, at (415) 399–7436, or at Christopher.A.Hartley@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior

notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event would occur before the rulemaking process would be completed. Because of the dangers posed by the pyrotechnics used in these fireworks displays, the safety zones are necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area.

For the same reasons, the Coast Guard also finds under 5 U.S.C. 553(d)(3) that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose members of the public to the dangers posed by the pyrotechnics used in the fireworks display.

Background and Purpose

Hornblower Cruises will sponsor a Fleet Week fireworks display on October 9 and 10, 2009 on the navigable waters of San Francisco Bay, CA. The fireworks displays are meant for entertainment purposes. This safety zone establishes temporary restricted areas on the waters surrounding the fireworks launch sites during loading of the pyrotechnics and during the fireworks displays. These restricted areas around the launch sites are necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barges. The Coast Guard has granted the event sponsor a marine event permit for the fireworks displays.

Discussion of Rule

During the setup of the fireworks and until the start of the fireworks displays, the temporary safety zone will be enforced within a radius of 100 feet around the fireworks sites. From 9:30 p.m. until 9:50 p.m., the temporary safety zone will be enforced within a radius of 1,000 feet around the fireworks launch sites.

The effect of the temporary safety zones will be to restrict navigation in the vicinity of the fireworks sites while the fireworks are set up, and until the conclusion of the scheduled displays.

Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels a safe distance away from the fireworks barges to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Analyses

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

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zones, the effect of this rule will not be significant because of the small size and short duration of the zone. Additionally, local waterway users will be able to pass safely around the zone, and will be notified via public Broadcast Notice to Mariners to ensure the zone will result in minimum impact.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which are small entities: The owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (1) Vessel traffic can pass safely around the area; (2) vessels engaged in recreational activities and

sightseeing have ample space outside of the affected portion of the areas of San Francisco, CA to engage in these activities; (3) this rule will encompass only a small portion of the waterway for a limited period of time; and (4) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

Assistance for Small Entities

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations, to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not 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 rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 0023.1 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction because the rule establishes a safety zone.

An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add temporary § 165–T11–223 to read as follows:

§ 165–T11–223 Safety Zone; Hornblower Cruises Fleet Week Fireworks Display, San Francisco Bay, CA

(a) *Location.* The following area is a safety zone: All waters of San Francisco Bay, from surface to bottom, within a 1,000 foot radius of fireworks launch sites that will be located approximately at: 37°47'55.61" N, 122°23'36.03" W; 37°48'41.95" N, 122°24'43.97" W; and, 37°48'38.00" N, 122°24'50.93" W. All coordinates are (NAD 83).

(b) *Enforcement.* During the loading of the fireworks, and until the start of the fireworks displays on October 9 and 10, 2009, this regulation will be enforced within a radius of 100 feet around the fireworks launch sites. From 9:30 p.m. until 9:50 p.m. on October 9 and 10, 2009, this regulation will be enforced within a radius of 1,000 feet around the fireworks launch sites.

(b) *Definitions.* As used in this section, "designated representative" means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the designated representative. Persons and vessels may request permission to enter the safety zones on VHF-16 or through the 24-hour Command Center at telephone (415) 399-3547.

(d) *Effective period.* This section is effective from 8:45 a.m. through 10 p.m. on October 9 and 8:45 a.m. through 10 p.m. on October 10, 2009.

Dated: July 16, 2009.

P.M. Gugg,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. E9-18494 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-15-P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 351

[Docket No. RM 2009-5]

Proceedings of the Copyright Royalty Board; Remand

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Interim rule and request for comments.

SUMMARY: The Copyright Royalty Board is issuing an interim regulation to amend its procedural regulations to include a provision governing remands of final determinations pursuant to the Copyright Act, which sets forth in significant detail the procedural structure to be followed by the Copyright Royalty Judges in making determinations to distribute royalty fees and establish royalty rates and terms under the various statutory licenses of the Copyright Act. The Judges have adopted regulations governing the conduct of these proceedings.

DATES: *Effective Date:* August 4, 2009.

Comments are due no later than September 3, 2009.

ADDRESSES: Comments may be sent electronically to crb@loc.gov. In the alternative, send an original, five copies, and an electronic copy on a CD either by mail or hand delivery. Please do not use multiple means of transmission. Comments may not be delivered by an overnight delivery service other than the U.S. Postal Service Express Mail. If by mail (including overnight delivery), comments must be addressed to: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024-0977. If hand delivered by a private party, comments must be brought to the Copyright Office Public Information Office, Library of Congress, James Madison Memorial Building, Room LM-401, 101 Independence Avenue, SE., Washington, DC 20559-6000. If delivered by commercial courier, comments must be delivered between 8:30 a.m. and 4 p.m. to the Congressional Courier Acceptance Site located at 2nd and D Street, NE., Washington, DC, and the envelope must be addressed to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM-403, 101 Independence Avenue, SE., Washington, DC 20559-6000.

FOR FURTHER INFORMATION CONTACT:

Richard Strasser, Senior Attorney, or Gina Giuffreda, Attorney Advisor, by telephone at (202) 707-7658 or e-mail at crb@loc.gov.

SUPPLEMENTARY INFORMATION: Section 803 of the Copyright Act, 17 U.S.C., sets forth in significant detail the procedural structure to be followed by the Copyright Royalty Judges in making determinations to distribute royalty fees and establish royalty rates and terms under the various statutory licenses of the Copyright Act. Pursuant to the authority granted us in 17 U.S.C. 803(b)(6), the Judges have adopted

regulations, set forth in Subchapter B, Chapter III of title 37 of the Code of Federal Regulations, governing the conduct of these proceedings. Every proceeding to distribute royalty fees or establish royalty rates and terms results in a final determination of the Judges that is reviewable by the United States Court of Appeals for the District of Columbia Circuit, 17 U.S.C. 803(d). The Court of Appeals may, inter alia, vacate a determination or portion thereof, and remand to the Judges for further action. Until today, the Judges did not have any procedural regulations in place for handling the disposition of a remand.

On July 7, 2009, and again on July 10, 2009, the Court of Appeals issued decisions reviewing the first two royalty rate proceedings conducted under the Copyright Royalty Judges system. *See SoundExchange, Inc. v. Librarian of Congress*, No. 08-1078, 2009 WL 1930180 (D.C. Cir. July 7, 2009); *Intercollegiate Broadcast System, Inc. v. Copyright Royalty Board*, No. 07-1123, 07-1168, 07-1172, 07-1174, 07-1177, 07-1178, 2009 WL 1978453 (D.C. Cir. July 10, 2009). Although the Court affirmed the determinations of the Judges in the main, each case remanded an issue for further consideration by the Judges. Lacking any regulations governing the procedures for disposing of remands, the adoption of today's interim regulation is necessary for these and any future cases.

The interim regulation provides that, within 45 days of the date of issuance of the mandate of a decision of the Court of Appeals remanding a determination of the Judges, the parties to the proceeding shall submit, in writing, their proposals setting forth the procedures and schedule to be followed in addressing the remand. The interim rule is purposely flexible to permit the Judges, and the parties, to address the particulars of each remand before the Judges in an effort to promote administrative efficiency and reduce costs.

Interested parties are encouraged to offer comments as to the interim regulation as well as propose any additional procedures or regulations necessary for the handling of remands.

List of Subjects in 37 CFR Part 351

Administrative practice and procedure, Copyright.

Interim Regulation

■ For the reasons set forth in the preamble, the Copyright Royalty Judges are amending part 351 of 37 CFR as follows:

PART 351—PROCEEDINGS

■ 1. The authority citation for part 351 is revised to read as follows:

Authority: 17 U.S.C. 803.

■ 2. Part 351 is amended by adding § 351.15 to read as follows:

§ 351.15 Remand.

In the event of a remand from the United States Court of Appeals for the District of Columbia Circuit of a final determination of the Copyright Royalty Judges, the parties to the proceeding shall within 45 days from the issuance of the mandate from the Court of Appeals file with the Judges written proposals for the conduct and schedule of the resolution of the remand.

Dated: July 16, 2009.

James Scott Sledge,
U.S. Chief Copyright Royalty Judge.

James H. Billington,
The Librarian of Congress.

[FR Doc. E9-18462 Filed 8-3-09; 8:45 am]

BILLING CODE 1410-72-P

POSTAL REGULATORY COMMISSION**39 CFR Part 3020**

[Docket Nos. MC2009-31 and CP2009-42; Order No. 255]

Express Mail and Priority Mail Contract

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding Express Mail & Priority Mail Contract 6 to the Competitive Product List. This action is consistent with changes in a recent law governing postal operations. Republication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

DATES: Effective August 4, 2009 and is applicable beginning July 27, 2009.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202-789-6820 and stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION: *Regulatory History*, 74 FR 33481 (July 13, 2009).

- I. Introduction
- II. Background
- III. Information Request
- IV. Comments
- V. Commission Analysis
- VI. Ordering Paragraphs

I. Introduction

The Postal Service seeks to add a new product identified as Express Mail & Priority Mail Contract 6 to the

Competitive Product List. For the reasons discussed below, the Commission approves the Request.

II. Background

On July 2, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30, *et seq.*, to add Express Mail & Priority Mail Contract 6 to the Competitive Product List.¹ On July 6, 2009, the Postal Service filed a revised version of its filing which includes attachments inadvertently omitted from the July 2, 2009 request.² The Postal Service asserts that the Express Mail & Priority Mail Contract 6 product is a competitive product “not of general applicability” within the meaning of 39 U.S.C. 3632(b)(3). *Id.* at 1. The Request has been assigned Docket No. MC2009-31.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* The contract has been assigned Docket No. CP2009-42.

On July 8, 2009, the Postal Service filed under seal revised versions of the financial analysis workbooks originally filed under seal on July 2, 2009.³

In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors’ Decision authorizing the new product which also includes an analysis of Express Mail & Priority Mail Contract 6 and certification of the Governors’ vote;⁴ (2) a redacted version of the contract which, among other things, provides that the contract will expire 3 years from the effective date, which is proposed to be 1 day after the Commission issues all regulatory approvals;⁵ (3) requested changes in the Mail classification Schedule product list;⁶ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁷ and (5) certification of compliance with 39 U.S.C. 3633(a).⁸

¹ Request of the United States Postal Service to Add Express Mail & Priority Mail Contract 6 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, July 2, 2009.

² Errata to Request of the United States Postal Service to Add Express Mail & Priority Mail Contract 6 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, July 6, 2009 (Request).

³ See Notice of the United States Postal Service of Filing Under Seal of Revised Financial Analysis Workbooks for Express Mail & Priority Mail Contract 6, July 8, 2009 (Revised Workbooks).

⁴ Attachment A to the Request. The analysis that accompanies the Governors’ Decision notes, among other things, that the contract is not risk free, but concludes that the risks are manageable.

⁵ Attachment B to the Request.

⁶ Attachment C to the Request.

⁷ Attachment D to the Request.

⁸ Attachment E to the Request.

In the Statement of Supporting Justification, Mary Prince Anderson, Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service’s total institutional costs. *Id.*, Attachment D. Thus, Ms. Anderson contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.* W. Ashley Lyons, Manager, Regulatory Reporting and Cost Analysis, Finance Department, certifies that the contract complies with 39 U.S.C. 3633(a). *See Id.*, Attachment E.

The Postal Service filed much of the supporting materials, including the unredacted Governors’ Decision and the unredacted contract, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer’s name and the accompanying analyses that provide prices, terms, conditions, and financial projections, should remain confidential. *Id.* at 2-3.

In Order No. 239, the Commission gave notice of the two dockets, appointed a public representative, and provided the public with an opportunity to comment.⁹

III. Information Request

On July 14, 2009, the Chairman issued an information request seeking responses to six questions.¹⁰ The information request was filed under seal. *Id.* On July 20, 2009, the Postal Service filed its responses to CHIR No. 1.¹¹

IV. Comments

Comments were filed by the Public Representative.¹² No filings were submitted by other interested parties. The Public Representative states that the Postal Service’s filing complies with applicable Commission rules of practice

⁹ PRC Order No. 239, Notice and Order Concerning Express Mail & Priority Mail Contract 6 Negotiated Service Agreement, July 7, 2009 (Order No. 239).

¹⁰ Chairman’s Information Request No. 1 and Notice of Filing of Questions under Seal, July 14, 2009 (CHIR No. 1).

¹¹ See Notice of the United States Postal Service of Filing Response to Chairman’s Information Request No. 1 Under Seal, July 20, 2009 (Response to CHIR No. 1).

¹² Public Representative Comments in Response to United States Postal Service Request to Add Express Mail & Priority Mail Contract 6 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, July 15, 2009 (Public Representative Comments).

and concludes that the Express Mail & Priority Mail Contract 6 agreements comport with the requirements of title 39. *Id.* at 3–4. He further states that the agreement appears beneficial to the general public. *Id.* at 1.

The Public Representative notes that the Postal Service has provided adequate justification for maintaining confidentiality in this case. *Id.* at 2–3. He also points out several contractual provisions that he believes are mutually beneficial to the parties and general public. *Id.* at 3.

V. Commission Analysis

The Commission has reviewed the Request, the contract, the financial analysis provided under seal, the Revised Workbooks, the Response to CHIR No. 1, and the comments filed by the Public Representative.

Statutory requirements. The Commission's statutory responsibilities in this instance entail assigning Express Mail & Priority Mail Contract 6 to either the Market Dominant Product List or to the Competitive Product List. 39 U.S.C. 3642. As part of this responsibility, the Commission also reviews the proposal for compliance with the Postal Accountability and Enhancement Act (PAEA) requirements. This includes, for proposed competitive products, a review of the provisions applicable to rates for competitive products. 39 U.S.C. 3633.

Product list assignment. In determining whether to assign Express Mail & Priority Mail Contract 6 as a product to the Market Dominant Product List or the Competitive Product List, the Commission must consider whether

the Postal Service exercises sufficient market power that it can effectively set the price of such product substantially above costs, raise prices significantly, decrease quality, or decrease output, without risk of losing a significant level of business to other firms offering similar products.

39 U.S.C. 3642(b)(1). If so, the product will be categorized as market dominant. The competitive category of products shall consist of all other products.

The Commission is further required to consider the availability and nature of enterprises in the private sector engaged in the delivery of the product, the views of those who use the product and the likely impact on small business concerns. 39 U.S.C. 3642(b)(3).

The Postal Service asserts that its bargaining position is constrained by the existence of other shippers who can provide similar services, thus precluding it from taking unilateral action to increase prices without the risk of losing volume to private

companies. Request, Attachment D, at para. (d). The Postal Service also contends that it may not decrease quality or output without risking the loss of business to competitors that offer similar expedited delivery services. *Id.* It further states that the contract partner supports the addition of the contract to the Competitive Product List to effectuate the negotiated contractual terms. *Id.* at para. (g). Finally, the Postal Service states that the market for expedited delivery services is highly competitive and requires a substantial infrastructure to support a national network. It indicates that large carriers serve this market. Accordingly, the Postal Service states that it is unaware of any small business concerns that could offer comparable service for this customer. *Id.* at para. (h).

No commenter opposes the proposed classification of Express Mail & Priority Mail Contract 6 as competitive. Having considered the statutory requirements and the support offered by the Postal Service, the Commission finds that Express Mail & Priority Mail Contract 6 is appropriately classified as a competitive product and should be added to the Competitive Product List.

Cost considerations. The Postal Service presents a financial analysis showing that Express Mail & Priority Mail Contract 6 results in cost savings while ensuring that the contract covers its attributable costs, does not result in subsidization of competitive products by market dominant products, and increases contribution from competitive products.

Based on the data submitted, the Commission finds that Express Mail & Priority Mail Contract 6 should cover its attributable costs (39 U.S.C. 3633(a)(2)), should not lead to the subsidization of competitive products by market dominant products (39 U.S.C. 3633(a)(1)), and should have a positive effect on competitive products' contribution to institutional costs (39 U.S.C. 3633(a)(3)). Thus, an initial review of proposed Express Mail & Priority Mail Contract 6 indicates that it comports with the provisions applicable to rates for competitive products.

Other considerations. The Postal Service shall promptly notify the Commission of the scheduled termination date of the agreement. If the agreement terminates earlier than anticipated, the Postal Service shall inform the Commission prior to the new termination date. The Commission will then remove the product from the Mail Classification Schedule at the earliest possible opportunity.

In conclusion, the Commission approves Express Mail & Priority Mail

Contract 6 as a new product. The revision to the Competitive Product List is shown below the signature of this Order and is effective upon issuance of this order.

VI. Ordering Paragraphs

It is ordered:

1. Express Mail & Priority Mail Contract 6 (MC2009–31 and CP2009–42) is added to the Competitive Product List as a new product under Negotiated Service Agreements, Domestic.

2. The Postal Service shall notify the Commission of the scheduled termination date and update the Commission if termination occurs prior to that date, as discussed in this order.

3. The Secretary shall arrange for the publication of this order in the **Federal Register**.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure; Postal Service.

Issued: July 27, 2009.

By the Commission.

Judith M. Grady,
Acting Secretary.

■ For the reasons stated in the preamble, under the authority at 39 U.S.C. 503, the Postal Regulatory Commission amends 39 CFR part 3020 as follows:

PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to Subpart A of Part 3020—Mail Classification Schedule to read as follows:

Part A—Market Dominant Products

1000 Market Dominant Product List

First-Class Mail

Single-Piece Letters/Postcards

Bulk Letters/Postcards

Flats

Parcels

Outbound Single-Piece First-Class Mail

International

Inbound Single-Piece First-Class Mail

International

Standard Mail (Regular and Nonprofit)

High Density and Saturation Letters

High Density and Saturation Flats/Parcels

Carrier Route

Letters

Flats

Not Flat-Machinables (NFM)/Parcels

Periodicals

Within County Periodicals

Outside County Periodicals

Package Services

Single-Piece Parcel Post

Inbound Surface Parcel Post (at UPU rates)

Bound Printed Matter Flats

Bound Printed Matter Parcels

Media Mail/Library Mail	Ancillary Services	[Reserved for Product Description]
Special Services	[Reserved for Product Description]	Bookspan Negotiated Service Agreement
Ancillary Services	Address Correction Service	[Reserved for Product Description]
International Ancillary Services	[Reserved for Product Description]	Bank of America Corporation Negotiated Service Agreement
Address List Services	Applications and Mailing Permits	The Bradford Group Negotiated Service Agreement
Caller Service	[Reserved for Product Description]	
Change-of-Address Credit Card	Business Reply Mail	
Authentication	[Reserved for Product Description]	
Confirm	Bulk Parcel Return Service	
International Reply Coupon Service	[Reserved for Product Description]	
International Business Reply Mail Service	Certified Mail	
Money Orders	[Reserved for Product Description]	
Post Office Box Service	Certificate of Mailing	
Negotiated Service Agreements	[Reserved for Product Description]	
HSBC North America Holdings Inc.	Collect on Delivery	
Negotiated Service Agreement	[Reserved for Product Description]	
Bookspan Negotiated Service Agreement	Delivery Confirmation	
Bank of America corporation Negotiated Service Agreement	[Reserved for Product Description]	
The Bradford Group Negotiated Service Agreement	Insurance	
Inbound International	[Reserved for Product Description]	
Canada Post—United States Postal Service	Merchandise Return Service	
Contractual Bilateral Agreement for	[Reserved for Product Description]	
Inbound Market Dominant Services	Parcel Airlift (PAL)	
Market Dominant Product Descriptions	[Reserved for Product Description]	
First-Class Mail	Registered Mail	
[Reserved for Class Description]	[Reserved for Product Description]	
Single-Piece Letters/Postcards	Return Receipt	
[Reserved for Product Description]	[Reserved for Product Description]	
Bulk Letters/Postcards	Return Receipt for Merchandise	
[Reserved for Product Description]	[Reserved for Product Description]	
Flats	Restricted Delivery	
[Reserved for Product Description]	[Reserved for Product Description]	
Parcels	Shipper-Paid Forwarding	
[Reserved for Product Description]	[Reserved for Product Description]	
Outbound Single-Piece First-Class Mail	Signature Confirmation	
International	[Reserved for Product Description]	
[Reserved for Product Description]	Special Handling	
Inbound Single-Piece First-Class Mail	[Reserved for Product Description]	
International	Stamped Envelopes	
[Reserved for Product Description]	[Reserved for Product Description]	
Standard Mail (Regular and Nonprofit)	Stamped Cards	
[Reserved for Class Description]	[Reserved for Product Description]	
High Density and Saturation Letters	Premium Stamped Stationery	
[Reserved for Product Description]	[Reserved for Product Description]	
High Density and Saturation Flats/Parcels	Premium Stamped Cards	
[Reserved for Product Description]	[Reserved for Product Description]	
Carrier Route	International Ancillary Services	
[Reserved for Product Description]	[Reserved for Product Description]	
Letters	International Certificate of Mailing	
[Reserved for Product Description]	[Reserved for Product Description]	
Flats	International Registered Mail	
[Reserved for Product Description]	[Reserved for Product Description]	
Not Flat-Machinables (NFM)s/Parcels	International Return Receipt	
[Reserved for Product Description]	[Reserved for Product Description]	
Periodicals	International Restricted Delivery	
[Reserved for Class Description]	[Reserved for Product Description]	
Within County Periodicals	Address List Services	
[Reserved for Product Description]	[Reserved for Product Description]	
Outside County Periodicals	Caller Service	
[Reserved for Product Description]	[Reserved for Product Description]	
Package Services	Change-of-Address Credit Card	
[Reserved for Class Description]	Authentication	
Single-Piece Parcel Post	[Reserved for Product Description]	
[Reserved for Product Description]	Confirm	
Inbound Surface Parcel Post (at UPU rates)	[Reserved for Product Description]	
[Reserved for Product Description]	International Reply Coupon Service	
Bound Printed Matter Flats	[Reserved for Product Description]	
[Reserved for Product Description]	International Business Reply Mail Service	
Bound Printed Matter Parcels	[Reserved for Product Description]	
[Reserved for Product Description]	Money Orders	
Media Mail/Library Mail	[Reserved for Product Description]	
[Reserved for Product Description]	Post Office Box Service	
Special Services	[Reserved for Product Description]	
[Reserved for Class Description]	Negotiated Service Agreements	
	[Reserved for Class Description]	
	HSBC North America Holdings Inc.	
	Negotiated Service Agreement	
		[Reserved for Product Description]
		Bookspan Negotiated Service Agreement
		[Reserved for Product Description]
		Bank of America Corporation Negotiated Service Agreement
		The Bradford Group Negotiated Service Agreement
		Part B—Competitive Products
		Competitive Product List
		Express Mail
		Express Mail
		Outbound International Expedited Services
		Inbound International Expedited Services
		Inbound International Expedited Services 1 (CP2008–7)
		Inbound International Expedited Services 2 (MC2009–10 and CP2009–12)
		Priority Mail
		Priority Mail
		Outbound Priority Mail International
		Inbound Air Parcel Post
		Royal Mail Group Inbound Air Parcel Post Agreement
		Parcel Select
		Parcel Return Service
		International
		International Priority Airlift (IPA)
		International Surface Airlift (ISAL)
		International Direct Sacks—M—Bags
		Global Customized Shipping Services
		Inbound Surface Parcel Post (at non-UPU rates)
		Canada Post—United States Postal service
		Contractual Bilateral Agreement for
		Inbound Competitive Services (MC2009–8 and CP2009–9)
		International Money Transfer Service
		International Ancillary Services
		Special Services
		Premium Forwarding Service
		Negotiated Service Agreements
		Domestic
		Express Mail Contract 1 (MC2008–5)
		Express Mail Contract 2 (MC2009–3 and CP2009–4)
		Express Mail Contract 3 (MC2009–15 and CP2009–21)
		Express Mail & Priority Mail Contract 1 (MC2009–6 and CP2009–7)
		Express Mail & Priority Mail Contract 2 (MC2009–12 and CP2009–14)
		Express Mail & Priority Mail Contract 3 (MC2009–13 and CP2009–17)
		Express Mail & Priority Mail Contract 4 (MC2009–17 and CP2009–24)
		Express Mail & Priority Mail Contract 5 (MC2009–18 and CP2009–25)
		Express Mail & Priority Mail Contract 6 (MC2009–31 and CP2009–42)
		Parcel Return Service Contract 1 (MC2009–1 and CP2009–2)
		Priority Mail Contract 1 (MC2008–8 and CP2008–26)
		Priority Mail Contract 2 (MC2009–2 and CP2009–3)
		Priority Mail Contract 3 (MC2009–4 and CP2009–5)
		Priority Mail Contract 4 (MC2009–5 and CP2009–6)
		Priority Mail Contract 5 (MC2009–21 and CP2009–26)
		Priority Mail Contract 6 (MC2009–25 and CP2009–30)
		Priority Mail Contract 7 (MC2009–25 and CP2009–31)

Priority Mail Contract 8 (MC2009–25 and CP2009–32)
 Priority Mail Contract 9 (MC2009–25 and CP2009–33)
 Priority Mail Contract 10 (MC2009–25 and CP2009–34)
 Priority Mail Contract 11 (MC2009–27 and CP2009–37)
 Priority Mail Contract 12 (MC2009–28 and CP2009–38)
 Priority Mail Contract 13 (MC2009–29 and CP2009–39)
 Priority Mail Contract 14 (MC2009–30 and CP2009–40)
 Outbound International
 Global Direct Contracts (MC2009–9, CP2009–10, and CP2009–11)
 Global Expedited Package Services (GEPS) Contracts
 GEPS 1 (CP2008–5, CP2008–11, CP2008–12, and CP2008–13, CP2008–18, CP2008–19, CP2008–20, CP2008–21, CP2008–22, CP2008–23, and CP2008–24)
 Global Plus Contracts
 Global Plus 1 (CP2008–9 and CP2008–10)
 Global Plus 2 (MC2008–7, CP2008–16 and CP2008–17)
 Inbound International
 Inbound Direct Entry Contracts with Foreign Postal Administrations (MC2008–6, CP2008–14 and CP2008–15)
 International Business Reply Service
 Competitive Contract 1 (MC2009–14 and CP2009–20)
 Competitive Product Descriptions
 Express Mail
 [Reserved for Group Description]
 Express Mail
 [Reserved for Product Description]
 Outbound International Expedited Services
 [Reserved for Product Description]
 Inbound International Expedited Services
 [Reserved for Product Description]
 Priority
 [Reserved for Product Description]
 Priority Mail
 [Reserved for Product Description]
 Outbound Priority Mail International
 [Reserved for Product Description]
 Inbound Air Parcel Post
 [Reserved for Product Description]
 Parcel Select
 [Reserved for Group Description]
 Parcel Return Service
 [Reserved for Group Description]
 International
 [Reserved for Group Description]
 International Priority Airlift (IPA)
 [Reserved for Product Description]
 International Surface Airlift (ISAL)
 [Reserved for Product Description]
 International Direct Sacks—M-Bags
 [Reserved for Product Description]
 Global Customized Shipping Services
 [Reserved for Product Description]
 International Money Transfer Service
 [Reserved for Product Description]
 Inbound Surface Parcel Post (at non-UPU rates)
 [Reserved for Product Description]
 International Ancillary Services
 [Reserved for Product Description]
 International Certificate of Mailing
 [Reserved for Product Description]
 International Registered Mail
 [Reserved for Product Description]

International Return Receipt
 [Reserved for Product Description]
 International Restricted Delivery
 [Reserved for Product Description]
 International Insurance
 [Reserved for Product Description]
 Negotiated Service Agreements
 [Reserved for Group Description]
 Domestic
 [Reserved for Product Description]
 Outbound International
 [Reserved for Group Description]
 Part C—Glossary of Terms and Conditions
 [Reserved]
 Part D—Country Price Lists for International Mail [Reserved]

[FR Doc. E9–18593 Filed 8–3–09; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2009–0033; FRL–8939–7]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of West Virginia. This revision establishes budget trading programs for nitrogen oxides (NO_x) annual, NO_x ozone season, and sulfur dioxides (SO₂) annual emissions to address the requirements of EPA's Clean Air Interstate Rule (CAIR), and recodifies and revises provisions pertaining to internal combustion engines and cement kilns that are subject to the NO_x SIP Call. West Virginia will meet its CAIR requirements by participating in the EPA-administered regional cap-and-trade program for NO_x annual, NO_x ozone season, and SO₂ annual emissions. EPA is determining that the SIP revision fully implements the CAIR requirements for West Virginia. Although the D.C. Circuit found CAIR to be flawed, the rule was remanded without vacatur and thus remains in place. Thus, EPA is continuing to take action on CAIR SIPs as appropriate. CAIR, as promulgated, requires States to reduce emissions of SO₂ and NO_x that significantly contribute to, or interfere with maintenance of, the national ambient air quality standards (NAAQS) for fine particulates and/or ozone in any downwind State. CAIR establishes budgets for SO₂ and NO_x for States that contribute significantly to nonattainment in downwind States and

requires the significantly contributing States to submit SIP revisions that implement these budgets. States have the flexibility to choose which control measures to adopt to achieve the budgets, including participation in EPA-administered cap-and-trade programs addressing SO₂, NO_x annual, and NO_x ozone season emissions. In the SIP revision that EPA is approving, West Virginia will meet CAIR requirements by participating in these cap-and-trade programs. EPA is approving the SIP revision, as interpreted and clarified herein, as fully implementing the CAIR requirements for West Virginia. Consequently, this action will also cause the CAIR Federal Implementation Plans (CAIR FIPs) concerning SO₂, NO_x annual, and NO_x ozone season emissions by West Virginia sources to be automatically withdrawn.

DATES: *Effective Date:* The final rule is effective on August 4, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2009–0033. All documents in the docket are listed in the <http://www.regulations.gov> Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.*, confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street, SE., Charleston, WV 25304.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by e-mail at powers.marilyn@epa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. What Action Did EPA Propose?
- II. Summary of West Virginia SIP Revision
- III. Final Action
- IV. What Is the Effective Date?
- V. Statutory and Executive Order Reviews

I. What Action Did EPA Propose?

On June 11, 2009 (74 FR 27731), EPA published a notice of proposed rulemaking (NPR) for the State of West Virginia. The NPR proposed approval of a revision to the West Virginia SIP that

addresses EPA's CAIR requirements and recodifies and revises provisions pertaining to internal combustion engines and cement kilns that are subject to the NO_x SIP Call. The formal SIP revision was submitted by West Virginia on April 22, 2008.

II. Summary of West Virginia SIP Revision

On April 22, 2008, the West Virginia Department of Environmental Protection (WVDEP) submitted a full CAIR SIP revision to meet the requirements of CAIR, which was promulgated on May 12, 2005 (70 FR 25162), and subsequently revised on April 28, 2006, and December 13, 2006. The SIP revision is comprised of new regulations as follows: 45CSR39—NO_x Annual Trading Program; 45CSR40—NO_x Ozone Season Trading Program; and 40CSR41—SO₂ Annual Trading Program. The regulations address all the requirements of the part 96 model rules set forth in the May 12, 2005 CAIR rulemaking.

On June 11, 2009 (74 FR 27731), EPA published a notice of proposed rulemaking (NPR) to approve West Virginia's CAIR SIP revision. A detailed discussion of the CAIR requirements, the CAIR history (including the CAIR remand), West Virginia's CAIR submittal, and EPA's rationale for approval of West Virginia's CAIR SIP revision may be found in the NPR and will not be repeated here. The NPR also includes a discussion of the recodification and revisions pertaining to internal combustion engines and cement kilns that are subject to the NO_x SIP Call.

On June 11, 2009, EPA received a comment from the West Virginia Department of Environmental Protection noting that the amount of Compliance Supplement Pool allowances in the NPR was incorrect. This comment was addressed by a correction notice published on July 6, 2009 (74 FR 31904).

III. Final Action

EPA is approving West Virginia's CAIR SIP revision submitted on April 22, 2008. Under the SIP revision, West Virginia will participate in the EPA-administered cap-and-trade programs for NO_x annual, NO_x ozone season, and SO₂ annual emissions. The SIP revision meets the applicable requirements in 40 CFR 51.123(o) and (aa), with regard to NO_x annual and NO_x ozone season emissions, and 40 CFR 51.124(o), with regard to SO₂ emissions. As a consequence of the SIP approval, the CAIR FIPs for West Virginia are automatically withdrawn, in accordance

with the automatic withdrawal provisions of EPA's November 2, 2007 rulemaking (72 FR 62338). The automatic withdrawal is reflected in the rule text that accompanies this notice and deletes and reserves the provisions in Part 52 that establish the CAIR FIPs for West Virginia sources. EPA is also approving the recodification and revisions to West Virginia provisions pertaining to internal combustion engines and cement kilns.

IV. What Is the Effective Date?

EPA finds that there is good cause for this approval to become effective upon publication because a delayed effective date is unnecessary due to the nature of the approval, which allows the State, as indicated in the NPR for this rulemaking, to include its non-electric generating units, implement its allowance allocations and remove the opt in provisions of the FIP. The expedited effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rule actions may become effective less than 30 days after publication if the rule "grants or recognizes an exemption or relieves a restriction" and section 5 U.S.C. 553(d)(3), which allows an effective date less than 30 days after publication "as otherwise provided by the agency for good cause found and published with the rule."

CAIR SIP approvals relieve states and CAIR sources within states from being subject to provisions in the CAIR FIPs that otherwise would apply to them, allowing states to implement CAIR based on their SIP-approved State rule. The relief from these obligations is sufficient reason to allow an expedited effective date of this rule under 5 U.S.C. 553(d)(1). In addition, West Virginia's relief from these obligations provides good cause to make this rule effective immediately upon publication, pursuant to 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in 5 U.S.C. 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Where, as here, the final rule relieves obligations rather than imposes obligations, affected parties, such as the State of West Virginia and CAIR sources within the State, do not need time to adjust and prepare before the rule takes effect.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the

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

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

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

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 5, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for

the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action to approve West Virginia's CAIR rules may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: July 22, 2009.

Judith M. Katz,

Acting Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart XX—West Virginia

■ 2. In § 52.2520, the table in paragraph (c) is amended by:

■ a. Adding entries for Sections 45–39–1 through 45–39–8, 45–39–10 through 45–39–15, 45–39–20 through 45–39–24, 45–39–43, 45–39–51 through 45–39–57, 45–39–60 through 45–39–62, and 45–39–70 through 45–39–75, 45–39–90.

■ b. Revising the entries for 45–39–40, 45–39–41, and 45–39–42.

■ c. Adding entries for 45–40–1 through 45–40–8, 45–40–10 through 45–40–15, 45–40–20 through 45–40–24, 45–40–43, 45–40–51 through 45–40–57, 45–40–60 through 45–40–62, 45–40–70 through 45–40–75, and 45–40–90 through 45–40–110.

■ d. Revising the entries for 45–40–40, 45–40–41, and 45–40–42.

■ e. Adding entries at the end of the table for 45–41–1 through 45–41–8, 45–41–10 through 45–41–15, 45–41–20 through 45–41–24, 45–41–51 through 45–41–57, 45–41–60 through 45–41–62, 45–41–70 through 45–41–75, and 45–41–90.

The amendment reads as follows:

§ 52.2520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
*	*	*	*	*
[45 CSR] Series 39 Control of Annual Nitrogen Oxide Emissions To Mitigate Interstate Transport of Fine Particle Matter and Nitrogen Oxides				
Section 45–39–1	General	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–2	Definitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–3	Measurements, Abbreviations and Acronyms	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–4	Applicability	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–5	Retired Unit Exemptions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–6	Standard Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–7	Computation of Time	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–8	Appeal Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–10	Authorization and Responsibilities of the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–39–11	Alternate CAIR Designated Representative	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–12	Changing the CAIR Designated Representative and Alternate CAIR Designated Representative; Changes in Owners and Operators.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–13	Certificate of Representation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–14	Objections Concerning the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–15	Delegation by CAIR Designated Representative and alternate CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–20	General CAIR NO _x Annual Trading Program Permit Requirements.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–21	Submission of CAIR Permit Applications	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–22	Information Requirements for CAIR Permit Applications.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–23	CAIR Permit Contents and Term	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–24	CAIR Permit Revisions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–40	CAIR NO _x Annual Trading Budget	5/1/08	8/4/09 [Insert page number where the document begins].	Adding annual trading budget for 2015 and thereafter.
Section 45–39–41	Timing Requirements for CAIR NO _x Annual Allowance Allocations.	5/1/08	8/4/09 [Insert page number where the document begins].	Adding requirements that apply to 2015 and thereafter.
Section 45–39–42	CAIR NO _x Annual Allowance Allocations	5/1/08	8/4/09 [Insert page number where the document begins].	Adding requirements that apply to 2015 and thereafter.
Section 45–39–43	Compliance Supplement Pool	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–51	Establishment of Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–52	Responsibilities of CAIR Authorized Account Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–53	Recordation of CAIR NO _x Annual Allowance Allocations.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–54	Compliance with CAIR NO _x Emissions Limitation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–55	Banking	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–56	Account Error	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–57	Closing of General Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–60	Submission of CAIR NO _x Annual Allowance Transfers.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–61	U.S. EPA Recordation	5/1/08	8/4/09 [Insert page number where the document begins].	

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–39–62	Notification	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–70	General Monitoring and Reporting Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–71	Initial Certification and Recertification Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–72	Out of Control Periods	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–73	Notifications	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–74	Recordkeeping and Reporting	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–75	Petitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–39–90	Inconsistency Between Rules	5/1/08	8/4/09 [Insert page number where the document begins].	
[45 CSR] Series 40 Control of Ozone Season Nitrogen Oxide Emissions To Mitigate Interstate Transport of Ozone and Nitrogen Oxides				
Section 45–40–1	General	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–2	Definitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–3	Measurements, Abbreviations and Acronyms	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–4	Applicability	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–5	Retired Unit Exemption	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–6	Standard Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–7	Computation of Time	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–8	Appeal Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–10	Authorization and Responsibilities of the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–11	Alternate CAIR Designated Representative	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–12	Changing the CAIR Designated Representative and Alternate CAIR Designated Representative; Changes in Owners and Operators.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–13	Certificate of Representation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–14	Objections Concerning the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–15	Delegation by CAIR Designated Representative and alternate CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–40–20	General CAIR NO _x Ozone Season Trading Program Permit Requirements.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–21	Submission of CAIR Permit Applications	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–22	Information Requirements for CAIR Permit Applications.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–23	CAIR Permit Contents and Term	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–24	CAIR Permit Revisions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–40	CAIR NO _x Ozone Season Trading Budget	5/1/08	8/4/09 [Insert page number where the document begins].	Adding ozone season trading budget for 2015 and thereafter, and non-EGU budget.
Section 45–40–41	Timing Requirements for CAIR NO _x Ozone Season Allowance Allocations.	5/1/08	8/4/09 [Insert page number where the document begins].	Adding requirements that apply to 2015 and thereafter.
Section 45–40–42	CAIR NO _x Ozone Season Allowance Allocations	5/1/08	8/4/09 [Insert page number where the document begins].	Adding requirements that apply to 2015 and thereafter.
Section 45–40–43	CAIR NO _x Ozone Season Allowance Allocation for PPG Unit 002.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–51	Establishment of Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–52	Responsibilities of CAIR Authorized Account Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–53	Recordation of CAIR NO _x Ozone Season Allowance Allocations.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–54	Compliance with CAIR NO _x Emissions Limitation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–55	Banking	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–56	Account Error	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–57	Closing of General Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–60	Submission of CAIR NO _x Ozone Season Allowance Transfers.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–61	U.S. EPA Recordation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–62	Notification	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–70	General Monitoring and Reporting Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–71	Initial Certification and Recertification Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–72	Out of Control Periods	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–73	Notifications	5/1/08	8/4/09 [Insert page number where the document begins].	

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–40–74	Recordkeeping and Reporting	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–75	Petitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–90	Ozone Season NO _x Reduction Requirements for Stationary Internal Combustion Engines.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–100	Ozone Season NO _x Reduction Requirements for Emissions of NO _x from Cement Manufacturing Kilns.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–40–110	Inconsistency Between Rules	5/1/08	8/4/09 [Insert page number where the document begins].	
[45 CSR] Series 41 Control of Annual Sulfur Dioxides Emissions To Mitigate Interstate Transport of Sulfur Dioxide				
Section 45–41–1	General	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–2	Definitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–3	Measurements, Abbreviations and Acronyms	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–4	Applicability	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–5	Retired Unit Exemption	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–6	Standard Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–7	Computation of Time	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–8	Appeal Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–10	Authorization and Responsibilities of the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–11	Alternate CAIR Designated Representative	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–12	Changing the CAIR Designated Representative and Alternate CAIR Designated Representative; Changes in Owners and Operators.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–13	Certificate of Representation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–14	Objections Concerning the CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–15	Delegation by CAIR Designated Representative and alternate CAIR Designated Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–20	General CAIR SO ₂ Trading Program Permit Requirements.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–21	Submission of CAIR Permit Applications	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–22	Information Requirements for CAIR Permit Applications.	5/1/08	8/4/09 [Insert page number where the document begins].	

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [Chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–41–23	CAIR Permit Contents and Term	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–24	CAIR Permit Revisions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–51	Establishment of Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–52	Responsibilities of CAIR Authorized Account Representative.	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–53	Recordation of CAIR SO ₂ Allowances	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–54	Compliance with CAIR SO ₂ Emission Limitation ...	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–55	Banking	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–56	Account Error	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–57	Closing of General Accounts	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–60	Submission of CAIR SO ₂ Allowance Transfers	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–61	U.S. EPA Recordation	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–62	Notification	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–70	General Monitoring and Reporting Requirements	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–71	Initial Certification and Recertification Procedures	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–72	Out of Control Periods	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–73	Notifications	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–74	Recordkeeping and Reporting	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–75	Petitions	5/1/08	8/4/09 [Insert page number where the document begins].	
Section 45–41–90	Inconsistency Between Rules	5/1/08	8/4/09 [Insert page number where the document begins].	

* * * * *

§ 52.2540 [Removed and Reserved]

■ 3. Section 52.2540 is removed and reserved.

§ 52.2541 [Removed and Reserved]

■ 4. Section 52.2541 is removed and reserved.

[FR Doc. E9-18536 Filed 8-3-09; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 300**

[Docket No. 090130104-91027-02]

RIN 0648-AX60

International Fisheries; Western and Central Pacific Fisheries for Highly Migratory Species; Fishing Restrictions and Observer Requirements in Purse Seine Fisheries for 2009–2011 and Turtle Mitigation Requirements in Purse Seine Fisheries

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFC Implementation Act) to implement certain decisions of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC). Those decisions require that the members of the WCPFC, including the United States, take certain measures with respect to their purse seine fisheries in the area of competence of the WCPFC, which includes most of the western and central Pacific Ocean (WCPO). The regulations include limits on the number of days that may be fished, periods during which fishing may not be done on schools in association with fish aggregating devices (FADs), areas of high seas closed to fishing, requirements to retain tuna on board up to the first point of landing or transshipment, requirements to carry observers, and requirements to handle sea turtles in a specified manner. This action is necessary for the United States to satisfy its international obligations under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the

Western and Central Pacific Ocean (Convention), to which it is a Contracting Party.

DATES: The rule is effective August 3, 2009, except for the amendments to §§ 300.222(aa) and 300.223(f), which are effective October 5, 2009.

ADDRESSES: Copies of supporting documents that were prepared for this final rule, including the regulatory impact review (RIR) and environmental assessment (EA), as well as the proposed rule, are available via the Federal e-Rulemaking portal, at <http://www.regulations.gov>. Those documents, and the small entity compliance guide prepared for this final rule, are also available from the Regional Administrator, NMFS, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814-4700. The initial regulatory flexibility analysis (IRFA) and final regulatory flexibility analysis (FRFA) prepared for this rule are included in the proposed rule and this final rule, respectively.

FOR FURTHER INFORMATION CONTACT: Tom Graham, NMFS PIRO, 808-944-2219.

SUPPLEMENTARY INFORMATION:**Electronic Access**

This final rule is also accessible at <http://www.gpoaccess.gov/fr>.

Background

On June 1, 2009, NMFS published a proposed rule in the **Federal Register** (74 FR 26160) that would revise regulations at 50 CFR part 300, subpart O, in order to implement certain decisions of the WCPFC. The proposed rule was open to public comment through June 22, 2009.

This final rule is implemented under authority of the WCPFC Implementation Act (16 U.S.C. 6901 *et seq.*), which authorizes the Secretary of Commerce, in consultation with the Secretary of State and the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to promulgate such regulations as may be necessary to carry out the obligations of the United States under the Convention, including the decisions of the WCPFC. The authority to promulgate regulations has been delegated to NMFS.

The objective of this final rule is to implement, with respect to U.S. purse seine vessels, two Conservation and Management Measures (CMM) adopted by the WCPFC in December 2008, at its Fifth Regular Annual Session. The first is CMM 2008-01, “Conservation and Management Measure for Bigeye and Yellowfin Tuna in the Western and Central Pacific Ocean” The second is

CMM 2008-03, “Conservation and Management of Sea Turtles.”

The proposed rule includes further background information, including information on the Convention and the WCPFC, the international obligations of the United States under the Convention, the provisions of CMM 2008-01 and CMM 2008-03 as they relate to purse seine vessels, and the basis for the proposed regulations.

New Requirements

This final rule establishes the following requirements:

(1) Fishing Effort Limits

Limits are established for 2009 through 2011 on the number of fishing days that may be spent by the U.S. purse seine fleet on the high seas and in areas under U.S. jurisdiction (including the U.S. exclusive economic zone, or EEZ) within the Convention Area. First, there is a limit of 7,764 fishing days for the entire three-year 2009–2011 period. Second, there is a limit of 6,470 fishing days for each of the two-year periods 2009–2010 and 2010–2011. Third, there is a limit of 3,882 fishing days for each of the one-year periods 2009, 2010, and 2011. Once NMFS determines during any of these time periods that, based on information collected in vessel logbooks and other sources, the limit is expected to be reached by a specific future date, NMFS will issue a notice in the **Federal Register** announcing the closure of the purse seine fishery in the Convention Area on the high seas and in areas of U.S. jurisdiction, starting on that specific future date until the end of the applicable time period. Upon closure of the fishery, it will be prohibited to use a U.S. purse seine vessel to fish in the Convention Area on the high seas or in areas under U.S. jurisdiction, effective until the end of the applicable time period. NMFS will publish the notice at least seven calendar days before the effective date of the closure to provide fishermen advance notice of the closure.

(2) FAD Prohibition Periods

During specified periods in each of the years 2009, 2010, and 2011 it will be prohibited to set purse seines around FADs, deploy FADs, or service FADs or their associated electronic equipment in the Convention Area. It will be prohibited during these periods to set a purse seine within one nautical mile of a FAD or to set a purse seine in a manner intended to capture fish that have aggregated in association with a FAD, such as by setting the purse seine in an area from which a FAD has been moved or removed within the previous eight hours or setting the purse seine in

an area into which fish were drawn by a vessel from the vicinity of a FAD. FADs are defined to include both artificial and natural floating objects that are capable of aggregating fish. In 2009, the FAD prohibition period will be August 1 through September 30. In each of 2010 and 2011, it will be July 1 through September 30.

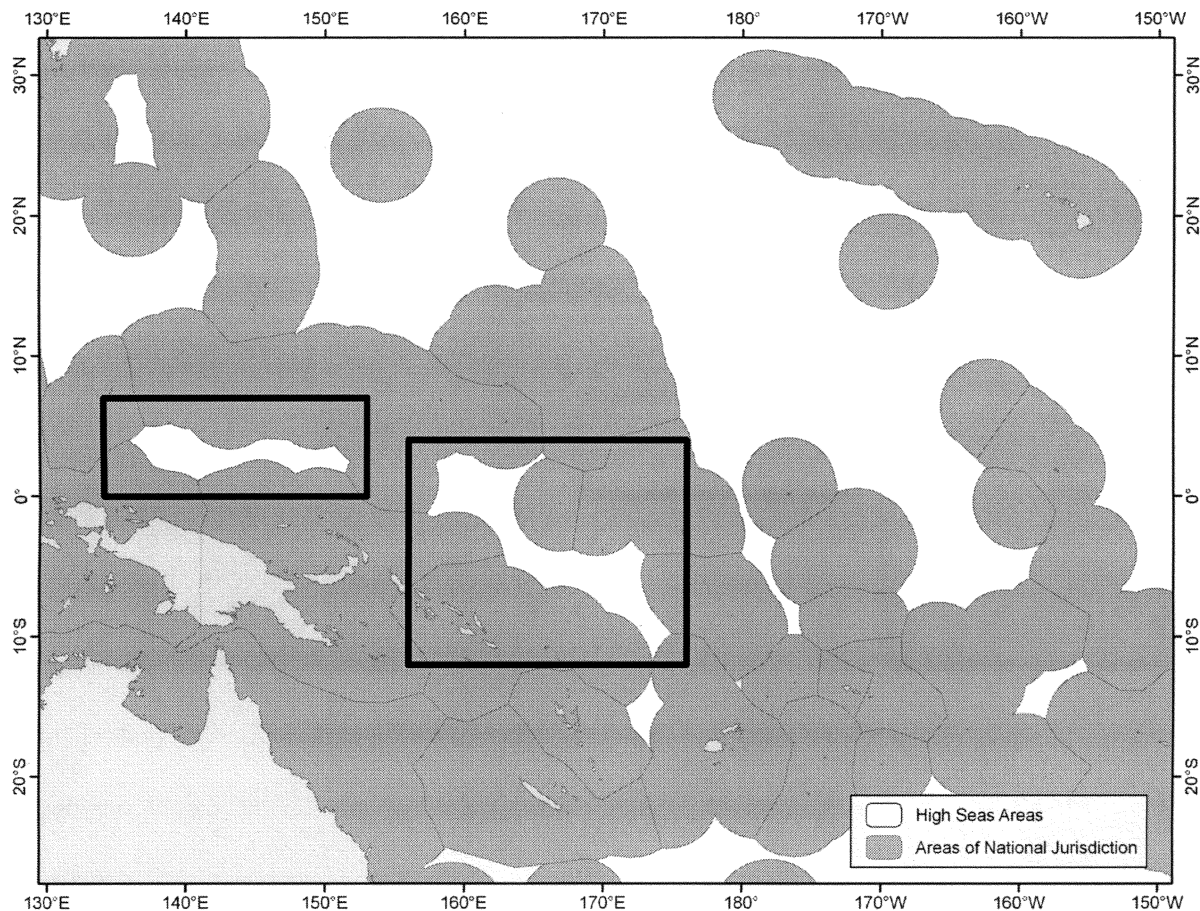
(3) High Seas Area Closures

Two areas will be closed to fishing by U.S. purse seine vessels from January 1, 2010, through December 31, 2011. The

areas are the two areas of high seas within the Convention Area that are depicted on the map in Figure 1. In CMM 2008–01, the WCPFC has reserved the option of reversing its adoption of the closed areas at its regular annual session in December 2009. If such a decision occurs, NMFS will take appropriate action to rescind, as appropriate, the closed areas that are established in this final rule.

Figure 1. High seas closed areas. Areas of high seas are indicated in

white; areas of claimed national jurisdiction, including territorial seas, archipelagic waters, and exclusive economic zones, are indicated in dark shading. Areas that will be closed to purse seine fishing from January 1, 2010, through December 31, 2011, are all high seas areas (in white) within the two rectangles bounded by the bold black lines. The coordinates of the two rectangles are set forth in the regulation. This map displays indicative maritime boundaries only.



(4) Catch Retention

It will be prohibited to discard any bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), or skipjack tuna (*Katsuwonus pelamis*) from a U.S. purse seine vessel at sea within the Convention Area. Exceptions are provided for fish that are unfit for human consumption for reasons other than their size, for the last set of the trip if there is insufficient well space to accommodate the entire catch, and for cases of serious malfunction of equipment that necessitate that fish be discarded. This requirement will become effective no earlier than January

1, 2010, and only upon NMFS' determination that an adequate number of WCPFC-approved observers is available for the purse seine vessels of all WCPFC members as necessary to ensure compliance by such vessels with the catch retention requirement. Once it makes that determination, NMFS will announce the effective date of the requirement in a notice published in the **Federal Register**. The requirement will then remain in effect through December 31, 2011.

(5) Observer Coverage

U.S. purse seine vessels must carry observers deployed as part of the

WCPFC Regional Observer Programme (WCPFC ROP) or deployed by NMFS on all trips in the Convention Area from August 1 through September 30, 2009 (the FAD prohibition period). It will also be required, from January 1, 2010, through December 31, 2011, that U.S. purse seine vessels carry WCPFC-approved observers on all trips in the Convention Area. These observer requirements will not apply to trips that take place exclusively within areas under the jurisdiction of the United States, including the U.S. EEZ and U.S. territorial sea, or under the jurisdiction of any other single nation. They also will not apply in cases where NMFS has

determined that an observer is not available.

(6) Sea Turtle Interaction Mitigation

U.S. purse seine vessels operating in the Convention Area must carry specific equipment and specific measures must be used on such vessels to disentangle, handle, and release sea turtles that are encountered in fishing gear, including purse seines and FADs. The required equipment is a dip net or turtle hoist that meets specified minimum design standards. The required measures are: immediately releasing sea turtles that are observed enclosed in purse seines; disentangling sea turtles that are observed entangled in purse seines or FADs; stopping net roll until a sea turtle is disentangled from a purse seine; resuscitating sea turtles that appear dead or comatose; and releasing sea turtles back to the ocean in a specified manner. Unlike the other elements of the final rule, these requirements are effective indefinitely.

Responses to Comments

Comment 1: It is vital to the survival of the U.S. purse seine fleet that the United States negotiate measures in regional fisheries management organizations (RFMO) that impose a comparable burden on all participants in the fishery, and that U.S. fishermen do not bear an unfair amount of the conservation burden. Furthermore, it is critical to the survival of the U.S. purse seine fleet that domestic regulations implementing RFMO measures not be significantly more burdensome on the U.S. fleet than those imposed on the fleet's foreign competitors. Also, it is the responsibility of the U.S. government to ensure that other governments implement substantially similar rules and regulations, and the U.S. government should promptly give notice to the appropriate RFMO of any shortcomings in the regulations and enforcement by other member countries of the RFMO.

Response: This comment does not pertain to the proposed rule itself. NMFS, as part of U.S. delegations to the WCPFC and other RFMOs, shares the view that all participants in affected fisheries should share comparable burdens when seeking to achieve conservation and management objectives, and NMFS applies this principle in its role as part of U.S. delegations to the WCPFC and other RFMOs. As part of such U.S. delegations, NMFS routinely endeavors to determine whether all RFMO members are satisfying their obligations to implement the decisions of the RFMOs, and to alert the RFMOs, as

appropriate, about any shortcomings in such implementation.

Comment 2: With respect to the proposed limits on fishing days, reports advising of the number of fishing days used to date should be issued on a monthly basis in order to assist vessels in planning their operations.

Response: NMFS recognizes the value of providing such information to affected fishing operations and will endeavor to provide it to the extent possible. NMFS intends to make periodic estimates and/or projections of the number of fishing days used and to make them publicly available in as timely a manner as possible. Exactly what information will be provided, how often it will be updated, when it will be provided, and how it will be disseminated to the public cannot be determined at this time.

Comment 3: The regulations should be clarified to say that upon the proposed August 1, 2009, start date of the FAD prohibition period, a purse seine vessel would be permitted to transit to port without an observer on board, provided that no fishing takes place during such transit.

Response: The proposed rule is consistent with the commenter's view. Under the proposed rule, it would be prohibited to use a U.S. vessel equipped with purse seine gear to "fish" in the Convention Area without an observer on board (with certain exemptions, not relevant to this comment). Under the proposed rule, "fishing" is defined to include searching for, catching, taking, or harvesting fish, as well as a number of other specific activities, but it does not include merely transiting or being at sea.

Comment 4: The activities related to fishing in association with FADs that would be prohibited during the FAD prohibition periods should be qualified to include the word "intentionally"; for example, it should not be prohibited to set a purse seine on a floating object if it is not done intentionally, such as if the object was submerged and not seen when the set is made.

Response: NMFS does not agree. In order to ensure that fishing on schools in association with FADs does not occur, it is necessary, for enforcement and compliance purposes, to prohibit all fishing in association with FADs. Even with the presence of an observer on board the vessel, requiring a determination of the intent behind the fishing vessel's activities would undermine the rule's effectiveness and unnecessarily complicate enforcement. However, the rule is aimed at ensuring that vessels do not fish on schools associated with FADs; therefore, factors

beyond the control of the vessel will, as always, be taken into consideration in the enforcement of this regulation.

Comment 5: During a FAD prohibition period, the following activities should not be prohibited: (1) in situations in which there are no FADs in the area of the fishing vessel, capturing a school of tuna that has aggregated under the fishing vessel; (2) capturing fish that are in the vicinity of a floating object but not associated with the object; and (3) removing a FAD from the water and securing it on the deck, provided that no servicing of the FAD takes place.

Response: Regarding activity (1), the commenter's view is consistent with the intent of the proposed rule; however, NMFS will revise the final rule to clarify that the meaning of a FAD does not include the purse seine vessel itself. Having said that, it is important to note that under the proposed rule it would be prohibited during a FAD prohibition period to set a purse seine in an area into which fish were drawn by a vessel from the vicinity of a FAD. Regarding activity (2), NMFS does not agree. Although fish may indeed be found in the vicinity of a FAD but not necessarily associated with it, NMFS finds that in order to ensure that fishing on schools in association with FADs does not occur, it is necessary to also prohibit fishing on schools that are merely in the vicinity of FADs. Under the proposed rule, this would be accomplished by prohibiting setting a purse seine within one nautical mile of a FAD. Regarding activity (3), the commenter's view is consistent with the intent of the proposed rule; however, NMFS will revise the final rule to clarify that during a FAD prohibition period it will not be prohibited to remove a FAD from the water, provided that it is not returned to the water.

Comment 6: Regarding the areas of high seas that would be closed to purse seine fishing in 2010 and 2011, consideration should be given to using MarZone, which is a geodetic software program specifically designed and developed to implement all provisions relating to the determination of maritime boundaries as set out in relevant articles of the United Nations Law of the Sea. The enforcement agencies of WCPFC member countries, including those of the United States, and vessel operators could best meet their responsibilities with the use of an accurate system, and the same system for mapping coordinates.

Response: NMFS recognizes that WCPFC members and their enforcement agencies do not all use the same tools to determine where a given geographical coordinate lies on the earth's surface,

and indeed, do not all necessarily agree on the same coordinates to describe a given boundary. NMFS agrees that use by all WCPFC members of common agreed-upon geodetic tools would enhance the collective ability of WCPFC members to satisfy their enforcement responsibilities under the Convention and would reduce the potential for misunderstandings and conflicts among WCPFC members. However, this issue is outside the scope of this rule; NMFS does not recognize any way in which the proposed rule could be revised to address the comment.

Comment 7: The proposed fishing effort limits are inconsistent with the provisions of CMM 2008–01, paragraph 10 of which establishes 2004 levels or the average of 2001–2004 as the baseline for the limits for the high seas. The proposed rule misconstrues the meaning and intent of CMM 2008–01 by asserting that the potential effort of all 40 U.S. purse seine vessel licenses authorized under the South Pacific Tuna Treaty (SPTT) should be included in the baseline levels of fishing effort for both the high seas and the U.S. EEZ, whereas paragraph 7 of CMM 2008–01, with its proviso that “the registration of bilateral agreements or arrangements does not provide a basis for establishing effort levels on the high seas,” explicitly prohibits such an expansion. Under NMFS’ proposal, the baseline effort level (and therefore the 2009–2011 effort limit) for the high seas would be expanded from 1,066 fishing days to 2,030 fishing days, and the EEZ baseline effort and 2009–2011 effort limit would be expanded from 279 days to 558 fishing days. NMFS should not attempt to circumvent the meaning or intent of CMM 2008–01, the unmistakable intent of which is to address depletion of bigeye tuna through, among other things, the imposition of purse seine effort limits reflective of those which occurred during the baseline period. If NMFS successfully applies the proposed methodology to the U.S. purse seine fleet, it must apply the same logic to the catch limits required in longline fisheries under CMM 2008–01, a proposed rule for which has not yet been published but alternatives for which are included in the EA for this purse seine-related proposed rule.

Response: NMFS disagrees with the comment that the proposed fishing effort limits are inconsistent with the provisions of CMM 2008–01. Paragraph 7 of CMM 2008–01 states that the determination of levels of fishing effort established in the CMM shall include, as applicable, fishing rights organized under existing regional or bilateral fisheries partnership agreements or

arrangements, subject to the following limitations: such agreements or arrangements have been registered with the WCPFC by December 2006 in accordance with CMM 2005–01 (a precursor of CMM 2008–01); the number of licenses authorized under such arrangements does not increase; and finally, that registered “bilateral agreements or arrangements” do not provide a basis for establishing effort levels on the high seas. Accordingly, CMM 2008–01, paragraph 7, clearly provides for effort determinations to be based on existing rights (rather than historical fishing effort) under regional agreements such as the SPTT, provided that they are not used as a means to circumvent the objectives of CMM 2008–01 for bigeye tuna by increasing the number of licenses authorized under such agreements. Under the SPTT, the number of U.S. purse seine vessels that may be authorized to fish in the SPTT Area, including its areas of high seas, is strictly limited to 45, five of which are reserved for vessels engaged in joint ventures with Pacific Island Parties to the SPTT. These fishing rights of the United States under the SPTT provide the basis under CMM 2008–01 for determining effort limits. That is, the determination of the effort limits is based on the product of the number of licenses available under the SPTT and the average numbers of fishing days spent per vessel on the high seas and in the U.S. EEZ in 2004. Finally, although CMM 2008–01 expressly prohibits the use of “bilateral agreements or arrangements” to establish effort levels on the high seas, such restriction does not apply to the SPTT, which is a regional fisheries agreement among seventeen parties. Clearly, the restriction is intended to prevent parties to such bilateral arrangements from circumventing the objectives of CMM 2008–01.

A portion of this comment refers to alternatives considered for the other action analyzed in the EA, “Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011,” which is not a part of this rulemaking. Although resubmission of this comment during the proposed rule comment period for that proposed rule is encouraged, NMFS will consider this comment, as appropriate, in the context of the longline-related rule. Please see response to comment 14 regarding how the two actions are treated together in the EA.

Comment 8: The proposed approach of using multiple-year management periods appears consistent with CMM 2008–01 with respect to the fishing effort limits in the U.S. EEZ, but not

with respect to the limits on the high seas. More importantly, nowhere does CMM 2008–01 contemplate combining effort limits for the two areas that would permit the allowable effort for either area to be exceeded by transferring effort from one to the other. NMFS should determine and implement separate limits for the two areas. If the two areas are combined, NMFS must consider and present the potential impacts on stocks, marine ecosystems, other fisheries, and domestic fishing communities of up to 2,588 purse seine fishing days being annually applied within the U.S. EEZ.

Response: Regarding the use of multiple-year periods for the purpose of the fishing effort limits, CMM 2008–01 does not specify that the limits must be implemented on an annual basis or on any other specific time scale. With respect to limiting fishing effort on the high seas, for example, paragraph 10 of CMM 2008–01 states that “the level of purse seine fishing effort in days fished [must] not exceed 2004 levels or the average of 2001–2004.” NMFS considered several alternative time scales for the fishing effort limits, including annual limits (including the calendar-year and the SPTT licensing-year, which runs from June 15 through June 14), a three-year limit, and the combination of one-year, two-year, and three-year limits, all of which NMFS believes are entirely consistent with the relevant requirements of CMM 2008–01. Based on the findings in the EA, RIR, and IRFA, NMFS concluded that the combination of one-year, two-year, and three-year limits would be the best alternative.

CMM 2008–01 does not prohibit WCPFC members from managing areas of high seas and areas under their national jurisdiction as a single area for the purpose of the required limits on fishing effort. NMFS believes that the proposed approach is not only consistent with CMM 2008–01, but also that it is, as concluded in the RIR and IRFA, the approach that would satisfy the requirements of CMM 2008–01 while minimizing adverse economic impacts (the alternative of establishing separate limits for the two areas was also considered in the RIR, IRFA, and EA see response to comment 16).

The objective of CMM 2008–01 is to reduce fishing mortality on bigeye tuna in the WCPO. The WCPFC has consistently treated bigeye tuna in the WCPO as a single stock for management purposes, and the objectives and approach of CMM 2008–01 continue that tradition. The separation in CMM 2008–01 of the high seas-related provisions from the national zone-related provisions has nothing to do

with differing management needs or objectives in the two respective areas. Rather, the two areas are treated separately because of the management approach adopted in CMM 2008–01. Specifically, CMM 2008–01 puts the responsibility to limit fishing effort in areas under national jurisdiction on coastal States, while the responsibility to limit fishing effort in areas of high seas is put on flag States. In the case where a WCPFC member is both a coastal State and a flag State with respect to purse seine vessels, such as the United States, it makes good sense for the WCPFC member to satisfy its dual responsibilities using measures that collectively are as effective and practical as possible. NMFS has attempted to do just that in considering an alternative that would combine the two areas and another alternative that would not. Because both alternatives would accomplish the objective of reducing fishing mortality on WCPO bigeye tuna by the required amount (i.e., by U.S. purse seine vessels operating on the high seas and by purse seine vessels in areas under U.S. jurisdiction, collectively), and because the alternative of combining the two areas is expected to result in lesser adverse economic impacts, NMFS adopted the alternative that would combine the two areas, and NMFS does not find good reason to revise the proposal.

With respect to considering potential impacts on stocks, marine ecosystems, other fisheries, and domestic fishing communities, NMFS has conducted the necessary environmental and economic analyses using the best available information and a reasonable range of assumptions. After considering historical fishing practices and patterns of the U.S. purse seine fleet in the region, NMFS does not agree with the commenter that the scenario presented of 2,588 purse seine fishing days being spent in the U.S. EEZ in a single year (i.e., essentially 100 percent of allowable fishing effort) is a reasonably foreseeable result of this action. During the years 1997–2007, the proportion of total fishing effort by the U.S. WCPO purse seine fleet that occurred in the U.S. EEZ ranged from 3 to 21 percent and averaged 7 percent (see Table 3 in the EA).

Comment 9: Regarding the minimum distance that would be required between a purse seine set and a FAD during a FAD prohibition period, the proposed one nautical mile is inadequate in terms of effectiveness and enforceability. A buffer zone of at least 10 miles is necessary to ensure that purse seine vessels do not act as de facto FADs and draw fish away from FADs,

as well as to allow enforcement of the requirement.

Response: NMFS has not identified any relevant standard or precedent adopted either in the United States or in international fisheries fora. However, NMFS has considered relevant deliberations in tuna RFMOs and regional fisheries bodies, including those within the Inter-American Tropical Tuna Commission, within the Pacific Islands Forum Fisheries Agency (FFA) on behalf of its members that are Parties to the Nauru Agreement (PNA), and within the WCPFC's Third Intersessional Working Group Regional Observer Programme. Based in part on those deliberations, as well as NMFS' own assessment of what an effective distance would be, NMFS believes that a distance of one nautical mile is appropriate. NMFS believes that the distance of 10 miles proposed by the commenter is impractical, in part because of the difficulty vessel operators would have in recognizing floating objects from such a great distance. NMFS does not find good reason to make any change from the proposed rule, but it recognizes that this aspect of the rule is largely untested, and NMFS intends to closely monitor its effectiveness and enforceability.

Comment 10: NMFS proposes to delay implementation of CMM 2008–01's catch retention requirement until an adequate number of observers is available for all (domestic and foreign) purse seine vessels managed under the WCPFC. The United States, whose purse seine fleet is already subject to 20 percent observer coverage, should take an immediate leadership role by implementing this important conservation and management measure as required under CMM 2008–01.

Response: Paragraph 27 of CMM 2008–01 states that the catch retention requirement is “subject to the Commission implementing the program in paragraph 28 for 100 percent coverage on purse seine vessels by the observers from the Regional Observer Program.” The proposed “delay” in implementation referred to by the commenter is in fact not a proposal to delay implementation, but simply a proposal to implement this aspect of paragraph 27 of CMM 2008–01. Specifically, the proposed regulations state that the catch retention requirement is contingent on a determination by NMFS that “an adequate number of WCPFC observers are available for the purse seine vessels of all Members of the Commission as necessary to ensure compliance by such vessels with the catch retention requirements established by the

Commission.” NMFS continues to find this aspect of the proposed rule to be consistent with CMM 2008–01.

Comment 11: The provisions in the proposed rule that would allow a purse seine vessel to be used to fish without an observer on board in cases that (1) the fishing trip is restricted entirely to areas under U.S. jurisdiction, or (2) NMFS determines an observer is not available, are inconsistent with paragraphs 13, 14, 28, and 29 of CMM 2008–01, which do not provide exemptions for such cases.

Response: Regarding the proposed rule's exemption for fishing trips that take place entirely in areas under U.S. jurisdiction, NMFS believes it is entirely consistent with CMM 2008–01. Paragraph 13 of CMM 2008–01 applies only to the high seas. Paragraphs 28 and 29 of CMM 2008–01 apply only to the following three cases (all within the Convention Area, between 20° N. and 20° S. lat.): (1) fishing exclusively on the high seas, (2) fishing on the high seas and in waters under the jurisdiction of one or more coastal States, and (3) fishing in waters under the jurisdiction of two or more coastal States. The case of fishing in waters under jurisdiction of a single coastal State is not included. This is consistent with the scope of the WCPFC ROP as established in Article 28.4 of the Convention, which states that WCPFC members shall ensure that their fishing vessels operating in the Convention Area are prepared to accept observers from the WCPFC ROP if required by the WCPFC, “except for vessels that operate exclusively within waters under the national jurisdiction of the flag State.” Paragraphs 12 and 14 of CMM 2008–01 speak to observer requirements for 2009 in areas under the jurisdiction of the flag State, but the requirement is only to implement measures that are “compatible” with those required under paragraph 11, which apply only to the WCPFC members that are PNA and not directly to the United States. NMFS finds the measures in the proposed rule to be compatible with those required of the PNA under paragraph 11 and, importantly, finds them consistent with the scope of the WCPFC ROP as established in Article 28.4 of the Convention.

Regarding the proposal to waive the observer requirement in cases that an observer is not available, NMFS agrees that CMM 2008–01 does not explicitly allow WCPFC members to provide exemptions for its vessels in such cases, but disagrees that it may not establish a waiver provision where, through no fault of the vessel, an observer is not available. During the 22 years that U.S.

purse seine vessels have operated in the WCPO, the fleet has maintained a 20-percent observer coverage rate using independent and impartial observers from various Pacific Island countries, deployed by the FFA Regional Observer Programme, based in Honiara, Solomon Islands. FFA observers are authorized to operate in the entire SPTT Area, which includes portions of the U.S. EEZ. Paragraphs 13, 14, 28, and 29 of CMM 2008-01 require that observers from the WCPFC ROP (or, in 2009 only, national observer programs) be deployed on purse seine vessels at levels of either 20 percent (in 2009, outside the FAD prohibition period) or 100 percent (at all other times in the years 2009-2011). The FFA Regional Observer Programme has received interim authorization under the WCPFC ROP, meaning that its observers are considered WCPFC ROP observers. At the 21st SPTT Formal Consultation, in Koror, Palau, the United States and the Pacific Island Parties to the SPTT agreed that the FFA Regional Observer Programme would continue to provide observer coverage for U.S. purse seine vessels as required under the SPTT, as well as provide the observers needed to satisfy the requirements for the United States of paragraphs 13, 14, 28, and 29 of CMM 2008-01. NMFS understands that the FFA is making preparations to move from the current 20-percent coverage rate under the SPTT to the 100-percent coverage rate required of U.S. purse seine vessels that fish any time between August 1 and September 30, 2009. NMFS anticipates that approximately 35 observers would be needed during that period, and that at least that number would be needed throughout 2010 and 2011. NMFS recognizes that accomplishing such a rapid increase may present considerable logistical and training challenges for the FFA Regional Observer Programme, and there is a possibility that the FFA would not be able to provide observers in a timely manner in all cases in which they are needed. The waiver provision included in the proposed rule is intended to address this circumstance, recognizing that fishing vessels could be prohibited from sailing due to circumstances outside their control and not of their making. The waivers would be granted on a trip-by-trip basis, and only upon a determination by the NMFS Pacific Islands Regional Administrator that an observer is not available. NMFS anticipates that such waivers would be granted rarely.

Comment 12: It is hoped that if an observer cannot be provided within 24 hours of a vessel's scheduled departure

date for lack of an observer, the vessel would be allowed to go fishing. Also, a fishing vessel should be compensated if its departure is delayed more than 24 hours waiting for an observer to arrive.

Response: U.S. purse seine vessels licensed under the SPTT are currently required to accommodate FFA-deployed observers in accordance with the South Pacific Tuna Act of 1988 and its regulations. These observers come from a variety of locations in the Pacific region. Both the FFA and NMFS do everything they can to ensure that observers are placed well before fishing vessels' estimated dates of departure. Scheduled vessel departure dates are merely estimated dates and often change for a variety of reasons unrelated to observer placement. As stated in the response to comment number 11, arrangements have been made with the FFA for observers to be deployed from the FFA Regional Observer Programme to provide the enhanced observer coverage that would be required under the proposed rule. During the 22 years that observers have been deployed on U.S. purse seine vessels under the SPTT, there have been relatively few instances in which vessels have been significantly delayed as a result of FFA observer placement. The proposed rule would allow a vessel to depart without an observer only if the NMFS Pacific Islands Regional Administrator determines that an observer is not available. This provision is intended to be applied in exceptional cases. In all circumstances, this provision would be applied at the sole discretion of the Regional Administrator. NMFS intends to work with the FFA to ensure that the successful record of the past 22 years is maintained. NMFS does not see the need to employ a time limit based on what are merely estimated dates of departure. Nor does NMFS believe that vessel owners or operators should be compensated in the event the departure of the vessel is delayed as a result of waiting for an observer, which could be caused by any number of factors outside the control of both NMFS and the FFA, such as delayed or cancelled airline flights to vessels' ports of departure.

Comment 13: The commenter should be provided with copies of the measures implemented by other WCPFC members to implement the WCPFC-adopted sea turtle mitigation requirements for their purse seine fleets.

Response: This comment does not pertain to the proposed rule itself. NMFS, as part of U.S. delegations to the WCPFC, routinely endeavors to determine whether all WCPFC members are satisfying their obligations to implement the decisions of the WCPFC,

such as by ascertaining what specific actions they have taken to implement WCPFC-adopted conservation and management measures. This applies to the WCPFC's CMM 2008-03 on sea turtles.

The following comments were specific to the EA prepared for this proposed rule.

Comment 14: The EA also analyzes another proposed rule, "Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011." However, the proposed rule for that action has not yet been published and a preferred alternative for that action has not been designated in the EA. It is unclear why the EA contains analysis of this other rule.

Response: As indicated in the "Note to the Reader" issued in conjunction with the draft version of the EA, the proposed rule, "Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011," is forthcoming. There is no requirement that a proposed rule and a draft EA be issued simultaneously. The Council on Environmental Quality's (CEQ) regulations for implementing the National Environmental Policy Act (NEPA) at 40 CFR § 1508.9 do not require the designation of a preferred alternative in an EA nor do the National Oceanic and Atmospheric Administration's Environmental Review Procedures for Implementing NEPA (NAO 216-6). As stated in Chapter 2 of the EA, for each rule, the EA compares the alternatives analyzed in depth to provide the decisionmaker and the public a clear basis for choosing among the alternatives.

As stated in Chapter 1 of the EA, "The CEQ's regulations at 40 CFR 1508.25(a)(3) state that agencies may analyze similar actions (e.g., actions that have common timing or geography) in the same NEPA document, although they are not required to do so." And further, "both rules stem from the same WCPFC decisions and share common objectives, as well as common timing and geography. Thus, in order to implement the immediately necessary provisions of the recent WCPFC decisions in an efficient manner, NMFS has prepared one EA document for the two proposed rules."

Comment 15: The EA should analyze an alternative that would cap purse seine fishing effort at the annual average of 2001-2004, instead of using only the 2004 fishing effort level as the baseline. Moreover, the EA expands the amount of the purse seine fishing effort limit for the high seas and U.S. EEZ by multiplying the 2004 baseline amount by 40, or the maximum number of

vessels allowed to be licensed under the SPTT. The EA should include an alternative that analyzes the fishing effort limit based on the number of vessels that was active in 2004.

Response: CMM 2008–01 requires that each WCPFC member take measures to ensure that the level of purse seine fishing effort is based on 2004 levels or the average of 2001–2004. The selection of the baseline period is left to the discretion of the WCPFC member. NMFS is satisfied that using the 2004 baseline period satisfies the requirements of the WCPFC decision without imposing undue or disproportionate burdens on the U.S. purse seine fishing fleet.

NMFS disagrees with the comment that NMFS should have included an alternative in the EA that would base the fishing effort limit on the number of vessels that were active in 2004. CMM 2008–01, paragraph 7, provides for WCPFC members, in determining current levels of fishing effort, to include fishing rights organized under existing regional arrangements such as the SPTT. NMFS properly considered in the EA alternatives that used the 40 non-joint venture licenses authorized under SPTT as a baseline for determining the fishing effort limits under CMM 2008–01. For an expanded discussion, see the response to comment 7.

Comment 16: The EA should include an alternative that sets a discrete fishing effort limit for the high seas. The extension of the PNA's Vessel Day Scheme approach to the high seas appears to be inconsistent with the provisions of the CMM 2008–01 that would be implemented in the rule.

Response: Alternative D in the EA includes discrete fishing effort limits for the high seas and the U.S. EEZ.

Comment 17: The EA should provide detailed analysis of the bigeye tuna catch limit alternative to the high seas FAD prohibition period set forth in paragraph 15 of CMM 2008–01. The EA rejected detailed consideration of this alternative because the United States did not meet the WCPFC's requirements for this alternative before the deadline of January 31, 2009. However, it appears that U.S. representatives declined to act upon this alternative and failed to provide the necessary information and commitments to the WCPFC in a timely manner. This alternative would provide a real incentive to explore methods to minimize bigeye tuna catches and achieve measurable conservation goals, whereas the use of fishing effort limits does not provide any such incentive or hard limit on bigeye tuna mortality. NMFS and U.S. representatives to the

WCPFC should seek an extension of the January 31, 2009 deadline and consider this approach in the 2010–2011 management of the domestic purse seine fishery.

Response: The comment is noted. The United States determined that it would not adopt the catch limit measures in paragraph 15 of CMM 2008–01 in lieu of implementing the high seas FAD closure established under paragraph 13. Accordingly, the WCPFC's deadline for proceeding under a catch limit program lapsed, and as stated in the EA, this alternative was not available for detailed consideration. Moreover, the bigeye tuna catch limit was set forth in CMM 2008–01 as an alternative to the high seas FAD prohibition period for 2009, not as an alternative to the fishing effort limit provisions.

Comment 18: The EA should consider a bigeye tuna catch limit for the swordfish sector of the longline fishery, which averages about 17 bigeye tuna incidentally caught per set [the commenter subsequently clarified this to mean 17 bigeye tuna per trip], which are brought to shore and sold. Such a catch limit would reduce bycatch, avoid waste, and promote optimum yields.

Response: This comment refers to alternatives considered for the other action analyzed in the EA, "Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011," which is not a part of this rulemaking. Although resubmission of this comment during the proposed rule comment period for that proposed rule is encouraged, NMFS will consider this comment, as appropriate, in the context of the longline-related rule.

Comment 19: The EA should include an alternative to the bigeye tuna catch limit for the longline fishery that would utilize the three-year rolling management period that has been proposed for the purse seine fishing effort limits.

Response: This comment refers to alternatives considered for the other action analyzed in the EA, "Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011," which is not a part of this rulemaking. Although resubmission of this comment during the proposed rule comment period for that proposed rule is encouraged, NMFS will consider this comment, as appropriate, in the context of the longline-related rule.

Comment 20: Table 4 of the EA provides combined yellowfin tuna and bigeye tuna catch data for 2007 and 2008, including by landing port, and aggregates the information for associated and unassociated fishing. Table 5 provides separate information on

yellowfin tuna and bigeye tuna catches for 2003–2008, including separate information for associated and unassociated fishing, but landing port information is not included. Detailed and fully disaggregated information should be included, discussed, and analyzed so that the differential impacts of the alternatives can be fully considered by decisionmakers and the public based on the best available information.

Response: The EA considered four action alternatives for the rule, as well as the No-Action or baseline alternative. Each of the action alternatives included six separate provisions, but only one of those provisions the fishing effort limit provision varied between the alternatives. Including information stating how much bigeye tuna and yellowfin tuna caught by associated or unassociated means is landed at each port would not provide additional information for the comparison of alternatives.

Comment 21: The information in Table 5 conflicts with other published reports regarding catches of bigeye tuna by the U.S. purse seine fleet, particularly the 2005 U.S. annual report to the WCPFC. Data in the EA for bigeye tuna catches in the purse seine fleet are incomplete, because they are only provided for the last five years. Moreover, the number for the 2008 bigeye tuna catches of the U.S. purse seine fleet included in Table 5 is inaccurate.

Response: NMFS acknowledges the discrepancy between the data in Table 5 of the EA and the information provided in the U.S. annual reports to the WCPFC. The annual reports contain the United States' best available information regarding the U.S. WCPO purse seine fishery's catch statistics. The data in Table 5 are from a report prepared by the Secretariat of the Pacific Community, as cited in the EA, and are based on information from vessel logsheets. As noted in the EA, the 2008 data are preliminary. Table 5 was included in the EA to provide the most recent information NMFS could obtain regarding the amounts of skipjack tuna, yellowfin tuna, and bigeye tuna caught by unassociated and associated sets, respectively. In order to account for any numerical inaccuracies, these data were aggregated and converted to percentages in Section 4.1.2.2 of the EA. This information was then used to support the qualitative analysis of the potential environmental impacts that could be caused by implementation of the FAD prohibition periods. NMFS does not believe that the inclusion of additional data beyond the past five years would

provide information pertinent to the analysis in the EA.

Comment 22: Table 8 of the EA conflicts with previously published information regarding catches by Hawaii-based longline vessels. Table 8 indicates that 5,779 metric tons (mt) of bigeye tuna were caught in 2007 while the U.S. report to the WCPFC indicates that 5,400 mt were caught. Also, information contained in the U.S. annual reports to the WCPFC for fishing during 2000–2008 should be included in a specific table format so that the differential impacts of the alternatives can be fully considered by decisionmakers and the public based on the best available information.

Response: The comment is noted. The Errata sheet for the Final EA contains a corrected version of Table 8. NMFS does not believe that the inclusion of the 2000–2008 data in the format suggested in the comment would provide information pertinent to the analysis in the EA. Moreover, the data for longline bigeye tuna catches in the U.S. annual reports to the WCPFC are not limited to the Hawaii fleet, and thus, are not comparable to the data in Table 8.

Comment 23: The EA fails to discuss the fact that the removal of swordfish effort limits [a separate regulatory action from this rule that would involve implementation of Amendment 18 to the Fishery Management Plan for Pelagic Fisheries in the Western Pacific Region] in the Hawaii longline fishery would result in increased direction of fishing effort toward swordfish and would likely reduce effort directed toward bigeye tuna.

Response: As stated in Chapter 5 of the EA, Cumulative Impacts, NMFS indicated that if and when Amendment 18 is implemented, the Hawaii longline fleet may have greater incentive to target swordfish. That, in turn, could lead to reduced fishing effort directed at bigeye tuna.

Comment 24: The EA fails to discuss or analyze how and to what magnitude the alternatives for purse seine fishing effort limits would reduce bigeye tuna catches from the available baseline periods.

Response: As discussed throughout Chapter 4, Section 4.1 of the EA, the fishing effort limits are not expected to appreciably affect the fleet's total fishing effort (relative to the no-action scenario). Moreover, the baseline for comparing the environmental effects of the alternatives in the EA is the No-Action, or baseline alternative, not the baseline periods used to derive the fishing effort limits.

Comment 25: The EA does not contain a comprehensive discussion of

economic or social impacts. There is no analysis of impacts on markets, communities, human nutrition, consumers, etc.

Response: As stated in Chapter 4 of the EA, the information regarding economic impacts in the EA is provided solely to determine whether and to what degree economic impacts are interrelated with environmental impacts. Moreover, the EA incorporates by reference the RIR and IRFA for the rule, which contain an appropriate analysis of economic impacts.

Comment 26: The cumulative impacts section of the EA is inadequate. A major discrepancy is the lack of discussion of the well documented transfer effects that occur when U.S. seafood production is curtailed and domestic consumption of imported seafood increases in response. If the longline fishery is closed when the bigeye tuna catch limit for that fishery is reached, the demand for bigeye tuna will be met by longline caught tuna imported from other countries, which have less stringent regulations to mitigate environmental impacts, such as interactions with seabirds and sea turtles.

Response: The RIR for this rule, which is incorporated by reference into the EA, examines the expected effects of this rule on consumers, including effects on quantities, quality, and prices of products available to U.S. consumers. Consumers in the United States of U.S. purse seine fishery-produced tuna are part of a large global market of tuna sourced from the fleets of many nations and produced from tuna stocks in all the world's oceans. Thus, production by the U.S. purse seine fleet in the WCPO has limited influence on the price, quantity, quality, or source of tuna products consumed in the United States. Moreover, this proposed action is expected to have relatively minor effects on production by the U.S. fleet. Therefore, NMFS believes the transfer effects mentioned in the comment are unlikely to occur.

A portion of this comment refers to the other action analyzed in the EA, "Bigeye Tuna Catch Limits in Longline Fisheries in 2009, 2010, and 2011." As indicated in the "Note to the Reader" issued in conjunction with the draft version of the EA, the proposed rule for that action had not been issued at the time the EA was made available, and the RIR for the longline-related rule consequently had not yet been made publicly available. For that reason, this comment will be addressed in the context of the longline-related rule and the RIR for that action.

Comment 27: The Environmental Justice section of the EA does not include sufficient analysis for a determination to be made regarding significant environmental impacts.

Response: The purpose of an Environmental Justice analysis is to determine whether a proposed action would have disproportionately high and adverse human health or environmental effects on minority or low-income populations. As discussed throughout the EA and summarized in Chapter 4, Section 4.6, implementation of the provisions in this rule and the longline-related rule would not lead to substantial adverse human health or environmental effects on any population minority, low income, or otherwise.

Comment 28: The EA is insufficient to make an informed determination regarding the significance of the likely environmental impacts of the alternatives considered. However, given that the Pacific purse seine fisheries are the biggest tuna fisheries in the world, that longline fishing is the biggest fishery in Hawaii, that many of the measures for purse seine fishing in the WCPO are being considered for the first time, and that there are increasingly loud concerns being expressed by governments and non-governmental organizations regarding overfishing of the world's marine ecosystems, it is clear that the actions being contemplated by NMFS are controversial and preparation of an Environmental Impact Statement (EIS) may better inform the public.

Response: NMFS disagrees that the proposed rule is controversial, but even assuming it is, controversy alone is insufficient to trigger the requirement for an EIS. NMFS received only two comment letters in response to the proposed rule. Based on the analysis in the EA, NMFS does not believe that the effects of the action on the quality of the human environment are significant, or that the proposed action or its effects are controversial.

Changes from the Proposed Rule

In the proposed regulations, regulatory instruction (3) said that "Subpart O, consisting of §§ 300.210 through 300.222, is added to part 300 to read as follows:" The instruction was meant to read "consisting of §§ 300.210 through 300.222..." and the corresponding instruction in this final rule is corrected accordingly.

On May 22, 2009, NMFS published in the **Federal Register** a proposed rule to implement, in part, the provisions of the Convention (74 FR 23965). The regulations in that proposed rule (called here the "WCPFC implementation

rule”) would establish a new subpart O in part 300 of title 50 of the *Code of Federal Regulations*, titled “Western and Central Pacific Fisheries for Highly Migratory Species.” The proposed rule that led to this final rule (called here the “WCPFC purse seine rule”) was published after the proposed WCPFC implementation rule, on June 1, 2009. Accordingly, the regulations in the proposed WCPFC purse seine rule were written as amendments to subpart O in part 300. However, this final rule is being published before the final WCPFC implementation rule. It is therefore necessary for subpart O of part 300 of title 50 to be created in this final rule, as well as to incorporate relevant elements of the WCPFC implementation rule into these final regulations. Specifically, the following elements of the regulations proposed in the WCPFC implementation rule are included in this final rule: § 300.210, “Purpose and scope,” is included in its entirety. From § 300.211, “Definitions,” the introductory sentence and all the terms used in the proposed WCPFC purse seine rule are included. From § 300.215, “Observers,” paragraph (c), “Accommodating observers,” which is referenced in § 300.223(e)(3) and (4) of the proposed WCPFC purse seine rule and this final rule, is included, with the exception of the sentence “All fishing vessels subject to this section must carry a WCPFC observer when directed to do so by NMFS.” From § 300.222, “Prohibitions,” the introductory sentence is included.

In § 300.211, “Definitions,” the definition of FAD has been revised to clarify that it does not include a fishing vessel, provided that the fishing vessel is not used for the purpose of aggregating fish.

In § 300.223, “Purse seine fishing restrictions,” in order to clarify when, exactly, all the specified dates begin and end, an introductory sentence is included that states that all dates used in this section are in Universal Coordinated Time, also known as UTC.

In § 300.223, “Purse seine fishing restrictions,” paragraph (b)(2) is revised to add that during a FAD prohibition period, a purse seine may not be set in an area in which a FAD has been inspected or handled within the previous eight hours.

In § 300.223, “Purse seine fishing restrictions,” paragraph (b)(4) is revised to clarify that during a FAD prohibition period, a FAD may be removed from the water and if removed may be cleaned, provided that it is not returned to the water.

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with the WCPFC Implementation Act and other applicable laws.

Administrative Procedure Act

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date for all of this final rule except §§ 300.222(aa) and 300.223(f) (the sea turtle mitigation requirements and associated prohibitions). Compliance with the 30-day requirement would be impracticable and contrary to the public interest the FAD prohibition period and associated observer requirement would be in effect for only about half of the specified period in 2009, meaning that NMFS would be frustrated in promulgating the regulations needed to satisfy the international obligations of the United States under the Convention. Also, NMFS had limited notice of the need to implement CMM 2008–01, which was adopted in the December 2008 regular annual session of the WCPFC.

National Environmental Policy Act

NMFS prepared an EA for this rule and concluded that there will be no significant impact on the human environment as a result of this rule. In the EA, NMFS compared the effects of the rule and four alternatives to the rule, including the No-Action or baseline alternative and three action alternatives. Although the alternatives would likely result in slightly different environmental impacts, all alternatives would have only minor impacts on bigeye tuna and other living marine resources in the WCPO. Overall, the expected impacts on bigeye tuna and other living marine resources from the rule or any of the action alternatives are expected to be similar and generally beneficial. The EA focuses on analyzing four alternatives for implementing the limit on the number of fishing days. NMFS initially considered two alternatives to the FAD prohibition period element of the rule that were eliminated from detailed consideration. For the other elements of the rule, NMFS was not able to identify any alternatives that were reasonable and feasible. The rule is neither the most restrictive nor the least restrictive manner in which to implement the limit on the number of fishing days. Rather, the rule seeks to establish a balance between the needs of fishery participants and the effects on the human environment.

The effects on the human environment from the rule are expected to be minor for the following reasons. First, the duration of the rule (with the exception of the sea turtle mitigation requirements) would be limited to three years, after which, unless similar or more restrictive future actions are taken, conditions would likely rebound to conditions similar to those under the No-Action or baseline alternative. Second, the rule would have relatively minor effects on the conduct or catches of the U.S. purse seine fleet, and consequently only minor effects on the total fishing mortality rates of the stocks captured by the fleet, including bigeye tuna and yellowfin tuna in the WCPO. However, other present and reasonably foreseeable future actions for the conservation and management of highly migratory species could cause similar beneficial effects, so overall, the cumulative impacts on the affected environment could be greater than if the rule were implemented in isolation. Specifically, implementation by the United States of the provisions of CMM 2008–01 applicable to longline vessels (which NMFS is undertaking via a separate rulemaking) and implementation by other WCPFC members of the provisions of CMM 2008–01 and CMM 2008–03 would enhance the beneficial impacts to bigeye tuna, yellowfin tuna, and other living marine resources. If the WCPFC adopts and its members implement similar or more restrictive measures after the three-year duration of CMM 2008–01, the beneficial impacts would be further enhanced (e.g., there could be a greater likelihood of attaining the objectives of CMM 2008–01).

The economic impacts of the rule are addressed in the EA only insofar as they are related to impacts to the biophysical environment. They are addressed more fully in the RIR, IRFA, and FRFA. A copy of the EA is available from NMFS (see **ADDRESSES**).

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

NMFS prepared this final regulatory flexibility analysis (FRFA) for the rule, Fishing Restrictions and Observer Requirements in Purse Seine Fisheries for 2009–2011 and Turtle Mitigation Requirements in Purse Seine Fisheries. The FRFA incorporates the IRFA prepared for the proposed rule (74 FR 26160; June 1, 2009; available from NMFS see **ADDRESSES**). The analysis

provided in the IRFA is not repeated here in its entirety.

The need for, reasons why action by the agency is being considered, and the objectives of the action are explained in the preambles to the proposed rule and final rule and are not repeated here. There are no disproportionate economic impacts between small and large vessels resulting from this rule. Furthermore, there are no disproportionate economic impacts from this rule based on vessel size, gear, or homeport. There are no new recordkeeping or reporting requirements associated with this rule. Other compliance requirements are described in the IRFA. This rule is issued under authority of the WCPFC Implementation Act.

Description of Small Entities to Which the Rule Will Apply

The rule will apply to owners and operators of U.S. purse seine vessels used for fishing in the Convention Area. The number of affected vessels is the number licensed under the SPTT. The current number of licensed vessels is 39, but the number could soon reach the maximum number of licenses available under the SPTT (excluding joint-venture licenses), which is 40. Based on (limited) financial information about the purse seine fleet, NMFS believes that as many as 10 of the affected vessels are owned by small entities (i.e., they are business entities with gross annual receipts of no more than \$4.0 million).

Steps Taken To Minimize the Significant Economic Impact on Small Entities

NMFS explored alternatives that would achieve the objective of this action (to satisfy the international obligations of the United States under WCPFC CMM 2008–01 and CMM 2008–03 with respect to U.S. purse seine vessels) while minimizing economic impacts on small entities. Several alternatives were identified and considered. All were limited to the way in which the fishing effort limits would be implemented. One alternative differed from the rule only in that the fishing effort limits would be allocated among individual vessels. This would likely alleviate any adverse impacts of the race-to-fish that might occur as a result of establishing the competitive fishing effort limits as in the rule. As described in the IRFA, those potential impacts include lower prices for landed product and risks to performance and safety stemming from fishing during sub-optimal times. However, as described in the IRFA, the fishing effort limits are not very constraining (i.e., the level of effort expected under no-action

is not much greater, if greater at all, than the level to which effort would be limited under this rule), so these adverse impacts are expected to be minor. For that reason, this alternative was rejected.

Another alternative differed from the rule only in that there would be a single limit of 7,764 fishing days (three times the fishing effort rate of 2,588 fishing days per year) for the entire three-year period 2009–2011. This would provide slightly more operational flexibility to affected vessels than the rule, which could bring lower compliance costs. However, the lack of any limits for a given year would bring the potential for a longer closed period (e.g., during a substantial part of 2011) than would likely occur under the rule (under which relatively brief closures might be expected in one or more of the years 2009–2011). To the extent that continuous fishing and continuity of supply are important for the fishery, several short closures might cause less adverse economic impacts than a single long closure, and for this reason, this alternative was rejected. For example, with a brief closure each year, vessel owners and operators might be able to schedule routine vessel maintenance during the closed periods and mitigate the losses of not being able to fish. This would be more difficult to do during a longer closed period. In any case, as described in the IRFA, because the majority of the fleet's traditional fishing grounds would not be subject to the limit or the closure, the potential losses caused by a closed period however short or long are likely to be relatively minor.

Another alternative would establish separate fishing effort limits for the high seas and for areas under U.S. jurisdiction and separate limits for each of the SPTT licensing years (which run from June 15 through June 14) during 2009–2011. In accordance with the baseline effort levels specified in CMM 2008–01, the limits would be 2,030 fishing days on the high seas and 558 fishing days in areas under U.S. jurisdiction. Because this alternative would provide less operational flexibility for affected purse seine vessels, the limits would be more constraining than those established under the rule, and consequently more costly. It was rejected for that reason.

The alternative of taking no action at all was rejected because it would fail to accomplish the objective of the WCPFC Implementation Act or satisfy the international obligations of the United States as a Contracting Party to the Convention.

The selected alternative would accomplish the objective of the WCPFC

Implementation Act and satisfy the international obligations of the United States with respect to implementing WCPFC CMM 2008–01 and CMM 2008–03, and do so with minimal adverse economic impacts on small entities, and for these reasons was adopted in the final rule.

Comments and Responses

Comment 1: The IRFA fails to consider an appropriate range of alternatives and appears to be lacking some required information and analyses. The analysis should also include an examination of the differential impacts of the alternatives on U.S.-built purse seine vessels versus foreign-built purse seine vessels.

Response: With respect to the range of analyses considered in the IRFA, NMFS disagrees with the comment. All the alternatives analyzed in detail in the EA were also considered in the IRFA, and NMFS finds those alternatives to comprise an appropriate range in the contexts of both NEPA and the Regulatory Flexibility Act.

With respect to differential impacts on the two types of vessels, a vessel built or rebuilt outside the United States, with limited exceptions, is not eligible for a fishery endorsement on its certificate of documentation and consequently is not authorized to be used for fishing in the U.S. EEZ. Therefore, under the no-action alternative, as well as under the proposed rule and all the action alternatives, U.S.-built vessels with fishery endorsements would have an advantage over the remainder of the U.S. purse seine fleet. The proposed rule would not alter the legal requirements with respect to eligibility for fishery endorsements, and it does not include any provisions that apply differently to U.S.-built vessels than to foreign-built vessels. Among the 39 U.S. purse seine vessels currently licensed under the SPTT and which would be directly affected by this rule, 11 have fishery endorsements and 28 do not. To give an indication of the magnitude of the advantage, in the years 1997–2007, the portion of the fleet's annual fishing effort (in days fished) that was spent in the U.S. EEZ (necessarily by vessels with fishery endorsements only) averaged seven percent (NMFS unpublished data), and through most of that period, the ratio in the number of vessels with fishery endorsements to the number without fishery endorsements was considerably higher than it is now. NMFS recognizes that two elements of the proposed rule would have the potential to enhance or diminish this advantage, as follows.

With respect to the fishing effort limits, once a limit is reached, vessels with fishery endorsements would be prohibited from fishing in a somewhat larger area (high seas plus U.S. EEZ in the Convention Area) than the area in which the vessels without fishery endorsements would be prohibited from fishing (only the high seas in the Convention Area). In absolute terms, therefore, operators of vessels with fishery endorsements could bear greater losses as a result of a limit being reached than operators of vessels without fishery endorsements. In relative terms, however, the expected impacts on the two types of vessels are the same: vessels of both types would be expected to experience approximately the same losses in terms of the proportion of revenues or profits that would be lost. Also, there would not be any differential impact at all until a limit is reached, and as described in the IRFA, the likelihood of a limit being reached in any given limit-period may not be high. Furthermore, as described in the IRFA, even if a limit is reached, the expected economic impacts, considering opportunity costs, are expected to be minor, since the most of the fleet's traditional fishing grounds—that is, foreign EEZs within the Convention Area, as well as the eastern Pacific Ocean—would remain open to fishing. In sum, the fishing effort limits would not be expected to bring substantial differential impacts according to whether a vessel is U.S.-built or foreign-built.

The high seas closed areas, in contrast to the fishing effort limits, could cause vessels without fishery endorsements to bear greater losses than vessels with fishery endorsements, since the former would be excluded from a greater proportion of their otherwise available fishing grounds than would vessels with fishery endorsements. As described in the IRFA, the economic impacts of the high seas closed areas, considering opportunity costs, are expected to be relatively minor because most of the fleet's traditional fishing grounds would remain open. Therefore, the high seas closed areas would not be expected to bring substantial differential impacts according to whether a vessel is U.S.-built or foreign-built.

None of the other elements of the proposed rule, including the FAD prohibition periods, catch retention requirements, observer coverage requirements, or turtle mitigation requirements, would be expected to have differential impacts according to whether a vessel is U.S.-built or foreign-built.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as “small entity compliance guides.” The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide (the guide) has been prepared. The guide will be sent to all holders of purse seine licenses issued pursuant to regulations implementing the South Pacific Tuna Act of 1988. Copies of this final rule and the guide are available from NMFS (see **ADDRESSES**) and are available at: http://www.fpir.noaa.gov/IFD/ifd_documents_data.html.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: July 29, 2009.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 300 is amended by adding subpart O, consisting of §§ 300.210 through 300.223, to read as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart O—Western and Central Pacific Fisheries for Highly Migratory Species

Sec.

- 300.210 Purpose and scope.
- 300.211 Definitions.
- 300.212 Vessel permit endorsements. [Reserved]
- 300.213 Vessel information. [Reserved]
- 300.214 Compliance with laws of other nations. [Reserved]
- 300.215 Observers.
- 300.216 Transshipment. [Reserved]
- 300.217 Vessel identification. [Reserved]
- 300.218 Reporting and recordkeeping requirements. [Reserved]
- 300.219 Vessel monitoring system. [Reserved]
- 300.220 Confidentiality of information. [Reserved]
- 300.221 Facilitation of enforcement and inspection. [Reserved]
- 300.222 Prohibitions.
- 300.223 Purse seine fishing restrictions.

Authority: 16 U.S.C. 6901 *et seq.*

Subpart O—Western and Central Pacific Fisheries for Highly Migratory Species

§ 300.210 Purpose and scope.

This subpart implements provisions of the Western and Central Pacific Fisheries Convention Implementation Act (Act) and applies to persons and vessels subject to the jurisdiction of the United States.

§ 300.211 Definitions.

In addition to the terms defined in § 300.2 and those in the Act and in the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, with Annexes (WCPF Convention), which was adopted at Honolulu, Hawaii, on September 5, 2000, by the Multilateral High-Level Conference on Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, the terms used in this subpart have the following meanings.

Commission means the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean established in accordance with the WCPF Convention, including its employees and contractors.

Convention Area means all waters of the Pacific Ocean bounded to the south and to the east by the following line: From the south coast of Australia due south along the 141st meridian of east longitude to its intersection with the 55th parallel of south latitude; thence due east along the 55th parallel of south latitude to its intersection with the 150th meridian of east longitude; thence due south along the 150th meridian of east longitude to its intersection with the 60th parallel of south latitude; thence due east along the 60th parallel of south latitude to its intersection with the 130th meridian of west longitude; thence due north along the 130th meridian of west longitude to its intersection with the 4th parallel of south latitude; thence due west along the 4th parallel of south latitude to its intersection with the 150th meridian of west longitude; thence due north along the 150th meridian of west longitude.

Effort Limit Area for Purse Seine, or *ELAPS*, means, within the area between 20° N. latitude and 20° S. latitude, areas within the Convention Area that either are high seas or are within the jurisdiction of the United States, including the EEZ and territorial sea.

Fish aggregating device, or *FAD*, means any artificial or natural floating object, whether anchored or not and

whether situated at the water surface or not, that is capable of aggregating fish, as well as any objects used for that purpose that are situated on board a vessel or otherwise out of the water. The meaning of FAD does not include a fishing vessel, provided that the fishing vessel is not used for the purpose of aggregating fish.

Fishing means using any vessel, vehicle, aircraft or hovercraft for any of the following activities, or attempting to do so:

(1) Searching for, catching, taking, or harvesting fish;

(2) Engaging in any other activity which can reasonably be expected to result in the locating, catching, taking, or harvesting of fish for any purpose;

(3) Placing, searching for, or recovering fish aggregating devices or associated electronic equipment such as radio beacons;

(4) Engaging in any operations at sea directly in support of, or in preparation for, any of the activities previously described in paragraphs (1) through (3) of this definition, including, but not limited to, bunkering;

(5) Engaging in transshipment, either unloading or loading fish.

Fishing day means, for the purpose of § 300.223, any day in which a fishing vessel of the United States equipped with purse seine gear searches for fish, deploys a FAD, services a FAD, or sets a purse seine, with the exception of setting a purse seine solely for the purpose of testing or cleaning the gear and resulting in no catch.

Fishing trip means a period that a fishing vessel spends at sea between port visits and during which any fishing occurs.

Fishing vessel means any vessel used or intended for use for the purpose of fishing, including bunkering and other support vessels, carrier vessels and other vessels that unload or load fish in a transshipment, and any other vessel directly involved in fishing.

High seas means the waters beyond the territorial sea or exclusive economic zone (or the equivalent) of any nation, to the extent that such territorial sea or exclusive economic zone (or the equivalent) is recognized by the United States.

Member of the Commission means any Contracting Party to the WCPF Convention, and, unless otherwise stated in context, any territory that has been authorized by an appropriate Contracting Party to participate in the Commission and its subsidiary bodies pursuant to Article 43 of the WCPF Convention and any fishing entity that has agreed to be bound by the regime established by the WCPF Convention

pursuant to Annex I of the WCPF Convention.

Pacific Islands Regional Administrator means the Regional Administrator, Pacific Islands Region, NMFS, or a designee (1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814).

Person means any individual (whether or not a citizen or national of the United States), any corporation, partnership, association, or other entity (whether or not organized or existing under the laws of any State), and any Federal, State, local, or foreign government or any entity of any such government.

Purse seine means a floated and weighted encircling net that is closed by means of a drawstring threaded through rings attached to the bottom of the net.

State means each of the several States of the United States, the District of Columbia, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, and any other commonwealth, territory, or possession of the United States.

Transshipment means the unloading of fish from one fishing vessel and its direct transfer to, and loading on, another fishing vessel, either at sea or in port.

WCPF Convention means the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (including any annexes, amendments, or protocols that are in force, or have come into force, for the United States) that was adopted at Honolulu, Hawaii, on September 5, 2000, by the Multilateral High-Level Conference on Highly Migratory Fish Stocks in the Western and Central Pacific Ocean.

WCPFC observer means a person authorized by the Commission in accordance with any procedures established by the Commission to undertake vessel observer duties as part of the Commission's Regional Observer Programme, including an observer deployed as part of a NMFS-administered observer program or as part of another national or sub-regional observer program, provided that such program is authorized by the Commission to be part of the Commission's Regional Observer Programme.

§ 300.212 Vessel permit endorsements. [Reserved]

§ 300.213 Vessel information. [Reserved]

§ 300.214 Compliance with laws of other nations. [Reserved]

§ 300.215 Observers.

(a) *Applicability.* [Reserved]

(b) *Notifications.* [Reserved]

(c) *Accommodating observers.* The operator and each member of the crew of the fishing vessel shall act in accordance with this paragraph with respect to any WCPFC observer.

(1) The operator and crew shall allow and assist WCPFC observers to:

(i) Embark at a place and time determined by NMFS or otherwise agreed to by NMFS and the vessel operator;

(ii) Have access to and use of all facilities and equipment on board as necessary to conduct observer duties, including, but not limited to: full access to the bridge, the fish on board, and areas which may be used to hold, process, weigh and store fish; full access to the vessel's records, including its logs and documentation, for the purpose of inspection and copying; access to, and use of, navigational equipment, charts and radios; and access to other information relating to fishing;

(iii) Remove samples;

(iv) Disembark at a place and time determined by NMFS or otherwise agreed to by NMFS and the vessel operator; and

(v) Carry out all duties safely.

(2) The operator shall provide the WCPFC observer, while on board the vessel, with food, accommodation and medical facilities of a reasonable standard equivalent to those normally available to an officer on board the vessel, at no expense to the WCPFC observer.

(3) The operator and crew shall not assault, obstruct, resist, delay, refuse boarding to, intimidate, harass or interfere with WCPFC observers in the performance of their duties, or attempt to do any of the same.

(d) *Related observer requirements.* [Reserved]

§ 300.216 Transshipment. [Reserved]

§ 300.217 Vessel identification. [Reserved]

§ 300.218 Reporting and recordkeeping requirements. [Reserved]

§ 300.219 Vessel monitoring system. [Reserved]

§ 300.220 Confidentiality of information. [Reserved]

§ 300.221 Facilitation of enforcement and inspection. [Reserved]

§ 300.222 Prohibitions.

In addition to the prohibitions in § 300.4, it is unlawful for any person to:

(a) through (u) [Reserved]

(v) Use a fishing vessel equipped with purse seine gear to fish in the ELAPS while the fishery is closed under § 300.223(a).

(w) Set a purse seine around, near or in association with a FAD or deploy or service a FAD in contravention of § 300.223(b).

(x) Use a fishing vessel equipped with purse seine gear to fish in an area closed under § 300.223(c).

(y) Discard fish at sea in the ELAPS in contravention of § 300.223(d).

(z) Fail to carry an observer as required in § 300.223(e).

(aa) Fail to comply with the sea turtle mitigation gear and handling requirements of § 300.223(f).

§ 300.223 Purse seine fishing restrictions.

All dates used in this section are in Universal Coordinated Time, also known as UTC; for example: the year 2009 starts at 00:00 on January 1, 2009 UTC and ends at 24:00 on December 31, 2009 UTC; and August 1, 2009, begins at 00:00 UTC and ends at 24:00 UTC.

(a) *Fishing effort limits.* This section establishes limits on the number of fishing days that fishing vessels of the United States equipped with purse seine gear may collectively spend in the ELAPS.

(1) The limits are as follows:

(i) For each of the years 2009, 2010, and 2011, there is a limit of 3,882 fishing days.

(ii) For each of the two-year periods 2009–2010 and 2010–2011, there is a limit of 6,470 fishing days.

(iii) For the three-year period 2009–2011, there is a limit of 7,764 fishing days.

(2) NMFS will determine the number of fishing days spent in the ELAPS in each of the applicable time periods using data submitted in logbooks and other available information. After NMFS determines that the limit in any applicable time period is expected to be reached by a specific future date, and at least seven calendar days in advance of the closure date, NMFS will publish a notice in the **Federal Register** announcing that the purse seine fishery in the ELAPS will be closed starting on that specific future date and will remain closed until the end of the applicable time period.

(3) Once a fishery closure is announced pursuant to paragraph (a)(2) of this section, fishing vessels of the United States equipped with purse seine gear may not be used to fish in the ELAPS during the period specified in the **Federal Register** notice.

(b) *Use of fish aggregating devices.* From August 1 through September 30, 2009, and from July 1 through September 30 in each of 2010 and 2011, owners, operators, and crew of fishing vessels of the United States shall not do any of the following in the Convention Area:

(1) Set a purse seine around a FAD or within one nautical mile of a FAD.

(2) Set a purse seine in a manner intended to capture fish that have aggregated in association with a FAD, such as by setting the purse seine in an area from which a FAD has been moved or removed within the previous eight hours, or setting the purse seine in an area in which a FAD has been inspected or handled within the previous eight hours, or setting the purse seine in an area into which fish were drawn by a vessel from the vicinity of a FAD.

(3) Deploy a FAD into the water.

(4) Repair, clean, maintain, or otherwise service a FAD, including any electronic equipment used in association with a FAD, in the water or on a vessel while at sea, except that:

(i) A FAD may be inspected and handled as needed to identify the owner of the FAD, identify and release incidentally captured animals, unfoul fishing gear, or prevent damage to property or risk to human safety; and

(ii) A FAD may be removed from the water and if removed may be cleaned, provided that it is not returned to the water.

(c) *Closed areas.* (1) Effective January 1, 2010, through December 31, 2011, a fishing vessel of the United States may not be used to fish with purse seine gear on the high seas within either Area A or Area B, the respective boundaries of which are the four lines connecting, in the most direct fashion, the coordinates specified as follows:

(i) Area A: 7° N. latitude and 134° E. longitude; 7° N. latitude and 153° E. longitude; 0° latitude and 153° E. longitude; and 0° latitude and 134° E. longitude.

(ii) Area B: 4° N. latitude and 156° E. longitude; 4° N. latitude and 176° E. longitude; 12° S. latitude and 176° E. longitude; and 12° S. latitude and 156° E. longitude.

(2) NMFS may, through publication of a notice in the **Federal Register**, nullify any or all of the area closures specified in paragraph (c)(1) of this section.

(d) *Catch retention.* (1) Based on its determination as to whether an adequate number of WCPFC observers is available for the purse seine vessels of all Members of the Commission as necessary to ensure compliance by such vessels with the catch retention requirements established by the Commission, NMFS will, through publication of a notice in the **Federal Register**, announce the effective date of the provisions of paragraph (d) of this section. The effective date will be no earlier than January 1, 2010.

(2) If, after announcing the effective date of these requirements under

paragraph (1) of this section, NMFS determines that there is no longer an adequate number of WCPFC observers available for the purse seine vessels of all Members of the Commission as necessary to ensure compliance by such vessels with the catch retention requirements established by the Commission, NMFS may, through publication of a notice in the **Federal Register**, nullify any or all of the requirements specified in paragraph (d) of this section.

(3) Effective from the date announced pursuant to paragraph (d)(1) of this section through December 31, 2011, a fishing vessel of the United States equipped with purse seine gear may not discard at sea within the Convention Area any bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), or skipjack tuna (*Katsuwonus pelamis*), except in the following circumstances and with the following conditions:

(i) Fish that are unfit for human consumption, including but not limited to fish that are spoiled, pulverized, severed, or partially consumed at the time they are brought on board, may be discarded.

(ii) If at the end of a fishing trip there is insufficient well space to accommodate all the fish captured in a given purse seine set, fish captured in that set may be discarded, provided that no additional purse seine sets are made during the fishing trip.

(iii) If a serious malfunction of equipment occurs that necessitates that fish be discarded.

(e) *Observer coverage.* (1) From August 1 through September 30, 2009, a fishing vessel of the United States that is equipped with purse seine gear may not be used to fish in the Convention Area without a WCPFC observer or an observer deployed by NMFS on board. This requirement does not apply to fishing trips that meet any of the following conditions:

(i) The portion of the fishing trip within the Convention Area takes place entirely within areas under U.S. jurisdiction or entirely within areas under jurisdiction of a single nation other than the United States.

(ii) No fishing takes place during the fishing trip in the Convention Area in the area between 20° N. latitude and 20° S. latitude.

(iii) The Pacific Islands Regional Administrator has determined that an observer is not available for the fishing trip and a written copy of the Pacific Islands Regional Administrator's determination, which must include the approximate start date of the fishing trip and the port of departure, is carried on

board the fishing vessel during the entirety of the fishing trip.

(2) Effective January 1, 2010, through December 31, 2011, a fishing vessel of the United States may not be used to fish with purse seine gear in the Convention Area without a WCPFC observer on board. This requirement does not apply to fishing trips that meet any of the following conditions:

(i) The portion of the fishing trip within the Convention Area takes place entirely within areas under U.S. jurisdiction or entirely within the areas under jurisdiction of a single nation other than the United States.

(ii) No fishing takes place during the fishing trip in the Convention Area in the area between 20° N. latitude and 20° S. latitude.

(iii) The Pacific Islands Regional Administrator has determined that a WCPFC observer is not available for the fishing trip and a written copy of the Pacific Islands Regional Administrator's determination, which must include the approximate start date of the fishing trip and the port of departure, is carried on board the fishing vessel during the entirety of the fishing trip.

(3) Owners, operators, and crew of fishing vessels subject to paragraphs (e)(1) or (e)(2) of this section must accommodate WCPFC observers in accordance with the provisions of § 300.215(c).

(4) Meeting any of the conditions in paragraphs (e)(1)(i), (e)(1)(ii), (e)(1)(iii), (e)(2)(i), (e)(2)(ii), or (e)(2)(iii) of this section does not exempt a fishing vessel from having to carry and accommodate a WCPFC observer pursuant to § 300.215 or other applicable regulations.

(f) *Sea turtle take mitigation measures.* (1) Possession and use of required mitigation gear. Any owner or operator of a fishing vessel of the United States equipped with purse seine gear that is used to fish in the Convention Area must carry aboard the vessel the following gear:

(i) *Dip net.* A dip net is intended to facilitate safe handling of sea turtles and access to sea turtles for purposes of removing sea turtles from fishing gear, bringing sea turtles aboard the vessel when appropriate, and releasing sea turtles from the vessel. The minimum design standards for dip nets that meet the requirements of this section are:

(A) *An extended reach handle.* The dip net must have an extended reach handle with a minimum length of 150 percent of the freeboard height. The extended reach handle must be made of wood or other rigid material able to support a minimum of 100 lb (34.1 kg) without breaking or significant bending or distortion.

(B) *Size of dip net.* The dip net must have a net hoop of at least 31 inches (78.74 cm) inside diameter and a bag depth of at least 38 inches (96.52 cm). The bag mesh openings may be no more than 3 inches 3 inches (7.62 cm 7.62 cm) in size.

(ii) *Optional turtle hoist.* A turtle hoist is used for the same purpose as a dip net. It is not a required piece of gear, but a turtle hoist may be carried on board and used instead of the dip net to handle sea turtles as required in paragraph (f)(2) of this section. The minimum design standards for turtle hoists that are used instead of dip nets to meet the requirements of this section are:

(A) *Frame and net.* The turtle hoist must consist of one or more rigid frames to which a bag of mesh netting is securely attached. The frame or smallest of the frames must have a minimum opening (e.g., inside diameter, if circular in shape) of 31 inches (78.74 cm) and be capable of supporting a minimum of 100 lb (34.1 kg). The frame or frames may be hinged or otherwise designed so they can be folded for ease of storage, provided that they have no sharp edges and can be quickly reassembled. The bag mesh openings may be no more than 3 inches x 3 inches (7.62 cm x 7.62 cm) in size.

(B) *Lines.* Lines used to lower and raise the frame and net must be securely attached to the frame in multiple places such that the frame remains stable when lowered and raised.

(2) *Handling requirements.* Any owner or operator of a fishing vessel of the United States equipped with purse seine gear that is used to fish in the Convention Area must, if a sea turtle is observed to be enclosed or entangled in a purse seine, a FAD, or other fishing gear, comply with these handling requirements, including using the required mitigation gear specified in paragraph (f)(1) of this section as prescribed in these handling requirements. Any captured or entangled sea turtle must be handled in a manner to minimize injury and promote survival.

(i) *Sea turtles enclosed in purse seines.* If the sea turtle is observed enclosed in a purse seine but not entangled, it must be released immediately from the purse seine with the dip net or turtle hoist.

(ii) *Sea turtles entangled in purse seines.* If the sea turtle is observed entangled in a purse seine, the net roll must be stopped as soon as the sea turtle comes out of the water, and must not start again until the turtle has been disentangled and released. The sea turtle must be handled and released in

accordance with paragraphs (f)(2)(iv), (f)(2)(v), (f)(2)(vi), and (f)(2)(vii) of this section.

(iii) *Sea turtles entangled in FADs.* If the sea turtle is observed entangled in a FAD, it must be disentangled or the FAD must be cut immediately so as to remove the sea turtle. The sea turtle must be handled and released in accordance with paragraphs (f)(2)(iv), (f)(2)(v), (f)(2)(vi), and (f)(2)(vii) of this section.

(iv) *Disentangled sea turtles that cannot be brought aboard.* After disentanglement, if the sea turtle is not already on board the vessel and it is too large to be brought aboard or cannot be brought aboard without sustaining further injury, it shall be left where it is in the water, or gently moved, using the dip net or turtle hoist if necessary, to an area away from the fishing gear and away from the propeller.

(v) *Disentangled sea turtles that can be brought aboard.* After disentanglement, if the sea turtle is not too large to be brought aboard and can be brought aboard without sustaining further injury, the following actions shall be taken:

(A) Using the dip net or a turtle hoist, the sea turtle must be brought aboard immediately; and

(B) The sea turtle must be handled in accordance with the procedures in paragraphs (f)(2)(vi) and (f)(2)(vii) of this section.

(vi) *Sea turtle resuscitation.* If a sea turtle brought aboard appears dead or comatose, the following actions must be taken:

(A) The sea turtle must be placed on its belly (on the bottom shell or plastron) so that it is right side up and its hindquarters elevated at least 6 inches (15.24 cm) for a period of no less than 4 hours and no more than 24 hours. The amount of the elevation varies with the size of the sea turtle; greater elevations are needed for larger sea turtles;

(B) A reflex test must be administered at least once every 3 hours. The test is to be performed by gently touching the eye and pinching the tail of a sea turtle to determine if the sea turtle is responsive;

(C) The sea turtle must be kept shaded and damp or moist (but under no circumstances place the sea turtle into a container holding water). A water-soaked towel placed over the eyes (not covering the nostrils), carapace and flippers is the most effective method of keeping a sea turtle moist; and

(D) If the sea turtle revives and becomes active, it must be returned to the sea in the manner described in paragraph (f)(2)(vii) of this section. Sea

turtles that fail to revive within the 24-hour period must also be returned to the sea in the manner described in paragraph (f)(2)(vii) of this section, unless NMFS requests that the turtle or part thereof be kept on board and delivered to NMFS for research purposes.

(vii) *Sea turtle release.* After handling a sea turtle in accordance with the requirements of paragraphs (f)(2)(v) and (f)(2)(vi) of this section, the sea turtle must be returned to the ocean after identification unless NMFS requests the retention of a dead sea turtle for research. In releasing a sea turtle the vessel owner or operator must:

(A) Place the vessel engine in neutral gear so that the propeller is disengaged and the vessel is stopped;

(B) Using the dip net or a turtle hoist to release the sea turtle with little impact, gently release the sea turtle away from any deployed gear; and

(C) Observe that the turtle is safely away from the vessel before engaging the propeller and continuing operations.

(viii) *Other sea turtle requirements.* No sea turtle, including a dead turtle, may be consumed or sold. A sea turtle may be landed, offloaded, transshipped or kept below deck only if NMFS requests the retention of a dead sea turtle or a part thereof for research.

[FR Doc. E9-18583 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 09100091344-9056-02]

RIN 0648-XQ72

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2009 total allowable catch (TAC) of Pacific ocean perch in the West Yakutat District of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 31, 2009, through 2400 hrs, A.l.t., December 31, 2009.

FOR FURTHER INFORMATION CONTACT: Patty Britza, 907-586-7376.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2009 TAC of Pacific ocean perch in the West Yakutat District of the GOA is 1,108 metric tons (mt) as established by the final 2009 and 2010 harvest specifications for groundfish of the GOA (74 FR 7333, February 17, 2009).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2009 TAC of Pacific ocean perch in the West Yakutat District of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,098 mt, and is setting aside the remaining 10 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting

directed fishing for Pacific ocean perch in the West Yakutat District of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific ocean perch in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 29, 2009.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

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

Dated: July 30, 2009.

Kristen C. Koch,

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

[FR Doc. E9-18582 Filed 7-30-09; 8:45 am]

BILLING CODE 3510-22-S

Proposed Rules

Federal Register

Vol. 74, No. 148

Tuesday, August 4, 2009

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 HOUSING FINANCE BOARD

12 CFR Part 914

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1235

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

12 CFR Part 1732

RIN 2590-AA10

Record Retention

AGENCIES: Federal Housing Finance Board; Federal Housing Finance Agency; Office of Federal Housing Enterprise Oversight.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Federal Housing Finance Agency (FHFA) is proposing a Record Retention regulation. The proposed regulation would set forth record retention requirements with respect to the record management programs of the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, the Federal Home Loan Banks, and the Office of Finance consistent with the safety and soundness authority of FHFA under the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended.

DATES: Comments on the proposed regulation must be received in writing on or before October 5, 2009. For additional information, see

SUPPLEMENTARY INFORMATION.

ADDRESSES: You may submit your comments on the proposed regulation, identified by regulatory information number (RIN) 2590-AA10, by any one of the following methods:

- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:*

The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590-AA10, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.

- *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590-AA10, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

- *E-mail:* Comments may be sent by e-mail to RegComments@fhfa.gov. Please include "RIN 2590-AA10" in the subject line of the message.

- *Federal eRulemaking:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal*, please also send it by e-mail to FHFA at RegComments@fhfa.gov to ensure timely receipt by the Agency. Please include "RIN 2590-AA10" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Andra Grossman, Senior Counsel, telephone (202) 343-1313 (not a toll-free number); Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877-8339.

SUPPLEMENTARY INFORMATION:

I. Comments

FHFA invites comments on all aspects of the proposed regulation, and will take all comments into consideration before issuing the final regulation. Copies of all comments will be posted without change, including any personal information you provide, such as your name and address, on the FHFA Web site at <http://www.fhfa.gov>.

In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414-6924.

II. Background

A. Establishment of the Federal Housing Finance Agency

The Housing and Economic Recovery Act of 2008 (HERA), Public Law No. 110-289, 122 Stat. 2654, amended the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 *et seq.*) (Safety and Soundness Act), and the Federal Home Loan Bank Act (12 U.S.C. 1421-1449) to establish FHFA as an independent agency of the Federal government.¹ FHFA was established to oversee the prudential operations of the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation (collectively, Enterprises), and the Federal Home Loan Banks (Banks) (collectively, regulated entities) to ensure that they operate in a safe and sound manner including being capitalized adequately; foster liquid, efficient, competitive and resilient national housing finance markets; comply with the Safety and Soundness Act and rules, regulations, guidelines and orders issued by the Director of FHFA (Director), and the respective authorizing statutes of the regulated entities; and carry out their missions through activities authorized and consistent with the Safety and Soundness Act and their authorizing statutes; and, that the activities and operations of the regulated entities are consistent with the public interest. FHFA also has regulatory authority over the Office of Finance under section 1311(b)(2) of the Safety and Soundness Act (12 U.S.C. 4511).

The Office of Finance is a joint office of the Banks that was established by a predecessor to FHFA. The Office of Finance is governed by a three-person board of directors consisting of two Bank presidents and one independent member. Under the regulations of the Federal Housing Finance Board (FHFB), the Office of Finance is subject to the same regulatory oversight authority and enforcement powers as are the Banks and their respective directors, officers, and employees.² The Office of Finance also is subject to the cease-and-desist authority of FHFA and its directors, officers and management are subject to

¹ See Division A, titled the "Federal Housing Finance Regulatory Reform Act of 2008," Title I, section 1101 of HERA.

² 12 CFR 985.4 and 985.7.

the removal and prohibition authority of FHFA.³ Although the Office of Finance is not directly covered by the Safety and Soundness Act, it is subject to the Director's "general regulatory authority" under section 1311(b)(2) of the Safety and Soundness Act (12 U.S.C. 4511(b)(2)), as amended by HERA. The Director is required to exercise that authority as necessary to ensure that the purposes of the Safety and Soundness Act, the authorizing statutes, and other applicable law are carried out. Based on its general regulatory authority over the Office of Finance, FHFA is proposing that this regulation apply to the Office of Finance.

The Office of Federal Housing Enterprise Oversight (OFHEO) and the FHFB will be abolished one year after enactment of the HERA. However, the regulated entities and the Office of Finance continue to operate under regulations promulgated by OFHEO and FHFB; and such regulations are enforceable by the Director of FHFA until such regulations are modified, terminated, set aside, or superseded by the Director of FHFA.⁴

B. Record Retention and Prudential Management and Operation Standards

The Safety and Soundness Act provides that the Director is to establish standards for each regulated entity and the Office of Finance to maintain adequate records, in accordance with consistent accounting policies and practices that enable the Director to evaluate the financial condition of each regulated entity and the Office of Finance and such other operational and management standards as the Director determines to be appropriate.⁵ The Safety and Soundness Act further provides the Director with general supervisory and regulatory authority over the regulated entities and the Office of Finance, and requires the Director to ensure that they operate in a safe and sound manner.⁶ Accordingly, this proposed regulation would address the record retention requirements of each regulated entity and the Office of Finance. The proposed regulation, when published in its final form, would supersede 12 CFR 914.3 (FHFB Access to Books and Records) and 12 CFR part 1732 (OFHEO Record Retention).

The proposed regulation would require the regulated entities and the Office of Finance to establish and maintain a record retention program to ensure that records are readily

accessible for examination and other supervisory purposes. FHFA recognizes that the effectiveness of the examination process is dependent upon the prompt production of complete and accurate records. FHFA, through the supervisory process, must have access to the records of a regulated entity and the Office of Finance that are necessary to determine the financial condition of the regulated entity and the Office of Finance or the details or the purpose of any transaction that may have a material effect on the financial condition of the regulated entity and the Office of Finance.

Retention of such records not only facilitates the examination process, but also allows a regulated entity and the Office of Finance to manage more effectively its business and detect improper behavior that might cause financial damage. Additionally, such records serve as documentation for a regulated entity and the Office of Finance in any controversy over its business activities or transactions.

The importance of sound record retention policies and procedures by regulated institutions also has been recognized by Congress and other federal regulators. Adequate record retention by the institutions has been determined to have a high degree of usefulness in criminal, tax, and regulatory investigations or proceedings, and has been identified as a requisite component of an institution's operation and management on a safety and soundness basis.⁷

In addition to facilitating the oversight and enforcement of federal banking laws, adequate record retention has been recognized by Congress as being essential to the oversight and enforcement of the federal securities laws. For example, as mandated by section 802 of the Sarbanes-Oxley Act,⁸ the U.S. Securities and Exchange Commission adopted rules requiring accounting firms to retain for seven years certain records relevant to their audits and reviews of issuers' financial statements. Records to be retained include an accounting firm's workpapers and certain other documents that contain conclusions, opinions, analyses, or financial data related to the audit or review.⁹ The proposed requirements would have no effect on the policies, rules, or guidance of other federal agencies that may require record retention terms or

practices different from those set forth in the proposal.

Section 1313(f) of the Safety and Soundness Act, as amended by section 1201 of HERA, requires the Director, when promulgating regulations relating to the Banks, to consider the differences between the Banks and the enterprises with respect to the Banks' cooperative ownership structure, mission of providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability. The Director may also consider any other differences that are deemed appropriate. In preparing the proposed regulation, the Director considered the differences between the Banks and the Enterprises as they relate to the above factors. The Director requests comments from the public about whether differences related to these factors should result in a revision of the proposed amendment as it relates to the Banks.

III. Section-by-Section Analysis

Section 1235.1 Purpose and Scope

This proposed section provides the purpose of the regulation is to set forth minimum requirements in connection with the record retention program of each regulated entity and the Office of Finance. Such requirements would be intended to ensure that complete and accurate records of each regulated entity and the Office of Finance are readily accessible by FHFA for examination and other supervisory purposes.

Section 1235.2 Definitions

This proposed section would provide definitions for the terms contained in the proposed regulation.

Active record would be defined as a record that is necessary to conduct the current business of an office or business unit of a regulated entity or the Office of Finance, and therefore, readily available for consultation and reference.

Director would be defined as the Director of FHFA, or his or her designee.

Electronic record would be defined as a record created, generated, communicated, or stored by electronic means.

E-mail would be defined as electronic mail, which is a method of communication in which—

(1) Usually, text is transmitted (but sometimes also graphics and/or audio information);

(2) Operations include sending, storing, processing, and receiving information;

(3) Users are allowed to communicate under specified conditions; and

(4) Messages are held in storage until called for by the addressee, including

³ 12 U.S.C. 4631(a) and 4636a(a).

⁴ See sections 1302 and 1312 of HERA.

⁵ 12 U.S.C. 4513b(a)(10) and (11).

⁶ 12 U.S.C. 4511(b), 4513(a).

⁷ See, e.g., 12 U.S.C. 1829b, and the Guidelines and Interagency Standards for Safety and Soundness at 12 CFR part 30, Appendix A, II, B.

⁸ Public Law 107-204, 116 Stat. 745 (2002).

⁹ 17 CFR part 210.

any attachment of separate electronic files.

Employee would be defined as any officer or employee of a regulated entity and the Office of Finance or any conservator appointed by FHFA.

Federal Home Loan Bank or *Bank* would be defined as a Bank established under the Federal Home Loan Bank Act; the term “Federal Home Loan Banks” or “Banks” would be defined to mean, collectively, all the Federal Home Loan Banks.

FHFA would be defined as the Federal Housing Finance Agency.

Financing Corporation (FICO) would mean the entity established by the Competitive Equality Banking Act of 1987, as a mixed-ownership government corporation whose purpose is to function as a financing vehicle for the Federal Savings & Loan Insurance Corporation. FICO has a board of directors consisting of the managing director of the Office of Finance and two Bank presidents.

Inactive record would be defined as a record that is seldom used but must be retained by a regulated entity and the Office of Finance for fiscal, legal, historical, or vital records purposes.

Office of Finance would be defined as the Office of Finance of the Federal Home Loan Bank System.

Record would be defined as any information, whether generated internally or received from outside sources by a regulated entity or the Office of Finance or employee, maintained in connection with a regulated entity or Office of Finance business (which business, in the case of the Office of Finance, shall include any functions performed with respect to the FICO), regardless of the following—

(1) Form or format, including hard copy documents (e.g., files, logs, and reports) and electronic documents (e.g., e-mail, databases, spreadsheets, PowerPoint presentations, electronic reporting systems, electronic tapes and back-up tapes, optical discs, CD-ROMS, and DVDs), and voicemail records;

(2) Where the information is stored or located, including network servers, desktop or laptop computers and handheld computers, other wireless devices with text messaging capabilities, and on-site or off-site at a storage facility;

(3) Whether the information is maintained or used on regulated entity-owned or Office of Finance equipment, or personal or home computer systems of an employee; or

(4) Whether the information is active or inactive.

Record hold would be defined as a requirement, an order, or a directive

from a regulated entity, the Office of Finance or FHFA that the regulated entity or the Office of Finance is to retain records relating to a particular issue in connection with an actual or a potential FHFA examination, investigation, enforcement proceeding, or litigation of which the regulated entity and the Office of Finance has received notice from FHFA.

Record retention schedule would be defined as a schedule that details the categories of records a regulated entity or the Office of Finance is required to retain and the corresponding retention periods. The record retention schedule includes all media, such as microfilm and machine-readable computer records, for each record category. Reproductions are also included for each record category if the original of the official record is not available.

Regulated entity would be defined as the Federal National Mortgage Association and any affiliate thereof, the Federal Home Loan Mortgage Corporation and any affiliate thereof, or any Federal Home Loan Bank; the term “regulated entities” would be defined to mean, collectively, the Federal National Mortgage Association and any affiliate thereof, the Federal Home Loan Mortgage Corporation and any affiliate thereof, and the Federal Home Loan Banks.

Retention period would be defined as the length of time that records must be kept before they are destroyed. Records not authorized for destruction have a retention period of “permanent.”

Safety and Soundness Act would be defined as the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 *et seq.*), as amended by the Housing and Economic Recovery Act of 2008, Public Law No. 110–289, 122 Stat. 2654 (2008).

Vital records would be defined as records that are needed to meet operational responsibilities of a regulated entity or the Office of Finance under emergency or disaster conditions (emergency operating records) or to protect the legal and financial rights of a regulated entity or the Office of Finance. Emergency operating records are the type of vital records essential to the continued functioning or reconstitution of a regulated entity or the Office of Finance during and after an emergency. A vital record may be both an emergency operating record and a legal and financial rights record.

Section 1235.3 Establishment and Evaluation of Record Retention Program

This proposed section would require each regulated entity and the Office of Finance to establish and maintain a

written record retention program and provide a copy of such program to the Deputy Director of the Division of Enterprise Regulation and the Deputy Director of the Division of Federal Home Loan Bank Regulation, or his or her designee (Deputy Director), as appropriate, within 120 days of the effective date of this part, and annually thereafter, and whenever a significant revision to the program has been made.

It would also require management of the regulated entity and the Office of Finance to evaluate in writing the adequacy and effectiveness of the record retention program at least every three years and provide a copy of the evaluation to the board of directors and the appropriate Deputy Director.

Section 1235.4 Minimum Requirements of Record Retention Program

This proposed section would provide the minimum requirements for the record retention program of each regulated entity and the Office of Finance, including requirements relating to a record retention schedule.

Section 1235.5 Record Hold

This proposed section would address record retention methods, record access and retrieval policies, and notification procedures for employees. Moreover, the section would require a regulated entity's or the Office of Finance's employee who is aware of a potential FHFA investigation, enforcement proceeding, or litigation involving the regulated entity or the Office of Finance or an employee to notify immediately the legal department of the regulated entity or the Office of Finance and retain any records that may be relevant to such investigation, enforcement proceeding, or litigation.

Section 1235.6 Access to Records

This proposed section would set forth the requirement that records must be readily available for inspection within a reasonable period upon request by FHFA, at a location acceptable to FHFA. For requests made during the course of an onsite examination and pursuant to an examination's scope, a reasonable period is no longer than one business day and for requests for documents made outside of an onsite examination, a reasonable period is presumed to be three business days.

Section 1235.7 Supervisory Action

This proposed section would provide that failure by a regulated entity or the Office of Finance to comply with the requirements of the proposed regulation may subject the regulated entity or the

Office of Finance, or its board members, officers, or employees to supervisory action by FHFA. The section also would provide that the proposed regulation does not limit the authority of FHFA under its safety and soundness mandate to take other actions such as conducting examinations, requiring reports and disclosures, and enforcing compliance with applicable laws, rules and regulations.

Regulatory Impact

Paperwork Reduction Act

Because the proposed regulation pertains to the regulated entities and the Office of Finance, it does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the proposed regulation under the Regulatory Flexibility Act. FHFA certifies that the proposed regulation, if adopted, is not likely to have a significant economic impact on a substantial number of small business entities because the regulation is applicable only to the regulated entities and the Office of Finance, which are not small entities for purposes of the Regulatory Flexibility Act.

List of Subjects

12 CFR Part 914

Federal home loan banks, Reporting and recordkeeping requirements.

12 CFR Part 1235

Federal home loan banks, Government-sponsored enterprises, Records, Reporting and recordkeeping requirements.

12 CFR Part 1732

Government-sponsored enterprises, Records, Reporting and recordkeeping requirements.

Authority and Issuance

Accordingly, for the reasons stated in the preamble, under the authority of 12 U.S.C. 4513b, FHFA proposes to amend Chapters IX, XII and XVII of title 12 of the Code of Federal Regulations, as set forth below:

CHAPTER IX—FEDERAL HOUSING FINANCE BOARD

PART 914—DATA AVAILABILITY AND REPORTING

1. The authority citation for part 914 is revised to read as follows:

Authority: 12 U.S.C. 1440 and 4526.

§ 914.3 [Removed and reserved]

2. Remove and reserve § 914.3.

CHAPTER XII—FEDERAL HOUSING FINANCE AGENCY

SUBCHAPTER B—ENTITY REGULATIONS

3. Add part 1235 to subchapter B to read as follows:

PART 1235—RECORD RETENTION

Sec.

1235.1 Purpose and scope.

1235.2 Definitions.

1235.3 Establishment and evaluation of record retention program.

1235.4 Minimum requirements of record retention program.

1235.5 Record hold.

1235.6 Access to records.

1235.7 Supervisory action.

Authority: 12 U.S.C. 4511(b), 4513(a), 4513b(a)(10) and (11), 4526.

§ 1235.1 Purpose and scope.

The purpose of this part is to set forth minimum requirements in connection with the record retention program of each regulated entity and the Office of Finance. The requirements are intended to ensure that complete and accurate records of each regulated entity and the Office of Finance are readily accessible by FHFA for examination and other supervisory purposes.

§ 1235.2 Definitions.

For purposes of this part, the term—

Active record means a record that is necessary to conduct the current business of an office or business unit of a regulated entity and the Office of Finance, and therefore, is readily available for consultation and reference.

Director means the Director of FHFA, or his or her designee.

Electronic record means a record created, generated, communicated, or stored by electronic means.

E-mail means electronic mail, which is a method of communication in which—

(1) Usually, text is transmitted (but sometimes also graphics and/or audio information);

(2) Operations include sending, storing, processing, and receiving information;

(3) Users are allowed to communicate under specified conditions; and

(4) Messages are held in storage until called for by the addressee, including any attachment of separate electronic files.

Employee means any officer or employee of a regulated entity or the Office of Finance or of any conservator appointed by FHFA.

Federal Home Loan Bank or *Bank* means a Bank established under the Federal Home Loan Bank Act; the term *Federal Home Loan Banks* or *Banks* means, collectively, all the Federal Home Loan Banks.

FHFA means the Federal Housing Finance Agency.

Financing Corporation (FICO) means the entity established by the Competitive Equality Banking Act of 1987, as a mixed-ownership government corporation whose purpose is to function as a financing vehicle for the Federal Savings & Loan Insurance Corporation. FICO has a board of directors consisting of the managing director of the Office of Finance and two Bank presidents.

Inactive record means a record that is seldom used but must be retained by a regulated entity or the Office of Finance for fiscal, legal, historical, or vital records purposes.

Office of Finance means the Office of Finance of the Federal Home Loan Bank System.

Record means any information, whether generated internally or received from outside sources by a regulated entity or the Office of Finance or employee, maintained in connection with a regulated entity or Office of Finance business (which business, in the case of the Office of Finance, shall include any functions performed with respect to the Financing Corporation), regardless of the following—

(1) Form or format, including hard copy documents (*e.g.*, files, logs, and reports) and electronic documents (*e.g.*, e-mail, databases, spreadsheets, PowerPoint presentations, electronic reporting systems, electronic tapes and back-up tapes, optical discs, CD-ROMS, and DVDs), and voicemail records;

(2) Where the information is stored or located, including network servers, desktop or laptop computers and handheld computers, other wireless devices with text messaging capabilities, and on-site or off-site at a storage facility;

(3) Whether the information is maintained or used on regulated entity-owned or Office of Finance equipment, or personal or home computer systems of an employee; or

(4) Whether the information is active or inactive.

Record hold means a requirement, an order, or a directive from a regulated entity, the Office of Finance, or FHFA that the regulated entity or the Office of Finance is to retain records relating to a particular issue in connection with an actual or a potential FHFA examination, investigation, enforcement proceeding, or litigation of which the regulated entity or the Office of Finance has received notice from FHFA.

Record retention schedule means a schedule that details the categories of records a regulated entity or the Office of Finance is required to retain and the corresponding retention periods. The record retention schedule includes all media, such as microfilm and machine-readable computer records, for each record category. Reproductions are also included for each record category if the original of the official record is not available.

Regulated entity means the Federal National Mortgage Association and any affiliate thereof, the Federal Home Loan Mortgage Corporation and any affiliate thereof, or any Federal Home Loan Bank; the term "regulated entities" means, collectively, the Federal National Mortgage Association and any affiliate thereof, the Federal Home Loan Mortgage Corporation and any affiliate thereof, and the Federal Home Loan Banks.

Retention period means the length of time that records must be kept before they are destroyed. Records not authorized for destruction have a retention period of "permanent."

Safety and Soundness Act means the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 *et seq.*), as amended.

Vital records means records that are needed to meet operational responsibilities of a regulated entity or the Office of Finance under emergency or disaster conditions (emergency operating records) or to protect the legal and financial rights of a regulated entity or the Office of Finance. Emergency operating records are the type of vital records essential to the continued functioning or reconstitution of a regulated entity or the Office of Finance during and after an emergency. A vital record may be both an emergency operating record and a legal and financial rights record.

§ 1235.3 Establishment and evaluation of record retention program.

(a) *Establishment.* Each regulated entity and the Office of Finance shall establish and maintain a written record retention program and provide a copy of such program to the Deputy Director of the Division of Enterprise Regulation, or his or her designee, or the Deputy Director of the Division of Federal Home Loan Bank Regulation, or his or her designee (Deputy Director), as appropriate, within 120 days of the effective date of this part, and annually thereafter, and whenever a significant revision to the program has been made.

(b) *Evaluation.* Management of each regulated entity and the Office of Finance shall evaluate in writing the adequacy and effectiveness of the record retention program at least every three years and provide a copy of the evaluation to the board of directors and the appropriate Deputy Director.

§ 1235.4 Minimum requirements of record retention program.

(a) *Requirements.* The record retention program established and maintained by each regulated entity and the Office of Finance under § 1235.3 shall:

(1) Be reasonably designed to assure that retained records are complete and accurate;

(2) Be reasonably designed to assure that the format of retained records and the retention period—

(i) Are adequate to support litigation and the administrative, business, external and internal audit functions of the regulated entity or the Office of Finance;

(ii) Comply with requirements of applicable laws and regulations; and

(iii) Permit ready access by the regulated entity or the Office of Finance and, upon request, by the examination and other staff of FHFA by reasonable means, consistent with the nature and availability of the records and existing information technology.

(3) Assign in writing the authorities and responsibilities for record retention activities;

(4) Include policies and procedures concerning record holds, consistent with § 1235.5;

(5) Include an accurate, current, and comprehensive record retention schedule that lists records by major categories, subcategories, record type, and retention period, which retention period is appropriate to the specific record and consistent with applicable legal, regulatory, fiscal, and operational and business requirements;

(6) Include adequate security and internal controls to protect records from

unauthorized access and data alteration; and

(7) Provide for adequate back-up and recovery of electronic records.

(b) *Training.* The record retention program shall provide for training of and notice to all employees on a periodic basis on their record retention responsibilities, including instruction regarding penalties provided by law for the unlawful removal or destruction of records. The record retention program also shall provide for training for the agents or independent contractors of a regulated entity or the Office of Finance, as appropriate, consistent with their respective roles and responsibilities to the regulated entity or the Office of Finance.

§ 1235.5 Record hold.

(a) *Notification by a regulated entity or the Office of Finance.* The record retention program of a regulated entity and the Office of Finance shall—

(1) Address how employees and, as appropriate, how agents or independent contractors consistent with their respective roles and responsibilities to the regulated entity or the Office of Finance, will receive prompt notification of a record hold;

(2) Designate an individual to communicate specific requirements and instructions, including, when necessary, the instruction to cease immediately any otherwise permissible destruction of records; and

(3) Provide that any employee and, as appropriate, any agent or independent contractor consistent with his or her respective role and responsibility to the regulated entity, who has received notice of a potential investigation, enforcement proceeding, or litigation by FHFA involving the regulated entity or the Office of Finance or an employee, or otherwise has actual knowledge that an issue is subject to such an investigation, enforcement proceeding or litigation, shall notify immediately the legal department of the regulated entity or the Office of Finance and shall retain any records that may be relevant in any way to such investigation, enforcement proceeding, or litigation.

(b) *Method of record retention.* The record retention program of each regulated entity and the Office of Finance shall address the method by which the regulated entity or the Office of Finance will retain records during a record hold. Specifically, the program shall describe the method for the continued preservation of electronic records, including e-mails, and the conversion of records from paper to electronic format as well as any alternative storage method.

(c) *Access to and retrieval of records during a record hold.* The record retention program of each regulated entity or the Office of Finance shall ensure access to and retrieval of records by the regulated entity or the Office of Finance and access, upon request, by FHFA, during a record hold. Such access shall be by reasonable means, consistent with the nature and availability of the records and existing information technology.

§ 1235.6 Access to records.

(a) *Access to records.* Each regulated entity or the Office of Finance shall make its records readily available for inspection and other supervisory purposes within a reasonable period upon request by FHFA, at a location acceptable to FHFA and by reasonable means, consistent with the nature and availability of the records and existing information technology.

(b) *Reasonable period.* For requests for documents made during the course of an on-site examination and pursuant to the examination's scope, a reasonable period is presumed to be no longer than one business day. For requests for documents made outside of an on-site examination, a reasonable period is presumed to be three business days.

§ 1235.7 Supervisory action.

(a) *Supervisory action.* Failure by a regulated entity or the Office of Finance to comply with this part may subject the regulated entity or the Office of Finance or the board members, officers, or employees thereof to supervisory action by FHFA under the Safety and Soundness Act, including but not limited to cease-and-desist proceedings, temporary cease-and-desist proceedings, and civil money penalties.

(b) *No limitation of authority.* This part does not limit or restrict the authority of FHFA to act under its safety and soundness mandate, in accordance with the Safety and Soundness Act. Such authority includes, but is not limited to, conducting examinations, requiring reports and disclosures, and enforcing compliance with applicable laws, rules, and regulations.

CHAPTER XVII—OFFICE OF FEDERAL HOUSING ENTERPRISE OVERSIGHT, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PART 1732—[REMOVED]

4. Remove part 1732.

Dated: July 28, 2009.

James B. Lockhart III,

Director, Federal Housing Finance Agency.

[FR Doc. E9-18489 Filed 8-3-09; 8:45 am]

BILLING CODE P

FEDERAL HOUSING FINANCE BOARD

12 CFR Parts 985, 989

FEDERAL HOUSING FINANCE AGENCY

12 CFR Parts 1273, 1274

RIN 2590-AA30

Board of Directors of Federal Home Loan Bank System Office of Finance

AGENCY: Federal Housing Finance Agency; Federal Housing Finance Board.

ACTION: Notice of proposed rulemaking; request for comment.

SUMMARY: Governed by the Federal Housing Finance Agency's (FHFA) regulations, the Federal Home Loan Bank System's (System) Office of Finance, issues debt ("consolidated obligations") on which the Federal Home Loan Banks (Banks) are jointly and severally liable and publishes combined financial reports on the Banks so that investors in the consolidated obligations can assess the strength of the System that stands behind them. The Office of Finance (OF) is governed by a board of directors, the composition and functions of which are determined by FHFA's regulations. The FHFA's experience with the System and with the OF's combined financial reports during the recent period of market stress suggests that the OF and the System could benefit from a reconstituted and strengthened board. This proposed regulation is intended to achieve that.

DATES: Comments on the proposed regulation must be received on or before October 5, 2009. For additional information, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: You may submit your comments on the proposed regulation, identified by regulatory information number (RIN) 2590-AA30 by any of the following methods:

- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590-AA30, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.
- *Hand Delivery/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590-AA30, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

• *E-mail:* Comments to Alfred M. Pollard, General Counsel may be sent by e-mail at RegComments@FHFA.gov. Please include "RIN 2590-AA30" in the subject line of the message.

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

FOR FURTHER INFORMATION CONTACT:

Joseph A. McKenzie, 202-408-2845, Division of Federal Home Loan Bank Regulation, Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006; or Neil Crowley, Deputy General Counsel, 202-343-1316, or Thomas E. Joseph, Senior Attorney-Advisor, 202-414-3095, Office of General Counsel, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877-8339.

SUPPLEMENTARY INFORMATION:

I. Comments

The FHFA invites comments on all aspects of the proposed regulation, and will adopt a final regulation with appropriate changes after taking all comments into consideration. Copies of all comments will be posted on the Internet Web site at <https://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414-6924.

II. Background

A. Creation of the Federal Housing Finance Agency and Recent Legislation

Effective July 30, 2008, the Housing and Economic Recovery Act of 2008 (HERA), Public Law 110-289, 122 Stat. 2654, transferred the supervisory and oversight responsibilities of the Office of Federal Housing Enterprise Oversight (OFHEO) over the Federal National Mortgage Association (Fannie Mae), and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises), the oversight responsibilities of the Federal Housing Finance Board (FHFB or Finance Board) over the Banks and the Office of Finance (OF) (which acts as the Banks' fiscal agent) and certain functions of the Department of Housing and Urban Development to a new independent executive branch agency, the FHFA. See *id.* at § 1101, 122 Stat. 2661-62 (*amending* 12 U.S.C. 4511). The FHFA

is responsible for ensuring that the Enterprises and the Banks operate in a safe and sound manner, including that they maintain adequate capital and internal controls, that their activities foster liquid, efficient, competitive and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See id.* at § 1102, 122 Stat. 2663–64. The Enterprises, the Banks, and the OF continue to operate under regulations promulgated by OFHEO and the FHFB until the FHFA issues its own regulations. *See id.* at §§ 1302, 1313, 122 Stat. 2795, 2798.

B. The Bank System Generally

The twelve Banks are instrumentalities of the United States organized under the Federal Home Loan Bank Act (Bank Act).¹ *See* 12 U.S.C. 1423, 1432(a). The Banks are cooperatives; only members of a Bank may purchase the capital stock of a Bank, and only members or certain eligible housing associates (such as State housing finance agencies) may obtain access to secured loans, known as advances or other products provided by a Bank. *See* 12 U.S.C. 1426(a)(4), 1430(a), 1430b. Each Bank is managed by its own board of directors and serves the public interest by enhancing the availability of residential mortgage and community lending credit through its member institutions. *See* 12 U.S.C. 1427. Any eligible institution (generally a Federally insured depository institution or State-regulated insurance company) may become a member of a Bank if it satisfies certain criteria and purchases a specified amount of the Bank's capital stock. *See* 12 U.S.C. 1424; 12 CFR part 925.

As government-sponsored enterprises (GSEs), the Banks are granted certain privileges under Federal law. In light of those privileges and their status as GSEs, the Banks typically can borrow funds at spreads over the rates on U.S. Treasury securities of comparable maturity lower than most other entities. The Banks pass along a portion of their GSE funding advantage to their members—and ultimately to consumers—by providing advances and other financial services at rates that would not otherwise be available to their members. Consolidated obligations (COs), consisting of bonds and discount notes, are the principal funding source for the Banks. The OF issues all COs on behalf of the twelve Banks. Although

each Bank is primarily liable for the portion of consolidated obligations corresponding to the proceeds received by that Bank, each Bank is also jointly and severally liable with the other eleven Banks for the payment of principal and interest on all COs. *See* 12 CFR 966.9.

C. The OF

The OF was one of a number of joint Bank offices established by regulation by the former Federal Home Loan Bank Board (FHLBB), a predecessor agency to the FHFA. *See* 65 FR 324, 326 (Jan. 4, 2000). The OF was originally formed from two other joint Bank Offices, the Office of System Finance and the Office of Fiscal Agent. Among other things, OF was assigned the duties previously vested in the Fiscal Agent which included facilitating the issuance of COs. *Id.*

In 1989, as part of the amendments made to the Bank Act by the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA),² all joint offices of the Bank System other than the OF were abolished. The FHLBB was also abolished and its regulatory authority over the Bank System, including OF, was transferred to the Finance Board. The FHLBB's regulations were also transferred to the Finance Board. *Id.* In 1992, the Finance Board reorganized the OF as fiscal agent of the Finance Board for issuing COs under section 11(c) of the Bank Act, and set forth other duties for OF.³ *See* 57 FR 11429 (Apr. 3, 1992) (*adopting* 12 CFR part 941). The regulation also instituted a three-member board of directors for the oversight and management of the OF, made up of two Bank presidents and a private United States citizen with demonstrated expertise in financial markets. *Id.*

In January 2000, the Finance Board proposed changes to its regulations to alter how COs were issued under section 11 of the Bank Act, reorganize the OF and its board of directors, and expand the duties of the OF, including assigning OF the duty to prepare the Bank System combined annual and quarterly financial reports. *See* 65 FR 324. As proposed, the January 2000 regulation transferred authority for issuance of the Bank COs from the Finance Board, which had been issuing

debt pursuant to then-existing authority under section 11(c) of the Bank Act, to the Banks themselves pursuant to authority under section 11(a) of the Bank Act and subject to the requirement, among other things, that all such debt issued by the Banks be the joint and several obligations of all twelve Banks and be issued through OF as their agent. *Id.* Under the proposed regulation, the Finance Board retained the option to issue COs itself under section 11(c) of the Bank Act at any point in the future.

The Finance Board also believed that “[a]s a natural and necessary adjunct to the issuance of COs, the Banks also should be responsible for the preparation of the disclosure documents that facilitate CO issuance and for the periodic combined financial statements for the Bank System.” *Id.* at 325. The Finance Board therefore proposed that OF, as the only joint Bank System office and existing agent for CO issuance, be assigned the duty of preparing the Bank System's combined financial reports. *Id.* The Finance Board also proposed to codify disclosure standards in the regulation, many of which had been set forth in a Finance Board policy statement. Other duties related to debt issuance and management were also proposed to be assigned to OF.

In light of the expanded duties assigned to OF as well as amendments to the Bank Act that had recently been made by the Gramm-Leach-Bliley Act (GLB Act),⁴ the Finance Board also thought it was appropriate to alter both the size and composition of the OF board. *Id.* at 326. The Finance Board had two main goals in proposing its changes. First, it wanted to build on the governance structure in the Bank Act by which the Banks should be provided greater autonomy to manage their affairs. Second, it wanted to assure each Bank had representation on the OF board to help achieve operational goals and wanted to assure that the OF board itself had directors with experience and qualification to help OF meet the evolving needs of the Bank System.

Under the 2000 proposal, the OF board of directors would have been expanded to 24 members, 12 of whom would have been appointed by the Banks, 6 of whom would have been elected by Bank members and 6 of whom would have been appointed by the Finance Board. The Finance Board also proposed that the chair and vice chair of the board be appointed by the Finance Board. The proposal would have required the OF board of directors

² Public Law 101–73, 103 Stat. 183 (Aug. 9, 1989).

³ As it existed in 1992, section 11(c) of the Bank Act provided the Finance Board authority to issue the debt on which the Banks were jointly and severally liable. 12 U.S.C. 1431(c)(1992). HERA recently amended this provision and removed authority from the regulator to issue such debt on behalf of the Banks and provided the OF as agent for the Banks with authority to issue the COs. *See* § 1204(3)(B), Public Law 110–289, 122 Stat. 2786.

¹ Each Bank is generally referred to by the name of the city in which it is located. The twelve Banks are located in: Boston, New York, Pittsburgh, Atlanta, Cincinnati, Indianapolis, Chicago, Des Moines, Dallas, Topeka, San Francisco, and Seattle.

⁴ Public Law 106–102, 113 Stat. 1338 (Nov. 12, 1999).

to establish an audit committee with duties similar to those established under the regulations for the Banks' audit committees, an executive committee, and a committee to coordinate the issuance and servicing of COs.

After consideration of the comments on the proposed regulation, the Finance Board adopted many of the changes including those authorizing the Banks to issue COs under section 11(a) of the Bank Act and assigning to OF the function of preparing the Bank System's combined financial reports, along with additional duties. *See* 65 FR 36290 (June 7, 2000) (*adopting* among other parts 12 CFR parts 966 and 985). The Finance Board did not, however, adopt the proposed changes to the OF board structure or composition. Instead, the new regulation incorporated the prior three-person board structure. The Finance Board also specified some additional duties for the OF board consistent with the additional functions that had been assigned to OF over the years. Since the 2000 rulemaking, no significant changes to the regulations governing the OF have been proposed.

D. Considerations of Differences Between the Banks and the Enterprises

Section 1201 of HERA requires the Director, when promulgating regulations relating to the Banks, to consider the following differences between the Banks and the Enterprises: Cooperative ownership structure; Mission of providing liquidity to members; Affordable housing and community development mission; capital structure; and Joint and several liability. *See* § 1201 Public Law 110–289, 122 Stat. 2782–83 (*amending* 12 U.S.C. 4513). The Director also may consider any other differences that are deemed appropriate. In preparing this proposed regulation, the FHFA considered the differences between the Banks and the Enterprises as they relate to the above factors. The FHFA requests comments from the public about whether differences related to these factors should result in any revisions to the proposal.

III. The Proposed Regulation

A. Reasons for the Proposed Regulation Changes

As discussed in detail below, the FHFA is proposing a number of changes to the size and structure of the OF board of directors and how the OF board exercises oversight over the process for preparing the Bank System's combined financial reports. The FHFA believes that these changes will assist the Banks in coordinating among themselves the

process of providing OF the necessary information to prepare the System combined financial reports, and that these changes will facilitate accurate and meaningful disclosure in the combined reports and, thereby, garner market confidence.

Because the Bank System's main source of funding is COs on which the Banks are jointly and severally liable, the combined financial reports prepared by OF remain an important source of information about the financial state of the Bank System as a whole and are an important tool in marketing System debt and in assuring the Banks' access to domestic and international financial markets. For these purposes, the combined financial reports provide a single source of information about the Bank System. Assuring that this information is consistent and can readily be compared across all Banks is important to market acceptance of Bank debt and hence to the continued financial health of the Banks.

The proposed regulation would achieve these purposes with two principal elements: first, by expanding the OF's board to include all of the Federal Home Loan Bank presidents plus an audit committee comprising three to five independent directors; and second, by empowering the audit committee to ensure that the combined financial reports are compiled using common accounting policies and procedures across the twelve Banks. The FHFA's authority to adopt this regulation is grounded in its general supervisory authority over the OF and the Banks, 12 U.S.C. 1311(b)(2), 1313(a)(1), 1319G, 1431.

B. Overview of the Proposed Regulation

The proposed regulation would re-adopt many of the provisions in current 12 CFR part 985, which established the OF and governs the duties and function of OF and its board of directors, and in 12 CFR part 989, which address audit requirements and financial statements for the Banks. It would, however, make a number of amendments to the current regulations, most significantly with regard to the structure and duties of both the OF board of directors and its audit committee. The proposed regulation also would make some changes with regard to the standards governing the Bank System's combined financial reports and would amend some of the current part 985 provisions to conform the regulatory language to statutory changes made by HERA. Under the proposed regulation, the regulations that had been set forth in the parts 985 and 989 of the former Finance Board regulations, would be removed

and adopted by the FHFA, respectively, as 12 CFR parts 1273 and 1274.

Proposed part 1273 would provide regulations which re-establish the OF and set forth its duties, and functions. Under part 1273 as proposed, the specification of the OF's authority and functions would remain substantially unchanged, although the language in the regulations would be altered to reflect the fact that the FHFA is no longer authorized to issue debt on behalf of the Banks and the OF would thus be acting only as an agent for the Banks with respect to its debt issuance duties. *See* n.3 *supra*. The Banks would also remain responsible for jointly funding the OF, and the process and requirements for providing such funding would not change to any great degree. Under proposed § 1273.5, however, the formula for calculating each Bank's *pro rata* share of the reimbursement owed the OF would no longer be based on a formula set forth in the regulation. Instead, the OF board of directors would be allowed to establish any reasonable formula, subject to the right of the FHFA to review such formula and require changes to it.

The debt management functions and duties assigned to OF also would also remain much the same under the proposed regulation as currently, although, as discussed more fully below, the FHFA is proposing some changes to the standards governing the preparation of the combined financial reports. Under the proposed regulation, the OF would also still be required to monitor the unsecured credit exposure of the Banks and would be required to compile relevant data on such exposures.

As proposed, the specific requirements now set forth in 12 CFR part 989 would be readopted in part 12 CFR part 1274 almost in their entirety. The proposed regulation would make some conforming changes in § 1274.2 to reflect the fact that the FHFA is proposing an audit committee to be established for OF which would have a composition that is different from that of the OF board of directors as a whole. In addition, current section 989.4 of this title, which relates to voluntary Bank disclosure of financials, would not be re-adopted as part of the proposed part 1274 regulations. This particular provision pre-dated the Banks' registration of their stock with the Securities and Exchange Commission (SEC). Given that an individual Bank's disclosure of financial information is now subject to the SEC's regulations and oversight, the FHFA does not see a need to maintain this provision going forward.

C. Proposed Changes in OF Board Structure and Process for Selecting Directors

The new structure being proposed for the OF board of directors is set forth in proposed § 1273.7. Under this provision, the OF board of directors would be composed of 15 to 17 part-time members—the twelve Bank presidents and three to five independent directors. The independent directors would be required to be citizens of the United States and none could be an officer, employee, or director of any Bank or Bank System member, nor could the independent director have any substantial financial interest in a Bank System member. Persons affiliated with or having substantial financial interests in any CO seller or dealer group member under contract with OF would not qualify to be an independent director. The proposed regulation would also require the independent directors, as a group, to have substantial experience in financial and accounting matters.

Under the proposed regulation, the FHFA would appoint the first independent directors that serve on the board after the effective date of the regulation from candidates nominated by the Banks. Thereafter, the independent directors would be elected by majority vote of the OF board of directors. If the FHFA objected to the election of any individual independent director, the FHFA would retain the ability to appoint a more qualified director. As a practical matter, the FHFA would expect the OF board of directors to provide the names of, and background information on, nominees for board positions in sufficient time for the FHFA to raise any concerns prior to the actual election.

Terms for independent directors would be set at five years, although the proposal would require staggering of the seats to assure that no more than one seat would be scheduled to become vacant in any one year, so the initial terms could range from one to five years. If an independent director's seat became vacant for any reason before the end of a scheduled term, the proposed regulation would allow that seat to be filled by majority vote of the OF board, but only for the remainder of the original term.

The proposed regulation would also allow the FHFA to appoint the initial chair and vice chair of the OF board. The chair would be one of the independent directors while the vice chair could be appointed from among any of the directors. After the term of the initial chair or vice chair expired or became vacant for any other reason, the

proposal would allow subsequent chairs and vice chairs to be elected by majority vote of the OF board. The chair would be elected from among the independent directors while the vice chair could be elected from among any of the directors. Under the proposal, the FHFA would retain the authority to object to the election of any chair or vice chair by providing the OF board of directors written notice within 20 calendar-days, upon FHFA receipt of notification of the election, and the board of OF would then be required to promptly elect a new chair or vice chair as appropriate.

The OF board of directors would be authorized to create committees, such as an executive committee, and to delegate authority to such committees, although the regulation would specifically require that an audit committee be established and would specify the duties of that committee. The functions and duties of any committee (including the scope of any delegation) would be specified in the board's bylaws or in specific committee charters. The bylaws and charters would be subject to review and approval by the FHFA. The OF board, or any committee thereof including the audit committee, would be authorized to hire outside counsel, independent accountants, or other outside experts at the expense of the OF to help it carry out its duties.

As under the current regulations, the proposed regulation would specify that Bank presidents would serve without additional compensation. The compensation for the independent directors would be set in accordance with 12 CFR part 918, which currently governs compensation for directors and chairs of the Banks' boards of directors. The current indemnification provision would also be carried over to the new regulation as now proposed.

The proposed duties of the OF board of directors are set forth in proposed § 1273.8. These duties closely correspond to those in the current regulations. Duties and functions related to the preparation of the combined financial reports and oversight of the internal and external audit function for OF and the combined reports, which are currently among the duties of the OF board of directors, would be specifically transferred to the audit committee, as is discussed in the next section.

D. Proposed Changes for Audit Committee

Under the proposed regulation, the audit committee, constituted as described above, would assume the board's responsibilities for overseeing the audit function of the OF and the OF's preparation of accurate combined

financial reports, including selection and appointment of the OF's internal and external auditors. As part of its responsibilities, the audit committee would be specifically authorized to ensure that the Banks adopt consistent accounting policies and procedures so that the combined financial reports will continue to be accurate and meaningful. If the Banks are not able to agree on such consistent accounting policies and procedures, the audit committee, in consultation with the FHFA, may prescribe them.

E. Proposed Changes in Disclosure Standards

Consistent with the responsibility of the audit committee to ensure consistency of accounting policies and procedures across the Bank System, the regulations governing the content of the combined financial reports would be amended to include a requirement that information about the Banks be presented using consistent accounting policies and procedures (proposed § 1273.6(b)(2)). In addition, in acknowledgement of the increasingly national business models of major holding companies who can access multiple Banks through subsidiaries in different Bank districts, the regulations would be amended to include requirements that the combined financial reports include lists of the top ten holders of advances and of stock in the Bank System by holding company (proposed Part 1273 Appendix A, paragraphs A and G).

IV. Paperwork Reduction Act

The proposed regulation does not contain any collections of information pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Therefore, the FHFA has not submitted any information to the Office of Management and Budget for review.

V. Regulatory Flexibility Act

The proposed regulation applies only to the Banks, which do not come within the meaning of small entities as defined in the Regulatory Flexibility Act (RFA). See 5 U.S.C. 601(6). Therefore in accordance with section 605(b) of the RFA, the FHFA certifies that this proposed regulation, if promulgated as a final regulation, will not have significant economic impact on a substantial number of small entities.

List of Subjects

12 CFR Part 985

Federal home loan bank, Securities.

12 CFR Part 989

Accounting, Federal home loan banks, financial disclosure.

12 CFR Part 1273

Federal home loan banks, securities.

12 CFR Part 1274

Accounting, Federal home loan banks, financial disclosure.

Accordingly, for reasons stated in the preamble, under the authority of 12 U.S.C. 1311(b)(2), 1313(a)(1), 1319G and 1431, the FHFA proposes to amend chapters IX and XII of title 12 of the Code of Federal Regulations as follows:

**CHAPTER IX—FEDERAL HOUSING
FINANCE BOARD**

Subchapter K—Office of Finance

PART 985—THE OFFICE OF FINANCE

1. Remove 12 CFR part 985.

**PART 989—FINANCIAL STATEMENT
OF THE BANKS**

2. Remove 12 CFR part 989.

**CHAPTER XII—FEDERAL HOUSING
FINANCE AGENCY**

Subchapter D—Federal Home Loan Banks

3. Add part 1273 to subchapter D to read as follows:

PART 1273—OFFICE OF FINANCE

Sec.

- 1273.1 Definitions.
 - 1273.2 Authority of the OF.
 - 1273.3 Functions of the OF.
 - 1273.4 FHFA oversight.
 - 1273.5 Funding of the OF.
 - 1273.6 Debt management duties of the OF.
 - 1273.7 Structure of the OF board of directors.
 - 1273.8 General duties of the OF board of directors.
 - 1273.9 Audit committee.
- Appendix A to Part 1273—Exceptions to the General Disclosure Standards

Authority: 12 U.S.C. 1431(a) and (c), 1440, 4511(b), 4513, 4514(a), 4526(a).

§ 1273.1 Definitions.

For purposes of this part:

Audit Committee means the OF Independent Directors acting as the committee established in accordance with § 1273.9 of this part.

Bank written in title case, means a Federal Home Loan Bank established under section 12 of the Bank Act (12 U.S.C. 1432).

Bank Act means the Federal Home Loan Bank Act, as amended (12 U.S.C. 1421 through 1449).

Bank System means the Federal Home Loan Bank System, consisting of the twelve Banks and the Office of Finance.

Chair means the chairperson of the board of directors of the Office of Finance.

Chief Executive Officer or *CEO* means the chief executive officer of the Office of Finance.

Consolidated obligations means any bond, debenture or note on which the Banks are jointly and severally liable and which was issued under section 11 of the Bank Act (12 U.S.C. 1431) and any implementing regulations, whether or not such instrument was originally issued jointly by the Banks or by the Federal Housing Finance Board on behalf of the Banks.

FHFA means the Federal Housing Finance Agency.

Financing Corporation or *FICO* means the Financing Corporation established and supervised by the FHFA under section 21 of the Bank Act (12 U.S.C. 1441).

Generally accepted accounting principles or *GAAP* means accounting principles generally accepted in the United States.

Independent Director means a member of the OF board of directors who meets the qualifications set forth in § 1273.7(a)(2) of this part.

NRSRO means a credit rating organization registered as a Nationally Recognized Statistical Rating Organization with the Securities and Exchange Commission.

Office of Finance or *OF* means the Office of Finance, a joint office of the Banks established under this part 1273 and referenced in the Bank Act and the Safety and Soundness Act.

Resolution Funding Corporation or *REFCORP* means the Resolution Funding Corporation established by section 21B of the Bank Act (12 U.S.C. 1441b).

Safety and Soundness Act means the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 *et seq.*), as amended.

§ 1273.2 Authority of the OF.

(a) *General.* The OF shall enjoy such incidental powers under section 12(a) of the Bank Act (12 U.S.C. 1432(a)), as are necessary, convenient and proper to accomplish the efficient execution of its duties and functions pursuant to this part, including the authority to contract with a Bank or Banks for the use of Bank facilities or personnel in order to perform its functions or duties.

(b) *Agent.* The OF, in the performance of its duties, shall have the power to act on behalf of the Banks in issuing consolidated obligations and in paying principal and interest due on the consolidated obligations, or other obligations of the Banks.

(c) *Assessments.* The OF shall have authority to assess the Banks for the funding of its operations in accordance with § 1273.5 of this part.

§ 1273.3 Functions of the OF.

(a) *Joint debt issuance.* Subject to parts 965 and 966 of this title, and this part, the OF as agent shall offer, issue and service (including making timely payments on principal and interest due) consolidated obligations.

(b) *Preparation of combined financial reports.* The OF shall prepare and issue the combined annual and quarterly financial reports for the Bank System in accordance with the requirements of § 1273.6(b) and Appendix A of this part, using consistent accounting policies and procedures as established under § 1273.9 of this part.

(c) *Fiscal agent.* The OF shall function as the fiscal agent of the Banks.

(d) *Financing Corporation and Resolution Funding Corporation.* The OF shall perform such duties and responsibilities for FICO as may be required under part 995 of this title, or for REFCORP as may be required under part 996 of this title or authorized by the FHFA pursuant to section 21B(c)(6)(B) of the Bank Act (12 U.S.C. 1441b(c)(6)(B)).

§ 1273.4 FHFA oversight.

(a) *Oversight and enforcement actions.* The FHFA shall have the same regulatory oversight authority over the OF, the OF board of directors, the officers, employees, agents, attorneys, accountants, or other OF staff, as it has over a Bank and its respective directors, officers, employees, agents, attorneys, accountants, or other staff.

(b) *Examinations.* Pursuant to section 20 of the Bank Act (12 U.S.C. 1440), the FHFA shall examine the OF, all funds and accounts that may be established pursuant to this part 1273, and the operations and activities of the OF, as provided for in the Bank Act, the Safety and Soundness Act, or any regulations promulgated pursuant thereto.

(c) *Combined financial reports.* The FHFA shall determine whether a combined Bank System annual or quarterly financial report complies with the standards of this part.

§ 1273.5 Funding of the OF.

(a) *Generally.* The Banks are responsible for jointly funding all the expenses of the Office of Finance, including the costs of indemnifying the members of the OF board of directors, the Chief Executive Officer, and other officers and employees of the OF, as provided for in this part.

(b) *Funding policies.* (1) At the direction of and pursuant to policies

and procedures adopted by the OF board of directors, the Banks shall periodically reimburse the OF in order to maintain sufficient operating funds under the budget approved by the OF board of directors. The OF operating funds shall be:

(i) Available for expenses of the OF and the OF board of directors, according to their approved budgets; and

(ii) Subject to withdrawal by check, wire transfer or draft signed by the Chief Executive Officer or other persons designated by the OF board of directors.

(2) Each Bank's respective *pro rata* share of the reimbursement described in paragraph (b)(1) of this section shall be based on a reasonable formula approved by the OF board of directors. Such formula shall be subject to the review of the FHFA, and the OF board of directors shall make any changes to the formula as may be ordered by the FHFA from time to time.

(c) *Alternative funding method.* With the prior approval of the FHFA, the OF board of directors may, by contract with a Bank or Banks, choose to be reimbursed through a fee structure, in lieu of or in addition to assessment, for services provided to the Bank or Banks.

(d) *Prompt reimbursement.* Each Bank from time to time shall promptly forward funds to the OF in an amount representing its share of the reimbursement described in paragraph (b) of this section when directed to do so by the Chief Executive Officer pursuant to the procedures of the OF board of directors.

(e) *Indemnification expenses.* All expenses incident to indemnification of the members of the OF board of directors, the Chief Executive Officer, and other officers and employees of the OF shall be treated as an expense of the OF to be reimbursed by the Banks under the provisions of this part.

(f) *Operating funds segregated.* Any funds received by the OF from the Banks pursuant to this section for OF operating expenses promptly shall be deposited into one or more accounts and shall not be commingled with any proceeds from the sale of consolidated obligations in any manner.

§ 1273.6 Debt management duties of the OF.

(a) *Issuing and servicing of consolidated obligations.* The OF shall issue and service (including making timely payments on principal and interest due, subject to §§ 966.8 and 966.9 of this title) consolidated obligations pursuant to and in accordance with the policies and procedures established by the OF board of directors under this part.

(b) *Combined financial reports requirements.* The OF, under the oversight of the Audit Committee, shall prepare and distribute the combined annual and quarterly financial reports for the Bank System in accordance with the following requirements:

(1) The scope, form and content of the disclosure generally shall be consistent with the requirements of the Securities and Exchange Commission Regulations S-K and S-X (17 CFR parts 229 and 210).

(2) Information about each Bank shall be presented as a segment of the Bank System as if generally accepted accounting principles regarding business segment disclosure applied to the combined annual and quarterly financial reports of the Bank System, and shall be presented using consistent accounting policies and procedures.

(3) The standards set forth in paragraphs (b)(1) and (b)(2) of this section are subject to the exceptions set forth in Appendix A to this part.

(4) The combined Bank System annual financial reports shall be filed with the FHFA and distributed to each Bank and Bank member within 90 days after the end of the fiscal year. The combined Bank System quarterly financial reports shall be filed with the FHFA and distributed to each Bank and Bank member within 45 days after the end of the of the first three fiscal quarters of each year.

(5) The Audit Committee shall ensure that the combined Bank System annual or quarterly financial reports comply with the standards of this part.

(6) The OF and the OF board of directors, including the Audit Committee, shall comply promptly with any directive of the FHFA regarding the preparation, filing, amendment, or distribution of the combined Bank System annual or quarterly financial reports.

(7) Nothing in this section shall create or be deemed to create any rights in any third party.

(c) *Capital markets data.* The OF shall provide capital markets information concerning debt to the Banks.

(d) *NRSROs.* The OF shall manage the relationships with NRSROs in connection with their rating of consolidated obligations.

(e) *Research.* The OF shall conduct research reasonably related to the issuance or servicing of consolidated obligations.

(f) *Monitor Banks' credit exposure.* The OF shall timely monitor, and compile relevant data on, each Bank's and the Bank System's unsecured credit exposure to individual counterparties.

§ 1273.7 Structure of the OF board of directors.

(a) *Membership.* The OF board of directors shall consist of fifteen to seventeen part-time members as follows:

(1) The twelve Bank presidents, *ex officio*, provided that if the presidency of any Bank becomes vacant, the person temporarily fulfilling the duties of president of that Bank may sit on the OF board of directors until the presidency is filled permanently; and

(2)(i) Three to five Independent Directors who each shall be a citizen of the United States and who, as a group, shall have substantial experience in financial and accounting matters. Such Independent Directors may not be officers, directors, or employees of any Bank or Bank System member, be affiliated with any consolidated-obligations selling or dealer group member under contract with OF, or hold shares or any other financial interest in any member of a Bank or in any such dealer group member in an amount greater than the lesser of—

(A) \$250,000 or

(B) 0.01% of the market capitalization of the member or dealer.

(ii) For purposes of this paragraph (a)(2), a holding company of a member of a Bank or a dealer group member shall be deemed to be a member if the assets of the holding company's member subsidiaries constitute 35% or more of the consolidated assets of the holding company.

(b) *Terms.* (1) Except as provided in paragraphs (b)(2) and (c)(1) of this section, each Independent Director shall serve for five-year terms (which shall be staggered so that no more than one Independent Director seat would be scheduled to become vacant in any one year), and shall be subject to removal or suspension or other enforcement action in accordance with § 1273.4(a) of this section. An Independent Director may not serve more than two full, consecutive terms. Time served by a private citizen member of the OF Board pursuant to an appointment made prior to the effective date of this part shall not count as a term for purposes of this restriction.

(2) The OF board of directors shall fill any vacancy among the Independent Directors occurring prior to the scheduled end of a term by majority vote, subject to the FHFA's review of, and non-objection to, the new Independent Director. The OF board of directors shall provide the FHFA with relevant biographic and background information, including information demonstrating that the new Independent Director meets the requirements of paragraph (a)(2) of this

section, at least 20 business days before the person assumes any duties as a member of the OF board of directors. A person elected under this paragraph to fill a vacancy on the OF board of directors shall serve only for the remainder of the term associated with the vacant directorship.

(c) *Initial selection of Independent Directors.* (1) As soon as practicable after the effective date of this regulation, the FHFA shall fill the initial Independent Director positions by appointment. The Independent Directors shall be appointed for such periods of time, not to exceed five years, to assure the terms are staggered in accordance with paragraph (b)(1) of this section.

(2) Each Bank shall have the right to nominate one person for consideration for appointment as an Independent Director by the FHFA under this paragraph (c). The nominations will be made according to any procedures established by the FHFA. The FHFA may appoint persons nominated by the Banks, or other persons meeting the requirements of paragraph (a)(2) of this section, or some combination.

(d) *Election of Independent Directors after the initial terms.* Once the terms of the Independent Directors initially appointed by the FHFA expire or the positions otherwise become vacant, the Independent Directors subsequently shall be elected by majority vote of the OF board of directors, subject to FHFA's review of, and non-objection to, each new Independent Director. The OF board of directors shall provide the FHFA with relevant biographic and background information, including information demonstrating that the new Independent Director meets the requirements of paragraph (a)(2) of this section, at least 20 business days before the person assumes any duties as a member of the OF board of directors. If the OF board of directors, in the FHFA's judgment, fails to elect a suitably qualified person, the FHFA may appoint some other person who meets the requirements of paragraph (a)(2) of this section.

(e) *Initial Selection of Chair and Vice Chair.* The first Chair and Vice Chair of the OF board of directors after the effective date of this regulation shall be appointed by the FHFA. The Chair shall be selected from among the Independent Directors appointed under paragraph (c)(1) of this section. The Vice-chair shall be selected from among all OF board directors.

(f) *Subsequent Election of Chair and Vice-Chair.* After the terms of the persons selected under paragraph (e) of

this section expire or the positions otherwise become vacant:

(1) Subsequent Chairs shall be elected by majority vote of the OF board of directors from among the Independent Directors then serving on the OF board of directors; and

(2) Subsequent Vice Chairs shall be elected by majority vote of the OF board of directors from among all directors.

(3) The OF board of directors shall promptly inform the FHFA of the election of a Chair or Vice Chair. If the FHFA objects to any Chair or Vice Chair elected by the OF board of directors, the FHFA shall provide written notice of its objection within 20 business days of the date that the FHFA first receives the notice of the election of the Chair and or Vice Chair, and the OF board of directors must then promptly elect a new Chair or Vice Chair, as appropriate.

(g) *Committees.* In addition to the Audit Committee required under § 1273.9 of this part, the OF board of directors may establish other committees, including an Executive Committee. The duties and powers of such committee, including any powers delegated by the OF board of directors, shall be specified in the by-laws of the board of directors or the charter of the committee, which shall be subject to review and approval by the FHFA.

(h) *Compensation.* (1) The Bank presidents shall not receive any additional compensation or reimbursement as a result of their service as a director of the OF board.

(2) The OF shall pay compensation and expenses to the Independent Directors in accordance with the requirements for payment of compensation and expenses to Bank chairs and directors as set forth in part 918 of this title.

(i) *Indemnification.* The OF shall indemnify its directors, the CEO, and other officers and employees of the OF under such terms and conditions as shall be determined by the OF board of directors, *provided that* such terms and conditions are consistent with the terms and conditions of indemnification of directors, officers, and employees of the Bank System generally.

(j) *Delegation.* In addition to any delegation to a committee allowed under paragraph (g) of this section, the OF board of directors may delegate any of its authority or duties to any employee of the OF in order to enable OF to carry out its functions, provided that such delegation remains subject to the review of the FHFA, and the FHFA reserves the right in its sole discretion to require the OF board of directors to withdraw or change the scope of the delegation.

(k) *Outside staff and consultants.* In carrying out its duties and responsibilities, the OF board of directors, or any committee thereof, shall have authority to retain staff and outside counsel, independent accountants, or other outside consultants at the expense of the OF.

§ 1273.8 General duties of the OF board of directors.

(a) *General.* (1) *Conduct of business.* Each director shall have the duties described in § 917.2(b) of this title, as appropriate.

(2) *Bylaws.* The OF board of directors shall adopt bylaws in accordance with the provisions of § 917.10 of this title.

(b) *Meetings and quorum.* The OF board of directors shall conduct its business by majority vote of its members at meetings convened in accordance with its bylaws, and shall hold no fewer than six in-person meetings annually. Due notice shall be given to the FHFA by the Chair prior to each meeting. A quorum, for purposes of meetings of the OF board of directors, shall not be less than ten members.

(c) *Duties regarding COs.* The OF board of directors shall oversee the establishment of policies regarding COs that shall:

(1) Govern the frequency and timing of issuance, issue size, minimum denomination, CO concessions, underwriter qualifications, currency of issuance, interest-rate change or conversion features, call features, principal indexing features, selection and retention of outside counsel, selection of clearing organizations, and the selection and compensation of underwriters for consolidated obligations, which shall be in accordance with the requirements and limitations set forth in paragraph (c)(4) of this section;

(2) Prohibit the issuance of COs intended to be privately placed with or sold without the participation of an underwriter to retail investors, or issued with a concession structure designed to facilitate the placement of the COs in retail accounts, unless the OF has given notice to the board of directors of each Bank describing a policy permitting such issuances, soliciting comments from each Bank's board of directors, and considering the comments received before adopting a policy permitting such issuance activities;

(3) Require all broker-dealers or underwriters under contract to the OF to have and maintain adequate suitability sales practices and policies, which shall be acceptable to, and subject to review by, the OF;

(4) Require that COs shall be issued efficiently and at the lowest all-in funding costs over time, consistent with—

(i) Prudent risk-management practices, prudential debt parameters, short and long-term market conditions, and the Banks' role as GSEs;

(ii) Maintaining reliable access to the short-term and long-term capital markets; and

(iii) Positioning the issuance of debt to take advantage of current and future capital market opportunities.

(d) *Other duties.* The OF board of directors shall:

(1) Set policies for management and operation of the OF;

(2) Approve a strategic business plan for the OF in accordance with the provisions of § 917.5 of this title, as appropriate;

(3) Review, adopt and monitor annual operating and capital budgets of the OF in accordance with the provisions of § 917.8 of this title, as appropriate;

(4) Select, employ, determine the compensation for, and assign the duties and functions of a Chief Executive Officer of the OF who shall—

(i) Be head of the OF and direct the implementation of the OF board of directors' policies;

(ii) Serve as a member of the Directorate of the FICO, pursuant to section 21(b)(1)(A) of the Bank Act (12 U.S.C. 1441(b)(1)(A)); and

(iii) Serve as a member of the Directorate of the REFCORP, pursuant to section 21B(c)(1)(A) of the Bank Act (12 U.S.C. 1441b(c)(1)(A)).

(5) Review and approve all contracts of the OF; and

(6) Assume any other responsibilities that may from time to time be assigned to it by the FHFA.

(e) *No rights created.* Nothing in this part shall create or be deemed to create any rights in any third party.

§ 1273.9 Audit committee.

(a) *Composition.* The Independent Directors shall serve as the Audit Committee.

(b) *Responsibilities.* (1) The Audit Committee shall be responsible for overseeing the audit function of the OF and the preparation and accuracy of the Bank System's combined financial reports.

(2) For purposes of the combined financial reports, the Audit Committee shall ensure that the Banks adopt consistent accounting policies and procedures such that the information submitted by the Banks to OF may be combined to create accurate and meaningful combined financial reports.

(3) The Audit Committee, in consultation with the FHFA, may

establish common accounting policies and procedures for the information submitted by the Banks to the OF for the combined financial reports where the Committee determines such information provided by the several Banks is inconsistent and that consistent policies and procedures regarding that information are necessary to create accurate and meaningful combined financial reports.

(4) To the extent possible the Audit Committee shall operate consistent with—

(i) The requirements of § 917.7 of this title; and

(ii) The requirements pertaining to audit committee reports set forth in Item 306 of Regulation S-K promulgated by the Securities and Exchange Commission.

(5) The Audit Committee shall oversee internal audit activities, including the selection, evaluation, compensation and, where appropriate, replacement of the internal auditor. The internal auditor shall report directly to the Audit Committee and administratively to executive management.

(6) The Audit Committee shall have the exclusive authority to employ and contract for the services of an independent, external auditor for the Banks' annual and quarterly combined financial statements.

(c) *No delegation.* The Audit Committee may not delegate the responsibilities assigned to it under this section to any person, or to any other committee or sub-committee of the OF board of directors.

Appendix A to Part 1273—Exceptions to the General Disclosure Standards

A. Related-party transactions. Item 404 of Regulation S-K, 17 CFR 229.404, requires the disclosure of certain relationships and related party transactions. In light of the cooperative nature of the Bank System, related-party transactions are to be expected, and a disclosure of all related-party transactions that meet the threshold would not be meaningful. Instead, the combined annual report will disclose the percent of advances to members an officer of which serves as a Bank director, and list the top ten holders of advances in the Bank System and the top five holders of advances by Bank, with a further disclosure indicating which of these members had an officer that served as a Bank director. The combined financial report will also disclose the top ten holders of advances in the Bank System by holding company, where the advances of all affiliates within a holding company are aggregated.

B. Biographical information. The biographical information required by Items 401 and 405 of Regulation S-K, 17 CFR 229.401 and 405, will be provided only for members of the OF board of directors,

including the Bank presidents, the chair and vice chair of the board of directors of each Bank, and the Chief Executive Officer of OF.

C. Compensation. The information on compensation required by Item 402 of Regulation S-K, 17 CFR 229.402, will be provided only for Bank presidents and the CEO of the OF. Since stock in each Bank trades at par, the OF will not include the performance graph specified in Item 402(1) of Regulation S-K, 17 CFR 229.402(1).

D. Submission of matters to a vote of stockholders. No information will be presented on matters submitted to shareholders for a vote, as otherwise required by Item 4 of the SEC's form 10-K, 17 CFR 249.310. The only item shareholders vote upon is the annual election of directors.

E. Exhibits. The exhibits required by Item 601 of Regulation S-K, 17 CFR 229.601, are not applicable and will not be provided.

F. Per share information. The statement of financial information required by Items 301 and 302 of Rule S-K, 17 CFR 229.301 and 302, is inapplicable because the shares of the Banks are subscription capital that trades at par, and the shares expand or contract with changes in member assets or advance levels.

G. Beneficial ownership. Item 403 of Rule S-K, 17 CFR 229.403, requires the disclosure of security ownership of certain beneficial owners and management. The combined financial report will provide a listing of the ten largest holders of capital stock in the Bank System and a listing of the five largest holders of capital stock by Bank. This listing will also indicate which members had an officer that served as a director of a Bank. The combined financial report will also disclose the top ten holders of Bank stock in the Bank System by holding company, where the Bank stock of all affiliates within a holding company is aggregated.

4. Add part 1274 to subchapter D to read as follows:

PART 1274—FINANCIAL STATEMENTS OF THE BANKS

Sec.

1274.1 Definitions.

1274.2 Audit requirements.

1274.3 Requirements to provide financial and other information to the FHFA and the OF.

Authority: 12 U.S.C. 1426, 1431, 4511(b), 4513, 4526(a).

§ 1274.1 Definitions.

For purposes of this part:

Audit means an examination of the financial statements by an independent accountant in accordance with generally accepted auditing standards for the purpose of expressing an opinion thereon.

Audit report means a document in which an independent accountant indicates the scope the audit made and sets forth an opinion regarding the financial statement taken as a whole, or an assertion to the effect that an overall opinion cannot be expressed. When an

overall opinion cannot be expressed, the reasons therefor shall be stated.

Bank written in title case, means a Federal Home Loan Bank established under section 12 of the Bank Act (12 U.S.C. 1432).

Bank System means the Federal Home Loan Bank System, consisting of the twelve Banks and the Office of Finance.

FHFA means the Federal Housing Finance Agency.

Financing Corporation or *FICO* means the Financing Corporation established and supervised by the FHFA under section 21 of the Bank Act (12 U.S.C. 1441).

Office of Finance or *OF* has the same meaning as set forth in § 1273.1 of this chapter.

§ 1274.2 Audit requirements.

(a) Each Bank, the OF and the FICO shall obtain annually an independent external audit of and an audit report on its individual financial statement.

(b) The OF audit committee shall obtain an audit and an audit report on the combined annual financial statements for the Bank System.

(c) All audits must be conducted in accordance with generally accepted auditing standards and in accordance with the most current government auditing standards issued by the Office of the Comptroller General of the United States.

(d) An independent, external auditor must meet at least twice each year with the audit committee of each Bank, the audit committee of OF, and the FICO Directorate.

(e) FHFA examiners shall have unrestricted access to all auditors' work papers and to the auditors to address substantive accounting issues that may arise during the course of any audit.

§ 1274.3 Requirement to provide financial and other information to the FHFA and the OF.

In order to facilitate the preparation by the OF of combined Bank System annual and quarterly reports, each Bank shall provide to the OF in such form and within such timeframes as the FHFA or the OF shall specify, all financial and other information and assistance that the OF shall request for that purpose. Nothing in this section shall contravene or be deemed to circumscribe in any manner the authority of the FHFA to obtain any information from any Bank related to the preparation or review of any financial report.

Dated: July 29, 2009.

James B. Lockhart III,

Director, Federal Housing Finance Agency.

[FR Doc. E9-18567 Filed 8-3-09; 8:45 am]

BILLING CODE P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1282

RIN 2590-AA27

Duty To Serve Underserved Markets for Enterprises

AGENCY: Federal Housing Finance Agency.

ACTION: Advance notice of proposed rulemaking and request for comment.

SUMMARY: Section 1129 of the Housing and Economic Recovery Act of 2008 (HERA) amended the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (Safety and Soundness Act) to establish a duty for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, Enterprises) to serve three underserved markets—manufactured housing, affordable housing preservation, and rural areas—in order to increase the liquidity of mortgage investments and improve the distribution of investment capital available for mortgage financing in those markets. Section 1335 of the Safety and Soundness Act, as amended, requires the Federal Housing Finance Agency (FHFA), beginning in 2010, to establish a manner for: evaluating whether and to what extent the Enterprises have complied with the duty to serve underserved markets; and rating the extent of compliance. To assist FHFA in rulemaking to implement the duty to serve underserved markets, FHFA seeks comment on the characteristics and types of Enterprise transactions and activities that should be considered and how such transactions and activities should be evaluated and rated, for purposes of determining the Enterprises' performance of the duty to serve underserved markets.

DATES: Written comments must be received on or before: September 18, 2009.

ADDRESSES: You may submit your comments, identified by regulatory information number (RIN) 2590-AA27, by any of the following methods:

- *U.S. Mail, United Parcel Post, Federal Express, or Other Mail Service:* The mailing address for comments is:

Alfred M. Pollard, General Counsel,
Attention: Comments/RIN 2590-AA27,
Federal Housing Finance Agency,
Fourth Floor, 1700 G Street, NW.,
Washington, DC 20552.

- *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590-AA27, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

- *E-mail:* Comments to Alfred M. Pollard, General Counsel, may be sent by e-mail to RegComments@fhfa.gov. Please include "RIN 2590-AA27" in the subject line of the message.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal*, please also send it by e-mail to FHFA at RegComments@fhfa.gov to ensure timely receipt by FHFA. Please include "RIN 2590-AA27" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Nelson Hernandez, Senior Associate Director, Housing Mission and Goals, (202) 408-2819, Brian Doherty, Acting Manager, Housing Mission and Goals—Policy, (202) 408-2991, or Paul Manchester, Acting Manager, Housing Mission and Goals—Quantitative Analysis, (202) 408-2946 (these are not toll-free numbers); Lyn Abrams, Attorney-Advisor, (202) 414-8951, Kevin Sheehan, Attorney-Advisor, (202) 414-8952, or Sharon Like, Associate General Counsel, (202) 414-8950 (these are not toll-free numbers), Office of General Counsel, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877-8339.

SUPPLEMENTARY INFORMATION:

I. Comments

FHFA invites comments on all aspects of the Advance Notice of Proposed Rulemaking. Copies of all comments will be posted without change, including any personal information you provide, such as your name and address, on the FHFA Web site at <http://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m. at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to

inspect comments, please call the Office of General Counsel at (202) 414-3751.

II. Background

A. Establishment of FHFA

Effective July 30, 2008, Division A of HERA, Public Law 110-289, 122 Stat. 2654 (2008), amended the Safety and Soundness Act, 12 U.S.C. 4501 *et seq.*, and created FHFA as an independent agency of the Federal government.¹ HERA transferred the safety and soundness supervisory and oversight responsibilities over the Enterprises from the Office of Federal Housing Enterprise Oversight (OFHEO) to FHFA. HERA also transferred the charter compliance authority and responsibility to establish, monitor and enforce the affordable housing goals for the Enterprises from the Department of Housing and Urban Development (HUD) to FHFA. HERA provides for the abolishment of OFHEO one year after the date of enactment. FHFA is responsible for ensuring that the Enterprises operate in a safe and sound manner, including maintenance of adequate capital and internal controls, that their operations and activities foster liquid, efficient, competitive, and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See* 12 U.S.C. 4513.

Section 1302 of HERA provides, in part, that all regulations, orders and determinations issued by the Secretary of HUD (Secretary) with respect to the Secretary's authority under the Safety and Soundness Act, the Federal National Mortgage Association Charter Act, 12 U.S.C. 1716 *et seq.*, and the Federal Home Loan Mortgage Corporation Act, 12 U.S.C. 1451 *et seq.*, (Charter Acts), shall remain in effect and be enforceable by the Secretary or the Director of FHFA, as the case may be, until modified, terminated, set aside or superseded by the Secretary or the Director, any court, or operation of law. The Enterprises continue to operate under regulations promulgated by OFHEO and HUD until FHFA issues its own regulations. *See* HERA at section 1302, 122 Stat. 2795; 12 U.S.C. 4603.²

The Enterprises are government-sponsored enterprises (GSEs) chartered by Congress for the purpose of

establishing secondary market facilities for residential mortgages. *See* 12 U.S.C. 1451, 1716. Specifically, Congress established the Enterprises to provide stability in the secondary market for residential mortgages, respond appropriately to the private capital market, provide ongoing assistance to the secondary market for residential mortgages (including activities relating to mortgages on housing for low- and moderate-income families involving a reasonable economic return that may provide less of a return than the Enterprises' other activities), and promote access to mortgage credit throughout the nation. *Id.*

B. Duty To Serve Underserved Markets

The Safety and Soundness Act provides that the Enterprises "have an affirmative obligation to facilitate the financing of affordable housing for low- and moderate-income families." 12 U.S.C. 4501(7). Section 1129 of HERA amended section 1335 of the Safety and Soundness Act to establish a duty for the Enterprises to serve three specified underserved markets, in order to increase the liquidity of mortgage investments and improve the distribution of investment capital available for mortgage financing for certain categories of borrowers in those markets. 12 U.S.C. 4565. Specifically, the Enterprises are required to provide leadership to the market in developing loan products and flexible underwriting guidelines to facilitate a secondary market for mortgages on housing for very low-, low-, and moderate-income families with respect to manufactured housing, affordable housing preservation, and rural markets.³ *Id.* In addition, section 1335 requires FHFA to establish, by regulation effective for 2010 and each subsequent year, a method for evaluating and rating the Enterprises' performance of the duty to serve underserved markets. *Id.* sec. 4565(d). Furthermore, FHFA is required to report annually to Congress on the Enterprises' performance of the duty to serve underserved markets. *Id.* A description of the duty to serve provisions and issues for consideration are set forth below.

III. Duty To Serve Provisions

A. Overview

The duty to serve underserved markets is separate from and additional to the Enterprises' affordable housing goals. Mortgage purchases that contribute to the affordable housing

goals may, under appropriate circumstances, also be considered for the duty to serve underserved markets. In addition, an activity or transaction may be considered for more than one underserved market. The rules for determining which types of mortgage purchases receive credit for purposes of the affordable housing goals could also be used to determine which types of mortgage purchases would be considered for purposes of the duty to serve underserved markets. FHFA seeks comment on whether there are any categories of mortgage purchase transactions for which the Enterprises receive housing goals credit that should not be considered for the duty to serve.

The affordable housing goals regulation applicable to the Enterprises prohibits housing goals credit for "HOEPA mortgages"⁴ and mortgages with unacceptable terms or conditions or resulting from unacceptable practices. *See* 24 CFR 81.2, 81.16(c)(12); proposed 12 CFR 1282.2, 1282.16(c)(12) (74 FR 20236 (May 1, 2009)). Purchases of these types of mortgages would be ineligible for consideration under the duty to serve underserved markets. Likewise, Enterprise purchases of mortgages that do not conform with the interagency "Statement on Subprime Lending" and the "Interagency Guidance on Nontraditional Mortgage Products Risk"⁵ would not be considered.

The duty to serve underserved markets is not an independent source of program authority for the Enterprise, and activities or transactions conducted in furtherance of this duty must be consistent with the Enterprise's Charter Act powers and limitations. In addition, any activity undertaken pursuant to the duty to serve must be consistent with the Safety and Soundness Act, as amended, the safe and sound operation of the Enterprise, and the public interest.

FHFA invites comment on the issues discussed above.

B. Underserved Markets

1. Manufactured Housing

Section 1335 of the Safety and Soundness Act, as amended, requires the Enterprises to "develop loan products and flexible underwriting guidelines to facilitate a secondary

¹ *See* Division A, titled the "Federal Housing Finance Regulatory Reform Act of 2008," Title I, Section 1101 of HERA.

² On May 1, 2009, FHFA issued a proposed rule to adopt portions of 24 CFR part 81 in new 12 CFR part 1282 and to adjust the levels of the Enterprises 2009 affordable housing goals to levels consistent with current market conditions. *See* 74 FR 20236 (May 1, 2009).

³ The terms "very low-income", "low-income" and "moderate-income" are defined in 12 U.S.C. 4502.

⁴ "HOEPA" refers to the Home Ownership Equity Protection Act.

⁵ *See* Office of Federal Housing Enterprises Oversight, "OFHEO Director James B. Lockhart Commends GSEs on Implementation of Subprime Mortgage Lending Guidance," News Release (Sept. 10, 2007), available at <http://www.fhfa.gov/webfiles/1608/LockhartCommendsGSEsSubprime91007.pdf>.

market for mortgages on manufactured homes for very low-, low- and moderate-income families.” 12 U.S.C. 4565(a)(1)(A). A “manufactured home” is a structure, transportable in one or more sections, which is built on a permanent frame and is designed to be used as a dwelling when connected to the required utilities. *See* 12 U.S.C. 5402. FHFA specifically invites comment on three aspects of the manufactured housing market further discussed below: Manufactured home parks; personal property loans; and land-home and real estate manufactured housing loans.

Manufactured Home Parks. Many manufactured home residents site their homes in manufactured home parks and rent the underlying land. Some manufactured home parks are investor-owned and others are resident-owned. Fannie Mae and Freddie Mac currently purchase loans secured by manufactured home parks. FHFA seeks comment on whether and how these transactions should be considered under the duty to serve the manufactured housing market and on the types of flexibility the Enterprises could add to their underwriting guidelines to facilitate financing these transactions. FHFA also solicits comment on whether there should be differences in how resident-owned parks and investor-owned parks are treated for purposes of the duty to serve the manufactured housing market.

Personal Property Loans.⁶ The Safety and Soundness Act, as amended, provides that FHFA may consider loans secured by both real and personal property in evaluating whether the Enterprises have complied with the duty to serve the manufactured housing market. 12 U.S.C. 4565(d)(3). In some jurisdictions manufactured homes are financed as personal property, and the loan to the homebuyer is secured by a lien only on the manufactured home. Neither Enterprise currently purchases personal property loans on manufactured housing on a flow basis. FHFA seeks comment on whether Enterprise purchases of manufactured housing loans secured by personal property should be considered for purposes of the duty to serve the manufactured housing market. FHFA also requests comment on whether there are consumer protection laws or standards, in addition to those mentioned above, that should apply to

personal property loans on manufactured homes.

Land-Home and Real Estate Manufactured Housing Loans. “Land-home” manufactured housing loans and “real estate” manufactured housing loans provide financing to the homebuyer for both the manufactured home and the underlying land. FHFA seeks comment on the types of flexibility the Enterprises could add to their underwriting guidelines to facilitate financing for land-home and real estate loans.

FHFA requests comment on the relative advantages and disadvantages to borrowers of personal property loans, land-home loans, and real estate loans and on appropriate definitions for these terms. FHFA also seeks comment on the safety and soundness considerations of Enterprise purchase or guarantee of these various loan types, and on how Enterprise leadership under the duty to serve requirements may provide greater standardization and liquidity to the market and protection to borrowers.

2. Affordable Housing Preservation

Under the Safety and Soundness Act, as amended, the Enterprises are required to develop loan products and flexible underwriting guidelines to facilitate a secondary market to preserve housing affordable to very low-, low-, and moderate-income borrowers, including housing projects subsidized under:

(i) Section 8 of the Housing Act of 1937 (project-based and tenant-based rental assistance housing programs) (42 U.S.C. 1437f);

(ii) Section 236 of the National Housing Act (rental and cooperative housing for lower income families) (12 U.S.C. 1715z–1);

(iii) Section 221(d)(4) of the National Housing Act (housing for moderate-income and displaced families) (12 U.S.C. 1715l);

(iv) Section 202 of the Housing Act of 1959 (supportive housing program for the elderly) (12 U.S.C. 1701q);

(v) Section 811 of the Cranston-Gonzalez National Affordable Housing Act (supportive housing program for persons with disabilities) (42 U.S.C. 8013);

(vi) Title IV of the McKinney-Vento Homeless Assistance Act (only permanent supportive housing projects subsidized under such programs) (42 U.S.C. 11301 *et seq.*);

(vii) Section 515 of the Housing Act of 1949 (rural rental housing program) (42 U.S.C. 1485);

(viii) Low-income housing tax credits under section 42 of the Internal Revenue Code of 1986 (26 U.S.C. 42); and

(ix) Comparable State and local affordable housing programs. 12 U.S.C. 4565(a)(1)(B).

Some of the housing preservation programs listed above are voucher, capital advance or grant programs rather than mortgage origination programs, and the Enterprises’ assistance may fall outside of their traditional role of purchasing, securitizing and guaranteeing mortgage loans. Moreover, compliance with the duty to assist with affordable housing preservation is not dependent on whether the Enterprise assists each enumerated program each year, because the needs and opportunities in some programs might change from year to year. FHFA seeks comment on how the Enterprises could assist these programs in meaningful and measurable ways.

The housing programs enumerated above are not exhaustive, and the Enterprises are not limited to assisting these programs as their sole means of fulfilling their duty to serve the affordable housing preservation market. For example, HUD’s Neighborhood Stabilization Program provides grants to State and local governments to acquire and redevelop foreclosed properties for the purpose of stabilizing communities that have suffered from home foreclosures and abandonment. FHFA requests comment on whether Enterprise assistance in connection with this program should be considered for the duty to serve the affordable housing preservation market and how the Enterprises might render assistance. FHFA also seeks comment on other State and local affordable housing programs, including foreclosure prevention programs, that could be considered for the duty to serve the affordable housing preservation market.

3. Rural Markets

The Safety and Soundness Act, as amended, requires the Enterprises to “develop loan products and flexible underwriting guidelines to facilitate a secondary market for mortgages on housing for very low-, low-, and moderate-income families in rural areas.” 12 U.S.C. 4565(a)(1)(C).

Definition of “Rural Area”. A clear delineation of which areas are rural⁷ is necessary to implement the duty to serve rural markets. Three definitions

⁷ The affordable housing goals regulation defines “rural areas” in connection with the underserved areas affordable housing goal. *See* 24 CFR 81.2, proposed 12 CFR 1282.2 (74 FR 20236 (May 1, 2009)). Beginning on January 1, 2010, this definition will no longer be in effect because section 1128 of HERA replaces the previous housing goals established by the Safety and Soundness Act of 1992 with new housing goals. *See* 12 U.S.C. 4561 through 4563.

⁶ In some jurisdictions, personal property loans on manufactured homes are known as “chattel loans.”

are set forth below for comment, and FHFA invites suggestions for other definitions.

The first definition would be based on classifications used by the U.S. Census Bureau for the 2000 census and would distinguish between urban and rural areas.⁸ Urban areas are classified as all territory, population, and housing units located within “urbanized areas” and “urban clusters.”⁹ In general, urbanized areas must have a core with a population density of 1,000 persons per square mile and may contain adjoining territory with at least 500 persons per square mile. “Urban clusters” have at least 2,500 but less than 50,000 persons. Rural areas are classified as all territory

located outside of urbanized areas and urban clusters.¹⁰

The second definition would define “rural areas” as all counties assigned a U.S. Department of Agriculture (USDA) Rural-Urban Continuum code¹¹ (RUC code), which the USDA uses to classify rural areas. These codes are available for all U.S. counties and for municipios (county equivalents) in Puerto Rico. Because data on other U.S. territories, including Guam and the Virgin Islands, is lacking, FHFA could regard these territories as “rural areas.” A disadvantage of using the RUC code is that because designations based on RUC codes are county-based, these designations could encompass both urban and rural areas, as occurs with

very large counties west of the Mississippi River.

The third definition would combine two different designations, one used by the U.S. Census Bureau and one used by the USDA. Under this two-pronged definition, all census tracts designated by the U.S. Census Bureau as “nonmetropolitan” would be considered rural areas, as would all census tracts outside of urbanized areas and urban clusters, as designated by USDA’s Rural-Urban Commuting Area¹² code (RUCA code). The number of census tracts that would be considered rural areas under this definition is indicated by the shaded cells in the table below.¹³

RUCA Code	Metropolitan Tracts	Nonmetropolitan Tracts
Urbanized Areas (UA)	44,822	61
Urban Clusters (UC)	1,556	4,985
Not a UA or UC	6,690	7,208

Using this definition, 29 percent of the census tracts in the 50 States would be rural areas. It would also capture 27 percent of the census tracts regarded as “underserved areas” under the affordable housing goals regulation applicable to the Enterprises. See 24 CFR 81.2; proposed 12 CFR 1282.2 (74 FR 20236 (May 1, 2009)). One drawback to this approach is that USDA does not plan to extend the RUCA code to Puerto Rico until at least 2012, and RUCA codes are not assigned to census tracts in the other U.S. territories. FHFA could fill this gap by using the RUC code described above to augment the RUCA code in Puerto Rico and other U.S. territories, or FHFA could create its own estimate of the RUCA code for these areas.

The definitions discussed above would cover most, but not all, Tribal lands. Accordingly, FHFA seeks comment on whether the definition of “rural areas” should include all Tribal lands.

Rural Transactions. FHFA seeks comment on the types of transactions and activities that should receive consideration toward the duty to serve rural markets, and on the types of flexibility the Enterprises could add to their underwriting guidelines to assist this market. In addition, while rural markets are served by a variety of Federal programs, principally through the USDA, FHFA seeks comment on opportunities available for the Enterprises to assist private sector initiatives for rural housing.

C. Evaluation of Performance

1. Evaluation Criteria

In determining whether the Enterprises have complied with the duty to serve underserved markets, the Safety and Soundness Act, as amended, requires FHFA to separately evaluate and rate the Enterprise’s performance for each of the three underserved markets based on four specific criteria, which are discussed below. 12 U.S.C. 4565(d). The Enterprises’ performance

under the three underserved markets may vary significantly from year to year because the needs and opportunities of one market may require more attention and resources than the needs of another market. Accordingly, the method for evaluating the Enterprises’ performance of the duty to serve underserved markets should be sufficiently flexible to account for these variations in market needs and opportunities.

Loan Product Test. The first criterion, referred to here as the “Loan Product Test,” requires evaluation of the Enterprise’s “development of loan products, more flexible underwriting guidelines, and other innovative approaches to providing financing to each” underserved market. *Id.* sec. 4565(d)(2)(A). FHFA invites comment on the types of loan products, underwriting flexibility and innovative approaches the Enterprises could develop to serve each of the three underserved markets.

⁸ See Appendix A—Census 2000 Geographic Terms and Concepts A–22, available at <http://www.census.gov/geo/www/tiger/glossry2.pdf>.

⁹ *Id.* For a discussion of urbanized areas and urbanized clusters, see generally, U.S. Department of Agriculture, “Measuring Rurality: What is Rural?” (Mar. 22, 2007), available at <http://www.ers.usda.gov/Briefing/Rurality/WhatIsRural/>.

¹⁰ See Census 2000, *supra* note 8.

¹¹ See U.S. Department of Agriculture, Measuring Rurality: Rural-Urban Continuum Codes (Updated Apr. 28, 2004), available at <http://www.ers.usda.gov/Briefing/Rurality/RuralUrbCon/>.

¹² See <http://www.ers.usda.gov/briefing/Rurality/RuralUrbanCommuteAreas/>.

¹³ This table is constructed from data available from the Office of Management and Budget at <http://www.whitehouse.gov/omb/assets/omb/>

[bulletins/fy2009/09-01.pdf](http://www.census.gov/geo/www/relate/rel_tract.html), the U.S. Census Bureau at http://www.census.gov/geo/www/relate/rel_tract.html, and the USDA at <http://www.ers.usda.gov/briefing/Rurality/RuralUrbanCommuteAreas/>. In order to make a direct comparison to the USDA data, which excludes census tracts for Guam, the Virgin Islands, and Puerto Rico, these census tracts were not included in the table.

Outreach Test. The second criterion, referred to here as the “Outreach Test,” requires evaluation of “the extent of outreach [by the Enterprises] to qualified loan sellers and other market participants” in each of the three underserved markets. *Id.* sec. 4565(d)(2)(B). FHFA seeks comment on the types of activities or programs in which the Enterprises could engage that would satisfy this Test, and on how FHFA could objectively measure the Enterprises’ outreach.

Purchase Test. The third criterion, referred to here as the “Purchase Test,” requires FHFA to consider “the volume of loans purchased in each of such underserved markets relative to the market opportunities available to the [E]nterprise.” *Id.* sec. 4565(d)(2)(C). The provision further states that FHFA “shall not establish specific quantitative targets nor evaluate the [E]nterprises based solely on the volume of loans purchased.” *Id.* FHFA requests comment on how to implement the Purchase Test consistent with this restriction and comment on any non-quantitative evaluation methods that would be appropriate. In addition, FHFA seeks comment on whether to measure the Enterprises’ mortgage purchases by number of units financed, number of mortgages purchased, or unpaid principal balance.¹⁴ FHFA further requests comment on the advantages and disadvantages of using each of these methods of measurement, and on the appropriateness of the different methods for different types of transactions.

Grants Test. The fourth criterion, referred to here as the “Grants Test,” requires evaluation of “the amount of investments and grants in projects which assist in meeting the needs of such underserved markets.” 12 U.S.C. 4565(d)(2)(D). FHFA seeks comment on types of investments and grants the Enterprises could make that could be considered under this Test. FHFA also seeks comment on methods available for evaluating the Enterprises’ performance in making the grants and investments.

2. Sizing the Market

The Purchase Test requires that the volume of loans purchased in each underserved market be evaluated “relative to the market opportunities available to the [E]nterprise.” 12 U.S.C. 4565(d)(2)(C). FHFA invites comment on how to estimate the size of the manufactured housing, affordable housing preservation, and rural markets. FHFA further invites comment on whether there are categories of mortgages that should be excluded from the market size because the mortgages are unavailable for purchase.

If market size estimation is not possible, the Enterprises’ performance in the specific underserved market could be evaluated based on their purchases in that market in recent previous years, although this approach would not be available for the 2010 evaluation year. FHFA seeks comment on this approach.

3. Evaluating Compliance

In order to evaluate the Enterprises’ performance under the duty to serve underserved markets, FHFA is considering developing a rating method similar to the method used to determine whether a financial institution has met the requirements under the Community Reinvestment Act of 1977 (CRA). *See* 12 U.S.C. 2901 *et seq.*; 12 CFR parts 25, 228, 345, and 563e. For each underserved market, the Enterprises’ performance would be evaluated based on the four criteria described above, with an overall rating for each underserved market of Outstanding, Satisfactory, Needs to Improve or Noncompliance. These terms would be defined in the regulation.

One way to implement this approach would be to devise a rating scheme in which achievements or receipt of a certain number of points would result in a particular rating.¹⁵ The Enterprise’s rating in a particular underserved market would be a combination of the ratings on each of the four Tests.

The four Tests need not be given equal consideration. For example, the Outreach Test might be weighted less than the Loan Product or Purchase

Tests, because it results in less tangible benefits to the markets served and may require less effort and devotion of resources by the Enterprise. Furthermore, FHFA could weigh the four Tests differently across the three underserved markets. For example, the Purchase Test might receive more consideration for the manufactured housing market than for the affordable housing preservation market. The ratings would also take into consideration the overall effort and effectiveness of the Enterprise’s service to the underserved market, its capital and portfolio positions, and the condition of the particular underserved market, which could vary from year to year.

FHFA seeks comment on the evaluation methodology discussed above and invites descriptions of other types of evaluation or rating methodologies that may be feasible.

D. Reporting Requirements

FHFA would require annual reports from the Enterprises on their performance of the duty to serve underserved markets. FHFA anticipates that part of the report would be narrative and part would be summary statistical information, supported by submission of appropriate transaction-level data. The narrative portion would likely include discussions of the Enterprise’s performance in each of the three underserved markets. Except for purchases of single-family mortgages, a complete listing and summary of each transaction for which the Enterprise seeks credit would likely be required. In addition, the Enterprise would certify to the accuracy of the information submitted. FHFA invites comment on specific requirements for the contents of the report.

IV. Request for Comment

FHFA invites comment on all of the issues discussed above, and will consider all comments received in developing a proposed rule to implement the duty to serve underserved markets.

Dated: July 28, 2009.

James B. Lockhart III,
Director, Federal Housing Finance Agency.
[FR Doc. E9–18515 Filed 8–3–09; 8:45 am]

BILLING CODE P

¹⁴ The Enterprises’ performance under the affordable housing goals is measured using dwelling units, mortgages or unpaid principal balance. *See* 24 CFR 81.12 through 81.14; proposed 12 CFR 1282.12 through 1282.14 (74 FR 20236 (May 1, 2009)).

¹⁵ *See generally* Notice, Community Reinvestment Act; Interagency Questions and Answers Regarding Community Reinvestment, 74 FR 498, 526–527 (Jan. 6, 2009), available at <http://edocket.access.gpo.gov/2009/pdf/E8-31116.pdf>.

Notices

Federal Register

Vol. 74, No. 148

Tuesday, August 4, 2009

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 30, 2009.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to

the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: U.S. Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from such Livestock.

OMB Control Number: 0581–NEW.

Summary of Collection: Section 203(c) of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1622) directs and authorizes the Secretary of Agriculture “to develop and improve standards quality, condition, quantity, grade, packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.” The Agricultural Marketing Service (AMS) is establishing a voluntary standard for a naturally raised marketing claim that livestock producers may request to have verified by USDA.

Need and Use of the Information: AMS will collect information from applicants requesting the services for the Quality Systems Verification Programs (QSVP) using Form LS–313, “Application for Service.” The QSVP is a collection of voluntary, audit-based, user-fee funded programs. This will allow applicants to have program documentation and program processes assessed by AMS auditor(s) and other USDA officials to provide validity to such naturally raised livestock claims and, in certain cases, access to markets that require AMS verification. AMS verification of a claim would be accomplished through an audit of the production process in accordance with procedures that are contained in 7 CFR part 62.

Description of Respondents: Business for profit.

Number of Respondents: 20.

Frequency of Responses/Reporting: On occasion.

Total Burden Hours: 483.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E9–18647 Filed 8–3–09; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 30, 2009.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Implementation of the APHIS Ag Discovery Program.

OMB Control Number: 0579–NEW.

Summary of Collection: Ag-Discovery is an outreach program designed to give

students ages 12–17 an opportunity to learn about agriculture, the mission of the Animal and Plant Health Inspection Service (APHIS) programs. The objective(s) of the Ag-Discovery Program is to: (1) Provide students an opportunity to live on a university campus while learning about APHIS programs; (2) identify and recruit students who are interested in agricultural science; (3) provide demonstrations in APHIS programs including veterinary medicine, animal science, plant pathology; and (4) increase awareness of career opportunities within APHIS. The Application and brochure is provided to the applicant via of the APHIS and University Web site.

Need and Use of the Information: APHIS will collect information annually to be used to select the participants for the various Ag Discovery Programs. The application provides the information needed to assess the students true interest in agriculture; provide references from others who are familiar with the students interest and character; and provides verification of the students age and enrollment in school. The information collected from the applications will help APHIS to rate and rank the applicants.

Description of Respondents: Individuals or households.

Number of Respondents: 210.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 3,780.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. E9–18586 Filed 8–3–09; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection

Activities: Proposed Collection; Comment Request—Negative QC Review Schedule, Status of Sample Selection of Completion

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed information collections for the FNS–245, Negative Case Action Review Schedule and FNS–248, Status of Sample Selection and Completion. The forms are currently used in the Quality

Control process for the Supplemental Nutrition Assistance Program. The proposed collection is a revision of a collection currently approved under OMB No. 0584–0034.

DATES: Written comments must be submitted on or before October 5, 2009.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Tiffany Susan Wilkinson, Program Analyst, Quality Control Branch, Program Accountability and Administration Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 822, Alexandria, VA 22302. You may also download an electronic version of this notice at <http://www.fns.usda.gov/fsp/rules/regulations/default.htm> and comment via e-mail at SNAPHQ-Web@fns.usda.gov or use the Federal e-Rulemaking Portal. Go to <http://www.regulations.gov> and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101 Park Center Drive, Room 822, Alexandria, Virginia 22302.

All responses to this notice will be included in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection form and instruction should be directed to Tiffany Susan Wilkinson, (703) 305–2410.

SUPPLEMENTARY INFORMATION:

Title: Negative Quality Control Review Schedule.

OMB Number: 0584–0034.

Form Number: FNS–245 and 248.

Expiration Date: November 30, 2009.

Type of Request: Revision of currently approved collections.

The FNS–245, Negative Case Action Review Schedule:

Abstract: The FNS–245, Negative Case Action Review Schedule, is designed to collect quality control (QC) data and serve as the data entry form for negative case action QC reviews in the Supplemental Nutrition Assistance Program (SNAP). State agencies complete the FNS–245 for each negative case in their QC sample. The reporting and recordkeeping burden associated with the completion of the FNS–245 has decreased from 123,374 hours to 117,651 hours. The 5,723 hour decrease is a result of a reduction in the total case selection from 39,782 in FY 2004 to 38,911 in FY2007.

Affected Public: State or Local Governments.

Estimated Number of Respondents: 53 State Agencies.

Estimated Number of Responses per Respondent: 734.17 Records.

Estimated Total Annual Response: 38,911.

Estimated Time per Report: 3.0236 Hours.

Estimated Total Annual Reporting Burden: 117,651 Hours.

The FNS–248, Status of Sample Selection and Completion:

Abstract: The FNS–248, Status of Sample Selection and Completion, tracks a State's progress in sample selection and case completion on a monthly basis. A proposed rule entitled "Food Stamp Program: Discretionary Quality Control Provisions of Title IV of Public Law 107–171", was published in the **Federal Register** on September 23, 2005 (70 FR 55776). The rulemaking proposed to eliminate this form as a means of collecting this information and would allow State agencies to report in a manner as directed by the regional offices. FNS expects to publish a final rule on this subject in 2010. Until then, the use of FNS–248 will be discontinued because the data collected has decreased to only four elements: Active and Negative Sampling Intervals and Active and Negative Number of Sample Cases Selected. These elements must be reported monthly by the States, but may be sent through various mediums to their regional offices. The annual reporting and recordkeeping burden associated with this new way of collecting the four elements significantly decreases the burden from 348 hours to approximately 64 hours.

Affected Public: State or local governments.

Estimated Number of Respondents: 53.

Estimated Number of Reports per Respondent: 12.
Estimated Number of Recordkeeping per Respondent: 12.
Estimated Total Annual Response: 636.
Estimated Time Reporting per Response: .0835 Hours.
Estimated Total Reporting Annual Burden: 53.106 Hours.
Estimated Time Recordkeeping per Response: .0167 Hours.
Estimated Total Recordkeeping Annual Burden: 10.6212 Hours.
Total Annual Reporting and Recordkeeping Burden: 63.7272 Hours.
Grand Total for Reporting: 117,704.
Grand Total for Recordkeeping: 10.62.
Grand Total Reporting and Recordkeeping Burden: 117,714.62.

Dated: July 29, 2009.

Julia Paradis,

Administrator, Food and Nutrition Service.

[FR Doc. E9-18562 Filed 8-3-09; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Rural Business-Cooperative Service

Rural Utilities Service

Notice of Funds Availability Under the American Recovery and Reinvestment Act, 2009; Correction

AGENCIES: Rural Housing Service, Rural Business-Cooperative Service, and Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Housing Service (RHS), Rural Business-Cooperative Service (RBS), and Rural Utilities Service (RUS) published a document in the *Federal Register* on July 23, 2009, at 74 FR 36448. The document contained an error related to the Catalog of Federal Domestic Assistance number.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding this correction should be directed to Michele Brooks, 202-690-1078.

SUPPLEMENTARY INFORMATION:

Need for Correction

The Catalog of Federal Domestic Assistance (CFDA) number for Broadband Loans and Grants is incorrectly identified, which could affect locating this program within the CFDA.

Correction of Publication

In the *Federal Register* of July 23, 2009, in FR Doc. E9-17512, on page

36450, column 2, under I. A. Affected Programs, the CFDA number “10.886” is corrected to read “10.787”.

Dated: July 28, 2009.

Dallas Tonsager,

Under Secretary, Rural Development.

[FR Doc. E9-18571 Filed 8-3-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-580-851]

Dynamic Random Access Memory Semiconductors from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is conducting an administrative review of the countervailing duty order on dynamic random access memory semiconductors from the Republic of Korea for the period January 1, 2007, through December 31, 2007. We preliminarily find that Hynix Semiconductor, Inc. received countervailable subsidies during the period of review, which result in a *de minimis* subsidy rate. If these preliminary results are adopted in our final results of this review, we will instruct U.S. Customs and Border Protection not to assess countervailing duties as detailed in the “Preliminary Results of Review” section of this notice. Interested parties are invited to comment on these preliminary results. See the “Public Comment” section of this notice.

EFFECTIVE DATE: August 4, 2009.

FOR FURTHER INFORMATION CONTACT:

David Neubacher or Shane Subler, Office of AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 3069, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-5823 and (202) 482-0189, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 11, 2003, the Department of Commerce (“the Department”) published a countervailing duty order on dynamic random access memory semiconductors (“DRAMs”) from the Republic of Korea (“ROK”). See *Notice of Countervailing Duty Order: Dynamic Random Access Memory*

Semiconductors from the Republic of Korea, 68 FR 47546 (August 11, 2003) (“CVD Order”). On August 1, 2008, the Department published a notice of “Opportunity to Request Administrative Review” for this countervailing duty order. See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 73 FR 44966 (August 1, 2008). On August 28, 2008, we received a request for review from Hynix Semiconductor, Inc. (“Hynix”). On September 2, 2008, we received a request for review of Hynix and its affiliates from the petitioner, Micron Technology, Inc. (“Micron”). In accordance with 19 CFR 351.221(c)(1)(i), we published a notice of initiation of the review on September 30, 2008. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 73 FR 56795 (September 30, 2008).

On December 12, 2008, we issued countervailing duty questionnaires to the Government of the Republic of Korea (“GOK”) and Hynix. We received responses to these questionnaires on January 29, 2009. On March 17, 2009, we issued supplemental questionnaires to the GOK and Hynix. We received timely responses to these supplemental questionnaires on April 14, 2009. We issued additional supplemental questionnaires to the GOK and Hynix on July 10, 2009 and received responses on July 23, 2009 and July 17, 2009, respectively.

We received new subsidy allegations from Micron on February 17, 2009.¹ On July 7, 2009, we decided not to initiate an investigation of any of the new subsidies that Micron alleged in this administrative review. In addition, we stated the timing of the benefit of a previously countervailed debt-to-equity swap (“DES”) is not a new subsidy, but rather a valuation issue, and we would not reexamine the issue absent new information that would cast substantial doubt on our finding. See Memorandum to Susan Kuhbach, Director, Office 1, entitled “Fifth Countervailing Duty Administrative Review: Dynamic Random Access Memory Semiconductors from Korea: New Subsidy Allegations Memorandum” (July 9, 2009) (“NSA Memo”), available in the Central Records Unit, Room 1117 of the main Department building.

On April 14, 2009, we published a postponement of the preliminary results in this review until August 3, 2009. See

¹ See submission from Micron to the Department, Re: Dynamic Random Access Memory Semiconductors From Korea: New Subsidy Allegation (February 17, 2009) (“New Subsidy Allegations”).

Dynamic Random Access Memory Semiconductors from the Republic of Korea: Extension of Time Limit for Preliminary Results of Countervailing Duty Administrative Review, 74 FR 17166 (April 14, 2009).

Scope of the Order

The products covered by the order are DRAMS from the ROK, whether assembled or unassembled. Assembled DRAMS include all package types. Unassembled DRAMS include processed wafers, uncut die, and cut die. Processed wafers fabricated in the ROK, but assembled into finished semiconductors outside the ROK are also included in the scope. Processed wafers fabricated outside the ROK and assembled into finished semiconductors in the ROK are not included in the scope.

The scope of the order additionally includes memory modules containing DRAMS from the ROK. A memory module is a collection of DRAMS, the sole function of which is memory. Memory modules include single in-line processing modules, single in-line memory modules, dual in-line memory modules, small outline dual in-line memory modules, Rambus in-line memory modules, and memory cards or other collections of DRAMS, whether unmounted or mounted on a circuit board. Modules that contain other parts that are needed to support the function of memory are covered. Only those modules that contain additional items which alter the function of the module to something other than memory, such as video graphics adapter boards and cards, are not included in the scope. The order also covers future DRAMS module types.

The scope of the order additionally includes, but is not limited to, video random access memory and synchronous graphics random access memory, as well as various types of DRAMS, including fast page-mode, extended data-out, burst extended data-out, synchronous dynamic RAM, Rambus DRAM, and Double Data Rate DRAM. The scope also includes any future density, packaging, or assembling of DRAMS. Also included in the scope of the order are removable memory modules placed on motherboards, with or without a central processing unit, unless the importer of the motherboards certifies with U.S. Customs and Border Protection ("CBP") that neither it, nor a party related to it or under contract to it, will remove the modules from the motherboards after importation. The scope of the order does not include DRAMS or memory modules that are re-imported for repair or replacement.

The DRAMS subject to the order are currently classifiable under subheadings 8542.21.8005, 8542.21.8020 through 8542.21.8030, and 8542.32.0001 through 8542.32.0023 of the Harmonized Tariff Schedule of the United States ("HTSUS"). The memory modules containing DRAMS from the ROK, described above, are currently classifiable under subheadings 8473.30.1040, 8473.30.1080, 8473.30.1140, and 8473.30.1180 of the HTSUS. Removable memory modules placed on motherboards are classifiable under subheadings 8443.99.2500, 8443.99.2550, 8471.50.0085, 8471.50.0150, 8517.30.5000, 8517.50.1000, 8517.50.5000, 8517.50.9000, 8517.61.0000, 8517.62.0010, 8517.62.0050, 8517.69.0000, 8517.70.0000, 8517.90.3400, 8517.90.3600, 8517.90.3800, 8517.90.4400, 8542.21.8005, 8542.21.8020, 8542.21.8021, 8542.21.8022, 8542.21.8023, 8542.21.8024, 8542.21.8025, 8542.21.8026, 8542.21.8027, 8542.21.8028, 8542.21.8029, 8542.21.8030, 8542.31.0000, 8542.33.0000, 8542.39.0000, 8543.89.9300, and 8543.89.9600 of the HTSUS. However, the product description, and not the HTSUS classification, is dispositive of whether merchandise imported into the United States falls within the scope.

Scope Rulings

On December 29, 2004, the Department received a request from Cisco Systems, Inc. ("Cisco"), to determine whether removable memory modules placed on motherboards that are imported for repair or refurbishment are within the scope of the order. *See CVD Order*. The Department initiated a scope inquiry pursuant to 19 CFR 351.225(e) on February 4, 2005. On January 12, 2006, the Department issued a final scope ruling, finding that removable memory modules placed on motherboards that are imported for repair or refurbishment are not within the scope of the *CVD Order* provided that the importer certifies that it will destroy any memory modules that are removed for repair or refurbishment. *See Memorandum from Stephen J. Claes to David M. Spooner, regarding Final Scope Ruling, Countervailing Duty Order on DRAMS from the Republic of Korea* (January 12, 2006).

Period of Review

The period for which we are measuring subsidies, *i.e.*, the period of review ("POR"), is January 1, 2007, through December 31, 2007.

Changes in Ownership

Effective June 30, 2003, the Department adopted a new methodology for analyzing privatizations in the countervailing duty context. *See Notice of Final Modification of Agency Practice Under Section 123 of the Uruguay Round Agreements Act*, 68 FR 37125 (June 23, 2003). The Department's new methodology is based on a rebuttable "baseline" presumption that non-recurring, allocable subsidies continue to benefit the subsidy recipient throughout the allocation period (which normally corresponds to the average useful life ("AUL") of the recipient's assets). However, an interested party may rebut this baseline presumption by demonstrating that, during the allocation period, a change in ownership occurred in which the former owner sold all or substantially all of a company or its assets, retaining no control of the company or its assets, and that the sale was an arm's-length transaction for fair market value. Hynix did not challenge this baseline presumption. *See Hynix's* January 29, 2009, questionnaire response at 12.

Subsidies Valuation Information

Allocation Period

Pursuant to 19 CFR 351.524(b), non-recurring subsidies are allocated over a period corresponding to the AUL of the renewable physical assets used to produce the subject merchandise. Section 351.524(d)(2) of the Department's regulations creates a rebuttable presumption that the AUL will be taken from the U.S. Internal Revenue Service's 1977 Class Life Asset Depreciation Range System (the "IRS Tables"). For DRAMS, the IRS Tables prescribe an AUL of five years. During this review, none of the interested parties disputed this

allocation period. Therefore, we continue to allocate non-recurring benefits over the five-year AUL.

Discount Rates and Benchmarks for Loans

For loans that we found countervailable in the investigation or in the prior administrative reviews, and which continued to be outstanding during the POR, we have used the benchmarks from the prior administrative reviews.

Long-term Rates

Countervailable Loans from Prior Reviews

For long-term, won-denominated loans originating in 1986 through 1995, we used the average interest rate for three-year corporate bonds as reported

by the Bank of Korea ("BOK") or the International Monetary Fund ("IMF"). For long-term won-denominated loans originating in 1996 through 1999, we used annual weighted averages of the rates on Hynix's corporate bonds, which were not specifically related to any countervailable financing. We did not use the rates on

Hynix's corporate bonds for 2000–2003 for any calculations because Hynix either did not obtain bonds or obtained bonds through countervailable debt restructurings during those years.

For U.S. dollar-denominated loans, we relied on the lending rates as reported in the IMF's *International Financial Statistics Yearbook*.

For the years in which we previously determined Hynix to be uncreditworthy (2000 through 2003), we used the formula described in 19 CFR 351.505(a)(3)(iii) to determine the benchmark interest rate. For the probability of default by an uncreditworthy company, we used the average cumulative default rates reported for the Caa- to C- rated category of companies as published in Moody's Investors Service, "Historical Default Rates of Corporate Bond Issuers, 1920–1997" (February 1998). For the probability of default by a creditworthy company, we used the cumulative default rates for investment grade bonds as published in Moody's Investors Service: "Statistical Tables of Default Rates and Recovery Rates" (February 1998). For the commercial interest rates charged to creditworthy borrowers, we used the rates for won-denominated corporate bonds as reported by the BOK and the U.S. dollar lending rates published by the IMF for each year.

Countervailable Loans during the current POR

For countervailable long-term foreign-currency denominated loans reported by Hynix, we used, where available, the company-specific, weighted-average interest rates on the company's comparable commercial foreign currency loans from foreign bank branches in the ROK, foreign securities, and direct foreign loans outstanding during the POR. For countervailable variable-rate loans outstanding during the POR, pursuant to 19 CFR 351.505(a)(5)(i), we used the interest rates of variable-rate lending instruments issued during the year in which the government loans were issued. Where such loans were unavailable, the Department, consistent with 19 CFR 351.505(a)(3)(ii), followed its prior practice and relied upon lending rates as reported in the IMF's *International Financial Statistics*

Yearbook. See *Final Affirmative Countervailing Duty Determination: Dynamic Random Access Memory Semiconductors from the Republic of Korea*, 68 FR 37122 (June 23, 2003) and accompanying Issues and Decision Memorandum at 5 7.

Analysis of Programs

I. Programs Previously Determined to Confer Subsidies

We examined the following programs determined to confer subsidies in the investigation

and prior administrative reviews and preliminarily find that Hynix continued to receive benefits under these programs during the POR.

A. GOK Entrustment or Direction Prior to 2004

In the investigation, the Department determined that the GOK entrusted or directed creditor banks to participate in financial restructuring programs, and to provide credit and other funds to Hynix, in order to assist Hynix through its financial difficulties. The financial assistance provided to Hynix by its creditors took various forms, including new loans, convertible and other bonds, extensions of maturities and interest rate reductions on existing debt (which we treated as new loans), Documents Against Acceptance ("D/A") financing, usance financing, overdraft lines of credit, debt forgiveness, and DES. The Department determined that these were financial contributions that constituted countervailable subsidies during the period of investigation.

In prior administrative reviews, the Department also found that the GOK continued to entrust or direct Hynix's creditors to provide financial assistance to Hynix throughout 2002 and 2003. The financial assistance provided to Hynix during this period included the December 2002 DES and the extensions of maturities and/or interest rate deductions on existing debt.

In an administrative review, we do not revisit past findings unless new factual information or evidence of changed circumstances has been placed on the record of the proceeding that would compel us to reconsider those findings. See, e.g., *Certain Pasta from Italy: Preliminary Results and Partial Rescission of the Seventh Countervailing Duty Administrative Review*, 69 FR 45676, 45680 (July 30, 2004), unchanged in *Certain Pasta from Italy: Final Results of the Seventh Countervailing Duty Administrative Review*, 69 FR 70657 (December 7, 2004). No such new factual information or evidence of changed circumstances

has been placed on the record in this review. Thus, we preliminarily find that a re-examination of the Department's findings in the investigation and prior administrative reviews with respect to the debt forgiveness, loans, and extensions of maturities and/or interest rate deductions on existing debt is unwarranted.

Micron argues in its New Subsidy Allegations submission that the Department should reconsider its decision on the timing of the 2002 DES and find that the DES occurred in 2003. As noted above, we stated that the issue was not a new subsidy allegation, but rather a subsidy valuation issue, and we would not consider reexamining the issue absent new information that casts substantial doubt on this finding. See NSA Memo at 7.

In its argument, Micron provides new information² with regard to one aspect of its claims, namely that the contingency requiring shareholder approval of a 21:1 capital reduction was not *pro forma*. Micron's "new information" is the list of Hynix board members at the time of the Micron deal in April 2002, who had unanimously rejected the deal, and the list of Hynix board members at the time of the Creditors' Council's restructuring plan in January 2003. See Micron's February 17, 2009, submission at 22. According to Micron, the lists show that three members of Hynix's board of directors ("BOD"), remained on the board following its vote on the Micron deal. Thus, Micron asserts, because the BOD still included members who had previously rejected the Micron deal, the BOD could still exercise independent judgment and would not merely "rubber stamp" any deal proposed by the Creditors' Council. As such, Micron concludes, the approval of the DES was not *pro forma*.

In *DRAMS 1st AR*, the Department determined that as the Creditors' Council controlled Hynix and its December 2002 approval was the singular factor in effectuating the restructuring. See *Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 71 FR 14174 (March 21, 2006), and accompanying Issues and Decision Memorandum at Comment 13 ("DRAMS 1st AR"). This decision was upheld by the Court of International Trade ("CIT").

² The list of Hynix board members at the time of the Micron vote, cited by Micron in its February 17, 2009, submission, was on the record of the second administrative review. However, Micron argues this same information was not on the record of the third administrative review when the Department last reconsidered this issue.

See *Micron Technology, Inc. v. United States*, 535 F. Supp. 2d 1336, 1344 (CIT 2007). In *DRAMS 3rd AR*, we reexamined the timing of the 2002 DES based on new information submitted by Micron and concluded,

As stated in the AR1 Decision Memorandum and the Preliminary Results, the Creditors' Council owned a majority of shares of the company and effectively controlled the company. {See *Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 71 FR 14174 (March 21, 2006), and accompanying Issues and Decision Memorandum at 77 ("AR1 Decision Memorandum") and *Dynamic Random Access Memory Semiconductors from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review* 72 FR 51611 (September 10, 2007) ("Preliminary Results").} This situation effectively made its December 2002 approval the singular factor in effectuating the restructuring and the new information does not call into question the Creditors' Council's dominant role in the process nor raise questions as to whether the minority shareholders' opposition was significant enough to have an impact on or to alter the eventual terms and passage of the agreement. See *Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 73 FR 14218 (March 17, 2008) ("DRAMS 3rd AR") and accompanying Issues and Decision Memorandum at Comment 1. Thus, in our original and subsequent determinations on the timing of the 2002 DES, one of the underlying bases for our decisions was the Creditors' Council's majority stake in Hynix and its effective control over the company.

In submitting the "new information," Micron does not contest this premise, but highlights the fact that three members of the BOD remained after its unanimous rejection of the Micron deal in April 2002 and, Micron argues, therefore, that the BOD vote on the restructuring in January 2003 was not *pro forma*. However, based upon the information submitted by Micron, the simple fact that three members remained on the BOD from the time of the Micron vote to the restructuring vote does not cast substantial doubt on our finding that the Creditors' Council's majority ownership and control of Hynix meant that the Creditors' Council's approval of the restructuring

in 2002 was the single effectuating event for the DES. Therefore, absent any other new information that might compel us to reconsider our prior determination, we will not reexamine it in the context of this administrative review. See *PPG Industries v. United States*, 978 F.2d 1232, 1242 (Fed. Cir 1992). See also, *Certain Pasta from Italy: Preliminary Results and Partial Rescission of the Seventh Countervailing Duty Administrative Review*, 69 FR at 45680, unchanged in *Certain Pasta from Italy: Final Results of Seventh Countervailing Duty Administrative Review*, 69 FR 70657.

As the benefit from the 2002 DES was fully allocated in the prior administrative review and we are not reexamining our prior decision, we are only including in our benefit calculation the following financial contributions countervailed in the investigation and prior administrative reviews: bonds, debt forgiveness, and long-term debt outstanding during the POR. In calculating the benefit, we have followed the same methodology used in prior administrative reviews.

For loans, we have followed the methodology described at 19 CFR 351.505(c) using the benchmarks described in the "Discount Rates and Benchmarks for Loans" section above.

We divided the total benefits allocated to the POR from the various financial contributions by Hynix's POR sales. On this basis, we preliminarily determine the countervailable subsidy from this program to be less than 0.005 percent *ad valorem* during the POR. Therefore, consistent with our past practice, we did not include this program in our preliminary net countervailing duty rate. See, e.g., *Coated Free Sheet Paper from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 72 FR 60645 (October 25, 2007), and accompanying Issues and Decision Memorandum at 16 ("CFS"); and *Final Results of Countervailing Duty Administrative Review: Low Enriched Uranium from France*, 70 FR 39998 (July 12, 2005), and accompanying Issues and Decision Memorandum at "Purchases at Prices that Constitute More than Adequate Remuneration," ("Uranium from France") (citing *Notice of Final Results of Countervailing Duty Administrative Review and Rescission of Certain Company-Specific Reviews: Certain Softwood Lumber Products From Canada*, 69 FR 75917 (December 20, 2004), and accompanying Issues and Decision Memorandum at "Other Programs Determined to Confer Subsidies")

B. Operation G-7/HAN Program

Implemented under the Framework on Science and Technology Act, the Operation G-7/HAN Program ("G-7/HAN Program") operated from 1992 through 2001. The purpose of this program was to raise the GOK's technology standards to the level of the G-7 countries. The Department found that the G7/HAN Program ended in 2001. See *Final Affirmative Countervailing Duty Determination: Dynamic Random Access Memory Semiconductors from the Republic of Korea*, 68 FR 37122 (June 23, 2003), and accompanying Issues and Decision Memorandum at 25. However, during the POR, Hynix had outstanding loans that it had previously received under this program. See Hynix's January 29, 2009, questionnaire response at 14 and Exhibit 10.

We found that the G-7/HAN Program provided countervailable subsidies in the investigation. No interested party provided new evidence that would lead us to reconsider our earlier finding. Therefore, we continue to find that these loans confer a countervailable subsidy.

To calculate the benefit of these loans during the POR, we compared the interest actually paid on the loans during the POR to what Hynix would have paid under the benchmark described in the "Subsidy Valuation Information" section of this notice. Next, we divided the total benefit by Hynix's total sales of subject merchandise for the POR to calculate the countervailable subsidy. On this basis, we preliminarily determine the countervailable subsidy to be 0.01 percent *ad valorem* during the POR.

C. 21st Century Frontier R&D Program

The 21st Century Frontier R&D Program ("21st Century Program") was established in 1999 with a structure and governing regulatory framework similar to those of the G-7/HAN Program, and for a similar purpose, *i.e.*, to promote greater competitiveness in science and technology. The 21st Century Program provides long-term interest-free loans in the form of matching funds. Repayment of program funds is made in the form of "technology usage fees" upon completion of the project, pursuant to a schedule established under a technology execution or implementation contract.

Hynix reported that it had loans from the 21st Century Program outstanding during the POR. See Hynix's January 29, 2009, questionnaire response at 15 and Exhibit 10.

In the investigation, we determined that this program conferred a

countervailable benefit on Hynix. No interested party provided new evidence that would lead us to reconsider our earlier finding. Therefore, we continue to find that these loans confer a countervailable subsidy.

To calculate the benefit of these loans during the POR, we compared the interest actually paid on the loans during the POR to what Hynix would have paid under the benchmark described in the “Discount Rates and Benchmarks for Loans” section above. We then divided the total benefit by Hynix’s total sales in the POR to calculate the countervailable subsidy rate. On this basis, we preliminarily find countervailable benefits of less than 0.005 percent *ad valorem* during the POR. Therefore, consistent with our past practice, we did not include this program in our preliminary net countervailing duty rate. *See CFS and Uranium from France.*

D. Import Duty Reduction Program for Certain Factory Automation Items

Article 95(1).4 of the Korean Customs Act provides for import duty reductions on imports of “machines, instruments and facilities (including the constituent machines and tools) and key parts designated by the Ordinance of the Ministry of Finance and Economy for a factory automatization applying machines, electronics or data processing techniques.”

Hynix reported that it had received duty reductions under this program during the POR. *See* Hynix’s January 29, 2009, questionnaire response at 16 and Exhibit 13.

In a prior administrative review, the Department found that the above program provided a financial contribution in the form of revenue forgone and a benefit in the amount of the duty savings. *See DRAMS 3rd AR Final* and the accompanying Issues and Decision Memorandum at 6 - 7 and Comment 6. The Department also found the program to be *de facto* specific under section 771(5A)(D)(iii)(III) of the Act. *Id.* No interested party provided new evidence that would lead us to reconsider our earlier finding. Therefore, we continue to find that these duty reductions confer a countervailable subsidy.

To calculate the benefit, we divided the total duty savings Hynix received during the POR by Hynix’s total sales during the POR. On this basis, we preliminarily determine the countervailable subsidy to be 0.01 *ad valorem* percent during the POR.

II. Program Preliminarily Determined To Confer Subsidies

A. Import–Export Bank of Korea Import Financing

In the fourth administrative review the Department did not make a finding on the countervailability of this program and said it would examine this program in a subsequent administrative review. *See Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 74 FR 7395 (February 17, 2009) and accompanying Issues and Decision Memorandum at 7.

As outlined in Article 18, paragraph 1, subparagraph 4 of the Import–Export Bank of Korea (“KEXIM”) Act, the “Import Financing Program” is provided to Korean importers to facilitate their purchase of essential materials, major resources, and operating equipment, the stable and timely supply of which is essential to the stability of the general economy. The equipment and materials eligible to be imported under the program fall under 13 headings listed in Article 14 of the KEXIM Business Manual. The listed items range from raw materials to factory automation equipment and include products and materials described in government notices.

Further, according to the GOK, any Korean company is eligible for the “Import Financing Program” as long as the equipment or material appears under the 13 headings of eligible items, the company can satisfy the financial criteria laid out in “KEXIM’s Credit Extension Regulation,” and KEXIM’s Credit Extension Committee approves the financing application. Regarding the last item, the GOK stated that all decisions to offer this financing are based on the application and financial status of the applicant company.

Hynix received loans from KEXIM under this program in 2006 and 2007. *See* Hynix’s April 14, 2009, supplemental questionnaire response at 3. *See also*, GOK’s April 14, 2009, supplemental questionnaire response at 1.

We preliminarily determine that loans under this program constitute financial contributions, pursuant to sections 771(5)(B)(i) and 771(5)(D)(i) of the Act, and also provide benefits equal to the difference between what Hynix paid on its loans and the amount it would have paid on comparable commercial loans within the meaning of section 771(5)(E)(ii) of the Act.

Regarding specificity, information submitted by the GOK shows that loans provided under the program are available to any enterprise that meets

the criteria as described above. *See, e.g.*, GOK’s January 29, 2009, questionnaire response at 12–14 and GOK’s April 14, 2009, supplemental questionnaire response at Exhibit 5. Further, the GOK reported that eligibility is not limited by law to any enterprise or group of enterprises, or to any industry or group of industries. *Id.* Therefore, we preliminarily determine that there is no basis to find this program *de jure* specific under section 771(5A)(D)(i) of the Act.

In determining whether this program is *de facto* specific, we examine the four *de facto* specificity factors under section 771(5A)(D)(iii) of the Act. The GOK provided program usage data for 2003 through 2007 showing the number of industries that received loans under this program as well as the number of recipients and the total amount financed for the same period grouped by industry, region, and eligible item. *See* GOK’s April 14, 2009, supplemental questionnaire response at 8–12 and 14–16, and GOK’s July 23, 2009, supplemental questionnaire response at 2–7. We preliminarily determine that the number of enterprises receiving this subsidy is limited within the meaning of section 771(5A)(D)(iii)(I) of the Act because only 482 companies received this award from 2003 through 2007. *See* GOK’s April 14, 2009, supplemental questionnaire response at 12. Thus, we find the program to be *de facto* specific within the meaning of section 771(5A)(D)(iii)(I) of the Act. Therefore, we preliminarily find loans provided by KEXIM under this program provide countervailable benefits to Hynix.

To calculate the benefit under this program, we used the benchmarks described in the “Discount Rates and Benchmarks for Loans” section above, as well as the methodology described in 19 CFR 351.505(c). On this basis, we preliminarily determine that Hynix received a countervailable subsidy of 0.04 percent *ad valorem* under this program.

III. Program Preliminarily Found to Have Provided No Benefits

A. Short–Term Export Financing

KEXIM provides short–term export financing to small-, medium- and large-sized companies (not including companies included in the largest five conglomerates in the ROK, unless the company’s headquarters is located outside the Seoul Metropolitan area). The loans are not tied to particular export transactions. However, a company, along with the financing application, must provide its export performance periodically for review by KEXIM. Further, any loan agreement

may only cover an amount ranging from 50 to 90 percent of the company's export performance up to 30 billion won.

Hynix received a loan under this program during the POR and provided documentation (e.g. loan application, approval document, and loan agreement), as well as data regarding the loan amount and interest paid during the POR. See Hynix's April 14, 2009, supplemental questionnaire response at 3 and 5. Upon examination of the documentation as well as the loan amount and interest paid during the POR, the Department preliminarily determines that there was no measurable benefit. Accordingly, it is unnecessary in this review for the Department to make a finding as to the countervailability of this program for this POR. We will include an examination of this program in a future administrative review.

IV. Programs Previously Found Not to Have Been Used or Provided No Benefits

We preliminarily determine that the following programs were not used during the POR:

- A. Reserve for Research and Human Resources Development (formerly Technological Development Reserve) (Article 9 of RSTA / formerly, Article 8 of TERCL)
- B. Tax Credit for Investment in Facilities for Productivity Enhancement (Article 24 of RSTA / Article 25 of TERCL)
- C. Tax Credit for Investment in Facilities for Special Purposes (Article 25 of RSTA)
- D. Reserve for Overseas Market Development (formerly, Article 17 of TERCL)
- E. Reserve for Export Loss (formerly, Article 16 of TERCL)
- F. Tax Exemption for Foreign Technicians (Article 18 of RSTA)
- G. Reduction of Tax Regarding the Movement of a Factory That Has Been Operated for More Than Five Years (Article 71 of RSTA)
- H. Tax Reductions or Exemption on Foreign Investments under Article 9 of the Foreign Investment Promotion Act ("FIPA")/ FIPA (Formerly Foreign Capital Inducement Law)
- I. Duty Drawback on Non-Physically Incorporated Items and Excessive Loss Rates
- J. Export Insurance
- K. Electricity Discounts Under the RLA Program
- L. Import Duty Reduction for Cutting Edge Products
- M. System IC 2010 Project

See Hynix's January 29, 2009, questionnaire response at 20 and the GOK's January 29, 2009, questionnaire response at 22.

In the first administrative review, the Department found that "any benefits provided to Hynix under the System IC 2010 Project are tied to non-subject merchandise" and, therefore, that "Hynix did not receive any countervailable benefits under this program during the POR," in accordance with 19 CFR 351.525(b)(5). See *Dynamic Random Access Memory Semiconductors from the Republic of Korea: Final Results of Countervailing Duty Administrative Review*, 71 FR 14174 (March 21, 2006), and the accompanying Issues and Decision Memorandum at 15. No new information has been provided with respect to this program. See Hynix's April 14, 2009 supplemental questionnaire at 1. Therefore, we preliminarily find that Hynix did not receive any countervailable benefits from the System IC 2010 Project during the POR.

Preliminary Results of Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated an individual subsidy rate for Hynix, the producer/exporter covered by this administrative review. We preliminarily determine that the total estimated net countervailable subsidy rate for Hynix for calendar year 2007 is 0.06 percent *ad valorem*, which is *de minimis* in accordance with 19 CFR 351.106(c)(1). Consequently, if these preliminary results are adopted in the final results of this review, the Department will instruct U.S. Customs and Border Protection ("CBP") to liquidate shipments of DRAMs by Hynix entered or withdrawn from warehouse, for consumption from January 1, 2007, through December 31, 2007, without regard to countervailing duties. See 19 CFR 351.106(c)(1). We intend to issue these instructions 15 days after publication of the final results of this review.

On October 3, 2008, the Department published a **Federal Register** notice that, *inter alia*, revoked this order, effective August 11, 2008. See *Dynamic Random Access Memory Semiconductors From the Republic of Korea: Final Results of Sunset Review and Revocation of Order*, 73 FR 57594 (October 3, 2008). As a result, CBP is no longer suspending liquidation for entries of subject merchandise occurring after the revocation. Therefore, there is no need to issue new cash deposit instructions in the final results of this administrative review.

Public Comment

Interested parties may submit written arguments in case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, limited to issues raised in case briefs, may be filed not later than five days after the date of filing the case briefs. Parties who submit briefs in this proceeding should provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR 351.303(f).

Interested parties may request a hearing within 30 days after the date of publication of this notice. Unless otherwise specified, the hearing, if requested, will be held two days after the scheduled date for submission of rebuttal briefs.

The Department will publish a notice of the final results of this administrative review within 120 days from the publication of these preliminary results.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 28, 2009.

Ronald K. Lorentzen,
Acting Assistant Secretary for Import Administration.

[FR Doc. E9-18597 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-946]

Prestressed Concrete Steel Wire Strand from the People's Republic of China: Correction to Notice of Initiation of Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 23, 2009

FOR FURTHER INFORMATION CONTACT: Robert Copyak, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Room 4014, Washington, DC 20230; telephone: (202) 482-2209.

SUPPLEMENTARY INFORMATION: On June 23, 2009, the Department published its notice of initiation of the countervailing duty investigation of prestressed concrete steel wire strand from the People's Republic of China ("PRC"). See *Prestressed Concrete Steel Wire Strand From the People's Republic of China:*

Initiation of Countervailing Duty Investigation, 74 FR 29670 (June 23, 2009). In that notice, the effective date was listed as June 16, 2009. The effective date should have read June 23, 2009, which was the date of publication of the notice of initiation.

Dated: July 21, 2009.

Ronald K. Lorentzen,

Acting Assistant Secretary for Import Administration.

[FR Doc. E9-18594 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-DS-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XP72

Endangered Species; File No. 1596-02

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

ACTION: Notice; issuance of permit modification.

SUMMARY: Notice is hereby given that National Marine Fisheries Service Southwest Fisheries Science Center has been issued a modification to scientific research Permit No. 1596-01.

ADDRESSES: The modification and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713-2289; fax (301)427-2521;

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213; phone (562)980-4001; fax (562)980-4018.

FOR FURTHER INFORMATION CONTACT: Patrick Opay (301)713-2289.

SUPPLEMENTARY INFORMATION: On May 13, 2009, notice was published in the **Federal Register** (74 FR 22517) that a modification of Permit No. 1596-01 had been requested by the above-named organization. The requested modification has been granted under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222-226).

The permit modification authorizes researchers to annually fat biopsy and ultrasound up to 38 leatherback sea turtles as part of a health and nutritional assessment of this species. It also

provides authority to close approach and attach VHR/TDR/sonic tag/GPS/video camera units by suction cup on up to 20 leatherback sea turtles annually, and to later capture the same animals to remove the unit and then sample, tag, and attach another VHR/TDR/sonic tag/GPS/video camera unit to the animals before release. Additionally, the permit modification authorizes researchers to annually attach a VHR/TDR/sonic tag/GPS unit and tissue sample 20 leatherback sea turtles using a biopsy pole. The permit currently authorizes researchers to attach the unit or tissue sample 20 animals, not both. The number of leatherback sea turtles captured does not increase under the modification, but the mix of activities conducted on each animal does. The research may continue to occur in waters off the coast of the western United States through February 1, 2012.

Issuance of this modification, as required by the ESA was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: July 29, 2009.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E9-18585 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO-P-2009-0028]

Grant of interim extension of the term of U.S. Patent No. 5,135,759; MicroSort® Sperm Separation Technology

AGENCY: United States Patent and Trademark Office.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,135,759.

FOR FURTHER INFORMATION CONTACT:

Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-

1450; by fax marked to her attention at (571) 273-7755, or by e-mail to Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On June 8, 2009, the patent owner, the United States of America, as represented by the Secretary of Agriculture, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,135,759. The patent claims the use of the medical device, MicroSort® Sperm Separation Technology. The application indicates, and the Food and Drug Administration has confirmed, that a Premarket Approval application (P090004) for the medical device, MicroSort® Sperm Separation Technology, has been filed by the licensee of the patent owner, Genetics & IVF Institute, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (August 4, 2009), an interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,135,759 is granted for a period of one year from the original expiration date of the patent, i.e., until August 4, 2010.

Dated: July 28, 2009.

John J. Doll,

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

[FR Doc. E9-18574 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XQ65

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Coral Advisory Panel in North Charleston, SC. See **SUPPLEMENTARY INFORMATION.**

DATES: The meeting will take place September 1–2, 2009. See **SUPPLEMENTARY INFORMATION.**

SUPPLEMENTARY INFORMATION.

ADDRESSES: The meeting will be held at the Hilton Garden Inn, 5265 International Boulevard, North Charleston, SC; telephone: (843) 308–9330.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; telephone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: Members of the Coral Advisory Panel will meet from 8:30 a.m. until 5 p.m. on September 1, 2009, and from 8:30 a.m. until 12 noon on September 2, 2009.

The Advisory Panel will receive updates from Council staff regarding the status of Comprehensive Ecosystem-based Amendment 1 establishing Deepwater Coral Habitat Areas of Particular Concern (CHAPCs) and an overview of the draft Comprehensive Ecosystem-based Amendment 2 currently under development. The AP will develop recommendations to the Council for the development of Acceptable Biological Catch (ABC), Overfishing Level (OFL), Annual Catch Limit (ACL), and Accountability Measures (AMs) for South Atlantic octocorals, as well as recommendations for new Essential Fish Habitat (EFH) and Habitat Areas of Particular Concern (HAPCs) proposed in Comprehensive Ecosystem-based Amendment 2, and management alternatives that address impacts to Acroporids from the spiny lobster fishery.

AP members will receive an update on outreach activities associated with the Oculina Bank HAPC and

Experimental Closed Area, and a summary of information needs for Florida presented at the Atlantic/Caribbean Coral Reef Integrated Observing System (CREIOS) Workshop. The AP will also be briefed on the outcomes of the NOAA Deep Sea Coral Priorities Workshop that took place in July 2009.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting. Note: The times and sequence specified in this agenda are subject to change.

Dated: July 29, 2009.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. E9–18505 Filed 8–3–09; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE**National Institute of Standards and Technology****Request for Nominations for Members To Serve on National Institute of Standards and Technology Federal Advisory Committees**

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites and requests nomination of individuals for appointment to its eight existing Federal Advisory Committees: Technology Innovation Program Advisory Board, Board of Overseers of the Malcolm Baldrige National Quality Award, Judges Panel of the Malcolm Baldrige National Quality Award, Information Security and Privacy Advisory Board, Manufacturing Extension Partnership Advisory Board,

National Construction Safety Team Advisory Committee, Advisory Committee on Earthquake Hazards Reduction, and Visiting Committee on Advanced Technology. NIST will consider nominations received in response to this notice for appointment to the Committees, in addition to nominations already received.

DATES: Nominations for all committees will be accepted on an ongoing basis and will be considered as and when vacancies arise.

ADDRESSES: See below.

SUPPLEMENTARY INFORMATION:**Technology Innovation Program (TIP) Advisory Board**

Addresses: Please submit nominations to Mr. Marc Stanley, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4700, Gaithersburg, MD 20899–4700. Nominations may also be submitted via FAX to 301–869–1150. Additional information regarding the Board, including its charter may be found on its electronic home page at: <http://www.nist.gov/tip>.

For Further Information Contact: Mr. Marc Stanley, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4700, Gaithersburg, MD 20899–4700; telephone 301–975–2162, fax 301–869–1150; or via e-mail at marc.stanley@nist.gov.

Committee Information: The Board will consist of ten members appointed by the Director of NIST, at least seven of whom shall be from United States industry, chosen to reflect the wide diversity of technical disciplines and industrial sectors represented in TIP projects. No member will be an employee of the Federal Government.

The Board will function solely as an advisory body, in compliance with the provisions of the Federal Advisory Committee Act.

Authority: 15 U.S.C 278n(k), as amended by the America COMPETES Act (Pub. L. 110–69), Federal Advisory Committee Act: 5 U.S.C. App. 2.

Board of Overseers of the Malcolm Baldrige National Quality Award

Addresses: Please submit nominations to Harry Hertz, Director, Baldrige National Quality Program, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020. Nominations may also be submitted via FAX to 301–975–4967. Additional information regarding the Committee, including its charter, current membership list, and executive summary may be found on its electronic home page at: <http://www.baldrige.nist.gov>.

For Further Information Contact: Harry Hertz, Director, Baldrige National Quality Program and Designated Federal Officer, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899-1020; telephone 301-975-2361; FAX 301-948-4967; or via e-mail at harry.hertz@nist.gov.

Committee Information: The Board was established in accordance with 15 U.S.C. 3711a(d)(2)(B), pursuant to the Federal Advisory Committee Act (5 U.S.C. App. 2).

Objectives and Duties

1. The Board shall review the work of the private sector contractor(s), which assists the Director of the National Institute of Standards and Technology (NIST) in administering the Award. The Board will make such suggestions for the improvement of the Award process as it deems necessary.

2. The Board shall provide a written annual report on the results of Award activities to the Director of NIST, along with its recommendations for the improvement of the Award process.

3. The Board will function solely as an advisory committee under the Federal Advisory Committee Act.

4. The Board will report to the Director of NIST.

Membership

1. The Board will consist of approximately eleven members selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance, and for their preeminence in the field of organizational performance management. There will be a balanced representation from U.S. service, manufacturing, education, health care industries, and the nonprofit sector.

2. The Board will be appointed by the Secretary of Commerce and will serve at the discretion of the Secretary. The term of office of each Board member shall be three years. All terms will commence on March 1 and end of February 28 of the appropriate year.

Miscellaneous

1. Members of the Board shall serve without compensation, but may, upon request, be reimbursed travel expenses, including *per diem*, as authorized by 5 U.S.C. 5701 *et seq.*

2. The Board will meet twice annually, except that additional meetings may be called as deemed necessary by the NIST Director or by the Chairperson. Meetings are usually one day in duration.

3. Board meetings are open to the public. Board members do not have access to classified or proprietary

information in connection with their Board duties.

Nomination Information

1. Nominations are sought from the private and public sector as described above.

2. Nominees should have established records of distinguished service and shall be familiar with the quality improvement operations of manufacturing companies, service companies, small businesses, education, health care, and nonprofits. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the Board, and will actively participate in good faith in the tasks of the Board. Besides participation at meetings, it is desired that members be able to devote the equivalent of seven days between meetings to either developing or researching topics of potential interest, and so forth, in furtherance of their Board duties.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Board membership.

Judges Panel of the Malcolm Baldrige National Quality Award

Addresses: Please submit nominations to Harry Hertz, Director, Baldrige National Quality Program, NIST, 100 Bureau Drive Mail Stop 1020, Gaithersburg, MD 20899-1020.

Nominations may also be submitted via FAX to 301-975-4967. Additional information regarding the Committee, including its charter, current membership list, and executive summary may be found on its electronic home page at: <http://www.baldrige.nist.gov>.

For Further Information Contact: Harry Hertz, Director, Baldrige National Quality Program and Designated Federal Official, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899-1020; telephone 301-975-2361; FAX 301-975-4967; or via e-mail at harry.hertz@nist.gov.

Committee Information: The Judges Panel was established in accordance with 15 U.S.C. 3711a(d)(1) and the

Federal Advisory Committee Act (5 U.S.C. App. 2).

Objectives and Duties

1. The Judges Panel will ensure the integrity of the Malcolm Baldrige National Quality Award selection process by reviewing the results of examiners' scoring of written applications, and then voting on which applicants merit site visits by examiners to verify the accuracy of claims made by applicants.

2. The Judges Panel will ensure that individuals on site visit teams for the Award finalists have no conflict of interest with respect to the finalists. The Panel will also review recommendations from site visits and recommend Award recipients.

3. The Judges Panel will function solely as an advisory body, and will comply with the provisions of the Federal Advisory Committee Act.

4. The Panel will report to the Director of NIST.

Membership

1. The Judges Panel is composed of at least nine, and not more than twelve, members selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance. There will be a balanced representation from U.S. service and manufacturing industries, education, health care, and nonprofits and will include members familiar with performance improvement in their area of business.

2. The Judges Panel will be appointed by the Secretary of Commerce and will serve at the discretion of the Secretary. The term of office of each Panel member shall be three years. All terms will commence on March 1 and end on February 28 of the appropriate year.

Miscellaneous

1. Members of the Judges Panel shall serve without compensation, but may, upon request, be reimbursed travel expenses, including *per diem*, as authorized by 5 U.S.C. 5701 *et seq.*

2. The Judges Panel will meet three times per year. Additional meetings may be called as deemed necessary by the NIST Director or by the Chairperson. Meetings are usually one to four days in duration. In addition, each Judge must attend an annual three-day Examiner training course.

3. Committee meetings are closed to the public pursuant to Section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, as amended by Section 5(c) of the Government in the Sunshine Act, Public Law 94-409, and in accordance with Section 552b(c)(4) of

Title 5, United States Code. Since the members of the Judges Panel examine records and discuss Award applicant data, the meetings are likely to disclose trade secrets and commercial or financial information obtained from a person that may be privileged or confidential.

Nomination Information

1. Nominations are sought from all U.S. service and manufacturing industries, education, health care, and nonprofits as described above.

2. Nominees should have established records of distinguished service and shall be familiar with the performance improvement operations of manufacturing companies, service companies, small businesses, education, health care, and nonprofit organizations. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the Judges Panel, and will actively participate in good faith in the tasks of the Judges Panel. Besides participation at meetings, it is desired that members be either developing or researching topics of potential interest, reading Baldrige applications, and so forth, in furtherance of their Committee duties.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Judges Panel membership.

Information Security and Privacy Advisory Board (ISPAB)

Addresses: Please submit nominations to Pauline Bowen, NIST, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930. Nominations may also be submitted via fax to 301–975–4007, Attn: ISPAB Nominations. Additional information regarding the Board, including its charter and current membership list, may be found on its electronic home page at: <http://csrc.nist.gov/ispab/>.

For Further Information Contact: Pauline Bowen, ISPAB Designated Federal Official, NIST, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930; telephone 301–975–

2938; fax: 301–975–8670; or via e-mail at pauline.bowen@nist.gov.

Committee Information: The ISPAB was originally chartered as the Computer System Security and Privacy Advisory Board (CSSPAB) by the Department of Commerce pursuant to the Computer Security Act of 1987 (Pub. L. 100–235). As a result of the E-Government Act of 2002 (Pub. L. 107–347), Title III, the Federal Information Security Management Act of 2002, Section 21 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–4) the Board's charter was amended. This amendment included the name change of the Board.

Objectives and Duties

The objectives and duties of the ISPAB are:

1. To identify emerging managerial, technical, administrative, and physical safeguard issues relative to information security and privacy.
2. To advise the NIST, the Secretary of Commerce and the Director of the Office of Management and Budget on information security and privacy issues pertaining to Federal Government information systems, including thorough review of proposed standards and guidelines developed by NIST.
3. To annually report its findings to the Secretary of Commerce, the Director of the Office of Management and Budget, the Director of the National Security Agency, and the appropriate committees of the Congress.
4. To function solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

Membership

The ISPAB is comprised of twelve members, in addition to the Chairperson. The membership of the Board includes:

1. Four members from outside the Federal Government eminent in the information technology industry, at least one of whom is representative of small or medium sized companies in such industries.
2. Four members from outside the Federal Government who are eminent in the field of information technology, or related disciplines, but who are not employed by or representative of a producer of information technology equipment; and
3. Four members from the Federal Government who have information system management experience, including experience in information security and privacy; at least one of these members shall be from the National Security Agency.

Miscellaneous

Members of the ISPAB who are not full-time employees of the Federal government are not paid for their service, but will, upon request, be allowed travel expenses in accordance with Subchapter I of Chapter 57 of Title 5, United States Code, while otherwise performing duties at the request of the Board Chairperson, while away from their homes or a regular place of business.

Meetings of the Board are usually two to three days in duration and are usually held quarterly. The meetings primarily take place in the Washington, DC, metropolitan area but may be held at such locations and at such time and place as determined by the majority of the Board.

Board meetings are open to the public and members of the press usually attend. Members do not have access to classified or proprietary information in connection with their Board duties.

Nomination Information

Nominations are being accepted in all three categories described above.

Nominees should have specific experience related to information security or electronic privacy issues, particularly as they pertain to Federal information technology. Letters of nomination should include the category of membership for which the candidate is applying and a summary of the candidate's qualifications for that specific category. Also include (where applicable) current or former service on Federal advisory boards and any Federal employment. Each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the ISPAB, and that they will actively participate in good faith in the tasks of the ISPAB.

Besides participation at meetings, it is desired that members be able to devote a minimum of two days between meetings to developing draft issue papers, researching topics of potential interest, and so forth in furtherance of their Board duties.

Selection of ISPAB members will not be limited to individuals who are nominated. Nominations that are received and meet the requirements will be kept on file to be reviewed as Board vacancies occur.

Nominees must be U.S. citizens.

The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse ISPAB membership.

Manufacturing Extension Partnership (MEP) Advisory Board

Addresses: Please submit nominations to Ms. Karen Lellock, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, MD 20899-4800. Nominations may also be submitted via Fax to 301-963-6556. Additional information regarding the Board, including its charter, may be found on its electronic home page at: <http://www.mep.nist.gov/about-mep/mep-advisory-board.htm>.

For Further Information Contact: Ms. Karen Lellock, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, MD 20899-4800; telephone 301-975-4269, fax 301-963-6556; or via e-mail at karen.lellock@nist.gov.

Committee Information: The MEP Advisory Board was established in accordance with the requirements of Section 3003(d) of the America COMPETES Act (Pub. L. 110-69) and the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Objectives and Duties

1. The Board will provide advice on MEP programs, plans, and policies.
2. The Board will assess the soundness of MEP plans and strategies.
3. The Board will assess current performance against MEP program plans.
4. The Board will function solely in an advisory capacity, and in accordance with the provisions of the Federal Advisory Committee Act.
5. The Board shall submit an annual report through the NIST Director to the Secretary for transmittal to Congress within 30 days after the submission to Congress of the President's annual budget request each year. The report will address the status of the MEP and comment on programmatic planning and updates.

Membership

1. The MEP Board is composed of 10 members, broadly representative of stakeholders. At least 2 members shall be employed by or on an advisory board for the Centers, and at least 5 other members shall be from U.S. small businesses in the manufacturing sector. No member shall be an employee of the Federal Government.
2. The Director of the National Institute of Standards and Technology (NIST) shall appoint the members of the Board. Members shall be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance. Members serve at the discretion of the NIST Director.

3. Committee members from the manufacturing industry and those representing specific stakeholder groups shall serve in a representative capacity. Committee members from the academic community shall serve as experts and will be considered Special Government Employees (SGEs) and will be subject to all ethical standards and rules applicable to SGEs.

4. The term of office of each member of the Board shall be three years, except that vacancy appointments shall be for the remainder of the unexpired term of the vacancy.

Miscellaneous

1. Members of the Board will not be compensated for their services but will, upon request, be allowed travel and *per diem* expenses as authorized by 5 U.S.C. 5701 *et seq.*, while attending meetings of the Board or subcommittees thereof, or while otherwise performing duties at the request of the Chair, while away from their homes or regular places of business.

2. The Board will meet at least two times a year. Additional meetings may be called by the NIST Director.

3. Committee meetings are open to the public.

Nomination Information

Nominations are being accepted in all categories described above.

Nominees should have specific experience related to industrial extension services. Letters of nomination should include the category of membership for which the candidate is applying and a summary of the candidate's qualifications for that specific category. Each nomination letter should state that the person agrees to the nomination and acknowledges the responsibilities of serving on the MEP Advisory Board.

Selection of MEP Advisory Board members will not be limited to individuals who are nominated. Nominations that are received and meet the requirements will be kept on file to be reviewed as Board vacancies occur.

The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse MEP Advisory Board membership.

National Construction Safety Team Advisory Committee

Addresses: Please submit nominations to Stephen Cauffman, National Construction Safety Team Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg,

MD 20899-8611. Nominations may also be submitted via FAX to 301-869-6275.

For Further Information Contact: Stephen Cauffman, National Construction Safety Team Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, MD 20899-8611, telephone 301-975-6051, fax 301-869-6275; or via e-mail at stephen.cauffman@nist.gov.

Committee Information: The Committee was established in accordance with the National Construction Safety Team Act, Public Law 107-231 and the Federal Advisory Committee Act (5 U.S.C. App. 2).

Objectives and Duties

1. The Committee shall advise the Director of the National Institute of Standards and Technology (NIST) on carrying out the National Construction Safety Team Act (Act), review and provide advice on the procedures developed under section 2(c)(1) of the Act, and review and provide advice on the reports issued under section 8 of the Act.

2. The Committee functions solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. The Committee shall provide a written annual report, through the Director of the NIST Building and Fire Research Laboratory (BFRL) and the Director of NIST, to the Secretary of Commerce for submission to the Congress, to be due at a date to be agreed upon by the Committee and the Director of NIST. Such report will provide an evaluation of National Construction Safety Team activities, along with recommendations to improve the operation and effectiveness of National Construction Safety Teams, and an assessment of the implementation of the recommendations of the National Construction Safety Teams and of the Committee. In addition, the Committee may provide reports at strategic stages of an investigation, at its discretion or at the request of the Director of NIST, through the Director of the BFRL and the Director of NIST, to the Secretary of Commerce.

Membership

1. The Committee will be composed of not fewer than five nor more than ten members that reflect a wide balance of the diversity of technical disciplines and competencies involved in the National Construction Safety Teams investigations. Members shall be

selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams.

2. The Director of the NIST shall appoint the members of the Committee, and they will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the Committee will not be paid for their services, but will, upon request, be allowed travel and *per diem* expenses in accordance with 5 U.S.C. 5701 *et seq.*, while attending meetings of the Committee or of its subcommittees, or while otherwise performing duties at the request of the chairperson, while away from their homes or a regular place of business.

2. The Committee will meet at least once per year at the call of the Chair. Additional meetings may be called whenever one-third or more of the members so request it in writing or whenever the Chair or the Director of NIST requests a meeting.

Nomination Information

1. Nominations are sought from all fields involved in issues affecting National Construction Safety Teams.

2. Nominees should have established records of distinguished service. The field of expertise that the candidate represents he/she is qualified should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the candidate agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Committee membership.

Advisory Committee on Earthquake Hazards Reduction (ACEHR)

Addresses: Please submit nominations to Tina Faেকে, Administrative Officer, National Earthquake Hazards Reduction Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8630, Gaithersburg, MD 20899–8630. Nominations may also be

submitted via FAX to 301–975–5433 or e-mail at tina.faecke@nist.gov. Additional information regarding the Committee, including its charter and executive summary may be found on its electronic home page at: <http://www.nehrp.gov>.

For Further Information Contact: Dr. Jack Hayes, Director, National Earthquake Hazards Reduction Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8610, Gaithersburg, MD 20899–8610, telephone 301–975–5640, fax 301–975–4032; or via e-mail at jack.hayes@nist.gov.

Committee Information: The Committee was established on June 27, 2006 in accordance with the National Earthquake Hazards Reduction Program Reauthorization Act, Public Law 108–360 and the Federal Advisory Committee Act (5 U.S.C. App. 2).

Objectives and Duties

1. The Committee will assess trends and developments in the science and engineering of earthquake hazards reduction, effectiveness of the Program in carrying out the activities under section 103(a)(2) of the Act, the need to revise the Program, the management, coordination, implementation, and activities of the Program.

2. The Committee functions solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. Not later than one year after the first meeting of the Committee, and at least once every two years thereafter, the Committee shall report to the Director of NIST, on its findings of the assessments and its recommendations for ways to improve the Program. In developing recommendations, the Committee shall consider the recommendations of the United States Geological Survey Scientific Earthquake Studies Advisory Committee.

Membership

1. The Committee will consist of not fewer than 11 nor more than 15 members, who reflect a wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. Members shall be selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Earthquake Hazards Reduction Program.

2. The Director of NIST shall appoint the members of the Committee, and they will be selected on a clear, standardized

basis, in accordance with applicable Department of Commerce guidance.

3. The term of office of each member of the Committee shall be three years, except that vacancy appointments shall be for the remainder of the unexpired term of the vacancy and that the initial members shall have staggered terms such that the committee will have approximately $\frac{1}{3}$ new or reappointed members each year.

4. No committee member may be an “employee” as defined in subparagraphs (A) through (F) of section 7342(a)(1) of Title 5 of the United States Code.

Miscellaneous

1. Members of the Committee will not be compensated for their services, but will, upon request, be allowed travel and *per diem* expenses in accordance with 5 U.S.C. 5701 *et seq.*, while attending meetings of the Committee or of its subcommittees, or while otherwise performing duties at the request of the chairperson, while away from their homes or a regular place of business.

2. Members of the Committee shall serve as Special Government Employees and are required to file an annual Executive Branch Confidential Financial Disclosure Report.

3. The Committee shall meet at least once per year. Additional meetings may be called whenever the Director of NIST requests a meeting.

4. Committee meetings are open to the public.

Nomination Information

1. Nominations are sought from industry and other communities having an interest in the National Earthquake Hazards Reduction Program, such as, but not limited to, research and academic institutions, industry standards development organizations, State and local government bodies, and financial communities, who are qualified to provide advice on earthquake hazards reduction and represent all related scientific, architectural, and engineering disciplines.

2. Nominees should have established records of distinguished service. The field of expertise that the candidate represents should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the

person agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Committee membership.

Visiting Committee on Advanced Technology (VCAT)

Addresses: Please submit nominations to Gail Ehrlich, Executive Director, Visiting Committee on Advanced Technology, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, MD 20899-1060. Nominations may also be submitted via FAX to 301-216-0529 or via e-mail at gail.ehrlich@nist.gov. Additional information regarding the Committee, including its charter, current membership list, and executive summary may be found on its electronic homepage at: <http://www.nist.gov/director/vcat/vcat.htm>.

For Further Information Contact: Gail Ehrlich, Executive Director, Visiting Committee on Advanced Technology, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, MD 20899-1060, telephone 301-975-2149, fax 301-216-0529; or via e-mail at gail.ehrlich@nist.gov.

Committee Information: The VCAT was established in accordance with 15 U.S.C. 278 and the Federal Advisory Committee Act (5 U.S.C. App. 2).

Objectives and Duties

1. The Committee shall review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs, within the framework of applicable national policies as set forth by the President and the Congress.

2. The Committee functions solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. The Committee shall provide a written annual report, through the Director of NIST, to the Secretary of Commerce for submission to the Congress no later than 30 days after the submittal to Congress of the President's annual budget request in each year. Such report shall deal essentially, though not necessarily exclusively, with policy issues or matters which affect the Institute, or with which the Committee in its official role as the private sector policy advisor of the Institute is concerned. Each such report shall

identify areas of program emphasis for the Institute of potential importance to the long-term competitiveness of the United States industry, which could be used to assist the United States enterprises and United States industrial joint research and development ventures. Such report also shall comment on the programmatic planning document and updates thereto submitted to Congress under subsections (c) and (d) of section 23 of the NIST Act (15 U.S.C. 278i). The Committee shall submit to the Secretary and Congress such additional reports on specific policy matters as it deems appropriate.

Membership

1. The Committee is composed of fifteen members that provide representation of a cross-section of traditional and emerging United States industries. Members shall be selected solely on the basis of established records of distinguished service and shall be eminent in such fields as business, research, new product development, engineering, labor, education, management consulting, environment, and international relations. No employee of the Federal Government shall serve as a member of the Committee.

2. The Director of the National Institute of Standards and Technology shall appoint the members of the Committee, and they will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the VCAT are not paid for their service, but will, upon request, be allowed travel expenses in accordance with 5 U.S.C. 5701 *et seq.*, while attending meetings of the Committee or of its subcommittees, or while otherwise performing duties at the request of the chairperson, while away from their homes or a regular place of business.

2. Members of the Committee shall serve as Special Government Employees and are required to file an annual Executive Branch Confidential Financial Disclosure Report.

3. Meetings of the VCAT take place at the NIST headquarters in Gaithersburg, Maryland, and once each year at the NIST site in Boulder, Colorado. Meetings are one or two days in duration and are held at least twice each year.

4. Committee meetings are open to the public.

Nomination Information

1. Nominations are sought from all fields described above.

2. Nominees should have established records of distinguished service and shall be eminent in fields such as business, research, new product development, engineering, labor, education, management consulting, environment and international relations. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the candidate agrees to the nomination, acknowledges the responsibilities of serving on the VCAT, and will actively participate in good faith in the tasks of the VCAT. Besides participation in one or two-day meetings held at least twice each year, it is desired that members be able to devote the equivalent of two days between meetings to either developing or researching topics of potential interest, and so forth in furtherance of the Committee duties.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse VCAT membership.

Dated: July 30, 2009.

Patrick Gallagher,

Deputy Director.

[FR Doc. E9-18591 Filed 8-3-09; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Director, Information Collection Clearance Division, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 3, 2009.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, New

Executive Office Building, Washington, DC 20503, be faxed to (202) 395-5806 or send e-mail to oir_submission@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: July 28, 2009.

Angela C. Arrington,

Director, Information Collection Clearance Official, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: Reinstatement.

Title: The School Survey on Crime and Safety (SSOCS), 2010 and 2012 Collection.

Frequency: Biennially.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 2,695.

Burden Hours: 2,022.

Abstract: The School Survey on Crime and Safety (SSOCS) is a nationally representative survey of elementary and secondary school principals that serve as the primary source of school-level data on crime and safety in public schools. SSOCS is the only recurring federal survey collecting detailed information on the incidence, frequency, seriousness, and nature of violence affecting students and school personnel from the school's perspective. Additionally, data are collected on

frequency and types of disciplinary actions taken for select offenses; perceptions of other disciplinary problems, such as bullying, verbal abuse and disorder in the classroom; and, school policies and programs concerning crime and safety. The SSOCS is done on a biennial basis in the spring of even-numbered years.

Requests for copies of the information collection submission for OMB review may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 4057. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202-4537. Requests may also be electronically mailed to the Internet address ICDocketMgr@ed.gov or faxed to 202-401-0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to ICDocketMgr@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. E9-18565 Filed 8-3-09; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement; Overview Information; Teacher Quality Partnership Grants Program

Revised notice inviting applications for new awards for fiscal year (FY) 2009.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.405A.

Note: On May 27, 2009, we published in the **Federal Register** (74 FR 25221) a notice inviting applications for new FY 2009 awards for the Teacher Quality Partnership Program (Initial TQP Application Notice). Since that time, Public Law (Pub. L.) 111-39 was enacted, which made certain technical amendments to the Higher Education Opportunity Act of 2008, the original statute authorizing the program. This notice inviting applications has been updated to respond to statutory changes made to the TQP program and supersedes the Initial TQP Application Notice.

Dates:

Applications Available: August 4, 2009.

Deadline for Transmittal of Applications: First Deadline: July 23, 2009. Second Deadline: October 6, 2009.

Deadline for Intergovernmental Review: First Deadline: September 21, 2009. Second Deadline: December 7, 2009.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of the Teacher Quality Partnership (TQP) Grants Program are to: Improve student achievement; improve the quality of new and prospective teachers by improving the preparation of prospective teachers and enhancing professional development activities for new teachers; hold teacher preparation programs at institutions of higher education (IHEs) accountable for preparing highly qualified teachers; and recruit highly qualified individuals, including minorities and individuals from other occupations, into the teaching force.

More specifically, the TQP Grants Program seeks to improve the quality of new teachers by creating partnerships among IHEs, high-need school districts (local educational agencies (LEAs)) their high-need schools, and/or high-need early childhood education (ECE) program. These partnerships would create model teacher preparation programs at the pre-baccalaureate or fifth-year level through the implementation of specific reforms of the IHE's existing teacher preparation programs, and/or model teaching residency programs for individuals with strong academic and/or professional backgrounds but without teaching experience. The TQP Grants Program may also support school leadership programs to train superintendents, principals, ECE program directors, and other school leaders in high-need or rural LEAs.

Background:

On May 27, 2009, we published in the **Federal Register** (74 FR 25221) the Initial TQP Application Notice. Since that time, Public Law 111-39 was enacted, which made certain technical amendments to the Higher Education Act of 1965, as amended by the Higher Education Opportunity Act—the original statute authorizing the program. This revised notice inviting applications incorporates changes to the competition that are based on technical amendments made to the TQP program in Public Law 111-39.

Summary of Changes

Substantive Changes Made to Priorities Based on Public Law 111-39 Technical Amendments

For the convenience of applicants, we summarize here the changes made to the

TQP program priorities since the publication of the Initial TQP Application Notice and based on the statutory amendments. The substantive changes affect the Pre-Baccalaureate Program described in *Absolute Priority 1* and the Teaching Residency Program described in *Absolute Priority 2*. We also have made technical conforming changes to other sections of this notice (i.e., Purpose of Program, General Application Requirements, Competitive Preference Priority 1, Competitive Preference Priority 4, the Invitational Priority, the definition of “high-need school,” and Performance Measures) to reflect the statutory amendments.

Changes to *Absolute Priority 1*. In the Initial TQP Application Notice, *Absolute Priority 1* provided that only eligible partnerships that include a partner institution with a pre-baccalaureate teacher preparation program were eligible for awards. The statutory amendment now also permits eligible partnerships with a partner institution that provides a fifth-year post-baccalaureate teacher preparation program to be eligible to receive TQP program funding.

The Department interprets this technical amendment to permit teacher preparation programs that may begin at the pre-baccalaureate level but continue into a fifth post-baccalaureate year also to be eligible for program funding, provided that both the pre-baccalaureate and post-baccalaureate partner institutions are part of the eligible partnership.

Changes to *Absolute Priority 2*. Paragraph (d) of *Absolute Priority 2* in the Initial TQP Application Notice states that the Teaching Residency Program must be one year in length. The statutory amendment in P.L. 111–39 extends the requirement to acquire a master’s degree and certification from one year to 18 months after beginning the program.

The Department interprets this technical amendment to permit teachers to become teachers of record while they are still working on their master’s degrees provided that the program is designed to have participants earn their master’s degrees within the requisite 18-month period, and the teachers have become highly qualified and have completed the mentored residency portion of the program.

Changes to *Requirements for the Fiscal Agent*. In addition to the changes resulting from the statutory amendments, the Department is changing the eligibility requirements to provide for additional flexibility regarding organizations that may be the

fiscal agent for applicants in this competition.

The Initial TQP Application Notice provided that only required partners could be the fiscal agent of the grant. We have decided to allow the eligible partnership to select which of their required or optional partners would be the fiscal agent for the grant.

Second Application Deadline Date. As a result of the technical changes and the change in eligibility requirements, we are establishing a second application deadline for applicants that are interested in conforming their applications to these changes but would not have sufficient time to do so by the July 23, 2009 deadline specified in the Initial TQP Application Notice.

The following is an updated version of the priorities and requirements originally published in the Initial TQP Application Notice that incorporate the changes noted in this section.

General Application Requirements:

All applicants must meet the following general application requirements in order to be considered for funding. Except as specifically noted in this section, the general application requirements are from section 202 of the Higher Education Act of 1965, as amended in 2008 by the Higher Education Opportunity Act (HEA) (20 U.S.C. 1022(a)).

Each eligible partnership desiring a grant under this program must submit an application that contains—

(a) A needs assessment of the partners in the partnership, for the preparation, ongoing training, professional development, and retention of general education and special education teachers, principals, and, as applicable, early childhood educators;

(b) A description of how the partnership will—

(1) Prepare prospective and new general education and special education teachers to understand and use research and data to modify and improve classroom instruction and prepare prospective and new teachers with strong teaching skills;

(2) Support in-service professional development strategies and activities;

(3) Engage faculty at the partner institution to work with highly qualified teachers in the classrooms of high-need schools served by the high-need LEA in the partnership in order to—

(i) Provide high-quality professional development to strengthen the content knowledge and teaching skills of elementary school and secondary school teachers; and

(ii) Train other classroom teachers to implement literacy programs that

incorporate the essential components of reading instruction;

(4) Design, implement, or enhance a year-long and rigorous teaching preservice clinical program component;

(5) Prepare general education teachers to teach students with disabilities, including training related to participation as a member of individualized education program teams, as defined in section 614(d)(1)(B) of the Individuals with Disabilities Education Act (IDEA);

(6) Prepare general education and special education teachers to teach limited English proficient students; and

(7) Collect, analyze, and use data on the retention of all teachers and early childhood educators in high-need schools and high-need ECE programs located in the geographic area served by the partnership to evaluate the effectiveness of the partnership’s teacher and educator support system;

(c) A description of the induction program activities that demonstrates—

(1) That the schools and departments within the IHE that are part of the induction program will effectively prepare teachers, including providing content expertise and expertise in teaching, as appropriate;

(2) The eligible partnership’s capability and commitment to, and the accessibility to and involvement of faculty in, the use of empirically-based practice and scientifically valid research on teaching and learning;

(3) How faculty involved in the induction program will be able to substantially participate in a high-need ECE program or a high-need elementary school or high-need secondary school classroom setting, as applicable, including release time and receiving workload credit for such participation; and

(4) How the teacher preparation program will support, through not less than the first two years of teaching, all new teachers who are prepared by the teacher preparation program in the partnership and who teach in the high-need LEA in the partnership, and, to the extent practicable, all new teachers who teach in such high-need LEA, in the further development of the new teachers’ teaching skills, including the use of mentors who are trained and compensated by the program for the mentors’ work with new teachers;

(d) A description of how the partnership will—

(1) Coordinate strategies and activities with other teacher preparation or professional development programs, including programs funded under the Elementary and Secondary Education Act of 1965, as amended (ESEA), and

the IDEA, and through the National Science Foundation; and how those activities will be consistent with State, local, and other education reform activities that promote teacher quality and student academic achievement; and

(2) Align the teacher preparation program with the—

(i) State early learning standards for ECE programs, as appropriate, and with the relevant domains of early childhood development; and

(ii) Student academic achievement standards and academic content standards under section 1111(b)(1) of the ESEA, established by the State in which the partnership is located;

(e) An assessment that describes the resources available to the partnership, including—

(1) The integration of funds from other related sources;

(2) The intended use of the grant funds; and

(3) The commitment of the resources of the partnership to the activities assisted under this program, including financial support, faculty participation, and time commitments, and to the continuation of the activities when the grant ends;

(f) A description of the partnership's evaluation plan that includes strong and measurable performance objectives, including objectives and measures for increasing—

(1) Achievement for all prospective and new teachers and their students, as measured by the eligible partnership. The HEA permits the Secretary to establish additional requirements for applications under this program. In that regard, in addition to the statutory requirement that each application describe in its evaluation plan the objectives and measures for increasing the achievement for prospective and new teachers, we also require the application to describe objectives and measures for increasing the achievement of students taught by teachers who have participated in the projects. As one of the key statutory purposes of the TQP Grants Program is to improve student achievement (section 201(1) of the HEA) we believe that any evaluation of the performance of the projects funded under this program should include an assessment of the impact of the project on student achievement and that applicants should describe the objectives and measures for doing so in their evaluation plan;

(2) Teacher retention in the first three years of a teacher's career;

(3) Improvement in the pass rates and scaled scores for initial State certification or licensure of teachers;

(4) The percentage of highly qualified teachers hired by the high-need LEA participating in the eligible partnership, including the percentage of those teachers—

(i) Who are members of underrepresented groups;

(ii) Who teach high-need academic subject areas (such as reading, mathematics, science, and foreign language, including less commonly taught languages and critical foreign languages);

(iii) Who teach in high-need areas (including special education, language instruction educational programs for limited English proficient students, and ECE); and

(iv) Who teach in high-need schools, disaggregated by the elementary school and secondary school levels;

(5) As applicable, the percentage of ECE program classes in the geographic area served by the eligible partnership taught by early childhood educators who are highly competent; and

(6) As applicable, the percentage of teachers trained—

(i) To integrate technology effectively into curricula and instruction, including technology consistent with the principles of universal design for learning; and

(ii) To use technology effectively to collect, manage, and analyze data to improve teaching and learning for the purpose of improving student academic achievement; and

(g) A description of—

(1) How the partnership will meet the purposes of the TQP Grants Program as specified in section 201 of the HEA;

(2) How the partnership will carry out the activities required under section 202(d) of the HEA (Partnership Grants for the Preparation of Teachers) and/or section 202(e) of the HEA (Partnership Grants for the Establishment of Teaching Residency Programs); and

(3) If the partnership chooses to use funds under the TQP Grants Program for a project or activities under section 202(f) of the HEA (Partnership Grants for the Development of Leadership Programs) or section 202(g) of the HEA (Partnership with Digital Education Content Developer), how the partnership will carry out the project or required activities based on the needs identified in the needs assessment described in paragraph (a), with the goal of improving student academic achievement.

Program Evaluation Requirements:

All applicants must cooperate with the national evaluation contractor selected by ED to evaluate the TQP Grants Program. This will include responding to modest data requests by

the evaluation contractor (for example, requested program information and program participant information such as GRE or SAT scores and contact information).

Priorities: This notice contains two absolute priorities, four competitive preference priorities, and one invitational priority that are explained in the following paragraphs.

Absolute Priorities: In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 1 is from section 202(d) of the HEA and Absolute Priority 2 is from section 202(e) of the HEA. For FY 2009 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet one or both of these absolute priorities. These priorities are:

Absolute Priority 1: Partnership Grants for the Preparation of Teachers. Under this priority, an eligible partnership must carry out an effective pre-baccalaureate teacher preparation program or a fifth year initial licensing program that includes all of the following:

(a) *Program Accountability.* Implementation of reforms, described in paragraph (b) of this priority, within each of the partnership's teacher preparation programs and, as applicable, each of the partnership's preparation program for ECE programs, to hold each program accountable for—

(1) Preparing—

(i) New or prospective teachers to be highly qualified (including teachers in rural school LEAs who may teach multiple subjects, special educators, and teachers of students who are limited English proficient who may teach multiple subjects);

(ii) Such teachers and, as applicable, early childhood educators, to understand empirically-based practice and scientifically valid research related to teaching and learning and the applicability of such practice and research, including through the effective use of technology, instructional techniques, and strategies consistent with the principles of universal design for learning, and through positive behavioral interventions and support strategies to improve student achievement; and

(iii) As applicable, early childhood educators to be highly competent; and

(2) Promoting strong teaching skills and, as applicable, techniques for early childhood educators to improve children's cognitive, social, emotional, and physical development.

(b) *Specific reforms.* The reform of the quality of each teacher preparation program, or each ECE program, by—

(1) Implementing teacher preparation program curriculum changes that improve, evaluate, and assess how well all prospective and new teachers develop teaching skills;

(2) Ensuring collaboration with departments, programs, or units of a partner institution outside of the teacher preparation program in all academic content areas to ensure that prospective teachers receive training in both teaching and relevant content areas in order to become highly qualified (which may include training in multiple subjects to teach multiple grade levels as may be needed for individuals preparing to teach in rural communities and for individuals preparing to teach students with disabilities as described in section 602(10)(D) of the IDEA);

(3) Developing admission goals and priorities aligned with the hiring objectives of the high-need LEA in the eligible partnership;

(4) Implementing program and curriculum changes, as applicable, to ensure that prospective teachers have requisite content knowledge, preparation, and degree to teach Advanced Placement or International Baccalaureate courses successfully;

(5) Developing and implementing an induction program for new teachers, or in the case of an ECE program, providing mentoring or coaching for new early childhood educators as described in paragraph (f) of this priority; and

(6) Using empirically based practice and scientifically valid research, where applicable, about teaching and learning so that all prospective students, and as applicable, early childhood educators—

(i) Understand and can implement research based teaching practices in classroom instruction;

(ii) Can successfully employ effective strategies for reading instruction using the essential components of reading instruction;

(iii) Possess skills to analyze student academic achievement data and other measures of student learning, and use such data and measures to improve classroom instruction;

(iv) Can effectively participate as a member of the individualized education program team, as defined in section 614(d)(1)(B) of the IDEA;

(v) Have knowledge of student learning methods; and

(vi) Possess teaching skills and an understanding of effective instructional strategies across all applicable content areas that enable general education and

special education teachers and early childhood educators in order to—

(A) Meet the specific learning needs of all students, including students with disabilities, students who are limited English proficient, students who are gifted and talented, students with low literacy levels, children in ECE programs; and

(B) Differentiate instruction for these students.

(c) *Literacy training.* Strengthening the literacy teaching skills of prospective and, as applicable, new elementary and secondary school teachers to—

(1) Implement literacy programs that incorporate the essential components of reading instruction;

(2) Use screening, diagnostic, formative and summative assessments to determine students' literacy levels, difficulties, and growth in order to improve classroom instruction and improve student reading and writing skills;

(3) Provide individualized, intensive, and targeted literacy instruction for students with deficiencies in literacy skills; and

(4) Integrate literacy skills in the classroom across subject areas.

(d) *Clinical experience.* Development and implementation (or improvement) of a sustained and high-quality preservice clinical education program, offered over the course of a program of teacher preparation, to further develop the teaching skills of all prospective teachers, and as applicable, early childhood educators involved in the project. This preservice clinical education program must—

(1) Incorporate year-long opportunities for enrichment, including—

(i) Clinical learning in classrooms in high-need schools served by the high-need LEA in the eligible partnership, and identified by the eligible partnership; and

(ii) Closely supervised interaction between prospective teachers and faculty, experienced teachers, principals, other administrators, and school leaders at ECE programs (as applicable), elementary schools, or secondary schools, and providing support for such interaction;

(2) Integrate pedagogy and classroom practices and effective teaching skills in academic content areas;

(3) Provide high-quality teacher mentoring;

(4) Be tightly aligned with course work (and may be developed as a fifth year of a teacher preparation program);

(5) Where feasible, allow prospective teachers to learn to teach in the same

LEA in which the teachers will work, learning the instructional initiatives and curriculum of that LEA; and

(6) As applicable, provide training and experience to enhance the teaching skills of prospective teachers to better prepare such teachers to meet the unique needs of teaching in rural or urban communities.

(e) *Support for program participation.* The provision of support and training for individuals participating in an activity for prospective or new teachers, whether in the teacher preparation program (or program for early childhood educators), the clinical experience, or in the LEA's induction program for new teachers, and for individuals who serve as mentors for these teachers, based on each individual's experience. This support and training may include—

(1) With respect to a prospective teacher or a mentor, release time for such individual's participation;

(2) With respect to a mentor, a stipend, which may include bonus, differential, incentive, or performance pay, based on the mentor's extra skills and responsibilities; and

(3) With respect to a faculty member, the receipt of course workload credit and compensation for time teaching in the eligible partnership's activities.

(f) *Participants in an ECE program.* Where a project focuses on preparation of early childhood educators, implementation of initiatives that increase compensation for time teaching in the eligible partnership's activities.

(g) *Teacher recruitment.* Development and implementation of effective mechanisms (which may include alternative routes to State certification of teachers) to ensure that the eligible partnership is able to recruit qualified individuals to become highly qualified teachers through the activities of the eligible partnership. These mechanisms may include an emphasis on recruiting into the teaching profession—

(1) Individuals from under represented populations;

(2) Individuals to teach in rural communities and teacher shortage areas, including mathematics, science, special education, and the instruction of limited English proficient students; and

(3) Mid-career professionals from other occupations, former military personnel, and recent college graduates with a record of academic distinction.

Absolute Priority 2: Partnership Grants for the Establishment of Effective Teaching Residency Programs. Under this priority, an eligible partnership must carry out a teaching residency program for high-need subjects and

areas, as determined by the needs of the high-need LEA in the partnership. The program must ensure that teaching residents who participate in the teaching residency program receive the preparation and support described in the following required program components:

(a) *Establishment and design.* The teaching residency program must be based upon models of successful teaching residencies that serve as a mechanism to prepare teachers for success in the high-need schools in the eligible partnership, and be designed to include the following characteristics of successful programs:

(1) Integration of pedagogy, classroom practice, and teacher mentoring.

(2) Engagement of teaching residents in rigorous graduate-level course work leading to a master's degree while undertaking a guided teaching apprenticeship.

(3) Grouping of teaching residents in cohorts to facilitate professional collaboration among such residents.

(4) The development of admissions goals and priorities—

(i) That are aligned with the hiring objectives of the high-need LEA partnering with the program, as well as the instructional initiatives and curriculum of the high-need LEA, in exchange for a commitment by the high-need LEA to hire qualified graduates from the teaching residency program; and

(ii) Which may include consideration of applicants who reflect the communities in which they will teach as well as consideration of individuals from underrepresented populations in the teaching profession.

(5) Experience and learning opportunities alongside a trained and experienced mentor teacher—

(i) Whose teaching complements the residency program so that classroom clinical practice is tightly aligned with coursework;

(ii) Who has been given extra responsibilities—

(A) As a teacher leader of the teaching residency program;

(B) As a mentor for residents;

(C) As a teacher coach during the induction program for new teachers; and

(D) For establishing, within the program, a learning community in which all individuals are expected to continually improve their capacity to advance student learning; and

(iii) Who may be relieved, if appropriate, from teaching duties as a result of these additional responsibilities.

(6) The establishment of clear criteria for the selection of mentor teachers

based on measures of teacher effectiveness and the appropriate subject area knowledge. For purposes of this section, evaluation of teacher effectiveness must be based on, but not limited to, observations of the following:

(i) Planning and preparation, including demonstrated knowledge of content, pedagogy, and assessment, including the use of formative and diagnostic assessments to improve student learning.

(ii) Appropriate instruction that engages students with different learning styles.

(iii) Collaboration with colleagues to improve instruction.

(iv) Analysis of gains in student learning, based on multiple measures that are valid and reliable and that, when feasible, may include valid, reliable, and objective measures of the influence of teachers on the rate of student academic progress.

(v) In the case of mentor candidates who will be mentoring new or prospective literacy and mathematics coaches or instructors, appropriate skills in the essential components of reading instruction, teacher training in literacy instructional strategies across core subject areas, and teacher training in mathematics instructional strategies, as appropriate.

(7) Support for teaching residents, once they are hired as teachers of record, through an induction program, professional development, and networking opportunities to support the residents through not less than the residents' first two years of teaching.

(b) *Additional support for residents after completing the program.* In addition to the services described in paragraph (a)(7) of this priority, a partnership must place graduates of the teaching residency program in cohorts that facilitate professional collaboration, both among graduates of the teaching residency program and between such graduates and mentor teachers in the receiving school.

(c) *Selection of individuals as teacher residents.*

(1) In order to be eligible to be a teacher resident in a teaching residency program, an individual must be a recent graduate of a four-year IHE or a mid-career professional from outside the field of education possessing strong content knowledge or a record of professional accomplishment, and submit an application to the teaching residency program.

(2) An eligible partnership must establish criteria for the selection of eligible individuals to participate in the teaching residency program based on the following characteristics—

(i) Strong content knowledge or record of accomplishment in the field or subject area to be taught;

(ii) Strong verbal and written communication skills, which may be demonstrated by performance on appropriate tests; and

(iii) Other attributes linked to effective teaching, which may be determined by interviews or performance assessments, as specified by the eligible partnership.

(d) *Provision of stipends or salaries.*

(1) A teaching residency program must provide a one-year living stipend or salary during the teaching residency program to any teacher resident candidate accepted into the program who requests the stipend or salary and submits the application described in paragraph (d)(2) of this priority.

(2) Each teaching residency candidate desiring a living stipend or salary during the period of the residency must submit an application to the eligible partnership at such time, and containing such information and assurances, as the eligible partnership may require.

(3) Each application submitted under paragraph (d)(2) of this priority, must contain or be accompanied by an agreement that the applicant will—

(i) Serve as a full-time teacher for a total of not less than three academic years immediately after successfully completing the teaching residency program;

(ii) Fulfill the requirement under paragraph (d)(3)(i) of this priority by teaching in a high-need school served by the high-need LEA in the eligible partnership and teach a subject or area that is designated as high need by the partnership;

(iii) Provide to the eligible partnership a certificate, from the chief administrative officer of the high-need LEA in which the teacher resident is employed, documenting the employment required under paragraph (d)(3)(i) and (ii) of this priority at the beginning of, and upon completion of, each year or partial year of service;

(iv) Meet the requirements to be a highly qualified teacher, as defined in section 9101 of the ESEA, or section 602 of the IDEA, when the applicant begins to fulfill the service obligation under the program; and

(v) Comply with the requirements established by the eligible partnership under paragraph (e) of this priority if the applicant is unable or unwilling to complete the service obligation required by the paragraph.

(e) *Repayments.*

(1) Each grantee carrying out a teaching residency program must require a recipient of a stipend or salary

under paragraph (d)(1) of this priority who does not complete, or who notifies the partnership that he or she intends not to complete, the service obligation required by paragraph (d)(3) of this priority to repay the stipend or salary to the eligible partnership—

(i) Together with interest at a rate specified by the partnership in the agreement; and

(ii) In accordance with such other terms and conditions specified by the eligible partnership, as necessary.

(2) Other terms and conditions specified by the eligible partnership may include, among other things, reasonable provisions for pro-rata repayment of the stipend or salary described in paragraph (e)(1) of this priority, or for deferral of a teaching resident's service obligation required by paragraph (d)(3) of this priority, on grounds of health, incapacitation, inability to secure employment in a school served by the eligible partnership, being called to active duty in the Armed Forces of the United States, or other extraordinary circumstances.

(3) An eligible partnership must use any repayment received under paragraph (e) to carry out additional activities that are consistent with the purposes of the Teaching Residency program.

Competitive Preference Priorities: Within these absolute priorities, we give competitive preference to applications that address one or more of the following priorities. For FY 2009 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are competitive preference priorities.

Competitive Preference Priority 1: We are establishing Competitive Preference Priority 1 in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1). Under 34 CFR 75.105(c)(2)(i) we award up to an additional 10 points to an application that meets Competitive Preference Priority 1, depending on how well the application meets the priority. We will add any competitive preference priority points only to highly rated applications on one or both of the absolute priorities.

This priority is:
Competitive Preference Priority 1: Student Achievement and Continuous Program Improvement. The Secretary gives priority to applications from an eligible partnership that would use appropriate means to—

(1) Collect and use data on student achievement to assess the effect of teachers prepared through the pre-

baccalaureate teacher preparation program, fifth year initial licensing program, and/or teaching residency program on student learning in the classrooms of the high-need schools in which they work; to be eligible to receive the maximum number of points, applicants must demonstrate their capacity to include longitudinal data capturing student achievement by teacher from year to year, and

(2) Provide for continuous improvement of the participating teachers, and of the pre-baccalaureate teacher preparation program, fifth year initial licensing program, and/or teaching residency program based on these data.

Our purpose in establishing this priority is to support the collection and use of data showing the effect of teachers on student learning and achievement. The relevant data would include both teachers in the program and teachers not in the program. As noted earlier, a key statutory purpose of this program is to improve student achievement. Having these data will enable grantees both to assess the effectiveness of their projects and to use the data to improve the project's impact on student achievement.

Competitive Preference Priority 2: Competitive Preference Priority 2 is from section 202(f) of the HEA. As used in this priority, the definition of "LEA located in a rural area" is established in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1). Under 34 CFR 75.105(c)(2)(i) we award up to an additional 5 points to an application that meets Competitive Preference Priority 2, depending on how well the application meets the priority. We will add any competitive preference priority points only to highly rated applications on one or both of the absolute priorities.

This priority is:

Competitive Preference Priority 2: Partnership Grants for the Development of Leadership Programs. Under this competitive preference priority the Secretary gives priority to applications from eligible partnerships that propose to carry out an effective school leadership program that will prepare individuals enrolled or preparing to enroll in those programs for careers as superintendents, principals, ECE program directors, or other school leaders (including individuals preparing to work in LEAs located in rural areas who may perform multiple duties in addition to the role of a school leader). An eligible partnership may carry out the school leadership program either in the partner high-need LEA or in further

partnership with an LEA located in a rural area.

The school leadership program carried out under this priority must include the following activities:

(a) *Preparation of school leaders.* In preparing school leaders, the school leadership program must include the following activities:

(1) Promoting strong leadership skills and, as applicable, techniques for school leaders to effectively—

(i) Create and maintain a data-driven, professional learning community within the leader's schools;

(ii) Provide a climate conducive to the professional development of teachers, with a focus on improving student achievement and the development of effective instructional leadership skills;

(iii) Understand the teaching and assessment skills needed to support successful classroom instruction and to use data to evaluate teacher instruction and drive teacher and student learning;

(iv) Manage resources and school time to improve student academic achievement and ensure a safe school environment;

(v) Engage and involve parents, community members, the LEA, businesses, and other community leaders, to leverage additional resources to improve student academic achievement; and

(vi) Understand how students learn and develop in order to increase academic achievement for all students.

(2) Developing and improving a sustained and high-quality preservice clinical education program to further develop the leadership skills of all prospective school leaders involved in the program. This clinical education program must do the following:

(i) Incorporate year-long opportunities for enrichment, including—

(A) Clinical learning in high-need schools served by the high-need LEA or an LEA located in a rural area in the eligible partnership and identified by the eligible partnership; and

(B) Closely supervised interaction between prospective school leaders and faculty, new and experienced teachers, and new and experienced school leaders, in those high-need schools.

(ii) Integrate pedagogy and practice and promote effective leadership skills, meeting the unique needs of urban, rural, or geographically isolated communities, as applicable.

(iii) Provide for mentoring of new school leaders.

(3) Creating an induction program for new school leaders.

(4) Ensuring that individuals who participate in the school leadership program receive—

(i) Effective preservice preparation as described in paragraph (a)(2) of this priority;

(ii) Mentoring; and

(iii) If applicable, full State certification or licensure to become a school leader.

(5) Developing and implementing effective mechanisms to ensure that the eligible partnership is able to recruit qualified individuals to become school leaders through activities that may include an emphasis on recruiting into school leadership professions—

(i) Individuals from underrepresented populations;

(ii) Individuals to serve as superintendents, principals, or other school administrators in rural and geographically isolated communities and school leader shortage areas; and

(iii) Mid-career professionals from other occupations, former military personnel, and recent college graduates with a record of academic distinction.

(b) *Selection of Participants.* In order to be eligible for the school leadership program, an individual must—

(i) Be enrolled in or preparing to enroll in an IHE;

(ii) Be a—

(A) Recent graduate of an IHE;

(B) Mid-career professional from outside the field of education with strong content knowledge or a record of professional accomplishment;

(C) Current teacher who is interested in becoming a school leader; or

(D) School leader who is interested in becoming a superintendent; and

(iii) Submit an application to the school leadership program containing such information as the eligible partnership may require.

Section 202(g) of the HEA, like this priority, permits an eligible partnership to implement a school leadership program in an LEA that is not a high-need LEA provided the LEA is located in a rural area. However, the statute does not define the phrase “LEA located in a rural area,” for the purpose of this priority. The National Center for Educational Statistics (NCES), which has established locale codes based on geographic location, and assigned codes to all LEAs, considers an LEA with an assigned locale code of 31, 32, 33, 41, 42, or 43 as located in a rural area. (Codes 41–43 correspond with former locale codes 7 and 8 used to determine eligibility for the Small Rural School Achievement program; while codes 31–33 correspond to former locale code 6 used to help determine eligibility for the Rural Low Income Schools program.) In order to extend the potential benefits of the TQP School Leadership program to as many rural LEAs as possible, we have

determined that any LEA assigned any of these six locale codes may qualify under this TQP program as an “LEA located in a rural area.”

Prospective applicants may determine whether a particular LEA has one of these six locale codes by referring to the following Web site: <http://www.nces@ed.gov> and using the following procedures:

a. From the options listed across the top of this web page, select “School, & College Library Search.”

b. From the menu that appears, select “Search for School Districts.”

c. On the “Search for Public School Districts” page, type in the LEA or school district name (do not include phrases like “School District” or “Public Schools” that follow the name, and the State in which it is located. Then select “Search.”

d. From the list of LEAs shown, select the appropriate LEA. On the “District Information” page, the NCES locale code for the district is shown under the subheading “District Details,” next to “Locale.”

Competitive Preference Priorities 3 and 4: Competitive Preference Priorities 3 and 4 are from section 203(b)(2) of the HEA. Under 34 CFR 75.105(c)(2)(ii) we give preference to an application that meets one or both of these priorities over an application of comparable merit that does not meet the priorities.

These priorities are:

Competitive Preference Priority 3: Rigorous Selection Process. Eligible partnerships that include an IHE whose teacher preparation program has a rigorous process for selecting students entering the program to ensure the highest quality of students entering the program.

Competitive Preference Priority 4: Broad-based Partners. Applications from broad-based eligible partnerships with significant involvement of businesses or community organizations.

Invitational Priority: Within Absolute Priorities 1 and 2, we are particularly interested in applications that address the following invitational priority. For FY 2009 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Partnership with Digital Education Content Developer. Consistent with section 202(g) of the HEA, we are interested in receiving applications that propose to use grant funds to carry out

one or both of the absolute priorities, through partnerships with a television public broadcast station, as defined in section 397(6) of the Communications Act of 1934, as amended (47 U.S.C. 397(6)), or another entity that develops digital educational content, for the purpose of improving the quality of teacher preparation programs or to enhance the quality of preservice training for prospective teachers.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for the TQP Grants Program authorized by section 202 of the HEA, and it therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on (a) the requirement that grantees include in their evaluations objectives and measures for improving student achievement; (b) Competitive Preference Priority 1; (c) the definition of “LEA located in a rural area” in Competitive Preference Priority 2, (d) the requirement that a required member of the eligible partnership be the fiscal agent for the grant; (e) the Teacher Need component of the definition of “high-need LEA;” and (f) the selection criteria, Quality of the Project Design and Significance, under section 437(d)(1) of GEPA. These priorities, definitions, and selection criteria will apply to the FY 2009 grant competition and any subsequent year in which we make awards from the list of unfunded applicants from this competition.

Program Authority: 20 U.S.C. 1021–1022(c).

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds:

\$143,000,000: The \$43,000,000 from the Department of Education’s FY 2009 appropriation is only available through

September 30, 2009, and must be awarded through the first round of this competition that closes on July 23, 2009. The Department will use the American Recovery and Reinvestment Act (ARRA) of 2009, Public Law No. 111–5, funds in the amount of \$100,000,000 to make awards to high scoring applicants from rounds one and two of this competition.

The purposes of the ARRA include the following:

- (1) To preserve and create jobs and promote economic recovery;
- (2) To assist those most impacted by the recession;
- (3) To provide investments needed to increase economic efficiency by spurring technological advances in science and health;
- (4) To invest in transportation, environmental protection, and other infrastructure that will provide long-term economic benefit; and
- (5) To stabilize State and local government budgets in order to minimize and avoid reductions in essential services and counterproductive State and local tax increases.

Estimated Range of Awards:

\$1,000,000–\$2,000,000.

Estimated Average Size of Awards:

\$1,500,000.

Estimated Number of Awards: 25–35.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months.

III. Eligibility Information

1. *Eligible Applicant:* An eligible applicant must be an “eligible partnership” as defined in section 200(6) of the HEA. The fiscal agent of the grant may be any of the partners as described in section 200 of the HEA. The eligible partnership means an entity that—

(1) Must include each of the following:

- (i) A high-need LEA.
- (ii) A high-need school or consortium of high-need schools served by the high-need LEA, or, as applicable, a high-need ECE program.
- (iii) A partner institution.
- (iv) A school, department, or program of education within such partner institution, which may include an existing teacher professional development program with proven outcomes within a four-year IHE that provides intensive and sustained collaboration between faculty and LEAs consistent with the requirements of Title II of the HEA.
- (v) A school or department of arts and sciences within such partner institution; and

- (2) May include any of the following:
 - (i) The Governor of the State.
 - (ii) The State educational agency.
 - (iii) The State board of education.
 - (iv) The State agency for higher education.

(v) A business.

(vi) A public or private nonprofit educational organization.

(vii) An educational service agency.

(viii) A teacher organization.

(ix) A high-performing LEA, or a consortium of high-performing LEAs, that can serve as a resource to the partnership.

(x) A charter school (as defined in section 5210 of the ESEA).

(xi) A school or department within the partner institution that focuses on psychology and human development.

(xii) A school or department within the partner institution with comparable expertise in the disciplines of teaching, learning, and child and adolescent development.

(xiii) An entity operating a program that provides alternative routes to State certification of teachers.

Definitions: For purposes of the definition of “eligible partnership,” the following definitions are from section 200 of the HEA, as amended.

(1) *High-Need Local Educational Agency:* To be eligible as a “high-need LEA,” an LEA must establish that it meets one of the criteria for requisite poverty or geographic location in component (i), below, and one of the requisite criteria for teacher need in component (ii). Thus, under section 200(10) of the HEA, the term “high-need LEA” means an LEA—

(i)(A) For which not less than 20 percent of the children served by the agency are children from low-income families;

(B) That serves not fewer than 10,000 children from low-income families;

(C) That meets the eligibility requirements for funding under the Small, Rural School Achievement (SRSA) Program under section 6211(b) of the ESEA, or

(D) That meets eligibility requirements for funding under the Rural and Low-Income School Program under section 6221(b) of the ESEA;

(ii) And—

(A) For which there is a high percentage of teachers not teaching in the academic subject areas or grade levels in which the teachers were trained to teach; or

(B) There is a high teacher turnover rate or a high percentage of teachers with emergency, provisional, or temporary certification or licensure.

So that the Department may be able to confirm the eligibility of the LEAs

participating in the partnership as “high-need LEAs,” applicants will need to include information in their applications that demonstrates that each participating LEA in the partnership meets the above definition of “high-need.” This information must be based on the most recent data available.

Poverty Data. Under component (i)(A) or (i)(B) of the definition of “high-need LEA,” an LEA must show that not less than 20 percent of the children served by the LEA are children from low-income families or that the LEA serves not fewer than 10,000 children from low-income families. Under section 200(2) of the HEA (20 U.S.C. 1021(2)), the term “children from low-income families” means children described in section 1124(c)(1)(A) of the ESEA (20 U.S.C. 6333(c)(1)(A)). Consistent with that provision, the eligibility of an LEA as a “high-need LEA” under component (i)(A) or (i)(B) must be determined on the basis of the most recent U.S. Census Bureau data, which is currently for 2007. U.S. Census Bureau data are available for all LEAs with geographic boundaries that existed when the U.S. Census Bureau collected its information. The link to the most recent census data is: <http://www.census.gov/hhes/www/saie/district.html>. The Department also makes these data available at its Web site at: <http://www.ed.gov/programs/lsl/eligibility.html>. Some LEAs, such as newly formed LEAs or charter schools in States that accord them LEA status, are not included in Census Bureau poverty data. Eligibility of these particular LEAs will be determined on a case-by-case basis after review of information in the application that addresses, as well as possible, the number or percentage of children from low-income families these LEAs serve.

Eligibility under the Small Rural School Achievement (SRSA) Program or Rural and Low-Income School (RLIS) Program. Under component (i)(C) or (i)(D) of the definition of “high-need LEA,” an LEA may show that it is eligible for the SRSA or RLIS programs authorized in the ESEA. Prospective applicants may determine whether a particular LEA is eligible for these programs by referring to information available on the following Department Web sites. For the SRSA: <http://www.ed.gov/programs/reapsrsa/eligible08/index.html>. For the RLIS: <http://www.ed.gov/programs/reaprlis/eligibility.html>.

Teacher Need. Under component (ii)(A) or (ii)(B) of the definition of a “high-need LEA,” to be a “high-need” LEA, an LEA must have (A) a high percentage of teachers not teaching in the academic subject areas or grade

levels in which the teachers were trained to teach, or (B) either a high teacher turnover rate, or a high percentage of teachers with emergency, provisional, or temporary certification or licensure.

Under component (ii)(A) of Teacher Need, for purposes of the TQP Grants Program, and in accordance with section 437(d)(1) of GEPA, an LEA has “a high percentage of teachers not teaching in the academic subject areas or grade levels in which the teachers were trained to teach” if either:

(1) The percentage of its classes taught by teachers of core academic subjects who are not highly qualified exceeds the average percentage for the State in which the LEA is located; or

(2) The applicant submits other information, which the Department accepts, that the percentage of the LEA’s teachers who lack training in the academic subject areas or grade levels in which the teachers were trained to teach perhaps because of the short amount of training that many highly qualified teachers may have received before becoming teachers of record, is “high.” Assuming that the Department accepts the applicant’s information, the Department will determine eligibility under this test on a case-by-case basis if the percentage of teachers who lack training in the subject area or grade levels they were trained to teach is below five percent.

Section 1119 of the ESEA requires that all of an LEA’s teachers of core academic subjects be highly qualified by the end of the 2005–2006 school year, and we know that most LEAs are relatively close to meeting this goal. Because highly qualified teachers are generally teachers with sufficient knowledge or training in the subject they teach, we believe the percentage of an LEA’s classes taught by teachers who are not highly qualified (data that SEAs and LEAs must publicly report under section 1111(h)(1)(C)(vii) and (h)(2)(B) of the ESEA, respectively), is a reasonable proxy for the “percentage of teachers not teaching in the academic subject areas or grade levels in which the teachers were trained to teach.” In order to extend eligibility to as many LEAs as possible we provide that an LEA has a “high percentage” of these teachers if the percentage of its classes taught by teachers who are not highly qualified exceeds the State’s average.

At the same time, we recognize that LEAs that do not meet this test may also have a high percentage of teachers not teaching in the academic subject areas or grade levels in which the teachers were trained to teach. For example, an LEA might (1) be in a State with a very

high average for LEAs statewide, or (2) have many teachers who, while highly qualified in one or more academic subject areas, are teaching an academic subject or grade level for which they are not highly qualified or have little training. In order to accommodate these other situations, we will determine on a case-by-case basis, and based on the data a partnership submits with its application, whether other LEAs also have a “high percentage” of such teachers.

Regarding component (ii)(B) of Teacher Need, an LEA is considered to meet this component of “high-need” if it demonstrates that it has either a high teacher turnover rate or a high percentage of teachers with emergency, provisional, or temporary certification or licensure. In determining what is a “high teacher turnover rate” for purposes of this program, pursuant to section 437(d)(1) of GEPA we adopt, with one minor difference, the same interpretation of this phrase that the Department used under the HEA Teachers for a Competitive Tomorrow (TCT) Baccalaureate and Master’s programs. For reasons explained in the notice inviting applications for new FY 2008 awards under the baccalaureate program (see 73 FR 31835, 31837, June 4, 2008), we thus determine that a “high teacher turnover rate” means an annual attrition rate of 16 percent among classroom teachers who did not return to the same school in the LEA, *i.e.*, those teachers who moved the following year to a different school as well as those who left teaching altogether. We adopt this 16 percent rate rather than the 15 percent rate used in the previously authorized HEA Teacher Quality Enhancement Grants program regulations referenced in the TCT notice because the higher rate better reflects the more current data on which ED relied. Consistent with the discussion in the TCT notice, an LEA may calculate this attrition rate by averaging data over the last three years.

The alternative criterion in component (ii)(B) of the definition of “high-need LEA” provides that the LEA must have a high percentage of teachers with emergency, provisional, or temporary certification or licensure. In accordance with section 437(d)(1) of GEPA, and for reasons the Department discussed in the April 30, 2004 notice announcing requirements for the Transition to Teaching Program (69 FR 24001, 24003), the Department adopts the same standard used in that program authorized in Title II, Part C of the ESEA. This standard relies on data that States collect for each LEA on the percentage of teachers in the LEA who

are teaching on waivers of State certification, for inclusion in the reports on the quality of teacher preparation that the States provide to the Department in October of each year as required by section 207 of the HEA, as previously authorized.

Consistent with the approach the Department has taken in the Transition to Teaching program, which includes this same criterion in its eligibility requirements, the Department will consider an LEA as meeting the teacher need component of the definition of “high-need LEA” if LEA data the State used for purpose of the State’s October 2008 HEA, section 207 report on teachers teaching on waivers of State certification demonstrate that at least 1.37 percent of its teachers (the national average for all 2008 HEA, State reports submitted under section 207 of the HEA, as previously authorized) were on waivers of State certification requirements.

(2) *High-Need School*: Under section 200(11) of the HEA, the term “high-need school” means a school that, based on the most recent data available, meets at least one of the following:

(i) The school is in the highest quartile of schools in a ranking of all schools served by an LEA, ranked in descending order by percentage of students from low-income families enrolled in such schools, as determined by the LEA based on one of the following measures of poverty:

(A) The percentage of students aged 5 through 17 in poverty counted in the most recent census data approved by the Secretary;

(B) The percentage of students eligible for a free or reduced price school lunch under the Richard B. Russell National School Lunch Act;

(C) The percentage of students in families receiving assistance under the State program funded under Part A of Title IV of the Social Security Act;

(D) The percentage of students eligible to receive medical assistance under the Medicaid program;

(E) A composite of two or more of the measures described in paragraphs (A) through (D).

(ii) If the school is—

(A) An elementary school, not less than 60 percent of its students are eligible for a free or reduced price school lunch under the Richard B. Russell National School Lunch Act; or

(B) Not an elementary school, not less than 45 percent of its students are eligible for a free or reduced price school lunch under the Richard B. Russell National School Lunch Act.

Note: For criterion (i)(A), the only school-level data for these criteria of which the

Department is aware are those that concern eligibility for free and reduced price school lunches (paragraph (i)(B)). In addition criterion (ii)(A) does not itself permit an LEA to determine that a middle school or high school is a "high-need school" on the basis of the percentage of students attending its feeder schools that are eligible for free and reduced price school lunch subsidies.

However, the Special Rule found in Section 200(11)(B)(i) of the HEA allows the Secretary, upon approval of an application submitted by an eligible partnership, to designate a school as a high-need school for purposes of this program even though that school does not meet the definition of "high need" under the above definition. Specifically, section 200(11)(B)(i) permits the Secretary to approve an eligible partnership's application to designate any school as a high-need school based on consideration of the specific information identified in section 200(11)(B)(ii) and, at the Secretary's option, any other information the eligible partnership submits.

The need that middle and high schools located in high-poverty areas served by high-need LEAs have for more able, higher quality teachers is abundantly clear. However, while criterion (i)(A) requires a high-need school to have a minimum percentage of its students eligible for free and reduced price school lunch subsidies, it is common knowledge that, as students get older, the percentage of them choosing to apply for these lunch subsidies decreases.

We do not believe that Congress intended to erect such a barrier to the ability of middle and high schools located in high-poverty areas to be able to benefit from teachers trained through the pre-baccalaureate teacher preparation program, fifth year initial licensing program, or teaching residency program. Therefore, the Secretary will identify a middle or high school as "high-need" if—

(a) The aggregate level of poverty of the school's feeder schools, based on the aggregate percentage of their students eligible for free and reduced price school lunch subsidies, yields the percentage provided in section 200(11)(A)(ii); and

(b) The eligible applicant provides in its application the information identified in section 200(11)(B)(ii).

(3) *High-Need Early Childhood Education Program*: Under section 200(9) of the HEA, the term "high-need ECE program" means an ECE program serving children from low-income families that is located within the geographic area served by a high-need LEA.

(4) *Partner Institution*: Under section 200(17) of the HEA, the term "partner institution" means an IHE, which may include a two-year IHE offering a dual

program with a four-year IHE, participating in an eligible partnership that has a teacher preparation program—

(i) Whose graduates exhibit strong performance on State-determined qualifying assessments for new teachers through—

(A) Demonstrating that 80 percent or more of the graduates of the program who intend to enter the field of teaching have passed all of the applicable State qualification assessments for new teachers, which shall include an assessment of each prospective teacher's subject matter knowledge in the content area in which the teacher intends to teach; or

(B) Being ranked among the highest-performing teacher preparation programs in the State as determined by the State using criteria consistent with the requirements for the State report card under section 205(b) of the HEA before the first publication of the report card.

(ii) And that requires—

(A) Each student in the program to meet high academic standards or demonstrate a record of success, as determined by the institution (including prior to entering and being accepted into a program), and participate in intensive clinical experience;

(B) Each student in the program preparing to become a teacher to become "highly qualified" (as defined in section 9010(23) of the ESEA); and

(C) Each student in the program preparing to become an "early childhood educator" to meet degree requirements, as established by the State, and become "highly competent."

Note: For purposes of paragraph (ii)(C) of this definition, the term "highly competent," under section 200(12) of the HEA, means the early child educator has—

(a) Specialized education and training in development and education of young children from birth up to entry into kindergarten; and

(b)(i) A baccalaureate degree in an academic major in the arts and sciences; or

(ii) An associate's degree in a related educational area; and

(c) Demonstrated a high level knowledge and use of content and pedagogy in the relevant areas associated with quality ECE.

(5) *Additional Definitions*: Definitions for the following terms that apply to this program are in section 200 of the HEA: "arts and sciences," "early childhood educator," "highly qualified," "induction program," "limited English proficient," "professional development," "scientifically valid

research," "teacher mentoring" and "teaching residency program."

2. *Cost Sharing or Matching*:

(1) Under section 203(c) of the HEA (20 U.S.C. 1022(b)), each grant recipient must provide, from non-Federal sources, an amount equal to 100 percent of the amount of the grant, which may be provided in cash or in-kind, to carry out the activities supported by the grant. Grantees must budget their matching contributions on an annual basis relative to each annual award of Teacher Quality Partnership Program funds.

However, the HEA also authorizes the Secretary to waive this matching requirement for any partnership for any fiscal year if the Secretary determines that "applying the matching requirement to the eligible partnership would result in serious hardship or an inability to carry out the authorized activities described in" the law. In view of the impact of the Nation's current economic difficulties on the fiscal situation of so many LEAs and IHEs, for purposes of this competition the Secretary will waive up to 100 percent of the required match for each of the first two years of the grant based on a certification of serious hardship from the applicant that is included in the application. The Department will not at this time entertain a request for a waiver of the matching requirement for project years three through five, and applicants must provide a proposed non-Federal budget for these project years. Applicants who do not request a waiver or who request a waiver for only a portion of the matching amount in years one and two must provide a non-Federal budget for the required portion of their years one and two match that they intend to provide.

(2) *Supplement-Not-Supplant*: This program involves supplement-not-supplant funding requirements. In accordance with section 202(k) of the HEA funds made available under this program must be used to supplement, and not supplant other Federal, State, and local funds that would otherwise be expended to carry out activities under this program.

IV. Application and Submission Information

1. *Address to Request Application Package*: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794-1398. Telephone, toll free: 1-877-433-7827. FAX: (301) 470-1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1-877-576-7734.

You can contact ED Pubs at its Web site, also: <http://www.ed.gov/pubs/>

[edpubs.html](#) or at its e-mail address: edpubs@inet.ed.gov.

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.405A.

2. Content and Form of Application Submission: Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. It is recommended that the application narrative (Part III) be no more than 50 pages, using the following standards:

- A "page" is 8.5" × 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions. However, you may single space all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

3. Submission Dates and Times:
Applications Available: August 4, 2009.
Deadline for Transmittal of Applications: First Deadline: July 23, 2009. Second Deadline: October 6, 2009.

Applications for grants under this program must be submitted electronically using the Electronic Grant Application System (e-Application) accessible through the Department's e-Grants site. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 6.

Other Submission Requirements of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: First Deadline: September 21, 2009. Second Deadline: December 7, 2009.

4. Intergovernmental Review: This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. Funding Restrictions: We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. Other Submission Requirements: Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

(a) **Electronic Submission of Applications.** Applications for grants under the Teacher Quality Partnership—CFDA Number 84.405A must be submitted electronically using e-Application, accessible through the Department's e-Grants Web site at: <http://e-grants.ed.gov>.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under **Exception to Electronic Submission Requirement**.

While completing your electronic application, you will be entering data online that will be saved into a database. You may not e-mail an electronic copy of a grant application to us.

Please note the following:

- You must complete the electronic submission of your grant application by 4:30 p.m., Washington, DC time, on the application deadline date. E-Application will not accept an application for this program after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the application process.
- The hours of operation of the e-Grants Web site are 6:00 a.m. Monday until 7:00 p.m. Wednesday; and 6:00 a.m. Thursday until 8:00 p.m. Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 8:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 7:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the e-Grants Web site.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password protected file, we will not review that material.
- Your electronic application must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After you electronically submit your application, you will receive an automatic acknowledgment that will include a PR/Award number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the SF 424 to the Application Control Center after following these steps:
 - (1) Print SF 424 from e-Application.

(2) The applicant's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

(4) Fax the signed SF 424 to the Application Control Center at (202) 245-6272.

- We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of e-Application Unavailability:

If you are prevented from electronically submitting your application on the application deadline date because e-Application is unavailable, we will grant you an extension of one business day to enable you to transmit your application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) You are a registered user of e-Application and you have initiated an electronic application for this competition; and

(2) (a) E-Application is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) E-Application is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension or to confirm our acknowledgment of any system unavailability, you may contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (see VII. Agency Contact) or (2) the e-Grants help desk at 1-888-336-8930. If e-Application is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of e-Application.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through e-Application because—

- You do not have access to the Internet; or

- You do not have the capacity to upload large documents to e-Application; and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date

falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Peggi Zelinko, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W306, Washington, DC 20202-5960. Fax: (202) 401-8466.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. **Submission of Paper Applications by Mail.** If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.405A), LBJ Basement Level 1, 400 Maryland Avenue, SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. **Submission of Paper Applications by Hand Delivery.** If you qualify for an

exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.405A), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this grant notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

V. Application Review Information

Selection Criteria: The selection criteria governing this competition are listed in the following paragraphs. The selection criterion, Quality of Project Evaluation, is from 34 CFR 75.210 in the Education Department General Administrative Regulations (EDGAR) and section 204 of the HEA. The selection criterion, Quality of the Management Plan, is from 34 CFR 75.210 in EDGAR. The selection criterion, Quality of the Project Design, includes a combination of the factors under that criterion in 34 CFR 75.210(c) EDGAR and the criterion, Quality of Project Services in 34.210(d); specifically, factor (2)(i) is from 34 CFR 75.210(c) and factors (2)(ii), (iii) and (iv) are from 34 CFR 75.210(d). The selection criterion, Significance, includes a combination of the factors under that criterion in 34 CFR 75.210(b) and the criterion, Quality of Project Personnel, in 34 CFR 75.210(e); specifically, factors (2)(i), (ii) and (iii) are from section 34 CFR 75.210(b) and factor (2)(iv) is from section 34 CFR 75.210(e). We are combining these factors under these specific criteria to provide greater clarity on how applicants should address the criteria in their applications.

The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is indicated in parentheses with the criterion. These criteria are for the FY 2009 grant competition and any subsequent year in which we make awards based on the list of unfunded applicants from this competition only.

(a) *Quality of the Project Design* (up to 40 points).

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the extent to which the proposed project consists of a comprehensive plan that includes a description of—

(i) The extent to which the proposed project represents an exceptional approach to the priority or priorities established for this competition;

(ii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services;

(iii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services; and

(iv) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

Note: The Secretary encourages applicants to address this criterion by discussing the overall project design and its key components, and the degree to which the design's key components are based on sound research and practice. Applicants are also encouraged to address this criterion by connecting the project design to the intended impact of the project and how the project will affect the participants, including preparation, placement, retention, and effect on improved student achievement. Finally, applicants are encouraged to discuss the role and commitment of each partner and document each partner's responsibilities and commitment to the project.

(b) *Quality of the Project Evaluation* (up to 25 points).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers—

(i) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to intended outcomes of the project and will produce quantitative and qualitative data to the extent possible;

(ii) The extent to which the methods of evaluation address the evaluation requirements in section 204(a) of the HEA; and

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

Note: The Secretary encourages applicants to include a plan of how the project's evaluation will address the TQP Grants Program performance measures established by the Department under the Government Performance and Results Act of 1993 (GPRA). (The specific performance measures established for the overall TQP Grants Program are discussed under *Performance Measures* in section VI of this notice.) Further, each applicant is encouraged to describe how the applicant's evaluation plan will be designed to collect both output data and outcome data including benchmarks to monitor progress. Finally, each applicant is encouraged to select an independent, objective evaluator who has experience in evaluating educational programs and who will play an active role in the design and development of the project. For resources on what to consider in designing and conducting project evaluations, go to <http://www.whatworkshelpdesk.ed.gov/>.

(c) *Significance* (up to 20 points).

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors—

(i) The likelihood that the proposed project will result in system change or improvement;

(ii) The extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population;

(iii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement; and

(iv) The potential for continued support of the project after Federal funding ends, including, as appropriate, the demonstrated commitment of appropriate entities to such support.

Note: The Secretary encourages applicants to describe the use of a needs assessment to determine the specific needs of project participants and how the project will address these needs. Applicants are also encouraged to indicate how the project will affect teaching and student achievement in the proposed service area. Finally, applicants are encouraged to include a description of the commitment to build local capacity for the project and how this capacity building will be achieved.

(d) *Quality of the Management Plan* (up to 15 points).

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors—

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(ii) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project; and

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

Note: The Secretary encourages applicants to address these criteria by including in the application narrative a clear, well thought-out implementation plan that includes annual timelines, key project milestones, and a schedule of activities with sufficient time for developing an adequate implementation plan, as well as a description of the personnel who would be responsible for each activity and the level of effort each activity entails.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

Applicants are encouraged to include in their budgets funds for at least two project staff members to attend two meetings of the TQP Grants Program in Washington DC during each year of the project.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual

performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to <http://www.ed.gov/fund/grant/apply/appforms/appforms.html>.

Some of the funds awarded through this program were appropriated under the American Recovery and Reinvestment Act (ARRA) of 2009, Public Law 111–5, and are subject to additional accountability and transparency reporting requirements, which are described in section 1512(c) of the ARRA. Grantees receiving funds provided by the ARRA must be able to distinguish these funds from any other funds they receive through this program. Recipients of ARRA funds will be required to submit quarterly reports on the expenditure of these funds no later than ten days after the end of each calendar quarter through a centralized reporting Web site administered by the Office of Management and Budget (OMB): <http://www.federalreporting.gov>. The information reported at this Web site will be available to the Department, the White House, OMB and the public on <http://www.Recovery.gov>. Additional guidance providing further detail on the quarterly report will be provided at a later time.

4. *Performance Measures*: The objective of the TQP Grants Program is to increase student achievement in K–12 schools by developing highly qualified teachers. Under GPRA, the following measures will be used by the Department in assessing the performance of this program:

(a) *Performance Measure 1: Graduation*. The percentage of program completers who—

(1) Attain initial certification/licensure by passing all necessary certification/licensure assessments and attain a bachelor's degree (pre-baccalaureate teacher preparation program) or initial license (fifth year initial licensing program) within six years of beginning the program, or a master's degree (residency program) within two years of beginning the program; or

(2) Attain Highly Competent Early Childhood Educator status by earning a bachelor's degree within six years of beginning the program or an associate's degree within three years of beginning the program.

(b) *Performance Measure 2: Employment Retention*. The percentage of beginning teachers who are retained in teaching in the partner high-need

LEA or high-need ECE program three years after being hired by the high-need LEA or high-need ECE program;

(c) *Performance Measure 3: Improved Scores*. The percentage of grantees that report improved scaled scores on assessments for initial State certification or licensure of teachers;

(d) *Efficiency Measure: Employment Retention*. The cost of a successful outcome where success is defined as retention of the teacher in the partner high-need LEA or high-need ECE program three years after the teacher is hired by the high-need LEA or high-need ECE program;

(e) *Short-Term Performance Measures*. Because the performance measures already listed would not provide data for a number of years, the Department has also established the following two measures that will provide data in a shorter timeframe—

(1) *Short-Term Performance Measure 1: Persistence*. The percentage of program participants, who were not scheduled to graduate in the previous reporting period, and persisted in the postsecondary program in the current reporting period; and

(2) *Short-Term Performance Measure 2: Employment Retention*. The percentage of beginning teachers who are retained in teaching in the partner high-need LEA or high-need ECE program one year after being hired by the LEA or high-need ECE program.

Note: If funded, you will be asked to collect and report data on these measures in your project's annual performance report (EDGAR, 34 CFR 75.590). Applicants are also advised to consider these measures in conceptualizing the design, implementation, and evaluation of their proposed projects because of their importance in the application review process. Collection of data on these measures should be a part of the evaluation plan, along with measures of progress on goals and objectives that are specific to your project.

All grantees will be expected to submit an annual performance report documenting their success in addressing these performance measures.

VII. Agency Contact

For Further Information Contact: Teacher Quality Partnership Grants Program, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W320, Washington, DC 20202. Telephone: (202) 260–0563 or by e-mail: TQPartnership@ed.gov.

If you use a TDD, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document

and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister>.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

Dated: July 30, 2009.

James H. Shelton, III,
Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. E9–18614 Filed 8–3–09; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Agency Information Collection Activities: Submission for OMB Review; Comment Request.

SUMMARY: The EIA has submitted the Office of Radioactive Waste Management's NWP-830R Surveys package to the Office of Management and Budget (OMB) for review and a three-year extension under section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) (44 U.S.C. 3501 *et seq.*).

DATES: Comments must be filed by September 3, 2009. If you anticipate that you will be submitting comments but find it difficult to do so within that period, you should contact the OMB Desk Officer for DOE listed below as soon as possible.

ADDRESSES: Send comments to OMB Desk Officer for DOE, Office of Information and Regulatory Affairs, Office of Management and Budget. To ensure receipt of the comments by the due date, submission by FAX (202-395-7285) or e-mail to

Christine J. Kymn@omb.eop.gov is recommended. The mailing address is 726 Jackson Place, NW., Washington, DC 20503. The OMB DOE Desk Officer may be telephoned at (202) 395-4638. (A copy of your comments should also be provided to EIA's Statistics and Methods Group at the address below.)

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Alethea Jennings. To ensure receipt of the comments by the due date, submission by FAX (202-586-5271) or e-mail

(*alethea.jennings@eia.doe.gov*) is also recommended. The mailing address is Statistics and Methods Group (EI-70), Forrestal Building, U.S. Department of Energy, Washington, DC 20585-0670. Ms. Jennings may be contacted by telephone at (202) 586-5879.

SUPPLEMENTARY INFORMATION:

This section contains the following information about the energy information collection submitted to OMB for review: (1) The collection numbers and title; (2) the sponsor (*i.e.*, the Department of Energy component); (3) the current OMB docket number (if applicable); (4) the type of request (*i.e.*, new, revision, extension, or reinstatement); (5) response obligation (*i.e.*, mandatory, voluntary, or required to obtain or retain benefits); (6) a description of the need for and proposed use of the information; (7) a categorical description of the likely respondents; and (8) an estimate of the total annual reporting burden (*i.e.*, the estimated number of likely respondents times the proposed frequency of response per year times the average hours per response).

1. Form NWP-830R, "Appendix G—Standard Remittance Advice for Payment of Fees (including Annex A and Annex B to Appendix G)."

2. Office of Radioactive Waste Management (OCRWM).

3. OMB Number 1901-0260.

4. Three-year extension.

5. Mandatory.

6. Form NWP-830R "Appendix G—Standard Remittance Advice for Payment of Fees", and "Annex A and Annex B to Appendix G—Standard Remittance Advice for Payment of Fees" are designed to serve as the source documents for entries into DOE accounting records to transmit data from Purchasers to the DOE concerning

payment of their fees for spent nuclear fuel and high-level waste disposal into the Nuclear Waste Fund. The Remittance Advice (RA) must be submitted by Purchasers who signed the Standard Contract for Disposal of Spent Nuclear Fuel and/or High-Level Radioactive Waste with the DOE. Appendix G is an appendix to the Standard Contract.

7. Business or other for-profit.

8. 2,080 hours.

Please refer to the supporting statement as well as the proposed forms and instructions for more information about the purpose, who must report, when to report, where to submit, the elements to be reported, detailed instructions, provisions for confidentiality, and uses (including possible nonstatistical uses) of the information. For instructions on obtaining materials, see the "**FOR FURTHER INFORMATION CONTACT**" section.

Statutory Authority: 10 CFR 961.11, at Art. VIII, § (B)(3)(6) and section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) (44 U.S.C. 3501 *et seq.*).

Issued in Washington, DC, July 28, 2009.

Stephanie Brown,

Director, Statistics and Methods Group, Energy Information Administration.

[FR Doc. E9-18555 Filed 8-3-09; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP09-443-000]

Columbia Gulf Transmission Company; Notice of Application

July 28, 2009.

Take notice that on July 10, 2009, Columbia Gulf Transmission Company tendered for filing an abbreviated application pursuant to section 7(b) of the Natural Gas Act, as amended, to abandon its obligation to provide transportation service through various facilities comprising the Project Central Texas Loop system.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to

be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5 p.m. Eastern Time Monday, August 3, 2009.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E9-18497 Filed 8-3-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 13393–000; Project No. 13422–000; Project No. 13425–000]

Consolidated Hydro New Hampshire, Inc.: Village of Swanton, VT; TransCanada Hydro Northeast Inc.; Notice of Competing Preliminary Permit Applications Accepted for Filing and Soliciting Comments, and Motions To Intervene

July 28, 2009.

Consolidated Hydro New Hampshire, Inc., the Village of Swanton, Vermont, and TransCanada Hydro Northeast Inc. filed applications, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Murphy Dam Project, to be located at the existing Murphy Dam owned by the State of New Hampshire located on the Connecticut River in Coos County, New Hampshire.

These permit applications are filed in competition with Rockhouse Mountain Energy, LLC's proposed Murphy Dam Project No. 13243–000, which was public noticed on January 9, 2009. The deadline for filing competing applications and notices of intent was March 10, 2009. Both the Village of Swanton, Vermont, and TransCanada Hydro Northeast Inc. filed timely notices of intent to file competing permit applications.

Descriptions of the proposed Murphy Dam Projects:

Consolidated Hydro New Hampshire, Inc.'s Project No. 13393–000 application was filed on March 10, 2009. The project would consist of: (1) A proposed 500-foot-long, 8-foot-diameter steel penstock; (2) a proposed powerhouse containing one generating unit having a total installed capacity of 3.0 MW; (3) a proposed 1,500-foot-long, 34.5-kV transmission line; (4) a 30-foot-wide, 100-foot-long tailrace; and (5) appurtenant facilities. The proposed project would have an average annual generation of 12.4 gigawatt-hours, which would be sold to a local utility.

The Village of Swanton, Vermont's Project No. 13422–000 application was filed on April 8, 2009. The project would consist of: (1) A proposed 300-foot-long, 8-foot-diameter penstock; (2) a proposed powerhouse containing one generating unit having a total installed capacity of 2.0 MW; (3) a proposed 1,500-foot-long, 34.5-kV transmission line; (4) a 30-foot-wide, 100-foot-long tailrace; and (5) appurtenant facilities. The proposed project would have an average annual generation of 12.4

gigawatt-hours, which would be sold to a local utility.

TransCanada Hydro Northeast Inc.'s Project No. 13425–000 application was filed on April 8, 2009. The project would consist of: (1) A proposed 2,500-foot-long, 8-foot-diameter penstock; (2) a proposed powerhouse containing one generating unit having a total installed capacity of 2.51 MW; (3) a proposed 1,500-foot-long, 34.5-kV transmission line; (4) a 30-foot-wide, 100-foot-long tailrace; and (5) appurtenant facilities. The proposed project would have an average annual generation of 11.1 gigawatt-hours, which would be sold to a local utility.

Applicants Contact: For Consolidated Hydro New Hampshire, Inc.: Mr. Victor Engel, Consolidated Hydro New Hampshire, Inc., c/o Enel North America, Inc., One Tech Drive, Suite 220, Andover, MA 01810; phone (978) 681–1900 Ext. 811. For the Village of Swanton, Vermont: Mr. Paul Nolan, 5515 North 17th Street, Arlington, VA 22205–2722; phone (703) 534–5509. For TransCanada Hydro Northeast Inc.: Mr. John L. Ragonesse, TransCanada Hydro Northeast Inc., 4 Park Street, Suite 402, Concord, NH 03301; phone (603) 225–5528.

FERC Contact: Michael Spencer, (202) 502–6093.

Deadline for filing comments, motions to intervene: 60 days from the issuance of this notice. Comments, motions to intervene and may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "eFiling" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. 20426. For more information on how to submit these types of filings please go to the Commission's Web site located at <http://www.ferc.gov/filing-comments.asp>. More information about this project can be viewed or printed on the "eLibrary" link of the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (P–13393–000, P–13422–000, or P–13425–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,
Secretary.

[FR Doc. E9–18552 Filed 8–3–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings No 2**

July 27, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP00–632–033.

Applicants: Dominion Transmission, Inc.

Description: Dominion Transmission, Inc. errata to Workpaper 5 to its Informational Annual Fuel Report.

Filed Date: 07/17/2009.

Accession Number: 20090717–5067.

Comment Date: 5 p.m. Eastern Time on Friday, July 31, 2009.

Docket Numbers: RP09–448–001.

Applicants: Texas Gas Transmission, LLC.

Description: Supplemental Information—Additional Support of Texas Gas Transmission, LLC.

Filed Date: 05/11/2009.

Accession Number: 20090511–5116.

Comment Date: 5 p.m. Eastern Time on Friday August 31, 2009.

Docket Numbers: RP09–748–001.

Applicants: Quest Pipelines (KPC).

Description: Quest Pipelines (KPC) submits Substitute First Revised Sheet 190 to FERC Gas Tariff, Second Revised Volume 1, to be effective 8/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090724–0098.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP06–298–009.

Applicants: Public Service Commission of New York v.

Description: Semi-Annual Report of Operational Sales of Gas of National Fuel Gas Supply Corporation.

Filed Date: 07/23/2009.

Accession Number: 20090723–5028.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09–447–003.

Applicants: Monroe Gas Storage Company, LLC.

Description: Monroe Gas Storage Company, LLC submits Non-Conforming Service Agreements with Citigroup Energy Inc pursuant to the Commission's 7/16/09 Order under RP09–447.

Filed Date: 07/23/2009.

Accession Number: 20090724–0074.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09–666–002.

Applicants: El Paso Natural Gas Company.

Description: El Paso Natural Gas Company submits Second Revised Volume 1A to its FERC Gas Tariff under RP09–666.

Filed Date: 07/23/2009.

Accession Number: 20090723–0164.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09–706–001.

Applicants: Southeast Supply Header, LLC.

Description: Southeast Supply Header, LLC submits FERC Gas Tariff, Original Volume 1,

an Sub First Revised Sheet 342, to be effective 8/1/09.

Filed Date: 07/23/2009.

Accession Number: 20090723-0165.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09-710-002.

Applicants: Clear Creek Storage Company, LLC.

Description: Clear Creek Storage Company, LLC submits Second Substitute Sixth Revised Sheet 77 *et al* to its FERC Gas Tariff, to be effective 8/1/09.

Filed Date: 07/23/2009.

Accession Number: 20090723-0168.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09-718-001.

Applicants: Egan Hub Storage, LLC.

Description: Egan Hub Storage, LLC submits Sub Fourth Revised Sheet 156 to its FERC Gas Tariff, First Revised Volume 1, to be effective 8/1/09.

Filed Date: 07/23/2009.

Accession Number: 20090723-0167.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Docket Numbers: RP09-753-001.

Applicants: TransColorado Gas Transmission Company LLC.

Description: TransColorado Gas Transmission Company, LLC submits Substitute First Revised Sheet 203 to FERC Gas Tariff, Second Revised Volume 1 to be effective 8/1/09.

Filed Date: 07/23/2009.

Accession Number: 20090723-0166.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 04, 2009.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FEROnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Nathaniel J. Davis,

Deputy Secretary.

[FR Doc. E9-18498 Filed 8-3-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

July 28, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP09-427-001.

Applicants: Southern Natural Gas Company.

Description: Southern Natural Gas Company submits Fourth Revised Sheet 1 *et al*, to be effective 9/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090727-0018.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09-505-000.

Applicants: Texas Gas Transmission, LLC.

Description: Motion of Texas Gas Transmission, LLC for an Extension of the Effective Date of Tariff Sheets or, in the Alternative, Waiver of Certain Tariff Sheet Provisions.

Filed Date: 07/24/2009.

Accession Number: 20090724-5060.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09-508-002.

Applicants: Texas Eastern Transmission LP.

Description: Texas Eastern Transmission, LP submits Sub Second Revised Sheet 612 to FERC Gas Tariff, Seventh Revised Volume 1, to be effective 8/13/09.

Filed Date: 07/24/2009.

Accession Number: 20090728-0005.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09-704-001.

Applicants: Destin Pipeline Company, L.L.C.

Description: Destin Pipeline Company, LLC submits Sub Eighth Revised Sheet 136 to FERC Gas Tariff, Original Volume 1, to be effective 8/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090727-0019.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09-748-001.

Applicants: Quest Pipelines (KPC).

Description: Quest Pipelines (KPC) submits Substitute First Revised Sheet 190 to FERC Gas Tariff, Second Revised Volume 1, to be effective 8/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090724-0098.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09-409-002.

Applicants: Cimarron River Pipeline, LLC.

Description: Refund Report of Cimarron River Pipeline, LLC.

Filed Date: 07/27/2009.

Accession Number: 20090727-5098.

Comment Date: 5 p.m. Eastern Time on Monday, August 10, 2009.

Docket Numbers: RP09-681-001.

Applicants: Transwestern Pipeline Company, LLC.

Description: Transwestern Pipeline Company, LLC submits Substitute Second Revised Sheet No 96 to its FERC Gas Tariff, Third Revised Volume No 1.

Filed Date: 07/27/2009.

Accession Number: 20090727-0040.

Comment Date: 5 p.m. Eastern Time on Monday, August 10, 2009.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to any subscribed docket(s). For assistance with any FERC Online service, please e-mail FEROnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Nathaniel J. Davis,

Deputy Secretary.

[FR Doc. E9-18499 Filed 8-3-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings # 1**

July 28, 2009.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC09–96–000.

Applicants: Hartwell Energy Limited Partnership, Oglethorpe Power Corporation.

Description: Joint application of Hartwell Energy Limited Partnership & Oglethorpe Power Corp for approval of the Disposition of Jurisdictional Facilities under section 203 of the Federal Power Act.

Filed Date: 07/24/2009.

Accession Number: 20090724–4008.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: EC09–97–000.

Applicants: MidAmerican Energy Company.

Description: MidAmerican Energy Company submits application for approval of the acquisition by MidAmerican of an ownership interest in the Hills-Parnell 161 kV transmission line and related assets owned by Resale Power Group of Iowa.

Filed Date: 07/27/2009.

Accession Number: 20090727–0035.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG09–77–000.

Applicants: Black Bear Hydro Partners, LLC.

Description: Notice of Exempt Wholesale Generator Status submitted by Black Bear Hydro Partners, LLC.

Filed Date: 07/24/2009.

Accession Number: 20090724–5065.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: EG09–78–000.

Applicants: Tilton Energy LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Tilton Energy LLC.

Filed Date: 07/27/2009.

Accession Number: 20090727–5072.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER08–1169–003.

Applicants: Midwest Independent Transmission System Operating, Inc.

Description: Midwest ISO submits First Revised Sheet 3102 et al. to FERC

Electric Tariff, Fourth Revised Volume 1.

Filed Date: 07/24/2009.

Accession Number: 20090727–0027.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–304–002; ER99–1005–011.

Applicants: KCP&L Greater Missouri Operations Company.

Description: Kansas City Power & Light Company et al. submits updated market power study in support of their respective market based rate authorizations.

Filed Date: 07/23/2009.

Accession Number: 20090727–0020.

Comment Date: 5 p.m. Eastern Time on Monday, September 21, 2009.

Docket Numbers: ER09–1178–001.

Applicants: Public Service Company of New Mexico.

Description: Public Service Company of New Mexico submits Second Revised Sheet 3 et al. to FERC Electric Tariff, 2nd Rev Vol 6.

Filed Date: 07/24/2009.

Accession Number: 20090724–0543.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1283–002.

Applicants: The Energy Cooperative of Pennsylvania, Inc.

Description: Energy Cooperative of Pennsylvania, Inc submits second amended petition for acceptance of initial tariff, waivers and blanket authority.

Filed Date: 07/27/2009.

Accession Number: 20090727–0043.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09–1294–001.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric Power Company submits revisions to the Control Area Operations Coordination Agreement Wisconsin Power and Light Company, to be effective 8/10/09.

Filed Date: 07/27/2009.

Accession Number: 20090728–0175.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09–1488–000.

Applicants: Black Bear Hydro Partners, LLC.

Description: Petition of Black Bear Hydro Partners, LLC for order accepting market based rate tariff for filing and granting waivers and blanket approvals and request for expedited action.

Filed Date: 07/24/2009.

Accession Number: 20090727–0017.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1489–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits letter agreement between SCE and Alta Windpower Development, LLC.

Filed Date: 07/24/2009.

Accession Number: 20090724–0086.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1490–000.

Applicants: Tampa Electric Company.

Description: Tampa Electric Company submits its cost-based rate tariff which is designated as Tampa Electric's FERC Electric, Original Volume 7.

Filed Date: 07/24/2009.

Accession Number: 20090724–0085.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1492–000.

Applicants: Florida Power & Light Company.

Description: Florida Power & Light Company submits Third Revised Sheet 161 et al. to FERC Electric Tariff, 2nd Rev Vol 6 to be effective 8/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090724–0542.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1493–000.

Applicants: Carolina Power & Light Company.

Description: Carolina Power & Light Company submits a Power Supply and Coordination Agreement with the Public Works Commission of the City of Fayetteville, North Carolina designated as Rate Schedule 184, effective 9/22/09.

Filed Date: 07/24/2009.

Accession Number: 20090727–0024.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1494–000.

Applicants: Entergy Services, Inc.

Description: Entergy Arkansas, Inc submits an Amended Rate Schedule providing for power coordination and interchange services to the City of Osceola, Arkansas, to be effective 10/1/09.

Filed Date: 07/24/2009.

Accession Number: 20090727–0025.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Docket Numbers: ER09–1491–000.

Applicants: Tilton Energy LLC.

Description: Tilton Energy, LLC submits application for market based rate authorization under section 205 of the Federal Power Act and request for waivers and blanket approvals.

Filed Date: 07/27/2009.

Accession Number: 20090728–0070.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09–1495–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submits executed Transmission Interconnection Agreement among ITC Midwest LLC, Northern States Power Company and Midwest ISO.

Filed Date: 07/27/2009.

Accession Number: 20090727-0037.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1497-000.

Applicants: Lehman Brothers
Commodity Services Inc.

Description: Lehman Brothers Commodity Services Inc submits notice of cancellation of First Revised FERC Electric Tariff No 1.

Filed Date: 07/27/2009.

Accession Number: 20090727-0042.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1499-000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc submits Service Agreement for Wholesale Distribution Service to be appended to Con Edison's Open Access Transmission Tariff, FERC Electric Tariff, First Revised Volume No 1.

Filed Date: 07/27/2009.

Accession Number: 20090727-0044.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1500-000.

Applicants: MH Partners LP.

Description: MH Partners, LP submits First Revised Sheet 1 to Rate Schedule FERC No 1, Original Volume 1.

Filed Date: 07/27/2009.

Accession Number: 20090728-0180.

Comment Date: 5:00 pm Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1501-000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits First Revised Sheet 17 *et al.* to FERC Electric Tariff, First Revised Volume 5, Service Agreement 192, to be effective 9/26/09.

Filed Date: 07/27/2009.

Accession Number: 20090728-0179.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1502-000.

Applicants: Southern Company Services, Inc.

Description: Alabama Power Company *et al.* submits Revisions No 2 to Agreement for Network Integration Transmission Service between Southern Companies and Georgia Transmission Corp etc.

Filed Date: 07/27/2009.

Accession Number: 20090728-0178.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1503-000.

Applicants: Niagara Mohawk Power Corporation.

Description: Niagara Mohawk Power Corp submits for acceptance two 1972 letters with Power Authority of the State of New York documenting agreement etc.

Filed Date: 07/27/2009.

Accession Number: 20090728-0181.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1504-000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits an executed service agreement for Point-to-Point Transmission Service with KCP&L Greater Missouri Operations Company, to be effective 9/25/09.

Filed Date: 07/27/2009.

Accession Number: 20090728-0166.

Comment Date: 5 p.m. Eastern Time on Monday, August 17, 2009.

Docket Numbers: ER09-1506-000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits Fourth Revised Service Agreement 607 *et al.* to FERC Electric Tariff, Fifth Revised Volume 1, to be effective 9/26/09.

Filed Date: 07/28/2009.

Accession Number: 20090728-0182.

Comment Date: 5 p.m. Eastern Time on Tuesday, August 18, 2009.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES09-40-000.

Applicants: Upper Peninsula Power Company.

Description: Upper Peninsula Power Company's application for renewed authorization to issue long term debt.

Filed Date: 07/24/2009.

Accession Number: 20090727-0023.

Comment Date: 5 p.m. Eastern Time on Friday, August 14, 2009.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.

Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E9-18543 Filed 8-3-09; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

July 29, 2009.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP09-842-000.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: Cheniere Creole Trail Pipeline, LP submits Second Revised Sheet No 199 *et al.* to its FERC Gas Tariff, Original Volume No 1.

Filed Date: 07/24/2009.

Accession Number: 20090727-0041.

Comment Date: 5 p.m. Eastern Time on Wednesday, August 05, 2009.

Docket Numbers: RP09–843–000.

Applicants: CenterPoint Energy Gas Transmission Company.

Description: CenterPoint Energy Gas Transmission Company submits Seventh Revised Sheet 1 *et al* to FERC Gas Tariff, Sixth Revised Volume 1, to be effective 8/26/09.

Filed Date: 07/27/2009.

Accession Number: 20090728–0068.

Comment Date: 5 p.m. Eastern Time on Monday, August 10, 2009.

Docket Numbers: RP09–844–000.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits First Revised Sheet No 407 *et al* to its FERC Gas Tariff, Third Revised Volume No 1, to be effective 9/1/09.

Filed Date: 07/28/2009.

Accession Number: 20090729–0122.

Comment Date: 5 p.m. Eastern Time on Monday, August 10, 2009.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington DC 20426.

The filings in the above proceedings are accessible in the Commission's

eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail FERCOnlineSupport@ferc.gov. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E9–18500 Filed 8–3–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF09–10–000]

Northwest Pipeline GP; Notice of Intent To Prepare an Environmental Impact Statement and Land and Resource Management Plan Amendment for the Planned Blue Bridge Pipeline Project and Request for Comments On Environmental Issues

July 28, 2009.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that will discuss the environmental impacts of the planned Blue Bridge Pipeline Project involving construction and operation of facilities by Northwest Pipeline GP (Northwest) in Benton, Klickitat, Skamania, and Clark Counties, Washington. This EIS will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process that will be used to gather input from the public and interested agencies on the project. Your input will help the Commission staff and cooperating agencies determine which issues need to be evaluated in the EIS. Please note that the scoping period for this project will close on August 30, 2009.

Comments may be submitted in writing or verbally. Details on how to submit written comments are provided in the "Public Participation" section of this notice. In lieu of or in addition to sending written comments, you are invited to attend the two public scoping meetings to verbally comment on the

project. The dates and locations of the meetings are listed below and will be posted on the Commission's calendar at www.ferc.gov/EventCalendar/EventsList.aspx. All meetings are scheduled to begin at 7 p.m. Pacific Daylight Time.

August 11, 2009—Goldendale, WA

Goldendale Grange #49
228 E. Darland Street
Goldendale, WA 98620

August 12, 2009—Stevenson, WA

Skamania Lodge
1131 SW Skamania Lodge Way
Stevenson, WA 98648

This notice is being sent to affected landowners; federal, state, and local government representatives and agencies; environmental and public interest groups; Native American tribes; other interested parties in this proceeding; and local libraries and newspapers.

The FERC is the lead federal agency for the preparation of the EIS. The U.S. Bureau of Land Management (BLM) is participating as a cooperating agency in the preparation of the EIS because the project would cross federally-administered lands in Washington. The U.S. Forest Service (USFS) is participating as a cooperating agency because the project would cross the Gifford Pinchot National Forest, the Columbia River Gorge National Scenic Area, and the Pacific Crest Trail in Washington. The U.S. Army Corps of Engineers (COE) is also participating as a cooperating agency.

The BLM has authority under the Mineral Leasing Act of 1920 (30 U.S.C. 185) for granting a right-of-way over all federal lands involved in the planned project. As a cooperating agency, the BLM intends to adopt the EIS per Title 40 of the Code of Federal Regulations, Part 1506.3, to meet its NEPA responsibilities for Northwest's application for a Right-of-Way Grant and Temporary Use Permit for the crossing of federally administered lands, including BLM lands, the Gifford Pinchot National Forest, the Columbia River Gorge National Scenic Area, the Pacific Crest Trail, and the Umatilla National Wildlife Refuge. The Umatilla National Wildlife Refuge is managed by the U.S. Fish and Wildlife Service (FWS). The concurrence or non-concurrence of the USFS and FWS would be considered in the BLM's decision, as well as impacts on resources and programs and the project's conformance with land use plans.

As planned, the Blue Bridge Pipeline project does not follow a designated

utility corridor through the Gifford Pinchot National Forest. If Blue Bridge's planned route were authorized, the Gifford Pinchot National Forest, Forest Plan would need to be amended. The USFS will use the EIS to consider amending the Forest Plan to allow pipeline construction outside of designated utility corridors.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" is available for viewing on the FERC Web site (www.ferc.gov). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Summary of the Planned Project

Northwest plans to construct and operate a new pipeline to transport natural gas from the Stanfield market hub located near Stanfield, Oregon, to major markets in the Pacific Northwest along the Interstate 5 corridor, including the Olympia and Seattle, Washington, areas. All of the planned project facilities would be located in Washington. The planned Blue Bridge project would transport up to 239,000 dekatherms per day of natural gas. According to Northwest, its project would allow its customers to meet forecasted growing demand for natural gas, diversify supply alternatives, and increase reliability.

The planned Blue Bridge Project would consist of the following facilities:

- Approximately 119.2 miles of 30-inch diameter pipeline loop along the Columbia River Gorge in Benton, Klickitat, and Skamania Counties, Washington;¹ and
- Install 15,015 horsepower of additional compression at two existing compressor stations near Plymouth (Benton County) and Washougal (Clark County).

¹ A pipeline loop is constructed parallel to an existing pipeline to increase capacity.

The general location of the project facilities is shown in appendix 1.²

Note that the planned location of the project has been modified since the original Northwest filing and project description dated June 1, 2009. On July 27, 2009, Northwest filed supplemental information indicating that about 34 miles of planned pipeline route had been removed from the project, including portions of the planned route in Klickitat, Skamania, and Clark Counties, Washington. Additionally, Northwest indicated that all previously planned project activities in Lewis County, Washington, have been eliminated.

Land Requirements for Construction

Construction of the planned facilities would affect about 1,733 acres of land for aboveground facilities, temporary extra work areas, uncleared storage areas, and the pipeline based on a planned construction right-of-way that typically would be 75-foot-wide. Northwest would retain approximately 949 acres permanently during operations as permanent right-of-way. The remaining acreage that was used for construction, but not needed as permanent right-of-way, would be restored and/or allowed to revert to former uses. About 74 percent of the planned pipeline route would parallel existing pipeline, utility, or road rights-of-way.

The EIS Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as "scoping". The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. All comments received will be considered during the preparation of the EIS.

In the EIS the FERC staff will discuss impacts that could occur as a result of the construction and operation of the

² The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices are available on the Commission's Web site at the "eLibrary" link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to eLibrary, refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

planned project under these general headings:

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

The FERC staff will also evaluate reasonable alternatives to the planned project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, the FERC staff has already initiated our NEPA review under the Commission's Pre-filing Process. The purpose of the Pre-filing Process is to encourage early involvement of interested stakeholders and to identify and resolve issues before an application is filed with the FERC. As part of our pre-filing review, the FERC staff has begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EIS.

Our independent analysis of the issues will be presented in the EIS. The draft EIS will be mailed to those on our environmental mailing list (see discussion of how to remain on our mailing list on page 7). A 90-day comment period will be allotted for review of the draft EIS. The FERC staff will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure your comments are considered, please carefully follow the instructions in the public participation section below.

With this notice, the FERC is formally asking agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EIS. These agencies may choose to participate once they have evaluated the proposal relative to their responsibilities. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, the BLM, USFS, and the COE have expressed their intention to participate as a cooperating agency in the preparation of the EIS to satisfy their NEPA responsibilities related to this project.

Currently Identified Environmental Issues

The FERC staff has already identified several issues that we think deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Northwest. This preliminary list of issues may be changed based on your comments and our analysis.

- Geohazards, including areas with high landslide potential;
- Sensitive waterbody crossings and wetlands;
- Fisheries and wildlife;
- Endangered and rare species, including the northern spotted owl and several salmonid species;
- Crossing of the Columbia River Gorge National Scenic Area and associated viewsheds;
- Crossing of the Gifford Pinchot National Forest;
- Crossing of the Umatilla National Wildlife Refuge;
- Crossing of the Pacific Crest Trail;
- Impacts to forested areas, including late successional reserve/old growth areas;
- Cultural resources, including areas of interest to Native American Tribes;
- Pipeline safety and reliability; and
- Residential areas.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send in your comments so that they will be received in Washington, DC on or before August 30, 2009.

For your convenience, there are three methods in which you can use to submit your comments to the Commission. In all instances, please reference the project docket number [PF09–10–000] with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at 202–502–8258 or efiling@ferc.gov.

(1) You may file your comments electronically by using the *Quick Comment* feature, which is located on the Commission's internet Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. A Quick Comment is an easy method for interested persons to submit text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission's Internet Web site at <http://www.ferc.gov> under the link to *Documents and Filings*. eFiling involves preparing your submission in the same manner as you would if filing on paper, and then saving the file on your computer's hard drive. You will attach that file to your submission. New eFiling users must first create an account by clicking on “Sign up” or “eRegister.” You will be asked to select the type of filing you are making. A comment on a particular project is considered a “Comment on a Filing”; or

(3) You may file your comments with the Commission via mail by sending an original and two copies of your letter to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Label one copy of the comments for the attention of Gas Branch 3, PJ–11.3.

Environmental Mailing List

An effort is being made to send this notice to all individuals, organizations, and government entities interested in and/or potentially affected by the planned project. This includes all landowners who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities (as defined in the Commission's regulations).

If you do not want to send comments at this time but still want to remain on our mailing list, please return the Information Request (appendix 2). If you do not return the Information Request, you will be taken off the mailing list.

Becoming an Intervenor

Once Northwest files its application with the Commission, you may want to become an “intervenor”, which is an official party to the proceeding. Intervenor play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in a Commission proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the “e-filing” link on the Commission's Web site. Please note that you may not request intervenor status at this time. You must wait until a formal application for the project is filed with the Commission.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Web site (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on “General Search” and enter the docket number, excluding the last three digits, in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to www.ferc.gov/esubscribenow.htm.

Finally, public meetings or site visits will be posted on the Commission's calendar located at <http://www.ferc.gov/EventCalendar/EventsList.aspx> along with other related information.

Kimberly D. Bose,
Secretary.

[FR Doc. E9–18551 Filed 8–3–09; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2008–0300; FRL–8940–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Shipbuilding and Ship Repair Facilities—Surface Coating (Renewal); EPA ICR Number 1712.06; OMB Control Number 2060–0330

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved

collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before September 3, 2009.

ADDRESSES: Submit your comments, referencing docket ID number EPA-HQ-OECA-2008-0300, to (1) EPA online using <http://www.regulations.gov> (our preferred method), or by e-mail to docket.oeca@epa.gov, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28331T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Leonard Lazarus, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: 202-564-6369; fax number: 202-564-0050; e-mail address: lazarus.leonard@epa.gov.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 30, 2008 (73 FR 31088) EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA-HQ-OECA-2008-0300, which is available for public viewing online at <http://www.regulations.gov>, in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, 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 Enforcement and Compliance Docket is (202) 566-1927.

Use EPA's electronic docket and comment system at <http://www.regulations.gov>, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then

key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at <http://www.regulations.gov>, as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to <http://www.regulations.gov>.

Title: NESHAP for Shipbuilding and Ship Repair Facilities—Surface Coating (Renewal).

ICR Numbers: EPA ICR Number 1712.06, OMB Control Number 2060-0330.

ICR Status: This ICR is scheduled to expire on August 31, 2009. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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 title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The respondents are owners or operators of Shipbuilding and Ship Repair Facilities. Operations covered include: primer and top coat application in manufacturing processes and in ship repair processes. The National Emission Standards for Hazardous Air Pollutants (NESHAP) regulation, 40 CFR part 63, subpart II, was promulgated on December 15, 1995. Owners or operators of the affected facilities described must make initial reports when a source becomes subject, conduct and report on a performance test, demonstrate and report on continuous monitor performance, and maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility. Semiannual reports of excess emissions are required. These notifications, reports, and records are essential in determining compliance; and are required, in general, of all sources subject to NESHAP.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain

the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office.

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 are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 255 hours per response. 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 which have subsequently changed; 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.

Respondents/Affected Entities: Owners or operators of shipbuilding and ship repair facilities.

Estimated Number of Respondents: 56.

Frequency of Response:

Semiannually, On Occasion, Initially.

Estimated Total Annual Hour Burden: 28,594 hours.

Estimated Total Annual Cost:

\$1,740,381 in labor costs, exclusively. There are no capital/startup or Operations and Maintenance costs associated with this ICR.

Changes in the Estimates: There is no change in the burden hours or cost to the respondents in this ICR compared to the previous ICR. This is due to two considerations: (1) the regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the respondents is very low, negative or nonexistent. Therefore, the labor hours and cost figures in the previous ICR reflect the current burden to the respondents and are reiterated in

this ICR. In the previous ICR, the cost figure was rounded-up to the nearest thousand. In this ICR, the figure is rounded to the nearest dollar.

Dated: July 29, 2009.

John Moses,

Director, Collection Strategies Division.

[FR Doc. E9-18589 Filed 8-3-09; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8940-1]

Notice of Final NPDES General Permit for Discharges From Concentrated Animal Feeding Operations (CAFOs) in New Mexico (NMG010000)

AGENCY: Environmental Protection Agency (EPA), Region 6.

ACTION: Notice of NPDES General Permit Reissuance.

SUMMARY: EPA Region 6 today issues a National Pollutant Discharge Elimination System general permit for discharges from eligible owners/operators of existing concentrated animal feeding operations (CAFOs), in New Mexico, except those discharges on Indian Country. All currently operating animal feeding operations that are defined as CAFOs or designated as CAFOs by the permitting authority (See part VII Definitions, "CAFOs") and that are subject to 40 CFR part 412, subparts A (Horses) and C (Dairy Cows and Cattle Other than Veal Calves) are eligible for coverage under this permit. This permit covers the types of animal feeding operations listed above which meet the definition of a CAFO and discharge or propose to discharge pollutants to waters of the United States. A CAFO proposes to discharge if it is designed, constructed, operated, or maintained such that a discharge will occur.

A copy of the Region's responses to comments and the final permit may be obtained from the EPA Region 6 Internet site: <http://www.epa.gov/region6/water/npdes/cafo/index.htm>.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Smith, Water Quality Protection Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, telephone: (214) 665-2145, or via e-mail at: smith.diane@epa.gov.

SUPPLEMENTARY INFORMATION:

Summary of Significant Changes From the Draft Permit

Pursuant to section 402 of the Clean Water Act (CWA), 33 U.S.C. section 1342, EPA proposed and solicited comments on NPDES general permit

NMG010000 at 74 FR 3592 (January 21, 2009). The comment period closed on February 20, 2009.

Region 6 received comments from the New Mexico Environment Department, US Fish and Wildlife Service, Bureau of Reclamation, New Mexico Department of Agriculture, Dairy Producers of New Mexico, Seaboard Foods, Oklahoma Farm Bureau, Texas Cattle Feeders Association, Oklahoma Pork Council, and Amigos Bravos.

EPA Region 6 has considered all comments received. In response to those comments the following significant changes were made to the proposed permit.

1. Based on NMED condition of certification under section 401 of the Clean Water Act, part III.A.8 of the permit has been changed to require the use of a certified specialist to develop, modify, review, and/or approve the nutrient management plan.

2. Part III.A.3.h has been added to the permit to require that the nutrient management plan (NMP) include site maps of the production and land application areas.

3. Part II.A.2.a.x has been modified to include the term "as appropriate." Part II.A.2.a.x and part III.A.3.b have also been modified to clarify that retention structures must include adequate storage capacity for clean water that is not diverted.

4. EPA has removed part III.A.3.f.i-iv from the permit and has modified part III.A.3.f to require that the NMP include any additional information necessary to assess the adequacy of the application rates included in the NMP.

5. EPA has modified part III.A.7.d of the permit to require that manure sampling be conducted annually prior to the first land application event of each year of permit coverage and to allow for representative sampling protocols to be established in the NMP.

6. The spills reporting requirement has been removed from part III.D.3 of the permit and was replaced with a requirement to document spills and clean-up activity.

7. Part III.D.3 of the permit has been modified to state that handling procedures and storage for any toxic and other pollutants must be specified in the NMP.

8. EPA has modified part III.D.1.c to state that any mechanical or structural damage to the liner must be evaluated by a Natural Resources Conservation Service (NRCS) Engineer or Professional Engineer and that the permittee shall have a NRCS Engineer or Professional Engineer review documentation.

9. The infiltration monitoring requirement of part III.D.1.c has been

modified to be based on a direct hydrological connection to waters of the United States. EPA has also modified this section to allow for other appropriate measures to be used in lieu of leak detection systems or monitoring wells.

10. EPA has modified the permit to require that annual reports be submitted to EPA and NMED on January 31 as opposed to basing the due date on the NOI submittal date.

11. Parts VI.B.1, VI.B.2, and VI.C.1 have been removed from the permit as they are repetitive of provisions found elsewhere in the permit.

12. EPA has added part I.H to address the procedure for a change in ownership.

13. The Water Quality-Based Reduction Plan requirement of part II.A.3.c has been removed from the permit.

14. EPA has modified part III.C to exclude amounts less than 10 tons per year to a single recipient from the transfer of manure, litter, and process wastewater recordkeeping requirement.

15. EPA has removed the notification requirement form part III.D.8.a and will rely on the notification requirement of part III.D.5, which has been modified to require notification within 48 hours.

16. The proposed corrective action requirement proposed as part II.A.3.d has been clarified to address discharges or proposed discharges to impaired waters and has been moved to part II.A.3.a.iv.

17. EPA has modified part IV.A of the permit to require CAFOs to orally report the discharge of pollutants to waters of the United States to NMED.

18. Part I.D.8 and part I.E.8 of the final permit have been amended to clarify that new sources must submit an Environmental Impact Document (EID), not a previous EPA National Environmental Policy Act (NEPA) review document, with their NOIs.

19. Part II.A.5.c has been amended to clarify that there shall be no unauthorized dry weather discharges from land application sites.

20. EPA has clarified part I.E.1.a.i to state that for any facility that received authorization to discharge under the 1993 CAFO general permit and complies with the 90-day NOI timeframe, authorization under the 1993 CAFO permit is automatically continued until coverage is granted under this permit or coverage is otherwise terminated.

21. EPA has amended part I.E.8 to clarify that the applicant must submit to EPA information describing an expansion so that EPA may determine if the expansion is a new source.

Revision to the Permit

EPA is through today's notice revising part I.E.6 of the proposed permit. The option to submit a notice of intent (NOI) and nutrient management plan (NMP) electronically via the EPA Region 6 Web site has been removed from the permit due to unforeseen technical problems. If at any time such a process is implemented by EPA Region 6 for CAFO general permits, CAFOs seeking permit coverage under this permit may use electronic submission.

Authority: Clean Water Act, 33 U.S.C. 1251 et seq.

Dated: July 24, 2009.

Claudia V. Hosch,

Acting Director, Water Quality Protection Division, EPA Region 6.

[FR Doc. E9-18588 Filed 8-3-09; 8:45 am]

BILLING CODE 6560-50-P

FARM CREDIT ADMINISTRATION

Privacy Act of 1974; Establishment of a New System of Records

AGENCY: Farm Credit Administration.

ACTION: Notice of establishment of a new system of records maintained on individuals; request for comments.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a), notice is hereby given that the Farm Credit Administration (FCA) is publishing an amended system notice, which indicates that the agency is now maintaining information on building security.

DATES: You may send written comments on or before September 3, 2009. The FCA filed an amended System Report with Congress and the Office of Management and Budget on July 14, 2009. This notice will become effective without further publication on September 14, 2009 unless modified by a subsequent notice to incorporate comments received from the public.

ADDRESSES: We offer a variety of methods for you to submit your comments. For accuracy and efficiency reasons, commenters are encouraged to submit comments by e-mail or through the FCA's Web site. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we are no longer accepting comments submitted by fax. Regardless of the method you use, please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *E-mail:* Send us an e-mail at reg-comm@fca.gov.

- *FCA Web site:* <http://www.fca.gov>. Select "Public Commenters," then "Public Comments," and follow the directions for "Submitting a Comment."

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

- *Mail:* Robert Taylor, Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102-5090.

You may review copies of comments we receive at our office in McLean, Virginia, or from our Web site at <http://www.fca.gov>. Once you are in the Web site, select "Public Commenters," then "Public Comments," and follow the directions for "Reading Submitted Public Comments." We will show your comments as submitted but, for technical reasons, we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove e-mail addresses to help reduce Internet spam.

FOR FURTHER INFORMATION CONTACT:

Bob Taylor, Privacy Act Officer, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4019, TTY (703) 883-4020, or

Jane Virga, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4071, TTY (703) 883-4020.

SUPPLEMENTARY INFORMATION: This publication satisfies the requirement of the Privacy Act of 1974 that agencies publish a system of records notice in the **Federal Register** when there is a revision, change, or addition to the system of records. The notice reflects designated points of contact for inquiring about the system, accessing the records, and requesting amendments to the records.

The amended system of records is: FCA-17, Organization Locator and Personnel Roster. As required by 5 U.S.C. 552a(r) of the Privacy Act, as amended, the FCA has sent notice of this proposed system of records to the Office of Management and Budget, the Committee on Oversight and Government Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate. The notice is published in its entirety below.

FCA-17

SYSTEM NAME:

Organization Locator and Personnel Roster System—FCA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at the Farm Credit Administration.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current FCA employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Paper and electronic records. Includes information such as names; home addresses; telephone numbers; cell phone numbers; official titles or positions and organizations; photographs; building security zones; and other information associated with identifying and contacting personnel. Locator records of Agency personnel.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

12 U.S.C. 2243, 2252.

PURPOSES:

To contact and recall personnel when required; locate personnel for routine and emergency matters; provide mail distribution and forwarding addresses; compile a social roster for official and non-official functions; send personal greetings and invitations; establish building security; and locate individuals during medical emergencies, facility evacuations, and similar threat situations. To identify Agency personnel.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See the "General Statement of Routine Uses."

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information stored in hard copy and electronically.

RETRIEVABILITY:

Retrievable by name.

SAFEGUARDS:

Access is limited to those whose official duties require access. File cabinets and rooms are locked during non-duty hours. Computers are protected by firewalls and passwords.

RETENTION AND DISPOSAL:

In accordance with National Archives and Records Administration General Records schedule requirements.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Management Services, Farm Credit Administration, McLean, VA 22102-5090.

NOTIFICATION PROCEDURE:

Direct all inquiries about this system of records to: Privacy Act Officer, Farm Credit Administration, McLean, VA 22102-5090.

RECORD ACCESS PROCEDURES:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Information in this system of records either comes from the individual to whom it applies or comes from information supplied by Agency officials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: July 30, 2009.

Roland Smith,

Secretary, Farm Credit Administration Board.
[FR Doc. E9-18603 Filed 8-3-09; 8:45 am]

BILLING CODE 6705-01-P

FEDERAL ELECTION COMMISSION**[NOTICE 2009-18]****Agency Procedure for Notice to Respondents in Non-Complaint Generated Matters**

AGENCY: Federal Election Commission.

ACTION: Agency procedure.

SUMMARY: The Federal Election Commission ("Commission") is establishing a new agency procedure that will provide respondents in certain enforcement matters brought under the Federal Election Campaign Act of 1971, as amended ("FECA") with notice of a non-complaint generated referral and an opportunity to respond thereto, prior to the Commission's consideration of whether it has reason to believe that a violation of the Act has been or is about to be committed by such respondent. This program will provide respondents in non-complaint generated matters procedural protections similar to those of respondents in complaint-generated matters. Further information about the procedures for providing notice to respondents in non-complaint generated matters is provided in the supplementary information that follows.

DATES: Effective August 4, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Shonkwiler, Assistant General

Counsel, 999 E Street, NW., Washington, DC 20463, (202) 694-1650 or (800) 424-9530.

SUPPLEMENTARY INFORMATION:**I. Background**

On June 11, 2003, the Commission held a hearing concerning its enforcement procedures. The Commission received public comments, many of which argued for increased transparency in Commission procedures and expanded opportunities to contest allegations. Comments and statements for the record are available at: <http://www.fec.gov/agenda/agendas2003/notice2003-09/comments.shtml>. In response to issues raised at the hearing, the Commission issued new agency procedures. See Statement of Policy Regarding Deposition Transcripts in Nonpublic Investigations, 68 FR 50688 (Aug. 22, 2003); Statement of Policy Regarding Treasurers Subject to Enforcement Proceedings, 70 FR 3 (Jan. 3, 2005).

On December 8, 2008, the Commission issued a notice of public hearing and request for public comment on the compliance and enforcement aspects of its agency procedures. Agency Procedures (Notice of public hearing and request for public comments), 73 FR 74495 (Dec. 8, 2008). On January 14-15, 2009, the Commission received comment and testimony. The comments received by the Commission, as well as the transcript of the hearing are available at: <http://www.fec.gov/law/policy/enforcement/publichearing011409.shtml>.

The Commission received numerous comments regarding respondents in non-complaint generated matters not receiving notice when a matter has been referred to the Commission's Office of General Counsel ("OGC") for enforcement. One commenter opined that the Commission should never find reason to believe ("RTB") that a violation occurred without first giving the respondent the opportunity to respond. Another commenter recommended instituting a program whereby potential respondents in non-complaint generated matters are given a written summary of the matter and an opportunity to respond in writing before the Commission makes an RTB finding, in order to put respondents on notice about the potential outcome of the proceeding. Other commenters urged the Commission to adopt procedures to notify committees of any internal referral, and to implement procedures to provide respondents with the opportunity to review and respond to any adverse course of action

recommended by OGC before the Commission considers such recommendation.

II. Procedures for Notice to Respondents in Non-Complaint Generated Matters

The Commission is issuing a new agency procedure to provide notification to respondents of enforcement proceedings based on information ascertained by the Commission in the normal course of carrying out its supervisory responsibilities (*i.e.*, non-complaint generated matters). See 2 U.S.C. 437g. In matters generated by complaints, the Commission may take no action on the complaint (other than dismissal) until respondents have at least 15 days after notification of the allegations contained in the complaint to answer the allegations. See 2 U.S.C. 437g(a)(1). However, the statute does not afford respondents the same opportunity to answer allegations in non-complaint generated matters. This agency procedure is intended to provide respondents in non-complaint generated enforcement matters with notice of the basis of the allegations, and an opportunity to respond.

For matters arising from a referral from the Commission's Reports Analysis Division or Audit Division ("internal referrals"), respondents will be notified of the referral within five days of receipt of the referral by OGC. The notice will contain a copy of the referral document and a cover letter setting forth the basis of the referral and potential violations of the Act and/or Commission regulations that arise based upon the referral. The respondent will then be given an opportunity to demonstrate that no action should be taken based on the referral, by submitting, within 15 days from receipt of the referral document and cover letter, a written explanation of why the Commission should take no action. The Commission will not take any action, or make any RTB finding against a respondent based on an internal referral unless it has considered such response or unless no such response has been served upon the Commission within 15 days.

Under current Commission practice, non-complaint generated matters based on referrals from the U.S. Department of Justice or any other law enforcement or governmental agency ("external referrals") are also deemed to be matters based on information ascertained in the normal course of carrying out its supervisory responsibilities. Under the new procedures, if OGC intends to initiate an enforcement proceeding based on an external referral, notice of

the referral will be provided to respondents in the same manner as an internal referral. However, where immediate notification to a respondent of an external referral is deemed inappropriate, OGC will notify the Commission of the referral within 5 days of receipt of the referral from the governmental agency. In cases where, due to law enforcement purposes, the referral document may not be provided to a respondent, OGC will provide the respondent with a letter containing sufficient information regarding the facts and allegations to afford the respondent an opportunity to demonstrate that no action should be taken. Absent exercise of the Commission's discretion (by the affirmative vote of four Commissioners), OGC will not proceed with an enforcement proceeding based on an external referral until the referral or substitute informational letter is provided to the respondent.

III. Conclusion

This notice establishes agency practices or procedures. This notice does not constitute an agency regulation requiring notice of proposed rulemaking, opportunities for public participation, prior publication, and delay effective under 5 U.S.C. 553 of the Administrative Procedures Act ("APA"). The provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), which apply when notice and comment are required by the APA or another statute, are not applicable. The above provides general guidance concerning notice to respondents in non-complaint generated matters and announces the general course of action that the Commission intends to follow. This notice sets forth the Commission's intentions concerning the exercise of its discretion in its enforcement program. However, the Commission retains that discretion and will exercise it as appropriate with respect to the facts and circumstances of each matter it considers. Consequently, this notice does not bind the Commission or any member of the general public.

On behalf of the Commission.

Dated: July 29, 2009.

Steven T. Walther,

Chairman, Federal Election Commission.

[FR Doc. E9-18542 Filed 8-3-09; 8:45 am]

BILLING CODE 6715-01-P

FEDERAL HOUSING FINANCE AGENCY

[No. 2009-N-10]

Federal Home Loan Bank Collateral for Advances and Interagency Guidance on Nontraditional Mortgage Products

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of study and recommendations and request for comment.

SUMMARY: Section 1217 of the Housing and Economic Recovery Act of 2008 (HERA) requires the Director of the Federal Housing Finance Agency (FHFA) to conduct a study on the extent to which loans and securities used as collateral to support Federal Home Loan Bank (FHLBank) advances are consistent with the interagency guidance on nontraditional mortgage products. The study must be submitted to the Committee on Banking, Housing and Urban Affairs of the Senate and the Committee on Financial Services of the House of Representatives no later than July 30, 2009, one year after the date of the HERA enactment. Further, the study (the HERA Section 1217 Study) must consider and recommend any additional regulations, guidance, advisory bulletins, or other administrative actions necessary to ensure that the FHLBanks are not supporting loans with predatory characteristics. Section 1217 of HERA also requires that the public have an opportunity to comment on any recommendations made as a result of the study. This Federal Register Notice is intended to inform the public about the HERA Section 1217 Study and provide the public with the requisite opportunity to comment.

DATES: Comments must be received on or before October 2, 2009.

ADDRESSES: You may submit your comments on the HERA Section 1217 Study, identified by a subject line of "HERA Section 1217 Study," by any of the following methods:

- *U.S. Mail, United Parcel Post, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/HERA Section 1217 Study, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.

- *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/HERA Section 1217 Study, Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at

the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

- *E-mail:* Comments to Alfred M. Pollard, General Counsel, may be sent by e-mail at RegComments@fhfa.gov. Please include "HERA Section 1217 Study" in the subject line of the message.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by e-mail to FHFA at RegComments@fhfa.gov to ensure timely receipt by the agency. Please include "HERA Section 1217 Study" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Louis M. Scalza, Associate Director, (202) 408-2953 or Linda L. Campbell, Senior Bank Examiner, (202) 408-2586, Division of Federal Home Loan Bank Regulation; or Neil R. Crowley, Deputy General Counsel, Office of General Counsel, (202) 343-1316, Federal Housing Finance Agency, 1625 Eye Street, NW., Washington, DC 20006. The telephone number for the Telecommunications Device for the Deaf is (800) 877-8339.

SUPPLEMENTARY INFORMATION: Section I of this Notice provides background on FHFA, the FHLBank System, and the collateral securing FHLBank advances. Section II summarizes the provisions of the interagency guidance and three Federal Housing Finance Board (FHFB) advisory bulletins relating to nontraditional, subprime, and anti-predatory lending. Section III describes the resources used to complete the HERA Section 1217 Study, including a collateral data survey that FHFA conducts annually, in-depth secured credit reviews performed during recent examinations, and a specific questionnaire related to the HERA Section 1217 issues that FHFA sent to the FHLBanks. Sections IV and V of this report present FHFA's analysis and conclusions from the HERA Section 1217 Study and Section VI requests comments on specific related questions.

The HERA Section 1217 Study reports that FHLBanks' reliance on collateral described as nontraditional, subprime or Alt-A declined during 2008, accounting for about one-fifth of collateral securing advances as of December 31, 2008. Some portion of this collateral predates the issuance of the interagency guidance, but the FHLBanks need to manage and mitigate the risks associated with all of the collateral supporting advances.

FHFA, through advisory bulletins issued by the prior regulator of the

FHLBanks, the FHFB, has issued explicit written guidance to the FHLBanks on anti-predatory, nontraditional, and subprime lending. The FHLBanks have adopted policies which address nontraditional and subprime collateral, although in-depth secured credit reviews found some weaknesses in those policies and practices. The FHLBanks' responses to an FHFA questionnaire indicate that they have adopted policies, procedures and practices that would require that loans and MBS used as collateral to support advances be consistent with the interagency guidance. FHFA will continue to assess the adequacy of the FHLBank's policies and procedures and monitor the FHLBank's remediation efforts. FHFA determines the appropriateness of issuing additional guidance based on examination results and its assessment of legislative developments.

I. Background

A. Federal Housing Finance Agency

Effective July 30, 2008, HERA, Public Law 110–289, 122 Stat. 2654 (2008), transferred the supervisory and oversight responsibilities of the Office of Federal Housing Enterprise Oversight (OFHEO) over the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, Enterprises), and the oversight responsibilities of the FHFB over the FHLBanks and the Office of Finance (which acts as the FHLBanks' fiscal agent) to FHFA, a new independent agency of the Federal Government. FHFA is responsible for ensuring that the Enterprises and the FHLBanks operate in a safe and sound manner, maintain adequate capital and internal controls, foster liquid, efficient, competitive and resilient national housing finance markets, and carry out their public policy missions through authorized activities. See § 1102, Public Law 110–289, 122 Stat. 2663–64. The Enterprises and the FHLBanks continue to operate under regulations promulgated by OFHEO and the FHFB until FHFA issues its own regulations. See *id.* at §§ 1302, 1312, 122 Stat. 2795, 2798. The Division of Federal Home Loan Bank Regulation is the principal organizational unit within FHFA responsible for supervision of the FHLBanks.

B. The FHLBank System

The twelve FHLBanks are instrumentalities of the United States organized under the Federal Home Loan Bank Act (Bank Act). See 12 U.S.C.

1423, 1432(a). The FHLBanks are cooperatives; only members of an FHLBank may own the capital stock of an FHLBank and only members or certain eligible housing associates (such as state housing finance agencies) may obtain access to the products provided by an FHLBank. See 12 U.S.C. 1426, 1430(a), 1430b. Each FHLBank is managed by its own board of directors and serves the public by enhancing the availability of residential mortgage and community lending credit through its member institutions. See 12 U.S.C. 1427. Any eligible institution (principally, federally-insured depository institutions or state-regulated insurance companies) may become a member of an FHLBank by satisfying certain criteria and by purchasing a specified amount of the FHLBank's capital stock. See 12 U.S.C. 1424, 1426; 12 CFR part 931.

As government sponsored enterprises (GSEs), the FHLBanks are normally able to borrow funds in the capital markets on terms more favorable than could be obtained by most private entities. Until recently, the FHLBank System could borrow funds at a modest spread over the rates on U.S. Treasury securities of comparable maturity, across a wide range of maturities. In 2008, market conditions contributed to substantially wider spreads between FHLBank consolidated obligations and U.S. Treasuries, particularly at longer maturities. Although the wider spreads may have contributed to a decline in advances that began in the fourth quarter of 2008, the FHLBanks continue to serve as a source of liquidity to their members.

The FHLBanks pass along their GSE funding advantage to their members—and ultimately to consumers—by providing advances (secured loans) and other financial services at rates that would not otherwise be available to their members. Some of the FHLBanks also have Acquired Member Asset (AMA) programs whereby they acquire fixed-rate, single-family mortgage loans from participating member institutions.

The FHLBanks raise funds in the capital markets by issuing consolidated obligations consisting of bonds and discount notes. Consolidated obligations are issued by the Office of Finance on behalf of the twelve FHLBanks and are the principal source of funding not only for FHLBank advances, but also for AMA programs, and investments. Although an FHLBank is primarily liable for the portion of the consolidated obligations corresponding to the proceeds received by that FHLBank, each FHLBank is also jointly and severally liable with the other eleven

FHLBanks for the payment of principal of, and interest on, all consolidated obligations. See 12 U.S.C. 1431; 12 CFR 966.9.

C. Collateral Securing FHLBank Advances

The United States Government established the Federal Home Loan Bank System in 1932 to stimulate mortgage finance by providing liquidity from the FHLBanks to its member financial institutions. Members, generally financial institutions, increase liquidity by obtaining advances from the FHLBanks. Those advances are secured by eligible collateral, typically government securities, residential mortgages, or other real estate related collateral (e.g., commercial real estate loans, home equity lines of credit and second mortgage loans). Total advances at the end of June 2009 were \$721 billion, down from a peak exceeding \$1 trillion in October 2008.

All advances are collateralized, which protects the FHLBank should the member default. The FHLBanks secure member advances in several ways: a blanket lien on all or specific categories of a member's assets, a lien on specific member assets for which the member provides a listing of collateral characteristics to the FHLBank, a lien on assets that a member delivers to the FHLBank, or some combination thereof. The level of collateralization depends on the level of risk associated with the collateral. To date, the FHLBanks have never incurred a credit loss on an advance.

A member may pledge only the following types of collateral for an advance: (a) Fully disbursed, whole first mortgages on improved residential property not more than 90 days delinquent; (b) securities issued, insured, or guaranteed by the U.S. Government or any agency thereof; (c) cash or deposits of an FHLBank; (d) other real estate related collateral acceptable to the FHLBank, provided the value of such collateral is readily ascertainable and the FHLBank can perfect its interest in the collateral; and (e) for institutions that qualify as "community financial institutions" (CFIs), secured loans for small business, agriculture, or community development activities, or securities representing a whole interest in such secured loans. See 12 U.S.C. 1430(a)(3) as amended. Whole first mortgage loans on residential real property represent the largest source of member-provided collateral to the System. As of December 31, 2008, whole residential mortgage loans pledged as collateral for advances

were \$859 billion or 59.7 percent of the total collateral securing advances.

II. HERA Section 1217 Study Regulatory Guidance

HERA Section 1217, which mandated this study, specifically refers to interagency guidance on nontraditional mortgage products. This section provides a summary of the interagency guidance on nontraditional mortgage products along with the related statement on subprime residential mortgage lending. It then summarizes the advisory bulletins issued by the FHFB to apply the principles of the interagency guidance to the supervision of the FHLBanks, as well as an advisory bulletin on anti-predatory lending.¹

A. Interagency Guidance

The term “interagency guidance” is not specifically defined in the HERA legislation. For purposes of this report, FHFA uses the term “interagency guidance” to mean the guidance issued jointly by five federal financial institution regulatory agencies—the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, and the National Credit Union Administration—concerning nontraditional mortgage products and subprime lending.² The principal interagency guidance on nontraditional and subprime residential mortgage loans can be summarized as follows.

Interagency Guidance on Nontraditional Mortgage Product Risks (2006)

The federal financial institution regulatory agencies issued the *Interagency Guidance on Nontraditional Mortgage Product Risks* on October 4, 2006. This notice instructs financial institutions on how to offer nontraditional mortgage products in a safe and sound manner and in a way that clearly discloses the benefits and risks to borrowers. The guidance focuses on nontraditional residential mortgage products that permit borrowers to defer payment of principal or interest, including interest-only residential

mortgage loans, payment option adjustable-rate residential mortgage loans, and negative amortization residential mortgage loans. It also covers other higher-risk practices often associated with nontraditional residential mortgage loans, such as simultaneous second-lien residential mortgage loans, variable interest rates with below-market introductory rates, and the use of reduced documentation in the evaluation of an applicant's creditworthiness. The guidance establishes that financial institutions should recognize and mitigate the risks inherent in these products by ensuring that loan terms and underwriting standards are clearly disclosed and consistent with prudent lending practices, including credible consideration of a borrower's repayment capacity.

Statement on Subprime Mortgage Lending (2007)

The federal financial institution regulatory agencies subsequently issued the *Statement on Subprime Mortgage Lending* on July 10, 2007. The Statement addresses issues relating to certain adjustable-rate mortgage products that can cause the borrower's monthly payment to increase significantly and potentially become unaffordable. The Statement establishes prudent safety and soundness and consumer protection standards that should be followed to ensure that consumers, especially subprime borrowers, obtain loans they can afford to repay and receive information that adequately describes product features. These standards include qualifying the borrower using a fully-indexed interest rate (*i.e.*, the interest rate after any lower, introductory interest rate in the early period of a loan) and a fully-amortizing repayment schedule. The standards also convey the regulators' expectation that stated income and reduced documentation should be accepted by the lender only if there are documented mitigating factors that clearly minimize the need for verification of a borrower's repayment capacity. The Statement reiterates that institutions should develop strong control systems to monitor compliance with risk management and consumer protection policies and practices, including clear disclosures to customers and limits on prepayment penalties.

B. FHFB Guidance

FHFA—like its predecessor agencies the Federal Housing Finance Board and the Office of Federal Housing Enterprise Oversight—is mindful of the potential risk to the FHLBanks and the impact on

the public if the FHLBanks were to provide liquidity to support predatory loans or inappropriately underwritten nontraditional and subprime residential mortgage loans. Accepting such loans as collateral for advances could pose a safety and soundness risk to the FHLBanks and would also be inconsistent with the overarching housing finance mission of the FHLBanks.

As a result of concerns about predatory lending, in 2005 the former FHFB issued an advisory bulletin to the FHLBanks requiring each FHLBank to establish and communicate to its member institutions its anti-predatory lending policies. The FHLBanks were required to establish those policies to avoid accepting loans with predatory characteristics as collateral for advances. In 2007 and 2008, the FHFB also issued advisory bulletins on nontraditional and subprime residential mortgage loans as a complement to the interagency guidance. The FHFB guidance established that any nontraditional or subprime mortgage loans originated or acquired by the member after July 10, 2007 could serve as eligible collateral only if those loans were underwritten consistent with the interagency guidance. The 2007 and 2008 guidance expanded the reach of the interagency guidance by establishing that the standards in the interagency guidance would apply not just to loans purchased by the FHLBanks, but also to whole loans collateralizing advances and to loans underlying MBS that serve as collateral for advances or that the FHLBanks purchase as investment securities. Further, the FHFB instructed the FHLBanks to apply the interagency standards to loans and MBS accepted as collateral from FHLBank member institutions that were not otherwise directly subject to the interagency guidance, *e.g.*, insurance companies. The following provides a summary of the three advisory bulletins.

Advisory Bulletin 2005–AB–08

In August of 2005, the FHFB issued Advisory Bulletin 2005–AB–08, *Guidance on FHLBank Anti-Predatory Lending Policies*. This Bulletin establishes that each FHLBank must have in place comprehensive anti-predatory lending policies to govern the purchases of residential mortgage loans and the level of advances that can be made to its members. Although the advisory bulletin acknowledged that there is no single definition of predatory lending in federal, state, and local laws and regulations, it noted that over the preceding several years, federal, state, and local jurisdictions had adopted anti-

¹ Advisory bulletins provide guidance to the FHLBanks regarding particular supervisory issues. Although an advisory bulletin does not have the force of a regulation or an order, it is integrated into the examination programs. Advisory bulletins are effective upon issuance and remain in effect until rescinded.

² Although HERA specifically refers to the interagency guidance on nontraditional mortgage products, the FHFA believes that the issue of subprime mortgage lending is closely related. Therefore, the FHFA has expanded the scope of the study to include subprime lending.

predatory lending measures to combat abusive practices in the mortgage market.

The 2005 advisory bulletin requires that the FHLBanks' policies preclude purchasing residential mortgage loans or accepting as eligible collateral for advances loans that violate applicable federal, state, or local anti-predatory lending laws. The FHLBanks' anti-predatory lending policies must also, at a minimum, address: residential mortgage loans subject to the Home Ownership and Equity Protection Act (HOEPA), prepaid single-premium credit life or similar insurance, prepayment penalties beyond the early years of the loan, and mandatory arbitration. In addition, the FHLBanks must require each member to certify that it is aware of the FHLBanks' anti-predatory lending policies and will comply with those policies in the sale of residential mortgage loans to the FHLBank or when obtaining advances from the FHLBank. Each FHLBank must also develop written procedures and standards for verifying member compliance with its anti-predatory lending mortgage purchase and advance policies, paying particular attention to any loans that are otherwise not subject to review by a federal financial institution supervisory agency. Finally, each FHLBank must have agreements in place with its members to provide for replacement or indemnity for any loan or collateral that is found to be in noncompliance with the FHLBanks' policies. See <http://www.fhfb.gov/webfiles/4201/2005-AB-08.pdf>.

Advisory Bulletin 2007–AB–01

Issued in April 2007, Advisory Bulletin 2007–AB–01, *Nontraditional and Subprime Residential Mortgage Loans*, requires the FHLBanks to implement policies and risk management practices that establish risk limits for, and mitigation of, credit exposure on nontraditional and subprime mortgage loans. The advisory

bulletin requires that an FHLBank's policies and procedures must address how the FHLBank measures, monitors and controls risks arising from exposures to nontraditional and subprime mortgage loans. The advisory bulletin further requires that an FHLBank's policies must be discussed with and approved by its board of directors and must identify the attributes of nontraditional and subprime residential mortgage loans that have the potential for increased risk. The policies should establish limits and require regular monitoring of exposure to nontraditional and subprime residential mortgage loans, including limits and acceptable adjustments to collateral coverage requirements or "haircuts." The procedures for monitoring collateral securing advances should allow an FHLBank to identify the volume of nontraditional and subprime residential mortgage loans pledged to secure advances. Finally, the collateral review procedures should also include assessments and testing of member underwriting and monitoring of nontraditional and subprime loans and address the acceptance of MBS with nontraditional and subprime collateral. See <http://www.fhfb.gov/webfiles/6372/2007-AB-01.pdf>.

Advisory Bulletin 2008–AB–02

Issued in July 2008, Advisory Bulletin 2008–AB–02, *Application of Guidance on Nontraditional and Subprime Residential Mortgage Loans to Specific FHLBank Assets*, provides written guidance regarding residential mortgage loans purchased under the FHLBank's Acquired Member Assets programs, investments in private-label MBS, and collateral securing advances. The advisory bulletin states that residential mortgage loans that were originated or acquired by the member after July 10, 2007 may be included in calculating the amount of advances that can be made to a member only if those loans were

underwritten consistent with all aspects of the interagency guidance. The guidance in the advisory bulletin applies to whole mortgage loans and to the residential mortgage loans that underlie private-label MBS used as collateral for advances.

Further, the advisory bulletin requires the FHLBanks to take the quality control steps necessary to ensure compliance with the 2006 and 2007 interagency guidance on nontraditional and subprime mortgage loans. Those quality controls include requiring the adoption of business practices including, but not limited to: conducting due diligence on the mortgages or assets it acquires or collateralizes itself, relying on an independent third party to assess compliance, or relying on certifications, representations or warranties provided by the member. The FHLBanks may rely on representations and warranties and third-party assurances only if the FHLBank has a credible plan to test and verify their dependability. See <http://www.fhfb.gov/webfiles/6906/2008-AB-02.pdf>.

Coverage and Applicability of FHFB Guidance

According to Advisory Bulletin 2008–AB–02, in order to be eligible collateral for advances, nontraditional and subprime residential mortgage loans originated or acquired by a member after July 10, 2007—and such loans backing private-label MBS issued after that date—must conform to the interagency guidance. By adopting the effective date of the interagency guidance,³ the FHFB chose not to apply the advance collateral guidance retroactively. To have done so might have reduced access to liquidity and potentially added to the financial stress of some FHLBank member institutions at a time of increasing uncertainty in financial and housing markets.

Recap of the Three FHFB Advisory Bulletins

FHFB advisory bulletins	2005–AB–08	2007–AB–01	2008–AB–02
Anti-predatory lending policies and procedures	X		
Home Ownership and Equity Protection Act	X		
Single-premium credit life or similar insurance	X		
Prepayment penalties beyond the early loan years	X		
Mandatory arbitration	X		
Nontraditional and subprime mortgage loan risk management		X	
Mitigation of nontraditional and subprime credit exposure		X	
Nontraditional and subprime collateral limitations		X	
Compliance with interagency guidance on nontraditional and subprime mortgage lending			X
Whole loans securing advances			X
MBS with underlying applicable loans securing advances			X

³ Statement on Subprime Mortgage Lending, 72 FR 37569 (July 10, 2007).

III. HERA Section 1217 Study Resources

For purposes of the HERA Section 1217 Study, FHFA primarily relied on three resources: a collateral data survey that FHFA conducts annually, in-depth secured credit reviews performed during recent examinations, and a questionnaire related to the HERA Section 1217 issues that FHFA sent to the FHLBanks. This section describes each of these information resources.

A. Collateral Data Survey

Each year FHFA surveys the FHLBanks and prepares a report on the levels and trends in collateral securing advances by type and FHLBank. The collateral data survey collects information on the minimum levels of collateral required by the FHLBanks' policies to secure outstanding advances. The survey focuses on the minimum levels of collateral required by FHLBank policies because most FHLBanks file a blanket lien on the assets of most of their borrowing members. The volume of collateral under blanket lien, however, is generally not the most meaningful indicator of collateral protection because it does not indicate the quality or liquidity of the collateral. In general, the FHLBanks that utilize a blanket lien establish a "collateral hierarchy" in which they first consider the highest quality and most liquid collateral when calculating collateral coverage before they look to other types of collateral. Thus, for the collateral data survey, the FHLBanks report the collateral that they would rely upon first to cover any repayment shortfall resulting from member default on an outstanding advance. The FHLBanks report in the collateral data survey the levels of collateral that consists of subprime and nontraditional residential mortgage loans, and Alt-A and subprime private-label MBS.⁴ The FHLBanks may use estimates for subprime and nontraditional mortgage loan amounts when the actual data are not available for all members, such as members to which an FHLBank lends by using a blanket lien on the members' assets.

B. Secured Credit Reviews

FHFA evaluates the policies, procedures and practices of each FHLBank as part of its examination and supervision program. FHFA regulates the FHLBanks and does not, in the normal course of an examination, examine the individual loans or MBS pledged by the FHLBanks' member institutions.⁵ During examinations of the FHLBanks, FHFA evaluates the FHLBanks' collateral policies, how the FHLBank manages and secures its collateral positions, and the measures the FHLBank takes to protect itself from risk. The FHLBanks are required to have appropriate controls in place to protect their financial safety and soundness, to adhere to regulatory guidance, and to carry out their housing finance mission.

In recognition of the rapid and serious deterioration in the residential mortgage market, as part of its examination process, FHFA conducted in-depth secured credit reviews in 2008–2009, which focused on the advances and collateral policies and practices of the FHLBanks. FHFA examiners commenced the in-depth reviews with FHLBank examinations opening the second quarter of 2008, prior to the passage of HERA. The review process was designed to closely evaluate whether the FHLBanks have taken appropriate steps to control and value collateral, secure advances, and plan for the potential for member failures. The review work program covered collateral risk management in seven areas: collateral control, haircut and valuation methodologies, risk limits, member failure plans, member monitoring, insurance company members, and nontraditional and subprime mortgage loan products. The last of the in-depth secured credit reviews was completed in the second quarter of 2009.

C. HERA Section 1217 Questionnaire

To complement the existing information on FHLBank collateral and in response to Section 1217 of HERA, FHFA's Division of Federal Home Loan Bank Regulation developed the HERA Section 1217 Questionnaire and delivered it to the FHLBanks in March 2009. The Section 1217 questionnaire was used to obtain consistent

information regarding the FHLBanks' policies, procedures, and practices on nontraditional and subprime residential mortgage loans acceptable as collateral for advances, either directly or through MBS that are backed by such loans. The questionnaire also requested information on anti-predatory lending policies, procedures, and practices. The questionnaire focused on whether the loans and securities used as collateral to support FHLBank advances are consistent with the requirements of the advisory bulletins and the interagency guidance on nontraditional and subprime mortgage products and anti-predatory lending. The questionnaire was also designed to complement the in-depth secured credit reviews, particularly to gauge the extent to which the FHLBanks are addressing concerns raised in the secured credit reviews regarding the acceptance of nontraditional and subprime residential mortgage loans as collateral for advances.

IV. HERA Section 1217 Study Results

This section presents an analysis of the information obtained for the HERA Section 1217 Study through the collateral data survey, the secured credit reviews, and the follow-up questionnaire to the FHLBanks. The analysis focuses on the extent to which loans and securities used as collateral supporting FHLBank advances are consistent with the interagency guidance on nontraditional and subprime mortgage products.

A. FHLBank Collateral

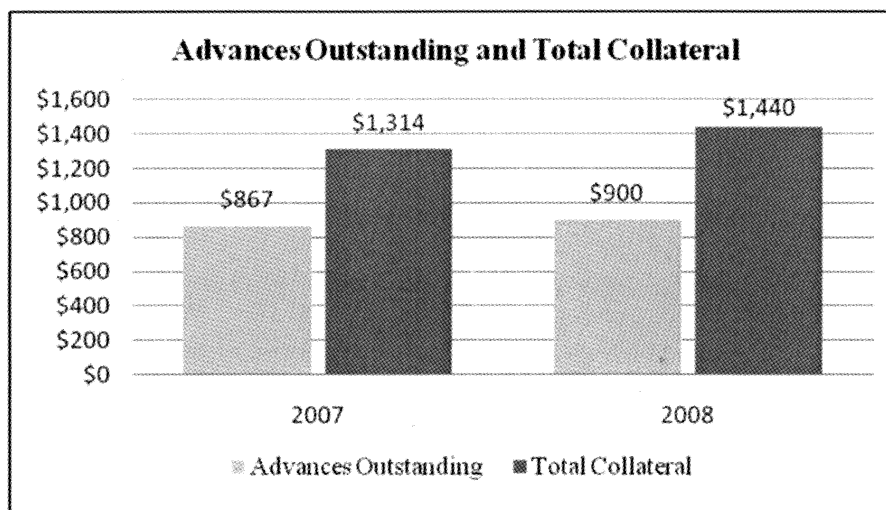
The tables below summarize information from the collateral surveys for year-ends 2007 and 2008 showing the types and amounts of collateral upon which the FHLBanks rely to secure advances. As of December 31, 2007, the par value of FHLBank advances outstanding totaled \$867 billion and the FHLBanks reported that the collateral on which they were relying to secure those advances totaled \$1.3 trillion. As of December 31, 2008, the par value of FHLBank advances outstanding increased to \$900 billion, secured by collateral totaling \$1.4 trillion.

⁴ An industry standard definition of Alt-A does not exist. Alt-A MBS have traditionally been considered to be those backed by mortgage loans to borrowers with prime credit scores but with features that included, for example, low or no borrower income or asset verification. Subprime

private-label MBS are those backed by residential mortgage loans to subprime borrowers. Since there is no industry standard for a credit score threshold under which a borrower is considered subprime, the FHLBanks may use different credit score

thresholds in reporting subprime residential mortgage loans in the survey.

⁵ The FHFA only evaluates or examines the collateral under compelling circumstances such as might be presented by large member institutions experiencing known financial stress.



From 2007 to 2008, whole loan collateral declined from \$890 billion to \$859 billion, a decrease of \$31 billion or 8 percentage points, yet whole loans

continue to comprise the majority of the collateral securing advances at the FHLBanks. During this period, MBS and other real estate related collateral grew

as a component of total collateral securing advances.

Collateral type	2007 collateral (\$ billions)	2007 (%)	2008 collateral (\$ billions)	2008 (%)
Whole Loans	\$890	67.7	\$859	59.7
Mortgage-backed Securities	195	14.8	218	15.1
Other Securities	6	0.5	17	1.2
Other Real Estate Related Collateral	213	16.2	329	22.8
Community Financial Institutions	10	0.8	17	1.2
Total Collateral	1,314	100.0	1,440	100.0

The collateral surveys for year-ends 2007 and 2008 show nontraditional and subprime residential mortgage loans declined as a proportion of the collateral on which the FHLBanks rely to secure advances. As of December 31, 2007, nontraditional and subprime residential mortgage loans represented \$410 billion or 31.2 percent of total advance collateral of \$1.3 trillion. Subprime

MBS and Alt-A MBS accounted for 3.3 percent of reported collateral. As of December 31, 2008, nontraditional and subprime residential mortgage loans represented \$267 billion or 18.5 percent of total advance collateral of \$1.4 trillion, a decline of 12.7 percentage points from 2007. Additionally, subprime MBS and Alt-A MBS represented 2.0 percent of reported

collateral, a decline of 1.3 percentage points from the previous year-end.⁶ Based on the totals reported, the FHLBanks relied on higher levels of nontraditional mortgage loan collateral than subprime mortgage loan collateral and higher levels of Alt-A MBS collateral than subprime MBS collateral.

Collateral type	2007 collateral (\$ billions)	2007 (%)	2008 collateral (\$ billions)	2008 (%)
Subprime Mortgage Loans	\$80	6.1	\$56	3.9
Nontraditional Mortgage Loans	297	22.6	186	12.9
Mortgage Loans that are both Subprime and Nontraditional	34	2.6	24	1.7
Private-label Subprime MBS	2	0.2	10	0.7
Private-label Alt-A MBS	41	3.1	19	1.3
Subtotal: Subprime/Nontraditional/Alt-A	454	34.6	295	20.5
Other Collateral	860	65.4	1,145	79.5
Total Collateral	1,314	100.0	1,440	100.0

As of December 31, 2008, collateral described as nontraditional, subprime or Alt-A accounted for about one-fifth of

the collateral securing advances at FHLBanks. This number is best understood as an approximation, given

the varying definitions of these terms in the financial industry in recent years. For example, purchasers of private-label

⁶ Percentages from the table may not sum to the exact figures reported in the text due to rounding.

MBS, including FHLBank member institutions, relied on rating agency characterization of the securities at the time of issuance. However, these designations might not capture all the variation in underlying loans within a given security nor would they reflect any subsequent deterioration in the quality of the underlying collateral.

Some portion of collateral described as nontraditional, subprime or Alt-A was originated or purchased prior to July 10, 2007, and therefore, under the guidance in FHFB's advisory bulletins, is not required to conform to the interagency guidance. The collateral survey does not contain information sufficient to allow FHFA to determine how much of the collateral would be subject to the interagency guidance. However, the FHFB guidance does require the FHLBanks to have policies in place to ensure that subprime and nontraditional loans that were originated or acquired by the FHLBank member subsequent to the issuance of the interagency guidance and certain effective dates in the FHFB advisory bulletins may not be pledged as collateral for advances if they do not conform to the guidance.

B. FHLBank Policies and Procedures Regarding Nontraditional and Subprime Collateral—Findings From the Secured Credit Reviews

As part of its examination process, FHFA conducted in-depth reviews of the FHLBanks' policies and procedures regarding secured credit. One part of FHFA's in-depth reviews of secured credit focused directly on subprime lending and nontraditional loan products. Other aspects of the secured credit reviews that are relevant for this study included collateral control, member monitoring, and haircut and valuation methodologies.

Although the reviews found that the FHLBanks had policies regarding the acceptance of subprime and nontraditional loans as collateral for advances, examiners questioned, in some cases, the appropriateness of the policies and implementing procedures and practices. In addition, a number of FHLBanks had difficulty determining their exposure to nontraditional and subprime residential mortgage loan collateral used to support FHLBank advances. Examiners identified weaknesses in FHLBanks' assessments and testing of member underwriting and monitoring of nontraditional and subprime loans, haircuts and discounts for nontraditional and subprime collateral, risk limits on the acceptance of these types of collateral, and board reporting of exposures to the collateral.

Specifically, examiners noted the following:

- Five FHLBanks did not require an assessment of member underwriting of nontraditional or subprime loans to ensure consistency with interagency guidance as part of their onsite collateral review procedures. Of the remaining FHLBanks, three did not consistently document their review of member underwriting of nontraditional or subprime loans.
- Three FHLBanks lacked analytical support or validation for haircuts used for subprime and nontraditional mortgage products. Two FHLBanks did not have differentiated haircuts for conventional mortgage loan collateral and nontraditional and subprime mortgage loan collateral.
- Four FHLBanks did not have risk limits on the volume of nontraditional and subprime mortgage loan collateral that members may pledge to support FHLBank advances.
- Three FHLBanks did not regularly report exposures of nontraditional and subprime collateral to their boards of directors.

FHFA examination staff communicated these weaknesses and expectations for corrective action to executive management and the boards of directors of the individual FHLBanks. Each FHLBank receiving regulatory criticisms of its policies committed to correct the weaknesses, and the examination staff has begun evaluating the FHLBanks' corrective actions through follow-up visitations and examinations. FHLBanks that have not adequately addressed the weaknesses identified during the secured credit reviews will be subject to a commensurately stricter supervisory response. Unsatisfactory remediation of adverse examination findings would be a factor that FHFA considers when determining whether formal supervisory enforcement actions would be warranted in the future.

C. Responses to the HERA Section 1217 Questionnaire

The Section 1217 Questionnaire complements and in some cases updates the information from the in-depth secured credit reviews. The responses provide the FHLBanks' perspectives on a consistent set of questions. During on-site examinations, FHFA will review documents and independently evaluate the FHLBanks' policies, procedures and practices. FHFA will draw final conclusions about the FHLBanks' progress in addressing criticisms from the secured credit reviews and in adhering to the advisory bulletins related to the interagency guidance after

completion of the next annual examinations of the FHLBanks.

1. Do the FHLBanks have policies that exclude from eligible collateral for advances residential mortgage loans and MBS backed by such loans that do not conform to the interagency guidance?

Nine of the twelve FHLBanks have board-approved policies to exclude from eligible collateral for advances nontraditional and subprime residential mortgage loans originated or acquired by the member after July 10, 2007 that do not conform to the interagency guidance, as well as private-label MBS issued after July 10, 2007, with underlying nontraditional or subprime residential mortgage loans that do not conform to the interagency guidance. The other three FHLBanks have adopted policies addressing, but not specifically excluding, the acceptance of applicable nontraditional and subprime residential mortgage loans or private-label MBS used as collateral for advances.

2. Do the FHLBanks require members to certify that residential mortgage loans used to calculate eligible collateral comply with the interagency guidance and obtain and provide to the FHLBank certifications from securities issuers that loans underlying private-label MBS serving as collateral conform to the interagency guidance?

All of the FHLBanks' policies require members to certify that the nontraditional and subprime residential mortgage loans used to calculate eligible collateral comply with the interagency guidance. One FHLBank, however, requires the certification regarding subprime residential mortgage loans only from members with established subprime lending programs.⁷ Nine FHLBanks require that members pledging private-label MBS certify or deliver to the FHLBank enforceable representations and warranties from the issuer or other credible evidence indicating that the loans backing the MBS comply with the interagency guidance. The remaining FHLBanks do not accept as eligible collateral for advances private-label MBS issued after July 10, 2007 that is collateralized by nontraditional and subprime residential mortgage loans.

⁷ FHFA established that for purposes of determining collateral eligibility the interagency guidance should apply regardless of whether a member has a subprime lending program. FHFA is addressing this matter with the FHLBank.

3. Do the FHLBanks evaluate, test, and validate member and issuer certifications?

To evaluate and test member certifications regarding the conformance of nontraditional and subprime residential mortgage loan collateral to the interagency guidance, the FHLBanks review members' underwriting policies, verify loan documentation on-site at members, or review members' internal or external examination reports.⁸ Regarding validation of certifications from securities issuers that loans underlying private-label MBS originated after July 10, 2007 conform to the interagency guidance, the FHLBanks commonly responded that although they adopted policies to require such certifications, members have not been able to obtain and provide them. Therefore, as a practical matter, the FHLBanks have not accepted private-label MBS originated after July 10, 2007 as collateral for advances.

4. Do the FHLBanks have in place policies and procedures that preclude the acceptance of residential mortgage loans with predatory characteristics as collateral for advances?

All FHLBanks have anti-predatory lending policies or procedures that preclude acceptance as eligible collateral for advances residential mortgage loans that violate applicable federal, state, or local predatory lending laws and other similar credit-related consumer protection laws. In addition, each of the FHLBanks specifically excludes from eligible collateral loans which: have an annual percentage rate or charge points or fees which exceed the thresholds established by HOEPA; include requirements for prepaid, single-premium credit life insurance; include a fee or charge for prepayment beyond the early years of a loan; or require mandatory arbitration to resolve disputes. Seven of the FHLBanks define "early years" for permissible prepayments as a period of five years. Five FHLBanks qualify their collateral ineligibility standard related to mandatory arbitration as a loan requiring mandatory arbitration that is prohibited by any applicable anti-predatory lending laws. One FHLBank qualifies its collateral ineligibility standard related to prepayment penalties as a loan including prepayment fees beyond the early years of the loan to the extent prohibited or

limited by any applicable anti-predatory lending laws. The FHLBanks perform procedures to evaluate and test member underwriting of collateral that are similar to those outlined above for nontraditional and subprime residential mortgage loans.

V. Conclusions and Recommendations

Approximately one-fifth of the collateral supporting FHLBank advances consists of subprime or nontraditional loans or Alt-A or subprime private-label MBS. Although a significant share of the loans or MBS in these categories may have been originated or issued prior to July 10, 2007, and thus not technically subject to the interagency guidance, the FHLBanks still need to manage and mitigate the risks associated with all of the collateral underlying advances. Going forward, the FHLBanks will need to ensure that the collateral supporting advances remains consistent with safety and soundness as well as the overarching housing finance mission of the FHLBanks.

Although all FHLBanks had policies addressing nontraditional and subprime collateral, findings from the in-depth secured credit reviews revealed some weaknesses in policies and practices, particularly in regard to the management of the risks of this type of collateral. The FHLBanks' responses to the HERA Section 1217 Questionnaire indicate that they have adopted policies, procedures, and practices that would require that the loans and MBS used as collateral to support advances be consistent with the interagency guidance. The next cycle of examinations will evaluate whether weaknesses that examiners previously identified in the FHLBanks' policies and practices for subprime and nontraditional residential mortgage loans have been corrected and verify their responses to the HERA Section 1217 Questionnaire regarding application of the principles of the interagency guidance to the acceptance of collateral used to support advances. Through its supervisory programs, FHFA will continue to assess the adequacy of the FHLBank's policies and procedures, determine weaknesses or deficiencies, and monitor the FHLBanks' remediation efforts.

The advisory bulletins issued by FHFB on the subjects of nontraditional and subprime mortgage loans and predatory lending between 2005 and 2008 provide explicit guidance for the FHLBanks. Adoption of the policies and practices expected by the guidance has received and will continue to receive focused attention through supervisory programs and particularly as part of

FHFA's examinations of the FHLBanks. FHFA uses the information obtained through its supervisory program of examinations, targeted reviews and surveys, and off-site monitoring to develop appropriate guidance to facilitate the FHLBanks' mission of providing liquidity to its members. For example, FHFA's Division of Federal Home Loan Bank Regulation has recently prepared guidance for examiners to address questions that the FHLBanks have asked when developing policies and procedures to implement the guidance contained in the advisory bulletins.

FHFA intends to reevaluate whether additional guidance or rules are necessary for the FHLBanks regarding anti-predatory lending or the acceptance of nontraditional or subprime residential mortgages as collateral for advances after the completion of the next cycle of examinations, which will determine if the FHLBanks have appropriately addressed attendant weaknesses identified by the in-depth secured credit reviews that began in 2008. At a minimum, FHFA expects to clarify one point made in Advisory Bulletin 2008-AB-02. The advisory bulletin states that residential mortgage loans underlying private-label MBS issued after July 10, 2007, must conform to the interagency guidance, but it is silent about MBS issued before that date that a member may acquire after that date. FHFA intends to clarify that MBS purchased by a member after July 10, 2007, is also subject to the guidance contained in Advisory Bulletin 2008-AB-02.

Since the passage of HERA, there have been several legislative developments addressing mortgage lending reform. FHFA is following these developments and intends to update its regulations and guidance, as appropriate, as issues surface in the legislative discussion. FHFA especially notes the provision in the Mortgage Reform and Anti-Predatory Lending Act recently passed by the House of Representatives that adopts a borrower's ability to repay as a minimum standard defined in the law; comments are invited on a question related to the concept of a borrower's ability to repay in the request for comments below.

VI. Request for Comments

FHFA welcomes comments on all aspects of the HERA Section 1217 Study presented in this Notice. FHFA invites comments on the following questions, in particular:

- Should FHFA replace its existing guidance on nontraditional, subprime,

⁸ The results of the secured credit reviews indicate that the quality of the FHLBanks' evaluations of member underwriting and certifications is uneven. FHFA examination staff is addressing identified issues with the FHLBanks.

or anti-predatory lending with formal regulatory standards?

- Does any guidance contained in Advisory Bulletins 2005–AB–08, 2007–AB–01, and 2008–AB–02 need additional emphasis or clarification?

- Should FHFA explicitly address other mortgage loan features as a control against predatory lending, or is it sufficient that Advisory Bulletin 2008–AB–02 requires an FHLBank to only accept residential mortgage loans (and such loans backing private-label MBS) as eligible collateral for advances when they conform to the interagency guidance? Some loan features that may be associated with either high risk or potentially predatory loans are addressed in the Federal Reserve Board's Amendments to Regulation Z (Truth in Lending) which will go into effect later in 2009 and 2010. For "higher-priced mortgages," the amended regulation addresses a borrower's ability to repay the loan, prepayment penalties, income verification, and escrow accounts.

- Should FHFA seek any additional statutory authority to support its ability to prohibit an FHLBank from accepting loans with predatory characteristics as collateral for advances?

- As the federal financial institution regulatory agencies, such as through the Federal Financial Institutions Examination Council, look to modify or enhance guidance with respect to nontraditional or subprime mortgage products, should FHFA be formally and directly involved?

Copies of all comments will be posted without change, including any personal information you provide, such as your name and address, on the FHFA internet web site at <http://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Federal Housing Finance Agency, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414–3751.

Dated: July 29, 2009.

James B. Lockhart III,

Director, Federal Housing Finance Agency.

[FR Doc. E9–18545 Filed 8–3–09; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

Arbitration Services; Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Notice to Mediation Agencies (Form F–7) Proposed Modifications.

SUMMARY: This notice announces that the Federal Mediation and Conciliation Service (FMCS) agency form F–7 is being revised. Following publication of this Notice and any responsive comments, FMCS will submit to the Office of Management and Budget (OMB) a request for review of this Notice to Mediation Agencies (Agency Form F–7) form. The request will seek OMB approval of a modified Form F–7 and new expiration date of approximately October 1, 2012. FMCS is soliciting comments on specific aspects of the collection as described below.

DATES: Comments must be submitted on or before September 3, 2009.

ADDRESSES: Submit written comments by mail to the Office of Arbitration Services, Federal Mediation and Conciliation Service, 2100 K Street, NW., Washington, DC 20427 or by contacting the person whose name appears under the section headed **FOR FURTHER INFORMATION CONTACT**. Comments may be submitted also by fax at (202) 606–3749 or electronic mail (e-mail) to arbitration@fmcs.gov. All comments must be identified by the appropriate agency form number. No confidential business information (CBI) should be submitted through e-mail. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of the information as "CBI." Information so marked will not be disclosed but a copy of the comment that does contain CBI must be submitted for inclusion in the public record. FMCS may disclose information not marked confidential publicly without prior notice. All written comments will be available for inspection in Room 704 at the Washington, DC address above from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Vella M. Traynham, Director of Arbitration Services, FMCS, 2100 K Street, NW., Washington, DC 20427. Telephone (202) 606–5111; Fax (202) 606–3749.

SUPPLEMENTARY INFORMATION: Copies of the modified Form F–7 are available from the Office of Arbitration Services

by calling, faxing or writing Vella M. Traynham at the address above. Please ask for the form by title and agency form number.

I. Information Collection Requests

FMCS is seeking comments on the following Information Collection Request (ICR).

Title: Notice to Mediation Agencies; Form F–7; OMB No. 3076–0004;

Expiration Date: January 31, 2006.

Type of Request: Reinstatement of a previously approved notice with changes in the substance of the form.

Affected Entities: Parties affected by this information collection are private sector employers and labor unions involved in interstate commerce that file notices for mediation services to the FMCS.

Frequency: Parties complete this form once, which is at the time of an impending expiration of a collective bargaining agreement.

Abstract: Under the Labor Management Relations Act of 1947, 29 U.S.C. 158(d), Congress listed specific notice provisions so that no party to a collective bargaining agreement can terminate or modify that contract, unless the party wishing to terminate or modify the contract sends a written notice to the other party sixty days prior to the expiration date (29 U.S.C. 158(d)(1)), and offers to meet and confer with the other party for the purpose of negotiating a new or modified contract (29 U.S.C. 158(d)(2)). Furthermore, the Act requires that parties notify the Federal Mediation and Conciliation Service within thirty days after such notice of the existence of a bargaining dispute (29 U.S.C. 158(d)(3)). The 1974 amendments to the National Labor Relations Act, which extended coverage to nonprofit health care institutions, also created a notification procedure in the health care industry requiring parties to notify each other 90 days in advance of termination and 60 days in advance to FMCS (29 U.S.C. 158(d)). This amendment also requires 30-day notification of bargaining for an initial agreement to the FMCS. To facilitate handling of more than 18,000 such notices a year, FMCS created a specific information collection form. The purpose of this information collection activity is for FMCS to comply with its statutory duty to receive these notices, to facilitate assignment of mediators to assist in labor disputes, and to assist the parties in knowing whether or not proper notice was given. The information from these notices is sent electronically to the appropriate field manager who assigns the cases to a mediator so that the mediator may

contact labor and management quickly, efficiently, and offer dispute resolution services. Either party to a contract may make a request in writing for a copy of the notice filed with FMCS. The F-7 form was created to allow FMCS to gather desired information in a uniform manner. The collection of such information, including the name of the employer or employer association, address and phone number, e-mail address, official contact, bargaining unit and establishment size, location of affected establishment and negotiations, industry, union address, phone number, e-mail address and official contact, contract expiration date or renewal date, whether the notice is filed on behalf of the employer or the union, and whether this is a health care industry notice is critical for reporting and mediation purposes.

Burden Statement: The current annual burden estimate is approximately 18,000 respondents. This one-page form takes about 10 minutes to complete.

II. Request for Comments

FMCS solicits comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information to be collected will have practical utility.

(ii) Enhance the accuracy of the agency's estimates of the burden of the proposed collection of information.

(iii) Enhance the quality, utility, and clarity of the information to be collected.

(iv) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic collection technologies or other forms of information technology.

III. The Official Record

The official record is the paper electronic record maintained at the address at the beginning of this document. FMCS will transfer all electronically received comments into printed-paper form as they are received.

Dated: July 30, 2009.

Michael J. Bartlett,

Deputy General Counsel.

[FR Doc. E9-18579 Filed 8-3-09; 8:45 am]

BILLING CODE 6732-01-P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12:00 p.m., Monday, August 10, 2009.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT:

Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202-452-2955.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, July 31, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E9-18757 Filed 7-31-09; 4:15 pm]

BILLING CODE 6210-01-S

FEDERAL MARITIME COMMISSION

[Docket No. 09-05]

Application of Leonardo Ortiz for Admission To Practice Before the Federal Maritime Commission; Order Initiating Proceeding

On December 31, 2007, Respondent Leonardo Ortiz ("Mr. Ortiz") filed his Application for Admission to Practice before the Federal Maritime Commission ("Form FMC-12"). According to his application, Mr. Ortiz is self-employed. His business is located at 4324 Belton Highway, Anderson, SC 29621.

The Federal Maritime Commission ("Commission") allows for attorney and non-attorney practitioners. In order to be admitted to practice before the

Commission as a non-attorney, Rule 27 of the Commission's Rules of Practice and Procedure, 46 CFR § 502.27, requires that the applicant file proof that he or she possesses, to the satisfaction of the Commission, "the necessary legal, technical, or other qualifications to render valuable service before the Commission and is otherwise competent to advise and assist in the presentation of matters before [it]." Further, if the Commission is not satisfied that the applicant has sufficient qualifications, it will notify the applicant and, if requested, the applicant will be granted a hearing "for the purpose of showing his or her qualifications." 46 CFR 502.29.

After reviewing his application, the Commission determined that Mr. Ortiz did not demonstrate that he possesses the qualifications required to practice before the Commission.¹ On April 15, 2009, the Secretary of the Commission notified Mr. Ortiz of the Commission's intent to deny his application for admission to practice before it and the procedures permitting a request for a hearing. On April 29, 2009, Mr. Ortiz filed his request for a hearing on the issue.

Now therefore, it is ordered that pursuant to Rule 29 of the Commission's Rules of Practice and Procedure, 46 CFR 502.29, the Commission institute a proceeding for the purpose of allowing Mr. Ortiz to show his qualifications to practice before it as a non-lawyer;

It is further ordered that this matter be heard before the Commission;

It is further ordered that this proceeding is limited to the submission of affidavits of fact and memoranda of law;

It is further ordered that any person having an interest and desiring to intervene in this proceeding shall file a petition for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 CFR 502.72. Such petition shall be accompanied by the petitioner's memorandum of law and affidavit of fact, if any, and shall be filed no later than the day fixed below;

It is further ordered that Leonardo Ortiz is named as Respondent in this proceeding. Affidavits of fact and memoranda of law shall be filed by the Respondent and any intervenors in support of the Respondent no later than September 4, 2009;

¹ Pursuant to 46 CFR 501.24(a), the Commission has delegated to the Secretary the authority to approve applications for permission to practice before the Commission and to issue admission certificates to approved applicants.

It is further ordered that the Commission's Bureau of Enforcement be made a party to this proceeding;

It is further ordered that rebuttal affidavits and memoranda of law shall be filed by the Bureau of Enforcement and any intervenors in opposition to the Respondent no later than October 5, 2009;

It is further ordered that reply affidavits and memoranda of law shall be filed by the Respondent and intervenors in support no later than October 20, 2009;

It is further ordered that:

(a) Should any party believe that an evidentiary hearing is required, that party must submit a request for such a hearing together with a statement setting forth in detail the facts to be proved, the relevance of those facts to the issues in this proceeding, a description of the evidence which would be adduced, and why such evidence cannot be submitted by affidavit;

(b) Should any party believe that an oral argument is required, that party must submit a request specifying the reasons therefor and why argument by memorandum is inadequate to present the party's case; and

(c) Any request for evidentiary hearing or oral argument shall be filed no later than October 5, 2009;

It is further ordered that notice of this proceeding be published in the **Federal Register** and that a copy thereof be served upon Respondent at his last known address;

It is further ordered that all documents submitted by any party of record in this proceeding shall be filed in accordance with Rule 118 of the Commission's Rules of Practice and Procedure, 46 CFR 502.118, as well as being mailed directly to all parties of record;

Finally, it is ordered that pursuant to the terms of Rule 61 of the Commission's Rules of Practice and Procedure, 46 CFR 502.61, the final decision of the Commission in this proceeding shall be issued by February 17, 2010.

By the Commission.

Karen V. Gregory,
Secretary.

[FR Doc. E9-18601 Filed 8-3-09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declarations Regarding Emergency Use of Certain *In vitro* Diagnostic, Antiviral, and Personal Respiratory Products Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 360bbb-3(b)(4). On April 26, 2009, the Acting Secretary of HHS determined that a public health emergency exists nationwide involving Swine Influenza A (now known as 2009-H1N1 Influenza A, or 2009-H1N1 influenza) that affects or has significant potential to affect national security. On the basis of this determination, on April 26 and April 27, 2009, the Acting Secretary declared emergencies justifying the authorization of emergency use of certain *in vitro* diagnostic, antiviral, and personal respiratory protection products accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs (Commissioner) under 21 U.S.C. 360bbb-3(a). The Acting Secretary also specified that these declarations are declarations of emergency as defined by former Secretary Michael O. Leavitt in the October 10, 2008 Declaration under the Public Readiness and Emergency Preparedness (PREP) Act for Influenza Antivirals Oseltamivir Phosphate and Zanamavir, as amended, and the December 17, 2008 Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices.

DATES: The declaration of an emergency justifying the authorization of emergency use of certain *in vitro* diagnostic products is effective April 26, 2009. The declaration of an emergency justifying the authorization of certain antiviral products is effective April 26, 2009. The declaration of an emergency justifying the authorization of emergency use of certain respiratory protection products is effective April 27, 2009.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., MSPH, Assistant Secretary for Preparedness and

Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FFDCA, the Commissioner, acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product, or an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare an emergency justifying the authorization based on one of three determinations: a determination of a domestic emergency, or a significant potential for a domestic emergency, by the Secretary of Homeland Security; a determination of a military emergency, or a significant potential for a military emergency, by the Secretary of Defense; or a determination of a public health emergency by the Secretary of HHS. See 21 U.S.C. 360bbb-3(b)(1). In the case of a determination by the Secretary of HHS (as was made here), the Secretary must determine that a public health emergency exists under section 319 of the Public Health Service (PHS) Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. Based on such a determination, the Secretary of HHS may then declare an emergency that justifies the EUA, at which point the Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FFDCA are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the Food and Drug Administration (FDA) issue EUAs for certain *in vitro* diagnostic, antiviral, and personal respiratory protection products accompanied by emergency use information. The determination of a public health emergency by the Acting Secretary of HHS and the declarations of an emergency by the Acting Secretary of HHS based on that determination, as described below, enabled the Acting Commissioner to issue EUAs for certain *in vitro* diagnostic, antiviral, and personal respiratory protection products

for emergency use under section 564(a) of the FFDCA, 21 U.S.C. 360bbb-3(a).

An *in vitro* diagnostic, CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel), is cleared by FDA for detection of seasonal Influenza A and subtype determination. CDC sought an EUA to allow this test to be used with specimen types and reagents additional to those of the cleared test as a first tier test for patients suspected of having 2009-H1N1 influenza. CDC also sought an EUA to allow an *in vitro* diagnostic that has not been previously approved or cleared by the FDA, Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel), to be used in detecting 2009-H1N1 influenza.

CDC also sought EUAs for certain antiviral drug products, which are approved by FDA for use in treatment and prophylaxis of influenza for adult and pediatric use. Relenza® (zanamivir) is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older. Tamiflu® (oseltamivir phosphate) is approved for the treatment of acute uncomplicated illness due to influenza in patients 1 year and older who have been symptomatic for less than two days, and for the prevention of influenza in patients 1 year and older. The EUA for Tamiflu allows for Tamiflu to also be used to treat and prevent influenza in children under one year, to treat influenza in patients who have been symptomatic for more than 2 days, and to provide alternate dosing recommendations for certain pediatric populations. The EUA for Tamiflu also authorizes distribution of Tamiflu deployed from the Strategic National Stockpile (SNS) and that has had its expiration date extended under the Federal government's Shelf Life Extension Program (SLEP). In addition, under the EUAs, both Tamiflu and Relenza may be distributed to large segments of the population without complying with certain prescription label requirements otherwise applicable to dispensed drug. Under the EUAs, Tamiflu and Relenza are authorized to be accompanied by certain written information pertaining to the emergency. The EUAs note that there may be distribution of these products by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable State and local laws and/or the public health and medical

emergency response of the authority having jurisdiction, subject to the terms and conditions of the EUA.

Finally, certain personal respiratory protection devices certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95 (known as N95 respirators) have been cleared by FDA for use by the general public in public health medical emergencies, such as an influenza pandemic. Other N95 respirators have been cleared by FDA for use in certain workplace settings. The disposable N95 respirators for which CDC sought an EUA were either not previously cleared or approved by FDA or were cleared by FDA but only for use in certain workplace settings. The EUA authorized the emergency use, by the general public,¹ of these products, as deployed from the SNS and accompanied by emergency use information, to help reduce wearer exposure to airborne germs during this emergency. The specific products covered by the EUA are identified in the EUA by manufacturer and model number; fifteen different models of disposable N95 respirators are covered.

With issuance of the EUAs for certain *in vitro* diagnostic products, laboratories may receive certain *in vitro* diagnostics covered by the EUAs for use in detection of 2009-H1N1 influenza, and patients and health care professionals may receive emergency use information regarding these *in vitro* diagnostic products during this public health emergency involving 2009-H1N1 influenza. With issuance of the EUAs for certain antiviral products and issuance of the EUA for certain personal respiratory products, members of the general public may receive certain antiviral and personal respiratory protection products covered by the EUAs, accompanied by emergency use information, for immediate use by them during this 2009-H1N1 influenza emergency. These products and accompanying information may help to detect the spread of 2009-H1N1 influenza, protect individuals against contracting 2009-H1N1 influenza, and treat individuals who are ill following exposure to 2009-H1N1 influenza.

¹For purposes of this EUA, the term "general public" is broad and includes people performing work-related duties. This EUA affects only requirements applicable under the Federal Food, Drug, and Cosmetic Act. It does not affect requirements arising from other sources of law, such as Occupational Safety and Health Administration (OSHA) requirements.

In this public health emergency involving 2009-H1N1 influenza, time is of the essence in detecting, preventing, and treating illness and death by getting *in vitro* diagnostic, antiviral and personal respiratory protection products, accompanied by emergency use information, to the general public, laboratories, and public health and health care professionals. By distributing certain *in vitro* diagnostic products accompanied by emergency use information, public health and health care professionals can ensure that spread of the 2009-H1N1 influenza is quickly and accurately detected. By dispensing certain personal respiratory products accompanied by emergency use information, the appropriate State and/or public health authority(ies) can ensure that the products are provided quickly, as appropriate, to help reduce wearer exposure to airborne germs. By dispensing certain antiviral products accompanied by emergency use information, public health and medical professionals and the authorities having jurisdiction to respond to the emergency in each locality can ensure that the products are provided quickly, as appropriate, to those who may have been exposed or are ill, accompanied by the information most important to their emergency use.

This is one part of the Federal Government's strategy to encourage preparedness at all levels of government to enable the nation to respond effectively in response to this public health emergency.

II. Determination of the Acting Secretary of Health and Human Services

On April 26, 2009, pursuant to section 564(b)(1)(C) of the FFDCA, 21 U.S.C. 360bbb-3(b)(1)(A), and section 319 of the PHS Act, 42 U.S.C. 247d, the Acting Secretary of HHS determined, as a consequence of confirmed cases of Swine Influenza A (swH1N1) (now called "2009-H1N1 influenza") in California, Texas, Kansas, and New York, and after consultation with public health officials as necessary, that a public health emergency exists nationwide involving 2009-H1N1 influenza that affects or has significant potential to affect national security.

III. Declarations of the Acting Secretary of Health and Human Services

On April 26, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving 2009-H1N1 influenza that affects or has significant

potential to affect national security, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain *in vitro* diagnostics for detection of Swine Influenza A (now called "2009-H1N1 influenza") accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, published at 73 FR 78362 (December 22, 2008).

Also, on April 26, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving Swine Influenza A that affects or has significant potential to affect national security, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals oseltamivir phosphate and zanamivir accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the October 10, 2008, Declaration under the PREP Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir, published at 73 FR 61861 (October 17, 2008), as amended. The Acting Secretary's April 26, 2009, amendment to the October 10, 2008 Declaration under the PREP Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir is separately published elsewhere in this issue of the **Federal Register**.

On April 27, 2009, on the basis of the Acting Secretary's determination on April 26, 2009, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. 247d, that a public health emergency exists involving Swine Influenza A that affects, or has significant potential to affect, national security; and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain personal

respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). The Secretary further specified that the declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the PREP Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 FR 78362 (December 22, 2008).

Notice of the authorizations issued by the FDA Commissioner under 21 U.S.C. 360bbb-3 is provided elsewhere in this **Federal Register**.

Dated: July 28, 2009.

Kathleen Sebelius,
Secretary.

[FR Doc. E9-18432 Filed 8-3-09; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office for Civil Rights; Delegation of Authority

Notice is hereby given, that I have delegated to the Director of the Office for Civil Rights (OCR), with authority to redelegate, the following authority vested in the Secretary of Health and Human Services:

1. The authority under section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, as amended, to the extent that these actions pertain to the "Security Standards for the Protection of Electronic Protected Health Information," at 45 CFR part 160 and part 164, subparts A and C, to

A. Impose civil money penalties under section 1176 of the Social Security Act for a covered entity's failure to comply with certain requirements and standards;

B. Issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply with certain requirements and standards; and

C. Make exception determinations, under section 1178(a)(2)(A) of the Social Security Act, concerning when provisions of State laws that are contrary to the Federal standards are not preempted by the Federal provisions.

2. The authority under section 262 of HIPAA, as amended, to administer the regulation "Security Standards for the Protection of Electronic Protected

Health Information," at 45 CFR part 160 and part 164, subparts A and C, and General Administrative Requirements, 45 CFR Part 160, as these requirements pertain to part 164, subparts A and C, and to make decisions regarding the interpretation and enforcement of these Standards and General Administrative Requirements.

This delegation shall be exercised under the Department's existing delegation of authority and policy relating to regulations.

This delegation supersedes the memorandum from the Secretary to the Administrator, Centers for Medicare & Medicaid Services, dated October 7, 2003, titled "Delegation of Authority for Certain Provisions Under Part C of Title XI of the Social Security Act."

I hereby affirm and ratify any actions taken by the Director of OCR or his/her subordinates which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: July 27, 2009.

Kathleen Sebelius,
Secretary.

[FR Doc. E9-18557 Filed 8-3-09; 8:45 am]

BILLING CODE 4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Implementation of Section 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA) for Adjustments to the Third Quarter of Fiscal Year 2009 Federal Medical Assistance Percentage (FMAP) Rates for Federal Matching Shares for Medicaid and Foster Care and Adoption Assistance

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period describes the methodology for calculating the higher federal matching funding that is made available under Section 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA). Section 5001 of the ARRA provides for temporary increases in the Federal Medical Assistance Percentage (FMAP) rates to provide fiscal relief to States and to protect and maintain State Medicaid programs in a period of economic downturn. The increased FMAP rates apply during a recession adjustment period that is defined as the period beginning on October 1, 2008 and ending on December 31, 2010.

EFFECTIVE DATE: The percentages listed are for the third quarter of Fiscal Year 2009 beginning April 1, 2009 and ending June 30, 2009.

Comment Date: To be assured consideration, comments must be received at the address provided below, no later than 5 p.m. on August 19, 2009.

ADDRESSES: Because of staff and resource limitations, we can only accept comments by regular mail. You may mail written comments (one original and one copy) to the following address only: Department of Health and Human Services, Room 447D, *Attention:* FMAP Notice—ARRA, 200 Independence Ave., SW., Washington, DC 20201.

Submitting Comments: We welcome comments from the public on the calculation methodology set forth in this notice with comment period to assist us in fully considering issues and developing policies. Please provide a reference to the section on which you choose to comment.

A. Background

The Federal Medical Assistance Percentage (FMAP) is used to determine the amount of Federal matching for specified State expenditures for assistance payments under programs under the Social Security Act. Sections 1905(b) and 1101(a)(8)(B) of the Social Security Act ("the Act") require the Secretary of Health and Human Services to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas set forth in sections 1905(b) and 1101(a)(8)(B), from the Department of Commerce's statistics of average income per person in each State and for the Nation as a whole. The percentages must be within the upper and lower limits given in section 1905(b) of the Act. The percentages to be applied to the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 States.

Section 1905(b) of the Social Security Act specifies the formula for calculating FMAP as follows:

The FMAP for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the FMAP shall in no case be less than 50 per centum or more than 83 per centum, and (2) the FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern

Mariana Islands, and American Samoa shall be 50 per centum. Section 4725 of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the FMAP for the District of Columbia for purposes of titles XIX (Medicaid) and XXI (CHIP) shall be 70 percent.

Section 5001 of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) provides for a temporary increase in FMAP rates for Medicaid, Foster Care and Adoption Assistance programs. The purposes of the increases to the FMAP rates are to provide fiscal relief to States and to protect and maintain State Medicaid programs in a period of economic downturn, referred to as the "recession adjustment period." The recession adjustment period is defined as the period beginning on October 1, 2008 and ending on December 31, 2010.

B. Calculation of the Increased FMAP Rates Under ARRA

Section 5001 of the ARRA specifies that the FMAP rates shall be temporarily increased for the following: (1) Maintenance of FMAP rates for fiscal year 2009, fiscal year 2010, and first quarter of fiscal year 2011, so that the FMAP rate will not decrease from the prior year, determined by using as the FMAP rate for the current year the greater of any prior fiscal year FMAP rates between 2008–2010 or the rate calculated for the current fiscal year; (2) in addition to any maintenance increase, the application of an increase in each State's FMAP of 6.2 percentage points; and (3) an additional percentage point increase based on the State's increase in unemployment during the recession adjustment period. The resulting increased FMAP cannot exceed 100 percent. Each State's FMAP will be recalculated each fiscal quarter beginning October 2008. Availability of certain components of the increased FMAP is conditioned on States meeting statutory programmatic requirements, such as maintenance of effort requirements, which are not part of the calculation process.

Expenditures for which the increased FMAP is not available under title XIX include expenditures for disproportionate share hospital payments, certain eligibility expansions, services received through an IHS or tribal facility (which are already paid at a rate of 100 percent which is not subject to increase), and expenditures that are paid at an enhanced FMAP rate. The increased FMAP is also not available for payments under title XXI. The increased FMAP is available for expenditures under part E of title IV (Foster Care Maintenance payments)

only to the extent of maintenance increase, if any, and the 6.2 percentage point increase.

For each qualifying State with an unemployment rate that has increased at a rate above a statutory threshold percentage, ARRA provides additional relief above the general 6.2 percentage point increase in FMAP through application of a different increase calculation. For those States, the FMAP for each qualifying State is increased by the number of percentage points equal to the product of the State matching percentage (as calculated under section 1905(b) and adjusted if necessary for the maintenance of FMAP without reduction from the prior year, and after applying half of the 6.2 percentage point general increase in the federal percentage) and the applicable percent determined from the State unemployment increase percentage for the quarter, in addition to the 6.2 percentage point increase.

The unemployment increase percentage for a calendar quarter is equal to the number of percentage points (if any) by which the average monthly unemployment rate for the State in the most recent previous 3-consecutive-month period for which data are available exceeds the lowest average monthly unemployment rate for the State for any 3-consecutive-month period beginning on or after January 1, 2006 and preceding the most recent previous 3-consecutive-month period. A State qualifies for additional relief based on an increase in unemployment if that State's unemployment increase percentage is at least 1.5 percentage points.

The applicable percent is: (1) 5.5 percent if the State unemployment increase percentage is at least 1.5 percentage points but less than 2.5 percentage points; (2) 8.5 percent if the State unemployment increase percentage is at least 2.5 percentage points but less than 3.5 percentage points; and (3) 11.5 percent if the State unemployment increase percentage is at least 3.5 percentage points.

If the State's applicable percent is less than the applicable percent for the preceding quarter, then the higher applicable percent shall continue in effect for any calendar quarter beginning on January 1, 2009 and ending before July 1, 2010.

Puerto Rico, the Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa can make a one-time election between (1) A 30 percent increase in their cap on Medicaid payments (as determined under subsections (f) and (g) of section 1108 of the Social Security Act), or (2)

applying the increase of 6.2 percentage points in the FMAP plus a 15 percent increase in the cap on Medicaid payments. There is no quarterly unemployment adjustment for Territories. As a result, we are not addressing the Territories or Commonwealth in this document, and will instead work with them separately and individually.

C. Methodology Utilized in the Calculation of Increased FMAP Rates for the Third Quarter of Fiscal Year 2009 and Subsequent Quarters During the Recession Adjustment Period

This notice sets forth increased FMAP rates for the third quarter of Fiscal Year 2009 that have been calculated pursuant to the ARRA and are set forth in the table at the end of the notice. The rates set forth in this notice are effective from April 1, 2009 through June 30, 2009. The table gives figures for each of the 50 States and the District of Columbia. Adjusted figures are not shown for Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. Under ARRA, the application of an increased FMAP calculation for the Territories and Commonwealth depends upon a one-time election of a higher FMAP and 15 percent increase in their cap on federal Medicaid payments, or a 30 percent increase in their cap. Moreover, there is no quarterly unemployment adjustment for the Territories or Commonwealth. As a result, we will instead work with the Territories and Commonwealth separately and individually.

The maintenance of FMAP calculation and the general 6.2 percentage point increase are non-discretionary calculations, and were included in a prior notice issued April 21, 2009, at 74 FR 18235. This notice specifically adjusts FMAP rates for States qualifying for additional increase based on currently available information on unemployment rates in the States as obtained from the Department of Labor's Bureau of Labor Statistics, and describes the methodology we intend to use throughout the recession adjustment period.

The methodology that we have used to calculate the unemployment adjustment is to utilize the final unemployment rate for the most recent previous 3-month period for which data are available prior to each quarter to calculate that quarter's FMAP. The unemployment rate for the most recent previous 3-month period includes final unemployment rates for all three months.

The timing of the availability of final State unemployment data for the month just prior to the start of the fiscal quarter prevents the publication of the FMAP rates until after the fiscal quarter has begun. For example, State unemployment data for the month of March, the month just prior to the start of the fiscal quarter beginning April 1, becomes available during the month of April on a preliminary basis. State unemployment data for March does not become final until May with the release of preliminary April state unemployment data and so forth for subsequent months and quarters.

Because States rely on timely publication of the percentages for their use in budget planning activities, HHS will calculate preliminary quarterly FMAP rates at the time preliminary monthly data for the month prior to the start of the quarter is available. HHS will provide these rates to the Centers for Medicare and Medicaid Services (CMS) for the purpose of calculating preliminary quarterly adjustments, as specified by ARRA, for States' federal matching amounts. HHS will calculate final quarterly FMAP rates at the time final monthly data for the month prior to the start of the fiscal quarter is available. HHS will provide these rates to CMS for the purpose of calculating the final quarterly adjustments, as specified by ARRA, for States' final quarterly federal matching amounts and publish these final quarterly rates in a **Federal Register** notice.

As an example of the methodology, HHS will calculate preliminary FMAP rates for the fiscal quarter beginning April 1, using State unemployment data from final January, final February, and preliminary March unemployment rates, in April when preliminary March data become available, and supply these to CMS. HHS will calculate final FMAP rates for the fiscal quarter beginning April 1, using State unemployment data from final January, final February, and final March unemployment rates, in May when final March data become available and supply these to CMS and publish these final quarterly rates in a **Federal Register** notice. The methodology and timing for the calculations and their release will proceed similarly for subsequent quarters during the recession adjustment period.

We intend to utilize annual updates to the historical BLS data to make changes in the States' lowest unemployment rate. Revised historical unemployment rates are part of the currently available data used at the time of calculating third quarter FMAP rates each year. These revisions to the historical data will

remain current until the following third quarter FMAP rate is calculated, when new historical data becomes available.

Using data for the final State unemployment rates for the 3-consecutive-month period prior to the start of the fiscal quarter beginning April 1, 2009 and historical periods of each 3-consecutive-months beginning on or after January 1, 2006, differences in States' unemployment rates were calculated to determine if a State qualifies for an adjustment in its FMAP due to changes in its unemployment rate. For the third quarter of fiscal year 2009, we compared each State's final unemployment rate for the 3-month period ending in March 2009 to the lowest average unemployment rate for the State for any 3-consecutive-month period from January 1, 2006 through February 2009. A State received an additional FMAP increase if the State's unemployment increase percentage was at least 1.5 percentage points.

ARRA adjustments to FMAP are shown by State in the accompanying table. The hold harmless FY09 FMAP is the higher of the original FY08 or FY09 FMAP. The 6.2 percentage point increase is added to the hold harmless FY09 FMAP. The unemployment tier is determined from the comparison of the 3-month average unemployment rate ending March 2009 and the lowest 3-month unemployment rate during January 2006 to February 2009. The unemployment adjustment is calculated according to the unemployment tier and added to the hold harmless FY09 FMAP with the 6.2 percentage point increase.

We are requesting public comment on the calculation methodology described above, which we have used in developing the third quarter increased FMAP rates. We will address any public comments in the next quarterly notice of increased FMAP rates.

FOR FURTHER INFORMATION CONTACT:

Thomas Musco or Rose Chu, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-6870.

(Catalog of Federal Domestic Assistance Program Nos. 93.558: TANF Contingency Funds; 93.563: Child Support Enforcement; 93.596: Child Care Mandatory and Matching Funds of the Child Care and Development Fund; 93.658: 93.659: Adoption Assistance; 93.769: Ticket-to-Work and Work Incentives Improvement Act (TWWIA) Demonstrations to Maintain Independence and Employment)

Dated: July 27, 2009.

Kathleen Sebelius,
Secretary.

ARRA ADJUSTMENTS TO FMAP Q3 FY09

State	FY08 original FMAP	FY09 original FMAP	Hold harm- less FY 09	Hold harm- less FY09 FMAP with 6.2%pt increase	1st and 2nd quar- ter FY09 FMAP Ad- just (incl HH-6.2- unemploy- ment)	3-Month average unemploy- ment end- ing Mar 2009	Minimum unemploy- ment	Unemploy- ment dif- ference	Unemploy- ment tier	Unemploy- ment ad- justment Q3 FY09	3rd quar- ter FY09 FMAP ad- just (incl HH-6.2- unemploy- ment)
Alabama	67.62	67.98	67.98	74.18	76.64	8.4	3.3	5.1	11.5	3.33	77.51
Alaska	52.48	50.53	52.48	58.68	58.68	8.0	6.0	2.0	5.5	2.44	61.12
Arizona	66.20	65.77	66.20	72.40	75.01	7.4	3.6	3.8	11.5	3.53	75.93
Arkansas	72.94	72.81	72.94	79.14	79.14	6.4	4.8	1.6	5.5	1.32	80.46
California	50.00	50.00	50.00	56.20	61.59	10.6	4.8	5.8	11.5	5.39	61.59
Colorado	50.00	50.00	50.00	56.20	58.78	7.1	3.6	3.5	11.5	5.39	61.59
Connecticut	50.00	50.00	50.00	56.20	60.19	7.4	4.3	3.1	8.5	3.99	60.19
Delaware	50.00	50.00	50.00	56.20	60.19	7.2	3.3	3.9	11.5	5.39	61.59
District of Columbia	70.00	70.00	70.00	76.20	77.68	9.6	5.4	4.2	11.5	3.09	79.29
Florida	56.83	55.40	56.83	63.03	67.64	9.4	3.3	6.1	11.5	4.61	67.64
Georgia	63.10	64.49	64.49	70.69	73.44	8.9	4.3	4.6	11.5	3.73	74.42
Hawaii	56.50	55.11	56.50	62.70	66.13	6.6	2.2	4.4	11.5	4.65	67.35
Idaho	69.87	69.77	69.87	76.07	78.37	6.8	2.8	4.0	11.5	3.11	79.18
Illinois	50.00	50.32	50.32	56.52	60.48	8.5	4.4	4.1	11.5	5.36	61.88
Indiana	62.69	64.26	64.26	70.46	73.23	9.6	4.4	5.2	11.5	3.75	74.21
Iowa	61.73	62.62	62.62	68.82	68.82	5.0	3.7	1.3	0.0	0.00	68.82
Kansas	59.43	60.08	60.08	66.28	66.28	5.9	4.0	1.9	5.5	2.03	68.31
Kentucky	69.78	70.13	70.13	76.33	77.80	9.3	5.4	3.9	11.5	3.08	79.41
Louisiana	72.47	71.31	72.47	78.67	80.01	5.6	3.5	2.1	5.5	1.34	80.01
Maine	63.31	64.41	64.41	70.61	72.40	7.9	4.4	3.5	11.5	3.74	74.35
Maryland	50.00	50.00	50.00	56.20	58.78	6.6	3.4	3.2	8.5	3.99	60.19
Massachusetts	50.00	50.00	50.00	56.20	58.78	7.6	4.4	3.2	8.5	3.99	60.19
Michigan	58.10	60.27	60.27	66.47	69.58	12.1	6.7	5.4	11.5	4.21	70.68
Minnesota	50.00	50.00	50.00	56.20	60.19	7.9	3.9	4.0	11.5	5.39	61.59
Mississippi	76.29	75.84	76.29	82.49	83.62	9.1	6.0	3.1	8.5	1.75	84.24
Missouri	62.42	63.19	63.19	69.39	71.24	8.4	4.7	3.7	11.5	3.88	73.27
Montana	68.53	68.04	68.53	74.73	76.29	5.9	3.2	2.7	8.5	2.41	77.14
Nebraska	58.02	59.54	59.54	65.74	65.74	4.5	2.8	1.7	5.5	2.05	67.79
Nevada	52.64	50.00	52.64	58.84	63.93	10.0	4.2	5.8	11.5	5.09	63.93
New Hampshire	50.00	50.00	50.00	56.20	56.20	5.7	3.4	2.3	5.5	2.58	58.78
New Jersey	50.00	50.00	50.00	56.20	58.78	7.9	4.2	3.7	11.5	5.39	61.59
New Mexico	71.04	70.88	71.04	77.24	77.24	5.5	3.5	2.0	5.5	1.42	78.66
New York	50.00	50.00	50.00	56.20	58.78	7.5	4.3	3.2	8.5	3.99	60.19
North Carolina	64.05	64.60	64.60	70.80	73.55	10.4	4.5	5.9	11.5	3.71	74.51
North Dakota	63.75	63.15	63.75	69.95	69.95	4.2	3.0	1.2	0.0	0.00	69.95
Ohio	60.79	62.14	62.14	68.34	70.25	9.3	5.3	4.0	11.5	4.00	72.34
Oklahoma	67.10	65.90	67.10	73.30	74.94	5.5	3.3	2.2	5.5	1.64	74.94
Oregon	60.86	62.45	62.45	68.65	71.58	10.8	5.0	5.8	11.5	3.96	72.61
Pennsylvania	54.08	54.52	54.52	60.72	63.05	7.5	4.3	3.2	8.5	3.60	64.32
Rhode Island	52.51	52.59	52.59	58.79	63.89	10.4	4.8	5.6	11.5	5.10	63.89
South Carolina	69.79	70.07	70.07	76.27	78.55	10.9	5.5	5.4	11.5	3.09	79.36
South Dakota	60.03	62.55	62.55	68.75	68.75	4.6	2.7	1.9	5.5	1.89	70.64
Tennessee	63.71	64.28	64.28	70.48	73.25	9.1	4.5	4.6	11.5	3.75	74.23
Texas	60.56	59.44	60.56	66.76	68.76	6.5	4.4	2.1	5.5	2.00	68.76
Utah	71.63	70.71	71.63	77.83	77.83	5.0	2.5	2.5	8.5	2.15	79.98
Vermont	59.03	59.45	59.45	65.65	67.71	7.0	3.5	3.5	11.5	4.31	69.96
Virginia	50.00	50.00	50.00	56.20	58.78	6.4	2.8	3.6	11.5	5.39	61.59
Washington	51.52	50.94	51.52	57.72	60.22	8.4	4.4	4.0	11.5	5.22	62.94
West Virginia	74.25	73.73	74.25	80.45	80.45	6.0	4.2	1.8	5.5	1.25	81.70
Wisconsin	57.62	59.38	59.38	65.58	65.58	7.8	4.4	3.4	8.5	3.19	68.77
Wyoming	50.00	50.00	50.00	56.20	56.20	4.0	2.8	1.2	0.0	0.00	56.20

[FR Doc. E9-18544 Filed 7-31-09; 11:15 am]

BILLING CODE 4210-01-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Renewal of Charter for the Presidential
Advisory Council on HIV/AIDS**

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5

U.S.C. Appendix 2), the U.S. Department of Health and Human Services is hereby announcing renewal of the charter for the Presidential Advisory Council on HIV/AIDS (PACHA).

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Bates, Interim Executive Director, PACHA, Department of Health and Human Services, 200 Independence Avenue, SW., Room 443H; (202) 690-5560.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June

14, 1996; and Section 222 of the Public Health Service Act (42 U.S.C. 217a). The Council was established to provide advice, information, and recommendations to the Secretary of Health and Human Services regarding programs and policies to promote effective prevention and cure of HIV disease and AIDS. The functions of the Council shall be solely advisory in nature.

Since PACHA was established, renewal of its charter has been carried out at the appropriate intervals as stipulated by FACA. The previous Council charter was scheduled to expire on July 27, 2009. On July 24, 2009, the

Secretary of Health and Human Services approved for the Council charter to be renewed. Renewal of the PACHA charter provides authorization for the Council to operate until July 27, 2011.

A copy of the Council charter is available on the PACHA Web site at <http://www.pacha.gov>. A copy of the Council charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is <http://fido.gov/facadatabase>.

Dated: July 28, 2009.

Christopher H. Bates,

Interim Executive Director, Presidential Advisory Council on HIV/AIDS.

[FR Doc. E9-18572 Filed 8-3-09; 8:45 am]

BILLING CODE 4150-43-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0372]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleman, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 15, 2008 (73 FR 53252), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910-0635. The approval expires on May 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-18532 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-09-09CH]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

A Controlled Evaluation of Expect Respect Support Groups (ERSG): Preventing and Interrupting Teen Dating Violence among At-Risk Middle and

High School Students—New—National Center for Injury Prevention and Control (NCIPC), Division of Violence Prevention (DVP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The prevalence and consequences of teen dating violence make it a public health concern that requires early and effective prevention. To date, only three prevention strategies—Safe Dates, the Youth Relationships Project, and 4th R—have demonstrated reductions in dating violence behaviors in rigorous, controlled evaluations. In order to protect young people and build an evidence-base of effective prevention strategies, evaluation of additional programs is needed, including those programs currently in the field. Expect Respect Support Groups (provided by SafePlace) are currently in use in the Austin Independent School District and demonstrated promising results in an uncontrolled program evaluation, suggesting a controlled evaluation is warranted to more rigorously examine program effects. The proposed study has one primary aim and two exploratory aims. The primary aim is to evaluate the effectiveness of Expect Respect Support Groups (ERSG) to prevent and reduce teen dating violence and increase healthy conflict resolution skills reported by at-risk male and female middle and high school students compared to at-risk students in control schools who do not receive ERSG. The exploratory aims are: (1) To evaluate whether or not the effectiveness of ERSG is enhanced by the presence of a universal, school-wide prevention program, and (2) To examine moderators and mediators of targeted and universal teen dating violence interventions, such as biological sex and history of abuse at intake.

The proposed evaluation will use a quasi-experimental/non-randomized design in which a convenience sample of participants in schools receiving targeted prevention services are compared to students in control schools in which no dating violence prevention services are available. Control schools will be selected that have characteristics (e.g., risk status, socio-economic status) similar to the Austin Independent School District intervention schools.

Based on past, uncontrolled program evaluation of Expect Respect Support groups, we anticipate that in the Austin Independent School District and neighboring district(s), 800 students will undergo an intake assessment, of whom 600 will be eligible for Expect Respect Support groups and will complete the baseline survey. We expect 400 students

to complete the survey and two-follow-up assessments. Therefore, over three years 2400 students will undergo an intake assessment, of whom we will

recruit 1800 students into the study (300 per year from intervention schools and 300 per year from control schools), of

whom we anticipate 1200 will have complete data.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Middle and High School Students	Intake assessment	800	1	15/60	200
	Baseline Survey	600	1	1	600
	Completion Survey	400	1	1	400
	Follow-up Survey 1	400	1	1	400
	Follow-up Survey 2	400	1	1	400
Total	2000

Dated: July 24, 2009.

Marilyn S Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9-18604 Filed 8-3-09; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Intervention Trials To Retain HIV-Positive Patients in Medical Care: (New)

The purpose of this project is to develop, implement, and test the efficacy of an intervention designed to increase client appointment attendance among patients at risk of missing scheduled appointments at HIV clinics. This project is a collaboration between the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and six university-affiliated HIV clinics in the United States. The proposed intervention will be implemented in two phases. Phase 1 is a clinic-wide

intervention that includes the following components: a theme slogan for the intervention, brochures, posters with messages to patients, brief verbal retention in care messages from providers to patients, buttons printed with the theme of the intervention worn by providers, and appointment reminder cards with information on how to cancel appointments. All clinic patients will receive the Phase 1 intervention. Phase 2 of the project is a three-arm randomized trial in which 300 patients in each of the six participating sites will be enrolled and randomly assigned to one of three study arms. In Arm 1 (control arm), patients (n=100) will receive the clinic-wide intervention only. Patients (n=100) assigned to Arm 2 (intervention arm) will continue to receive the clinic-wide intervention plus a comprehensive client-centered intervention from two trained interventionists. The remaining 100 patients will be assigned to Arm 3 and will receive the clinic-wide intervention plus a brief client-centered intervention.

The efficacy of the intervention will be assessed through data collection efforts tailored to each phase of the intervention. Phase 1 uses a pre-post comparison of clinic attendance rates before and during a clinic-wide intervention. Specifically, in Phase 1, the attendance rate for HIV primary care is currently being assessed via electronic medical records during the 12-month period before the clinic-wide intervention begins. This pre-intervention assessment is being collected for all patients who had at least one HIV primary care visit at the clinic during the preceding 12 months. This cohort of patients will be reassessed via electronic medical records during the 12-month intervention period. In addition, provider surveys will be administered

quarterly during Phase 1 and semi-annually during Phase 2 to obtain information from primary care providers (MD, DO, nurse practitioner, physician assistant) about whether they talked to their patients about the importance of regular care. Patient exit interviews will be administered every other month to assess patient exposure to the theme slogan for the intervention and posters with messages to patients as well as receipt of brochures and brief verbal retention in care messages from clinicians and clinic staff that comprise the Phase 1 intervention.

In Phase 2, participants will be enrolled over a period of 4-9 months to allow flexibility for faster or slower enrollment in the clinics. It is anticipated that most clinics will complete their enrollment in approximately 6 months. On a daily basis, clinic staff or the study coordinator will generate a list of patients who meet eligibility criteria based on attendance history. The list will be given to the study coordinator who will approach patients to ask about their interest in being screened for eligibility in the study. When patients agree to be screened for eligibility, the study coordinator will administer an eligibility screener. Patients who are found to be eligible will be enrolled in the project and all enrollees will complete a baseline survey (that will take approximately 30 minutes) before being randomized to one of the two intervention arms or the control arm. No follow-up surveys will be collected. The survey will be administered in a private setting at the clinic using Audio Computer-Assisted Self-Interview (ACASI) in which respondents can read and listen via earphones to survey questions presented on the computer screen and respond directly into the computer.

Participants randomly assigned into the intervention arms will receive comprehensive or brief interventional services from two trained interventionists. The interventions will be delivered in face-to-face encounters as well as over the telephone and the first dose of the intervention will be delivered on the day the participant is enrolled into study. During the first face-to-face encounter, an interventionist will administer a retention risk screener. This screener is a clinical tool that will help identify attitudes, barriers, and unmet needs that

might prevent a patient from staying in care. The screener contains three sections: (1) Attitudes and beliefs about HIV care and treatment, (2) barriers to consistent clinic attendance (e.g., transportation, child care, housing instability, scheduling problems, and lack of social support), and (3) recent drug/alcohol use and mental health. The information obtained from the risk screener will be used to tailor the interventions to each individual patient's needs. Because a patient's situation or needs may change over time, the screener will be re-

administered to intervention arm participants at a minimum every 3–4 months during a clinic visit or other arranged face-to-face meetings outside of the clinic. In addition, the study coordinator will obtain contact/locator information for all participants enrolled in the intervention arm. Contact information will be updated as necessary by the intervention staff.

The response burden for the six participating sites and patients enrolled in the study is estimated as:

ESTIMATED ANNUALIZED BURDEN HOURS

Type of form by phase	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden (in hours)
Phase 1					
Primary Care Provider Survey	150	4	600	0.167	100
Clinic Staff Survey	270	4	1,080	0.167	180
Patient Exit Survey	1,800	1	1,800	0.033	60
.....					
Electronic data abstraction	6	4	24	40.0	960
Phase 1 Burden	2,226	3,504	1,300
Phase 2					
Primary Care Provider Survey	150	2	300	0.167	50
Clinic Staff Survey	270	2	540	0.167	90
Patient Exit Survey	1,800	1	1,800	0.033	60
Patient Eligibility Screener *	3,000	1	3,000	0.083	249
Patient Baseline Survey *	1,800	1	1,800	0.50	900
Retention Risk Screener	1,200	4	4,800	0.25	1,200
Retention Specialist/Patient Navigator Encounter	12	300	3,600	0.017	61
Contact/locator information	1,200	4	4,800	0.083	398
Electronic data abstraction	6	4	24	40.0	960
Phase 2	8,238	20,664	3,968
Total Burden	11,664	24,168	5,268

* Only administered one time during the entire project period.

Written comments and recommendations concerning this proposed information collection should be sent within 30 days of this notice to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for HRSA.

Dated: July 27, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-18524 Filed 8-3-09; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0277]

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations), one of which was amended, for certain in vitro diagnostic devices. FDA is issuing the Authorizations under the Federal Food, Drug, and Cosmetic Act (the act), as

requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow the determination by the Acting Secretary of the Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics, accompanied by emergency use information subject to the terms of any authorization issued under the act.

The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain antiviral drug products and the issuance of an EUA for certain personal respiratory protection devices.

DATES: The authorization for the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) is effective as of April 27, 2009. The Authorization for the previously-cleared CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA2) and Viral Culture is effective as of May 2, 2009.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C-26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Public Law 108-276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds: “(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or (C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.”

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish, in the **Federal Register**, a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and CDC (to the extent feasible and appropriate given the circumstances of the emergency), FDA¹ concludes: (1) That an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled

clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing—(1) such disease or condition; or (2) a serious or life-threatening disease or condition caused by a product authorized under Section 564, approved or cleared under this Act, or licensed under Section 351 of the Public Health Service Act (PHS Act), for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, in the **Federal Register** of July 26, 2007 (72 FR 41083), FDA announced the availability of a guidance entitled “Emergency Use Authorization of Medical Products.” The guidance provides more information for stakeholders and the public about the EUA authority and the agency’s process for the consideration of EUA requests.

II. EUA Request for Certain In Vitro Diagnostic Products

On April 26, 2009, under section 564(b)(1)(C) of the act, the Acting Secretary determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of certain in vitro diagnostics for detection of Swine Influenza A (2009 H1N1 flu virus), accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). Notice of the determination and the declaration of the Acting Secretary is published elsewhere in this issue of the **Federal Register**.

On April 27, 2009, in response to a CDC request, FDA issued an EUA for the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) with certain written

¹ The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

information, including fact sheets for healthcare providers and patients and adequate directions for use, which are authorized under the EUA. On May 2, 2009, in response to a CDC request to allow use of the rRT-PCR Swine Flu Panel for different sample types and different reagents, FDA amended the rRT-PCR Swine Flu Panel Authorization letter and reissued the Authorization letter in its entirety, with amended written information, including adequate directions for use. In addition, on May 2, 2009, in response to a CDC request, FDA issued an EUA with certain written information, including adequate

directions for use, to allow the use of the FDA-cleared in vitro diagnostic device, CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (NPS, NS, TS, NPS/TS, NA2) and Viral Culture) (CDC rRT-PCR flu panel), for patient specimen types and reagents in addition to those of the cleared CDC rRT-PCR flu panel.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at <http://www.regulations.gov>.

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations, one as amended, under section 564(c) of the act are met, FDA has authorized the emergency use of certain in vitro diagnostic devices.

The Authorization for the rRT-PCR Swine Flu Panel, as amended and reissued in its entirety on May 2, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road, MS C-12
Atlanta, GA 30333
Clifton, Bldg. 1, Room 6430

Dear Dr. Besser:

On April 27, 2009, FDA issued a letter authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) for the presumptive diagnosis of swine influenza A (H1N1), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by public health and other qualified laboratories. On May 1, 2009, CDC submitted a request for an amendment to the Emergency Use Authorization. In response to that request, the letter authorizing emergency use of the rRT-PCR Swine Flu Panel is being reissued in its entirety with the amendments, as requested by CDC, incorporated.¹

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents -- in this case, swine influenza A (H1N1).² Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of the Department of Health and Human Services then declared an emergency justifying the authorization of the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel)³ for the presumptive diagnosis of swine influenza A (H1N1) virus infection in human individuals who have been diagnosed with influenza A caused by a virus not subtypeable by currently available FDA-cleared devices, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection for human individuals who are diagnosed with influenza A caused by a virus that is not subtypeable by currently available FDA-cleared devices meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

- (1) The recently isolated novel 2009 influenza A (H1N1), or swine flu, virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;
- (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the rRT-PCR Swine Flu Panel may be effective in the presumptive diagnosis of swine influenza A (H1N1) virus infection, and that the known and potential benefits of the rRT-PCR Swine Flu Panel, when used in the presumptive diagnosis of swine influenza A (H1N1) virus infection, outweigh the known and potential risks of such products; and
- (3) there is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection.⁴

Therefore, I have concluded that the emergency use of the rRT-PCR Swine Flu Panel for the presumptive diagnosis of swine influenza A (H1N1) virus infection in human individuals who are diagnosed with influenza A infections not subtypeable by currently available FDA-cleared devices meets the above criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized rRT-PCR Swine Flu Panel for the presumptive diagnosis of 2009 H1N1 influenza A virus infection for individuals who are diagnosed with influenza A caused by a virus not subtypeable by currently available FDA-cleared devices.

The authorized rRT-PCR Swine Flu Panel is as follows:

The Swine Influenza Virus Real-time RT-PCR Detection Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis (Taqman®) probes for use in the real-time RT-PCR assay on the ABI 7500 Fast Dx Real-Time PCR instrument for the *in vitro* qualitative detection of 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection and viral culture. The universal 2009 H1N1 influenza swInfA (NP gene) and swH1 (HA gene) primer and probe sets are designed for detection of 2009 A/H1N1 influenza viruses. In addition rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) authorized for emergency use utilizes the AgPath-ID™ One-Step RT-PCR Kit Human amplification reagents.

The rRT-PCR Swine Flu Panel includes the following primer and probe sets:

- **InfA** detects universal influenza A strains in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and virus culture.
- **swInfA** specifically detects swine influenza A strains (NP gene) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and virus culture.
- **swH1** is specific for swine influenza A, subtype H1 (HA gene) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens from patients with signs and symptoms of respiratory infection, and virus culture.

The rRT-PCR Swine Flu Panel also includes control materials:

- **RNase P (RP)** detects human RNase P and is used as a positive control with human clinical specimens to indicate that adequate isolation of nucleic acid resulted from the extraction of the clinical specimen.
- **Swine Influenza Panel Real-Time RT-PCR Positive Control (SIPC)** is a positive control designed to react with all the primer and probe sets including RNase P.

The above rRT-PCR Swine Flu Panel, when labeled consistent with the attached template is authorized to be distributed to public health and other qualified laboratories⁵ under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The following written information pertaining to the emergency use of the authorized rRT-PCR Swine Flu Panel is authorized to be made available to health care providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting Swine Influenza Rt-Pcr Detection Panel Test Results
- Fact Sheet For Patients: Understanding Swine Influenza Kit Test Results

See attached. As described in section IV below, CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized rRT-PCR Swine Flu Panel in the specified population, when used in the presumptive diagnosis of swine influenza A (H1N1) virus infection, outweigh the known and potential risks of such product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized rRT-PCR Swine Flu Panel may be effective in the presumptive diagnosis of swine influenza A (H1N1) virus infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Swine Flu Panel, when used to presumptively diagnose swine influenza A (H1N1) virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized rRT-PCR Swine Flu Panel under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the rRT-PCR Swine Flu Panel described above is authorized to presumptively diagnose swine influenza A (H1N1) virus infection in human individuals who are diagnosed with influenza A caused by a virus not subtypeable by currently available FDA cleared devices.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the rRT-PCR Swine Flu Panel during the duration of this emergency use authorization:

- current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the rRT-PCR Swine Flu Panel;
- registration and listing requirements under section 510 of the Act;
- labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12);

- investigational device requirements, including requirements under 21 CFR Part 812; and
- reporting requirements that apply to cleared or approved devices, including requirements under 21 CFR Parts 803 and 806.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

- A. CDC will distribute the rRT-PCR Swine Flu Panel labeled with the intended use statement, adequate directions for use, any appropriate limitations on the use of the device, and any available information regarding performance of the device only to qualified laboratories.
- C. CDC will provide to the qualified state and/or local public health authority(ies) the authorized rRT-PCR Swine Flu Panel Fact Sheets for health care providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for patients.
- D. CDC will make available on its website the authorized rRT-PCR Swine Flu Panel Fact Sheets for health care providers, and the authorized rRT-PCR Swine Flu Panel Fact Sheets for patients.
- E. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- F. CDC will ensure qualified laboratories have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.
- G. CDC will track adverse events.
- H. Through a process of inventory control, CDC will maintain records of device usage.
- I. CDC will collect information on the performance of the assay, to include the incidence of false positive and negative results.

Public Health and Other Qualified Laboratories

- J. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-time PCR instrument or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its laboratory performance (proficiency testing with the CDC sample panel not performed).
- K. Qualified laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

CDC and state and/or Local Public Health Authority(ies)

- M. CDC and the appropriate state and/or local public health authority(ies) are authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Swine Flu Panel that is consistent with, and does not exceed, the terms of this letter of authorization.
- N. Only CDC may request changes to the authorized Fact Sheet for health care providers or the authorized rRT-PCR Swine Flu Panel Fact Sheet for patients. Such requests will be made by contacting FDA concerning FDA review and approval.
- O. CDC and the appropriate state/and or local public health authority(ies) will ensure that records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized rRT-PCR Swine Flu Panel as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Acting Commissioner

¹ The amendments to the April 27, 2009 letter allow use of different sample types (throat swabs (TS), dual NPS/TS swab, or nasal aspirate (NA) specimens) and different reagents.

² Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).

³ FDA is authorizing the emergency use of the Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) as described in the scope section of this letter (Section II). For ease of reference, this letter will use the term the "rRT-PCR Swine Flu Panel."

⁴ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

⁵ All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See "Conditions of Authorization" below.

The Authorization for the cleared CDC rRT-PCR flu panel follows and provides an explanation of the reasons

for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road, MS C-12
Atlanta, GA 30333
Clifton, Bldg. 1, Room 6430

Dear Dr. Besser:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the CDC¹ Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**²) and Viral Culture (rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)) as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3) by public health and other qualified laboratories.

The CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel) was cleared by FDA on September 30, 2008 for use with nasopharyngeal and/or nasal swab specimens. Because of issues of availability and adequacy of the cleared test associated with the need for testing additional specimen types, this letter authorizes the emergency use of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) with specimen types and reagents in addition to those of the cleared test, as described below. The rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) is authorized as a first tier test for patient specimens with suspected 2009 H1N1 influenza virus and is an integral component of the testing algorithm for the rRT-PCR Swine Flu Panel authorized for use under an April 27, 2009 Emergency Use Authorization.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency under 42 U.S.C. § 247d that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such an agent or agents -- in this case, 2009 H1N1 influenza virus.³ Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of the Department of Health and Human Services then declared an emergency justifying the authorization of the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**) and Viral Culture subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**) and Viral Culture (rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**))⁴ as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in individuals suspected of having a 2009 H1N1 influenza virus infection. The rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) is a first tier test because it should be used to test specimens from such individuals first. If the test result of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) is positive for influenza A and negative for H1 (seasonal) and H3 subtypes, then the laboratory should test the specimen with the rRT-PCR Swine Flu Panel.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

- (1) The recently isolated novel 2009 influenza A (H1N1), or swine flu, virus can cause influenza, a serious or life threatening disease or condition to humans infected by this virus;
- (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) may be effective as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection suspected of having a 2009 H1N1 influenza virus infection and/or from viral culture, and that the known and potential benefits of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**), when used as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3), outweigh the known and potential risks of such products; and
- (3) there is no adequate, approved, and available alternative to the emergency use of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection and/or from viral culture specimens suspected of having a 2009 H1N1 influenza virus infection.⁵

Therefore, I have concluded that the emergency use of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) as a first tier test for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection meets the above criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) for the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection.

The authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**):

CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**) and Viral Culture is a panel of oligonucleotide primers and dual-labeled hydrolysis probes for use in the real-time RT-PCR assay on the ABI 7500 Fast Dx Real-Time PCR instrument for the *in vitro* qualitative detection of human influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and/or dual NPS/TS swab specimens and nasal aspirates (NA) from patients with signs and symptoms of respiratory infection and/or from viral culture.⁶

The rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) uses the same primer and probe sequences as the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel as the device cleared under K080570 except that the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) authorized for emergency use also utilizes the AgPath-ID™ One-Step RT-PCR Kit Human amplification reagents.

Assay principle

- The **rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)** is used in real-time RT-PCR assays on the ABI 7500 Fast instruments. The primer and probe sets are designed for detection and subtyping of influenza A viruses.
- One-step RT-PCR assays are one-tube assays that first reverse-transcribe specific Ribonucleic acid (RNA) templates into cDNA copies. The complementary deoxyribonucleic acid (cDNA) then undergoes a polymerase chain reaction (PCR) that utilizes a thermocyclic heating and cooling of the reaction to logarithmically amplify a specific region of DNA. The probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle.
- No template controls (NTCs) and positive template controls for all primer and probe sets are included in each run. An extraction control (HSC) provides a secondary negative control that validates the extraction procedure and reagent integrity. The RNase P assay serves as a control to ensure adequate RNA resulted from extraction of each clinical specimen and that no inhibitors were present in the specimen. RNA extracted from clinical samples contains human RNA. The RP primer and probe set targets the human ribonuclease P gene. Therefore, the level of the RNase P primer and probe set reaction reflects the relative amount of human RNA recovered from the specimen and its suitability for clinical testing.

The above rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**), when labeled consistent with the attached template, is authorized to be distributed to public health and other qualified laboratories⁷ under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The following written information pertaining to the emergency use of the authorized rRT-PCR Swine Flu Panel is authorized to be made available to health care providers and patients:

- Fact Sheet For Healthcare Providers: Interpreting rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Test Results
- Fact Sheet For Patients: Understanding rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Kit Test Results

See attached. As described in section IV below, CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) in the specified population, when used as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection, outweigh the known and potential risks of such product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) may be effective as a first tier test in the qualitative detection of influenza virus type A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**), when used for qualitative detection of influenza virus types A or B and subtype determination of seasonal human influenza A virus (seasonal A/H1 or A/H3) from individuals suspected of having a 2009 H1N1 influenza virus infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) described above is authorized as a first tier test to qualitatively detect influenza virus types A or B and subtype seasonal human influenza A virus (seasonal A/H1 or A/H3) for individuals suspected of having a 2009 H1N1 influenza virus infection.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) during the duration of this emergency use authorization⁸:

- current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**);
- registration and listing requirements under section 510 of the Act;
- labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5) and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12);
- investigational device requirements, including requirements under 21 CFR Part 812; and
- reporting requirements that apply to cleared or approved devices, including requirements under 21 CFR Parts 803 and 806.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

- A. CDC will distribute the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) labeled with the intended use statement, adequate directions for use, any appropriate limitations on the use of the device, and any available information regarding performance of the device only to qualified laboratories.
- B. CDC will provide to the qualified state and/or local public health authority(ies) the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Fact Sheets for health care providers, and the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Fact Sheets for patients.
- C. CDC will make available on its website the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Fact Sheets for health care providers, and the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Fact Sheets for patients.
- D. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- E. CDC will ensure qualified laboratories have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.
- F. CDC will track adverse events.
- G. Through a process of inventory control, CDC will maintain records of device usage.
- H. CDC will collect information on the performance of the assay, to include the incidence of false positive results.

Public Health and Other Qualified Laboratories

- I. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-time PCR instrument or the RUO marketed Applied Biosystems 7500 Real-time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its laboratory performance (proficiency testing with the CDC sample panel not performed).
- J. Qualified laboratories will have a process in place for reporting test results to health care providers and federal, state and/or local public health authorities, as appropriate.

CDC and State and/or Local Public Health Authority(ies)

- K. CDC and the appropriate state and/or local public health authority(ies) are authorized to make available additional information relating to the emergency use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) that is consistent with, and does not exceed, the terms of this letter of authorization.
- L. Only CDC may request changes to the authorized Fact Sheet for health care providers or the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) Fact Sheet for patients. Such requests will be made by contacting FDA concerning FDA review and approval.
- M. CDC and the appropriate state and/or local public health authority(ies) will ensure that records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

The emergency use of the authorized rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Acting Commissioner

¹ Centers for Disease Control and Prevention

² Nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, nasal aspirates.

³ Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).

⁴ FDA is authorizing the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens (**NPS, NS, TS, NPS/TS, NA**) and Viral Culture (rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)) as described in the scope section of this letter (Section II). For ease of reference, this letter will use the term the "rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**)."

⁵ The cleared test for in vitro qualitative detection of human influenza viral RNA (The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570) is not adequate because of the need to test additional types of samples during this emergency and it is not sufficiently available because of limited availability of certain reagents. No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

⁶ The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570 is indicated for the *in vitro* qualitative detection of human influenza viral RNA in nasopharyngeal swabs (NPS) and nasal swabs (NS) only.

⁷ All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See "Conditions of Authorization" below.

⁸ These requirements are waived only for the rRT-PCR Flu Panel (**NPS, NS, TS, NPS/TS, NA**) that is authorized for emergency use. These requirements, and all other applicable statutory and regulatory requirements, continue to apply to the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570.

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-18569 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0278]

Authorization of Emergency Use of Certain Personal Respiratory Protection Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization), as amended, for certain personal respiratory protection devices.¹ FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized personal respiratory protection devices. The Authorization follows the determination by the Acting Secretary of the Department of Health and Human

Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain disposable National Institute for Occupational Safety and Health (NIOSH) certified N95 respirators, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorization, as amended, which includes an explanation of the reasons for its issuance, is reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate and the issuance of EUAs for certain in vitro diagnostic devices.

DATES: The Authorization is effective as of April 27, 2009.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C-26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Public Law 108-276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds: "(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military

¹ The Authorization covers certain disposable respirators certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95 (certain disposable NIOSH certified N95 respirators).

emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or (C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.”

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish, in the **Federal Register**, a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and CDC (to the extent feasible and appropriate given the circumstances of the emergency), FDA² concludes: (1) That an agent specified in a declaration of emergency can cause a serious or life-

threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing—(1) such disease or condition; or (2) a serious or life-threatening disease or condition caused by a product authorized under Section 564, approved or cleared under this Act, or licensed under Section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, in the **Federal Register** of July 26, 2007 (72 FR 41083), FDA announced the availability of a guidance entitled “Emergency Use Authorization of Medical Products.” The guidance provides more information for stakeholders and the public about the EUA authority and the agency’s process for the consideration of EUA requests.

II. EUA Request for Certain Personal Respiratory Protection Devices

On April 26, 2009, under section 564(b)(1)(C) of the act, the Acting Secretary determined that a public health emergency exists involving

Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain disposable NIOSH certified N95 respirators, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). Notice of the determination and the declaration of the Acting Secretary is published elsewhere in this issue of the **Federal Register**. On April 27, 2009, the CDC requested and FDA issued an EUA for certain disposable NIOSH certified N95 respirators, deployed from the Strategic National Stockpile with certain written information, including emergency use instructions, which are authorized under this EUA. On May 1, 2009, in response to a CDC request to make certain clarifications, FDA amended the authorization letter and reissued the Authorization letter in its entirety.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at <http://www.regulations.gov>.

IV. The Authorization

Having concluded that the criteria for issuance of this Authorization under section 564(c) of the act are met, FDA has authorized the emergency use of certain disposable NIOSH certified N95 respirators. The Authorization, as amended and reissued in its entirety on May 1, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, M.D.
Acting Director
Centers for Disease Control and Prevention
Clifton Building 1, Room 6430
1600 Clifton Road, NE MS C-12
Atlanta, GA 30333

Dear Dr. Besser:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), for the emergency use of certain personal respiratory protection devices deployed from the Strategic National Stockpile, specifically certain disposable respirators certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95.^{1,2}

² The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that a public health emergency exists involving *Swine Influenza A* that affects, or has a significant potential to affect, national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then on April 27 declared an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use, by the general public,³ of certain N95 respirators to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving *Swine Influenza A*, subject to the terms of this authorization.⁴

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain N95 respirators meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

- (1) *Swine Influenza A* can cause influenza, a serious or life-threatening disease or condition;
- (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain N95 respirators may be effective in preventing influenza by reducing wearer exposure to pathogenic biological airborne particulates, and that the known and potential benefits of certain N95 respirators, when used for the prevention of influenza, outweigh the known and potential risks of such products; and
- (3) there is no adequate, approved, and available alternative to the emergency use of certain N95 respirators in the prevention of influenza.^{5,6}

Therefore, I have concluded that the emergency use of certain N95 respirators for the prevention of influenza through reduced wearer exposure to pathogenic biological airborne particulates meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use, by the general public, of authorized N95 respirators to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving *Swine Influenza A*.

The authorized N95 respirators are as follows:

Manufacturer	Model
3M	8210
	8000
	9210
	1860
	1870
Moldex	2200
	2212
	2201
Moldex-Metrics	3000
	3001
	3002
	3003
Gerson	1730
Kimberley-Clark	PFR95-170
	PFR95-174

The above products, as deployed from the Strategic National Stockpile before or after the signing of this letter of authorization, are authorized to be made available to recipients when accompanied by the following written information pertaining to the emergency use:

- Summary Fact Sheet for Disposable Respirators for Use During the Swine Flu Emergency, as attached⁷

In addition, they may be made available to recipients in the form (i.e., with the packaging and labeling) in which they are customarily sold for use, as long as they are accompanied by the above-mentioned Summary Fact Sheet.⁸

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized N95 respirators, when used to prevent influenza by reducing wearer exposure to pathogenic biological airborne particulates, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized N95 respirators may be effective for the prevention of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized N95 respirators, when used for the prevention of influenza by reducing wearer exposure to pathogenic biological airborne particulates, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized N95 respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the N95 respirators described above are authorized for use, by the general public, to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving *Swine Influenza A*.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

I am waiving current good manufacturing practice requirements with respect to the authorized N95 respirators that are used in accordance with this emergency use authorization.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

- A. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- B. CDC will make available to state and/or local health authority(ies) through appropriate means the authorized Summary Fact Sheet, as attached.
- C. CDC will make available to the public through appropriate means, including through internet posting, general instructions for use to assist with donning the respirators. These instructions will be categorized, or adjusted as necessary, to account for any differences related to the following different respirator designs: molded/cone, folded, and duckbill respirators.

State and/or Local Public Health Authority(ies)

- D. The appropriate state and/or local public health authorities will make available through appropriate means the authorized Summary Fact Sheet, as attached.
- E. The appropriate state and/or local public health authority(ies) will ensure that authorized N95 respirators are distributed to recipients in accordance with applicable state and local laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.

CDC and State and/or Local Public Health Authority(ies)

- F. CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized N95 respirators that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized N95 respirators as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

¹ The specific products covered are listed below, in Section II (scope of authorization). For purposes of this document, we will refer to the devices covered by this authorization as "certain N95 respirators." Only respirators that have passed specific testing by NIOSH may be labeled as NIOSH-certified. Each NIOSH-certified respirator (also called a filtering facepiece) bears a rating which refers to its certified level of filtration efficiency: for example, N95 signifies that the respirator filters at least 95% of airborne particles (and is not resistant to oil). 42 CFR 84.170. For more information on disposable NIOSH-certified respirators, see http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/.

² FDA has cleared four models of disposable N95 respirators for use by the general public in public health medical emergencies, such as influenza pandemic: 3M Respirators 8612F and 8670F, and Pasture Pharma Respirators F550G and A520G. See 21 CFR 880.6260 (product code NZJ) and <http://www.fda.gov/cdrh/ode/guidance/1626.pdf>. These four models of N95 respirators are already FDA-cleared for a use contemplated by this letter of authorization.

³ For purposes of this letter of authorization, the term "general public" is broad and includes people performing work-related duties. This authorization affects only requirements applicable under the Federal Food, Drug, and Cosmetic Act. If respirators are used for people performing work-related duties, employers must comply with the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard, 29 CFR 1910.134, found at www.OSHA.gov.

⁴ FDA is authorizing the emergency use of certain N95 respirators as described in the scope section of this letter (Section II).

⁵ As described in footnote 2, FDA has cleared four models of N95 respirators for use by the general public in public health medical emergencies, such as influenza pandemic. A shortage of FDA-cleared respirators is nonetheless expected for the following reasons: not all of the four cleared models have been marketed extensively to date, and in fact two such models were only recently cleared by FDA; the respirators are disposable, and so one user is expected to use multiple respirators over a span of time; and, to ensure proper fit, each user may need to try on various sizes and models of respirators before selecting one for use. There are also some models of N95 respirators that are cleared by FDA for use in certain workplace settings. However, under the circumstances of this emergency, shortage of supplies of these models is expected.

⁶ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

⁷ This Summary Fact Sheet contains, among other information, known and potential risks of use, including risks to children as a result of breathing difficulties and improper fit.

⁸ In a work setting, OSHA requirements also apply (see note 3 of this letter).

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-18570 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0276]

Authorizations of Emergency Use of Certain Antiviral Drugs—Zanamivir and Oseltamivir Phosphate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for certain products from the neuraminidase class of antivirals—Zanamivir and oseltamivir phosphate. FDA is issuing the Authorizations under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized zanamivir and oseltamivir phosphate products. The Authorizations follow the determination by the Acting Secretary of the Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that

affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals—Zanamivir and oseltamivir phosphate, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain in vitro diagnostic devices and the issuance of an EUA for certain personal respiratory protection devices.

DATES: The Authorizations are effective as of April 27, 2009.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C-26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT:

Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF-29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Public Law 108-276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds: "(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military

forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or (C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.”

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish, in the **Federal Register**, a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and CDC (to the extent feasible and appropriate given the circumstances of the emergency), FDA¹ concludes: (1) That an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the

product may be effective in diagnosing, treating, or preventing—(1) such disease or condition; or (2) a serious or life-threatening disease or condition caused by a product authorized under Section 564, approved or cleared under this Act, or licensed under Section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, in the **Federal Register** of July 26, 2007 (72 FR 41083), FDA announced the availability of a guidance entitled “Emergency Use Authorization of Medical Products.” The guidance provides more information for stakeholders and the public about the EUA authority and the agency’s process for the consideration of EUA requests.

II. EUA Request for Certain Products From the Neuraminidase Class of Antivirals, Zanamivir and Oseltamivir Phosphate

On April 26, 2009, under section 564(b)(1)(C) of the act, the Acting Secretary determined that a public health emergency exists, involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On April 26, 2009, under section 564(b) of the act, and on the basis of such

determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals—Zanamivir and oseltamivir phosphate, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). Notice of the determination and the declaration of the Acting Secretary is published elsewhere in this issue of the **Federal Register**. On April 26, 2009, CDC requested and, on April 27, 2009, FDA issued EUAs for zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use instructions, which are authorized under the EUAs. On April 27, 2009, FDA also amended the EUAs for zanamivir and oseltamivir phosphate, including the emergency use instructions authorized under the EUAs.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the Internet at <http://www.regulations.gov>.

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the act are met, FDA has authorized the emergency use of certain zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use information, subject to the terms and conditions of the authorizations.

The Authorization (as amended) for certain zanamivir inhalation powder follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Besser:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of zanamivir inhalation powder for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

¹ The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (DHHS) determined that a public health emergency exists involving Swine Influenza A that affects or has significant potential to affect national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of DHHS then declared an emergency justifying the authorization of the emergency use of certain zanamivir products subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use of certain zanamivir products¹ for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

- (1) Swine Influenza A can cause influenza, a serious or life-threatening disease or condition;
- (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain zanamivir products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain zanamivir products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products; and
- (3) there is no adequate, approved, and available alternative to the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza.²

Therefore, I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized zanamivir products for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A. The emergency use of authorized zanamivir products under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized zanamivir products are as follows:

- Relenza (zanamivir) Inhalation Powder

Zanamivir products are approved and indicated for the treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than 2 days. Zanamivir products are also approved and indicated for prophylaxis of influenza in adults and pediatric patients 5 years of age and older.³

1. The above zanamivir products are authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).
2. The above zanamivir products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription).
3. The above zanamivir products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers⁴ and recipients:

- Fact Sheet for Health Care Provider
- Fact Sheet for Recipients

CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized zanamivir products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized zanamivir products may be effective for the treatment and prophylaxis of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized zanamivir products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the zanamivir products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

I am waiving current good manufacturing practice requirements with respect to the holding of authorized zanamivir products by CDC and other public health authority(ies) for a period of ninety days.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

- A. CDC will verify that authorized zanamivir products distributed to the Receive, Stage, Storage (RSS) sites are within their labeled expiration dates.
- B. CDC will ensure that the appropriate state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- C. CDC will make available to the appropriate state and/or local public health authority(ies) through appropriate means the authorized Fact Sheet for Health Care Providers, authorized Fact Sheet for Recipients, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.
- D. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Recipients. Such requests will be made by contacting FDA concerning FDA review and approval.

State and/or Local Public Health Authority(ies)

- E. The appropriate state and/or local public health authority(ies) will ensure that authorized zanamivir products are distributed to recipients in accordance with applicable state and local laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.
- F. The appropriate state and/or local public health authority(ies) will make available through appropriate means authorized Fact Sheets for Health Care Providers, authorized Fact Sheets for Recipients, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.

CDC and State and/or Local Public Health Authority(ies)

- G. CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized zanamivir products as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

¹ FDA is authorizing the emergency use of Relenza (zanamivir) inhalation powder for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain zanamivir product(s)" and "authorized zanamivir product(s)."

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

³ Zanamivir products are not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm. Zanamivir products have not been proven effective for treatment of influenza in individuals with underlying airways disease. Zanamivir products have not been proven effective for prophylaxis of influenza in the nursing home setting. Zanamivir products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use zanamivir products. There is no evidence for efficacy of zanamivir in any illness caused by agents other than Influenza A and B. Patients should be advised that the use of zanamivir products for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

⁴ It is possible that public health officials or other volunteers might distribute authorized zanamivir products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

(Please note that certain written emergency use information was also amended).

The Authorization (as amended) for certain oseltamivir phosphate capsules and oral suspension follows and

provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Besser:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of certain oseltamivir phosphate capsules and oral suspension for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (DHHS) determined that a public health emergency exists involving Swine Influenza A that affects or has significant potential to affect national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of DHHS then declared an emergency justifying the authorization of the emergency use of certain oseltamivir phosphate products subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use of certain oseltamivir phosphate products¹ for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

- (1) Swine Influenza A can cause influenza, a serious or life-threatening disease or condition;
- (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain oseltamivir phosphate products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products; and
- (3) there is no adequate, approved, and available alternative to the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza.²

Therefore, I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of authorized oseltamivir phosphate products for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A. The emergency use of authorized oseltamivir phosphate products under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The authorized oseltamivir phosphate products are as follows:

- Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules
- Tamiflu (oseltamivir phosphate) oral suspension

Oseltamivir phosphate products are approved and indicated for the treatment of uncomplicated acute illness due to influenza infections in patients 1 year and older who have been symptomatic for no more than 2 days. Oseltamivir phosphate products are also approved and indicated for the prophylaxis of influenza in patients 1 year and older.³

1. The above oseltamivir phosphate products are authorized for use in patients less than 1 year old. Such products are also authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).

2. The above oseltamivir phosphate products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription).

3. The above oseltamivir phosphate products may include products that are deployed from the Strategic National Stockpile (SNS) and that are authorized to have their expiration date extended under the federal government's Shelf Life Extension Program (SLEP).

4. The above oseltamivir phosphate products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers⁴ and recipients:

- Fact Sheet for Health Care Provider
- Fact Sheet for Patients and Parents

CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized oseltamivir phosphate products may be effective for the treatment and prophylaxis of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.⁵

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the oseltamivir phosphate products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

I am waiving current good manufacturing practice requirements with respect to the holding of authorized oseltamivir phosphate products by CDC and other public health authority(ies) for a period of ninety days.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

- A. CDC will verify that authorized oseltamivir phosphate products distributed to the Receive, Stage, Storage (RSS) sites are within their labeled (or SLEP-re-labeled) expiration dates.
- B. CDC will ensure that the appropriate state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- C. CDC will make available to the appropriate state and/or local public health authority(ies) through appropriate means the authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.
- D. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Patients and Parents. Such requests will be made by contacting FDA concerning FDA review and approval.

State and/or Local Public Health Authority(ies)

- E. The appropriate state and/or local public health authority(ies) will ensure that authorized oseltamivir phosphate products are distributed to recipients in accordance with applicable state and local laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.
- F. The appropriate state and/or local public health authority(ies) will make available through appropriate means authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.

CDC and State and/or Local Public Health Authority(ies)

G. CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized oseltamivir phosphate products as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

¹ FDA is authorizing the emergency use of Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules and oral suspension for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain oseltamivir phosphate product(s)" and "authorized oseltamivir phosphate product(s)."

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

³ The following points should be considered before initiating treatment or prophylaxis with oseltamivir phosphate products. Oseltamivir phosphate products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use oseltamivir phosphate products.

⁴ It is possible that public health officials or other volunteers might distribute authorized oseltamivir phosphate products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

⁵ Please note that with respect to authorized oseltamivir phosphate products for use in patients less than 1 year old, the conclusions above are based on limited data available for review under the limited timeframe given the circumstances of the emergency. The conclusions above may evolve as the emergency circumstances evolve and as more information becomes available.

(Please note that certain written emergency use information was also amended).

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-18568 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families; Office of Refugee Resettlement

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice to Award Five Program Expansion Supplements to Wilson-Fish Projects.

CFDA Number: 93.583.

Legislative Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Amount of Award: \$1,744,533.

Period Of Support: 09/30/2009–09/29/2010.

SUMMARY: The Office of Refugee Resettlement (ORR) announces the award of program expansion supplements to five Wilson-Fish Program grantees. The Wilson-Fish Program is an alternative to traditional State-administered refugee assistance programs and provides integrated assistance and services to refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, Trafficking Victims and Iraqi/Afghani Special Immigrant Visas (SIVs). The five

supplemental awards will allow the grantees to provide cash and medical assistance to arriving refugees and to others who are also eligible for refugee benefits through the remainder of Fiscal Year (FY) 2009. The expansion supplemental awards will enable the grantees to provide services needed to a higher number of arrivals than originally planned. The Refugee Act of 1980 mandates that the ORR reimburse State agencies and Wilson-Fish projects for the costs of cash and medical assistance for newly arriving refugees. Since 1991, ORR has reimbursed State agencies and Wilson-Fish agencies for providing cash and medical assistance to eligible individuals during their first eight months in the United States. The following Wilson-Fish Program grantees are awarded program expansion supplemental funding:

Grantee organization	Location	Amount of award
Catholic Social Services	Anchorage, AK	\$86,931
Colorado Department of Human Services	Denver, CO	798,411
Catholic Charities of Louisville	Louisville, KY	575,000
Catholic Charities Diocese of Baton Rouge	Baton Rouge, LA	94,368
Massachusetts Office of Refugees and Immigrants	Boston, MA	189,823

FOR FURTHER INFORMATION CONTACT: Carl Rubenstein, Wilson-Fish Program

Manager, Office of Refugee Resettlement, Aerospace Building, 8th

Floor West, 901 D Street SW., Washington, DC 20447. *Telephone:*

202–205–5933 E-mail:
crubenstein@acf.hhs.gov.

Dated: July 27, 2009.

Eskinder Negash,

Director, Office of Refugee Resettlement.

[FR Doc. E9–18521 Filed 8–3–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0353]

Cooperative Agreement Between the Food and Drug Administration and the Dauphin Island Sea Lab

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2009 (FY09) to the Dauphin Island Sea Lab (DISL). The goal of the DISL is marine science education, basic and applied marine science research, coastal zone management policy and educating the general public.

DATES: Important dates are as follows:

1. The application due date is August 24, 2009.
2. The anticipated start date is in September 2009.
3. The opening date is August 3, 2009.
4. The expiration date is August 25, 2009.

FOR FURTHER INFORMATION AND

ADDITIONAL REQUIREMENTS CONTACT:

Center Contact: LaQuia Geathers,
Center for Food Safety and Applied
Nutrition (CFSAN) (HFS–669),
Food and Drug Administration
(FDA), 5100 Paint Branch, Pkwy.,
College Park, MD 20740, 301–436–
2821, e-mail:
LaQuia.Geather@fda.hhs.gov.

Scientific/Programmatic Contact:

Julia Pryor, Division of Seafood
Science and Technology, FDA,
CFSAN, Office of Food Safety, Gulf
Coast Seafood Laboratory, 1
Iberville Dr., Dauphin Island, AL
36528, 251–694–4479; FAX: 251–
694–4477, e-mail:
Julia.Pryor@fda.hhs.gov.

Grants Management Contact: Camille
Peake, Division of Acquisition
Support and Grants, FDA (HFA
500), 5630 Fishers Lane (rm. 2139),
Rockville, MD 20857, 301–827–

7175, FAX: 301–827–7101, e-mail:
Camille.Peake@fda.hhs.gov.

For more information on this funding
opportunity announcement (FOA) and
to obtain detailed requirements, please
refer to the full FOA located at [http://
www.cfsan.fda.gov/list.html](http://www.cfsan.fda.gov/list.html). Click on
National Food Safety Program; click
www.FoodSafety.gov; click search and
site index; search on “CFSAN Grants.”

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

[RFA-FD–09–017]

[Catalog of Federal Domestic Assistance
Number: 93.103]

A. Background

This FOA issued by the Office of Food
Safety is soliciting a sole source grant
application from the DISL. FDA is
authorized to enforce the Federal Food,
Drug, and Cosmetic Act (the act) as
amended (21 U.S.C. 301 *et seq.*). In
fulfilling its responsibilities under the
act, FDA among other things, directs its
activities toward promoting and
protecting the public health by ensuring
the safety and security of foods
(Appendix A). To accomplish its
mission, FDA must stay abreast of the
latest developments in research and also
communicate with stakeholders about
complex scientific and public health
issues. Increased development of
research, education and outreach
partnerships with the Marine
Environmental Science Consortium–
Dauphin Island Sea Lab (DISL) will
greatly contribute to FDA’s mission.

The DISL is one of Alabama’s most
valuable assets and adds immeasurably
to the quality of life in the State and
beyond. The DISL network of 21
institutions enrolls students worldwide
in degree programs delivered in
classrooms, laboratories, education
centers and online. The DISL nationally
ranked programs, leading-edge research
collaborations, and innovative business
partnerships provide an environment to
support diverse multidisciplinary
exchanges with FDA. The scientific,
public health and policy expertise
within FDA provide opportunities for
collaborations that support the DISL
mission and strategic themes to provide
access to high-quality education,
research discovery, and knowledge-
based services responsive to both the
promises and demands of the state and
the nation in the new century.

B. Research Objectives

The FDA Gulf Coast Seafood
Laboratory (GCSL) and the Marine
Environmental Science Consortium of
the DISL (the Parties) have a shared
interest in scientific progress in the

diverse disciplines that directly and
indirectly affect seafood safety and
human and animal health. The Parties
also endorse scientific training for
faculty, students and staff to foster a
well-grounded foundation in
interdisciplinary fields in which
academia and government share mutual
interest.

The cooperative agreement will
establish terms of collaboration between
FDA and DISL to support these shared
interests that can be pursued through
programs of collaborative research,
public outreach, cooperative
international initiatives, disciplinary
training, and exchange of scientists and
staff, including a program of graduate
student internships.

The types of activities expected to
develop from this agreement include:

- Exchanges between university
faculty and staff and FDA scientists and
staff;
- Educational opportunities for
qualified students (graduate), staff
members and faculty members in the
Parties’ laboratories, classroom and
offices;
- Joint meetings for education and
research;
- Research collaborations;
- Cooperative international activities
including outreach; and
- Sharing of unique facilities and
equipment for increased cost
efficiencies for scientific endeavors;
- Promulgation and communication
of identified collaborative efforts
through appropriate means;
- Adjunct, affiliates and research
facility appointments for appropriate
FDA professional staff, provided that
appointment of such candidates will
advance specific programmatic
objectives of the parties as appropriate,
and provided that such appointments
comply with university policies on
appointment of facility/affiliates;
- In an effort to enhance collaborative
interactions and communication
between both institutions, FDA and
DISL will collaborate in the
development of regular workshops
where faculty from all the institutions
within the DISL and FDA scientists and
staff share information about on going
research, education and outreach efforts
of mutual interest.

C. Eligibility Information

Competition is limited to the DISL.
There are no other sources that can
provide the required proximity to the
FDA/GCSL and independent marine
fieldwork capability required. The DISL
is a diverse institutional consortium of
undergraduate and graduate education
and research. University programs

faculty at the DISL are actively involved in both basic and applied research in coastal waters of the northern Gulf of Mexico. The DISL operates marine research vessels (boats) crewed by faculty and students for field studies and sample collections. DISL possesses extensive laboratory and wet-laboratory resources relevant to the mission of the FDA/GCSL. The DISL is located within 1 mile of the FDA/GCSL which will engage the proposed program of collaboration and internships. This unique circumstance of capability, capacity and proximity is irreplaceable without extended and costly concessions.

II. Award Information/Funds Available

A. Award Amount

The estimated amount of support in FY09 will be up to \$250,000 total costs (direct plus indirect costs).

B. Length of Support

The award will provide 12 months of support contingent upon satisfactory performance in the achievement of project and program reporting.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.cfsan.fda.gov/list.html>. Persons interested in applying for a grant may obtain an application from the PHS 398 application instructions available at <http://grants.nih.gov/grants/forms.htm>. The following steps are required for paper submission:

- Step 1: Obtain a Dun and Bradstreet Number (DUNS)

Applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number that uniquely identifies business entities. To obtain a DUNS number, call DUN and Bradstreet at 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet. For foreign entities the Web site <https://eupdate.DNB.com>.

- Step 2: Register With Central Contractor Registration (CCR)

Applicants must register with the CCR database. You must have a DUNS number to begin your registration. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for

completing a registration is through the Web site at <https://www.ccr.gov>. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process.

- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit paper applications to: Camille Peake, Division of Acquisition Support and Grants, Food and Drug Administration (HFA 500), 5630 Fishers Lane, rm. 2139, Rockville, MD 20857, 301-827-7175, FAX: 301-827-7101, e-mail: Camille.Peake@fda.hhs.gov.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-18533 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0582]

Kim C. Hendrick: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Kim C. Hendrick, M.D., from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Hendrick was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and for conduct otherwise relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Dr. Hendrick failed to request a hearing. Dr. Hendrick's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 4, 2009.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Robert Hummel, Sr., Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On September 11, 2007, the U.S. District Court for the Eastern District of Michigan accepted Dr. Hendrick's guilty plea and entered judgment against him for one count of mail fraud, a federal felony offense under 18 U.S.C. 1341. This offense was committed when Dr. Hendrick was a licensed physician practicing medicine in the State of Michigan. Dr. Hendrick agreed to participate in the clinical research trial for Augmentin XR, including its use in the treatment of adults with Acute Bacterial Sinusitis (ABS). As part of his participation in the clinical study, he agreed to conduct the study in conformity with the protocol established by GlaxoSmithKline and to comply with FDA regulations. He also agreed to take X-rays, before and after treatment, of persons he diagnosed with ABS, and to have an independent radiologist analyze these and issue reports regarding the X-rays.

Dr. Hendrick admitted that instead of having an independent radiologist review the X-rays and issue reports, he allowed certain X-rays to be sent in batch form, which was a direct violation of the protocol. Further, he did not verify the purported signatures of the independent radiologist reports and, instead, failed to disclose to GlaxoSmithKline and/or FDA that the signatures were unverified and possibly

forged, with the intent to create a false impression of a state of facts. Dr. Hendrick was paid by GlaxoSmithKline approximately \$116,800 in X-ray fees for his participation in the clinical research trial. In so doing he caused a check to be mailed to him through the Postal Service at the direction of GlaxoSmithKline as partial payment for his participation in the clinical trial for the purpose of executing the scheme to defraud.

As a result of this conviction, FDA sent Dr. Hendrick by certified mail on May 4, 2009, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Hendrick was convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, including the process for development or approval of a drug product, and conduct otherwise relating to the regulation of a drug product under the act. The proposal also offered Dr. Hendrick an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Hendrick did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act, and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Dr. Hendrick has been convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Dr. Hendrick is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii),

and 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Hendrick, in any capacity, during Dr. Hendrick's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Hendrick, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Hendrick during his permanent debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Hendrick for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2008-N-0582 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 15, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. E9-18621 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0501]

Paul H. Kornak: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Paul H. Kornak from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Paul H. Kornak was convicted of three felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and for

conduct otherwise relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Kornak failed to request a hearing. Mr. Kornak's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 4, 2009.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Robert L. Hummel, Sr., Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On January 18, 2005, the U.S. District Court for the Northern District of New York accepted Mr. Kornak's plea of guilty and entered judgment against Mr. Kornak for one count of making and using a materially false statement, one count of mail fraud, and one count of criminally negligent homicide, federal felony offenses under 18 U.S.C. 1001(a)(3), 1341 and 1346, and 13, respectively. The actions underlying these convictions were committed while Mr. Kornak was employed by the Department of Veterans Affairs as the coordinator of several clinical studies of drug products. Mr. Kornak participated in a scheme to defraud the sponsors of these studies by repeatedly submitting false documentation and enrolling and causing to be enrolled persons as study subjects who did not qualify under particular study protocols. Mr. Kornak admitted to submitting a case report form with regard to a study subject knowing the document contained

materially false laboratory entries and altered information from a radiology display report, which were critical factors in determining whether the individual was eligible to participate in the clinical study. He also admitted to knowingly and willfully misrepresenting the results of a blood chemistry analysis related to the participation of a study subject who would not otherwise have met the criteria for that study. The subject was administered chemotherapeutic drugs in connection with the clinical study and died as a result thereof. Mr. Kornak's failure to perceive a substantial and unjustifiable risk that death would occur when he knowingly and willingly made and used such false documents constituted a gross deviation from the standard of care that a reasonable person would observe in the situation. Mr. Kornak further admitted to knowingly and willfully using interstate mail for the purpose of executing the aforesaid scheme and artifice to defraud, deprive, and obtain money and property.

As a result of these convictions, FDA sent Mr. Kornak by certified mail on May 4, 2009, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Mr. Kornak was convicted of felonies under Federal law for conduct relating to the development or approval of a drug product, and for conduct otherwise relating to the regulation of a drug product under the act. The proposal also offered Mr. Kornak an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kornak did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act, and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Mr. Kornak has been convicted of felonies under Federal law for conduct relating to the development or approval of a drug product and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Kornak is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii), and 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains Mr. Kornak as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Kornak during Mr. Kornak's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kornak, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kornak during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Kornak for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2007-N-0501 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. E9-18619 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-E-0258; FDA-2008-E-0260; and FDA-2008-E-0261]

Determination of Regulatory Review Period for Purposes of Patent Extension; RECOTHROM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RECOTHROM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of three applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human biological product.

ADDRESSES: Submit written comments and petitions 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.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the human biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the human biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include

all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product RECOTHROM (Thrombin, topical (Recombinant)). RECOTHROM is indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques is ineffective or impractical. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for RECOTHROM (U.S. Patent Nos. 5,476,777, 5,502,034, and 5,527,692) from ZymoGenetics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of RECOTHROM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for RECOTHROM is 1,511 days. Of this time, 1,115 days occurred during the testing phase of the regulatory review period, while 396 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* November 30, 2003. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on November 30, 2003.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 18, 2006. FDA has verified the applicant's claims that the biologics license application (BLA) for RECOTHROM (BLA 125248/0) was initially submitted on December 18, 2006.

3. *The date the application was approved:* January 17, 2008. FDA has verified the applicant's claims that BLA 125248/0 was approved on January 17, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and

Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 952 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by October 5, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 1, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–18528 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0551]

Determination of Regulatory Review Period for Purposes of Patent Extension; XIENCE V EECSS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XIENCE V EECSS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions 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.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device, XIENCE V EECSS. XIENCE V EECSS is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length = 28 millimeters (mm)) with reference vessel diameters of 2.5 mm to 4.25 mm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XIENCE V EECSS (U.S. Patent No. 5,451,233) from Abbott Cardiovascular Systems, Inc., and the Patent and Trademark Office requested

FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 2009, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of XIENCE V EECSS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XIENCE V EECSS is 1,157 days. Of this time, 759 days occurred during the testing phase of the regulatory review period, while 398 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* May 4, 2005. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on May 4, 2005.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* June 1, 2007. The applicant claims the premarket approval application (PMA) XIENCE V EECSS (PMA 70015) was submitted in three modules and that Module 1 was initially submitted on July 14, 2006. The applicant claims July 14, 2006, as the date PMA 70015 was initially submitted. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records indicates that PMA 70015 was submitted as a complete application on June 1, 2007, which is considered to be the initially submitted date for PMA 70015.

3. *The date the application was approved:* July 2, 2008. FDA has verified the applicant's claim that PMA 70015 was approved on July 2, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 937 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or

electronic comments and ask for a redetermination by October 5, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 1, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–18530 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0020]

Determination of Regulatory Review Period for Purposes of Patent Extension; EOVISt

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for EOVISt and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product EOVISt (gadoxetate disodium). EOVISt is indicated for intravenous use in T1–weighted magnetic resonance imaging of the liver to detect and characterize lesions in adults with known or suspected focal liver disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EOVISt (U.S. Patent No. 6,039,931) from Bayer Schering Pharma Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EOVISt represented the first permitted commercial marketing or

use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EOVI is 3,818 days. Of this time, 3,450 days occurred during the testing phase of the regulatory review period, while 368 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* January 21, 1998. The applicant claims January 19, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* July 2, 2007. The applicant claims June 29, 2007, as the date the new drug application (NDA) for EOVI (NDA 22-090) was initially submitted. However, FDA records indicate that NDA 22-090 was submitted on July 2, 2007.

3. *The date the application was approved:* July 3, 2008. FDA has verified the applicant's claim that NDA 22-090 was approved on July 3, 2008. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,699 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by October 5, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 1, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9-18527 Filed 8-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2001-D-0129 (formerly Docket No. 2001D-0064)]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy." This guidance document describes a means by which manufacturers of dental amalgam, mercury, and amalgam alloy may comply with special controls that apply to these class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify dental amalgam into class II (special controls), reclassify dental mercury from class I (general controls) to class II (special controls), and designate a special controls guidance document to support the class II classification of these two devices, as well as the current class II classification of amalgam alloy.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Michael Adjodha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2606, Silver Spring, MD 20993-0002, 301-796-6276.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 20, 2002 (67 FR 7620), FDA issued a proposed rule to issue a separate regulation classifying encapsulated dental amalgam into class II (special controls); amending the class II classification of amalgam alloy by designating special controls; and reclassifying dental mercury from class I (general controls) to class II (special controls). Also, in the **Federal Register** of February 20, 2002 (67 FR 7703), FDA announced the availability of the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling," which would serve as a special control for all three devices. The comment period on the proposed rule closed on May 21, 2002. FDA reopened the comment period in July 2002 (67 FR 46991) and again in April 2008 (73 FR 22877) to provide the public with additional opportunities to comment and to submit data and information that may have become available since publication of the proposed rule. The comment period closed on July 28, 2008.

FDA received more than 1,400 comments on the proposed rule and the draft special controls guidance document. Because of the intertwined nature of the proposed rule and the draft guidance, and because of the significant overlap in comments, FDA considered all comments in preparing both the final rule and the special controls guidance document. The analysis of comments is contained in the preamble to the final rule.

II. Significance of Special Controls Guidance Document

The final rule designates the guidance document entitled "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy" as the special control for mercury, amalgam alloy, and dental amalgam. FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), will provide reasonable assurance of the safety and effectiveness of dental amalgam, mercury, and amalgam alloy. Following the effective date of the final rule, any firm submitting a 510(k) premarket notification for dental amalgam, mercury, or amalgam alloy, as well as any firm currently marketing the devices, must address the issues covered in the special controls guidance. The firm must show that its device addresses the issues of safety and effectiveness identified in the special controls guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy" you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1192) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>.

Guidance documents are also available at <http://www.regulations.gov>.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-18445 Filed 7-29-09; 4:15 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

Dates and Times: September 24, 2009, 8:30 a.m. to 5 p.m. September 25, 2009, 8:30 a.m. to 3 p.m.

Place: Bethesda Marriott-Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration web site at <http://events.SignUp4.com/ACHDNC0909>. The registration deadline is Wednesday, September 23, 2009. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration web site. The deadline for special accommodation requests is Friday, September 18, 2009. If there are technical problems gaining access to the web site, please contact Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, by telephone (202) 828-5100 or via e-mail conferences@altarum.org.

Purpose: The Secretary's ACHDNC was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and

programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The ACHDNC also provides advice and recommendations concerning the grants and projects authorized under the Public Health Service Act, 42 U.S.C. 300b-10, (Heritable Disorders Program) as amended in the Newborn Screening Saves Lives Act of 2008.

Agenda: The meeting will include presentations and continued discussions on the nomination/evaluation process for newborn screening candidate conditions. The agenda will include presentations on the Newborn Screening Use Case, the National Health Information Network, and Newborn Screening Quality Measures, as well as presentations on the continued work and reports of the ACHDNC's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training.

Proposed agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Web site at <http://events.SignUp4.com/ACHDNC0909>.

Webcast: The meeting will be Webcast. Information on how to access the Webcast will be available on the day of the meeting by clicking on the meeting date link at <http://events.SignUp4.com/ACHDNC0909>.

Public Comments: Members of the public can present oral comments during the public comment periods of the meeting, which are scheduled for both days of the meeting. Those individuals who want to make a comment are requested to register online by Wednesday, September 23, 2009, at <http://events.SignUp4.com/ACHDNC0909>. Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the web site. Written comments should be emailed no later than Wednesday, September 23, 2009, for consideration. Comments should be submitted to Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, telephone: 202 828-5100; fax: 202 785-3083, or e-mail: conferences@altarum.org.

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-0721, aharris@hrsa.gov. More information on the Advisory Committee is available at <http://mchb.hrsa.gov/heritabledisorderscommittee>.

Dated: July 28, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-18526 Filed 8-3-09; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, Centers for Medicare & Medicaid Service (CMS), 68 FR 60694, dated October 23, 2003, is superseded to include the following delegation of authority from the Secretary to the Administrator, CMS, with the authority to redelegate, to carry out the following administrative and enforcement activities invested in the Secretary of the Department of Health and Human Services under part C, of title XI of the Social Security Act, as amended.

- Section F.30., Delegations of Authority, is superseded to include the following delegation of authority for certain provisions under part C, of title XI of the Social Security Act.

WW. 1. The authority under section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, as amended, except to the extent these actions pertain to the “Security Standards for the Protection of Electronic Protected Health Information,” or the “Standards for Privacy of Individually Identifiable Health Information” at 45 CFR, part 160 and part 164, subparts A, C, and E to:

A. Impose civil money penalties under section 1176 of the Social Security Act for a covered entity’s failure to comply with certain requirements and standards;

B. Issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or compliance review for failure to comply with certain requirements and standards; and

C. Make exception determinations, under section 1178(a)(2)(A) of the Social Security Act, concerning when provisions of State laws that are contrary to the Federal standards are not preempted by the Federal provisions.

2. The authority under section 262 of HIPAA, Public Law 104–191, as amended, to administer and to make decisions regarding the interpretation, implementation and enforcement of the regulations adopting standards and general administrative requirements under 45 CFR, part 160 and part 162, except to the extent these actions

pertain to the “Security Standards for the Protection of Electronic Protected Health Information,” or the “Standards for Privacy of Individually Identifiable Health Information” at 45 CFR, part 160 and part 164, subparts A, C, and E.

Exclusion to This Authority

All actions under Part C of Title XI of the Social Security Act that pertain to “Security Standards for the Protection of Electronic Protected Health Information” or the “Standards for Privacy of Individually Identifiable Health Information”, were delegated by the Secretary to the Director, Office for Civil Rights, and are excluded from this delegation. This delegation to the Administrator also excludes the authority to issue regulations and to hold hearings and issue final determinations if the respondent has requested a hearing on the imposition of civil monetary penalties. This delegation shall be exercised under the Department’s existing delegation of authority and policy relating to regulations.

This delegation supersedes the memorandum from the Secretary to the Administrator, Centers for Medicare & Medicaid Services, dated October 7, 2003, titled “Delegation of Authority for Certain Provisions Under Part C of Title XI of the Social Security Act.”

I hereby affirm and ratify any actions taken by the Administrator of CMS or his/her subordinates which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: July 27, 2009.

Kathleen Sebelius,
Secretary.

[FR Doc. E9–18561 Filed 8–3–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Exportation of Used Self-Propelled Vehicles

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651–0054.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the

following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Exportation of Used Self-Propelled Vehicles. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 16227) on April 9, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before September 3, 2009.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION:

U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Exportation of Used-Propelled Vehicles.

OMB Number: 1651-0054.

Form Number: None.

Abstract: 19 U.S.C. 1627 requires the exporter of a used self-propelled vehicle to present both the vehicle and a document describing it (which includes the vehicle identification number) to CBP prior to lading if the vehicle is to be transported by vessel or aircraft, or prior to export if the vehicle is transported by rail, highway, or under its own power. This information helps CBP ensure that stolen vehicles are not exported from the U.S.

Current Actions: There are no changes to the information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Individuals.

Estimated Number of Respondents: 750,000.

Estimated Number of Total Annual Responses: 750,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 125,000.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: July 29, 2009.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E9-18610 Filed 8-3-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Petroleum Refineries in Foreign Trade Sub-Zones

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing information collection: 1651-0063.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Petroleum Refineries in

Foreign Trade Sub-zones. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 16228) on April 9, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before September 3, 2009.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395-5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104-13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies'/components' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Petroleum Refineries in Foreign Trade Sub-zones.

OMB Number: 1651-0063.

Form Number: None.

Abstract: This is a record keeping requirement that involves data

necessary to account for admissions into, and operations occurring within each phase of the refining operation for all withdrawals of crude petroleum from Foreign Trade Sub-zones.

Current Actions: There are no changes to this information collection. This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Record Keepers: 81.

Estimated Annual Time per Record Keeper: 1000 hours.

Estimated Total Annual Burden: 81,000 hours.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: July 29, 2009.

Tracey Denning,

Agency Clearance Officer, Customs and Border Protection.

[FR Doc. E9-18611 Filed 8-3-09; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: New Information Collection; Comment Request

ACTION: 30-Day Notice of New Information Collection; Form 10-002, Electronic Funds Transfer Waiver Request.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The Information Collection was previously published in the **Federal Register** on June 2, 2009, Vol. 74 No. 101 26416, allowing for a 60 day public comment period. USICE received no comments on this Information Collection from the public during this 60 day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days, until September 3, 2009.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice

and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of Information Collection:* New Information Collection.

(2) *Title of the Form/Collection:* Electronic Funds Transfer Waiver Request.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form 10-002, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individual or Households, Business or other non-profit. The information collected on the Form 10-002 is necessary for U.S. Immigration and Customs Enforcement (ICE) to determine if an individual or business is exempt from the Electronic Funds Transfer requirements of the Debt Collection Improvement Act by meeting certain conditions.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to*

respond: 650 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 325 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be requested via e-mail to: forms.ice@dhs.gov with "ICE Form 10-002" in the subject line.

Dated: July 30, 2009.

Joseph M. Gerhart,

Records Management Branch Chief, Office of Asset Management, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E9-18613 Filed 8-3-09; 8:45 am]

BILLING CODE 9111-28-P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; Form I-246, Application for Stay of Deportation or Removal; OMB Control No. 1653-0021.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The Information Collection was previously published in the **Federal Register** on June 2, 2009 Vol. 74 No. 104 26417, allowing for a 60 day public comment period. USICE received no comments on this Information Collection from the public during this 60 day period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days September 3, 2009.

Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to

oir_submission@omb.eop.gov or faxed to (202) 395-5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of Information Collection:* Extension of a currently approved Information Collection.

(2) *Title of the Form/Collection:* Application for Stay of Deportation or Removal.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-246, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* *Primary:* Individual or Households, Business or other non-profit. The information collected on the Form I-246 is necessary for U.S. Immigration and Customs Enforcement (ICE) to make a determination that the eligibility requirements for a request for a stay of deportation or removal are met by the applicant.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 10,000 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 5000 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information regarding this Information Collection should be requested via e-

mail to: forms.ice@dhs.gov with "ICE Form I-246" in the subject line.

Dated: July 30, 2009.

Joseph M. Gerhart,

Chief, Records Management Branch, Office of Asset Management, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E9-18612 Filed 8-3-09; 8:45 am]

BILLING CODE 9111-28-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2008-0126]

Application for the Tank Ship S/R AMERICAN PROGRESS, Review for Inclusion in the Shipboard Technology Evaluation Program; Final Environmental Assessment

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of the Final Environmental Assessment (FEA) for the tank ship S/R AMERICAN PROGRESS. The FEA describes the S/R AMERICAN PROGRESS application for the Shipboard Technology Evaluation Program (STEP) Ballast Water Management System (BWMS) initiative. The FEA for the S/R AMERICAN PROGRESS also addresses potential effects on the human and natural environments from installing, testing, and using the SevernTrentDeNora (STDN) BalPure™ ballast water treatment system as the vessel operates in U.S. waters.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, are part of the docket USCG-2008-0126. These documents are available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You can also find all docketed documents on the Federal Document Management System at <http://www.regulations.gov>, United States Coast Guard docket number USCG-2008-0126.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail LCDR Brian Moore, U.S. Coast Guard; telephone 202-372-1434, e-mail brian.e.moore@uscg.mil. If you have

questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

In the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as reauthorized, and as amended by the National Invasive Species Act of 1996, Public Law 101-646 and Public Law 104-332, respectively, Congress directed the Coast Guard to prevent, to the maximum extent practicable, introduction of aquatic nonindigenous species from ballast water discharged by ships (16 U.S.C. 4711). To achieve this objective, the Coast Guard wrote new regulations in 33 CFR 151, subparts C and D. (58 FR 18330, Apr. 8, 1993, and 69 FR 44952, Jul. 28, 2004, respectively).

On December 8, 2004, the Coast Guard published a notice in the **Federal Register** (69 FR 71068, Dec. 8, 2004), announcing its Shipboard Technology Evaluation Program (STEP) for experimental shipboard ballast water treatment systems. The program goal is to promote development of alternatives to ballast water exchange as a means of preventing invasive species from entering U.S. waters through ships' ballast water. The comments we received support testing prototype treatment equipment and developing effective and practicable standards for approving this equipment.

In accordance with the National Environmental Policy Act of 1969 (Section 102(2)(c)), as implemented by the Council of Environmental Quality regulations in 40 CFR parts 1500-1508, and Coast Guard Commandant Instruction M16475.1D, "National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts," the Coast Guard prepared a Programmatic Environmental Assessment (PEA) for the STEP to evaluate the environmental impacts from installing and operating a limited number of prototype ballast water treatment systems (69 FR 71068, Dec. 8, 2004). The PEA can be found in docket USCG-2001-9267. The PEA addresses potential effects to the natural and human environments including fish, marine mammals, invertebrates, microorganisms and plankton, submerged and emergent aquatic vegetation, threatened and endangered species, and essential fish habitat. It also requires each system to be evaluated for localized effects on the ports and waterways where a vessel involved in the program operates.

The Coast Guard announced the availability and request for public comments of the Draft Environmental Assessment (DEA) for the tank ship S/R AMERICAN PROGRESS by **Federal Register** notice on December 1, 2008 (73 FR 72825, Dec. 1, 2008). The comment period was open until December 31, 2008. The California State Lands Commission (CSLC) had commented on previous Draft Environmental Assessments regarding three other vessels with STEP applications, specifically, STEP applications regarding the cruise ship CORAL PRINCESS (73 FR 72817, Dec. 1, 2008), the integrated tug and barge MOKU PAHU (73 FR 72819, Dec. 1, 2008), and the vessel ATLANTIC COMPASS (73 FR 72814, Dec. 1, 2008). Due to the high level of interest previously shown by CSLC, and that just prior to the end of the comment period on the DEA for S/R AMERICAN PROGRESS there were no public comments, the Coast Guard contacted CSLC prior to the closing of the comment period to ensure CSLC was aware of the posting. Soon after the comment period had expired, CSLC replied directly to Coast Guard via e-mail with comments. The CLSC submitted 23 substantive comments, and 19 editorial comments. All comments from CSLC were posted by the Coast Guard to the docket. The Coast Guard received no other comments from any source.

The 19 editorial comments from CLSC were adopted and incorporated in the Final Environmental Assessment (FEA) to improve readability. The adopted edits made no substantive changes to the FEA. The remaining comments with the Coast Guard's response are provided as appendix G in the FEA.

This notice is issued under authority of the National Environmental Policy Act of 1969 (Section 102 (2)(c)), as implemented by the Council of Environmental Quality regulations (40 CFR parts 1500-1508) and Coast Guard Commandant Instruction M16475.1D.

Dated: July 28, 2009.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. E9-18495 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****[Docket No. USCG-2009-0714]****National Maritime Security Advisory Committee; Meeting****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of meeting.

SUMMARY: The National Maritime Security Advisory Committee (NMSAC) will conduct a meeting by teleconference on August 24, 2009. This teleconference will be open to the public.

DATES: The Committee will meet on August 24, 2009 from 1 p.m. to 3 p.m. This meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before August 17, 2009. Requests to have a copy of your material distributed to each member of the committee or subcommittee should reach the Coast Guard on or before August 17, 2009.

ADDRESSES: The NMSAC teleconference calls will be hosted in room 6228, U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, DC 20593. Public participation is limited to monitoring the teleconference only, except at the time allotted by the chairperson for public comment; special note, the number of teleconference lines is limited and available on a first-come, first-served basis. For call-in information or to send written material and requests to make oral presentations contact Mr. Ryan Owens, Executive Secretary of NMSAC, at ryan.f.owens@uscg.mil, Commandant (CG-5441), ATTN NMSAC DFO/EA, U.S. Coast Guard, 2100 2nd St., SW., STOP 7581, Washington, DC 20593-7581. This notice is available in our online docket, USCG-2009-0714, at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Ryan F. Owens Executive Secretary of NMSAC at 202-372-1108.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

Agenda of Meeting

The agenda for the August 24 Committee meeting is as follows:

- (1) Maritime Information Sharing Taskforce Briefing
- (2) Discussion of a Certain Dangerous Cargo (CDC) Tasking for the Committee

Procedural

This meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at a meeting, please notify the Executive Secretary no later than August 17. Written material for distribution at a meeting should reach the Coast Guard no later than August 17. If you would like a copy of your material distributed to each member of the committee or subcommittee in advance of a meeting, please submit 25 copies to the Executive Secretary no later than August 17.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Executive Secretary as soon as possible.

Dated: 28 July, 2009.

Ryan F. Owens,

Acting Designated Federal Official, U.S. Coast Guard, Office of Port and Facility Activities.

[FR Doc. E9-18511 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service**

[FWS-R2-R-2009-N0073; 22570-1261-0000-V3]

Limiting Mountain Lion Predation on Desert Bighorn Sheep on Kofa National Wildlife Refuge, Yuma and La Paz Counties, AZ

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of draft environmental assessment; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce that our draft environmental assessment (EA) for limiting mountain lion (*Puma concolor*) predation on desert bighorn sheep (*Ovis canadensis mexicana*) on the Kofa National Wildlife Refuge (Refuge) is available. The Refuge is located in southwest Arizona. The draft EA describes alternatives, including a proposed action alternative, that address how we intend to manage mountain lion predation to help achieve bighorn sheep population objectives.

DATES: To ensure consideration, we must receive your written comments on

the draft EA 60 days from date of publication.

ADDRESSES: Please provide written comments to the Southwest Arizona National Wildlife Refuge Complex, by U.S. mail at U.S. Fish and Wildlife Service, 9300 East 28th Street, Yuma, AZ 85365; via facsimile at 928-783-8611; or electronically to KofaLionComments@fws.gov. You may obtain a copy of the draft EA by writing to the address above, or by download from <http://www.fws.gov/southwest/refuges/arizona/kofa>.

FOR FURTHER INFORMATION CONTACT: Jose Viramontes, 505-248-6455 (phone); 505-248-6915 (fax); or Jose_Viramontes@fws.gov (e-mail). If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:**Background**

The Refuge contains a major portion of the largest contiguous habitat for desert bighorn sheep in southwestern Arizona and historically has been home to a population averaging 760 bighorns. The Refuge has served as the primary source of bighorn sheep for translocations to reestablish and supplement extirpated or declining populations throughout southern Arizona, New Mexico, Texas, and Colorado. Population estimates from systematic aerial surveys indicate that a 50-percent decline in the Refuge sheep population occurred during the period 2000-2008.

In response to this decline, the Service and the Arizona Game and Fish Department (AZGFD) have conducted an analysis of the probable causes of the decline and are currently implementing a strategic management program intended to lead to the recovery of this important wildlife resource. Several studies and monitoring projects have been initiated or enhanced. Some of the more important aspects of this broad program include more frequent bighorn population surveys, monitoring and maintaining water availability, assessing body condition and disease in the bighorn population, monitoring disturbance attributable to human recreation, and monitoring the extent of predation and its impacts on the population. Many of the elements in this management program have been addressed through prior planning documents and require little additional review. Others, such as the proposed lethal control of mountain lions, have not been previously addressed and

therefore require National Environmental Policy Act analysis and public review.

Draft Environmental Assessment

This draft EA identifies and evaluates three alternatives for managing mountain lion predation on desert bighorn sheep on the Refuge.

Alternative A: Under this alternative, the Refuge would continue to be managed as it has been in the past. We currently have no plan to guide the management of mountain lions. Current management efforts, described in the Refuge's general management plan, focus on maintaining critical wildlife water sources for bighorn sheep, and, in coordination with the AZGFD, monitoring desert bighorn sheep numbers, and considering desert bighorn sheep transplants to augment populations elsewhere. Research on wildlife and wildlife water sources would continue. We would not take action to prevent mountain lion predation on desert bighorn sheep within the Refuge boundaries under this alternative.

Alternative B: This is the our proposed action, which would allow the option of removing specific, individually identified offending mountain lions, through translocation or lethal removal, from the Refuge under certain circumstances, in order to recover and maintain an optimal population of desert bighorn sheep. The proposed action has several components. We would trap mountain lions and fit them with tracking devices to monitor their activities. When the Refuge bighorn sheep population estimate is below 600 animals, active mountain lion removal would occur. Active mountain lion control is the removal of mountain lions found to kill two or more bighorn sheep within a 6-month period. The Service, or its agents, would carry out the lethal removal or translocation. However, when the Refuge bighorn sheep population estimate is between 600 and 800 animals, active mountain lion control may or may not be employed based on the totality of the circumstances at the time. In order to meet the bighorn sheep population objectives while minimizing the necessary impacts to mountain lions, some flexibility is desired. Decisions regarding whether active mountain lion control is necessary will be based on an adaptive management approach and based on the following factors: The current sheep population estimate; the current sheep population trend; bighorn sheep lamb survival and recruitment; the estimate of the number of mountain lions currently using the

Refuge; current and forecasted habitat conditions; and available funding and manpower. When the Refuge bighorn sheep population estimate is at or above 800 animals, active mountain lion control would not occur, although mountain lions on the Refuge would continue to be captured and fitted with tracking devices to aid in continuing research.

Alternative C: Under this alternative, there would be no attempts to radio collar and distinguish which mountain lions are preying on bighorn sheep. Mountain lions would be lethally removed or translocated at a rate of approximately 2 mountain lions per year from the area until the sheep population reaches an estimated 800 animals and has exhibited an increasing trend based on at least 3 sheep population surveys. Mountain lion removals would resume if the Refuge bighorn sheep population was found to again go below 800 animals.

Additional Refuge Information

Additional information on the history of the Refuge and its purpose, goals, objectives, and management strategies can be found in the *Kofa National Wildlife Refuge & Wilderness and New Water Mountains Wilderness Interagency Management Plan and Environmental Assessment: EA-AZ-055-95-105, October 1996*. Pertinent information can also be found in the April 2007 report titled *Investigative Report and Recommendations for the Kofa Bighorn Sheep Herd*, prepared jointly by the Service and the AZGFD. Both documents, along with other detailed information, are available at the following Web site: <http://www.fws.gov/southwest/refuges/arizona/kofa>.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authorities

The Environmental Review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*); NEPA Regulations (40 CFR parts 1500–1508); other appropriate Federal laws and regulations; Executive Order

12996; the National Wildlife Refuge System Improvement Act of 1997; and Service policies and procedures for compliance with those laws and regulations.

Dated: April 3, 2009.

Benjamin N. Tuggle,

Regional Director, U.S. Fish and Wildlife Service, Albuquerque, New Mexico.

[FR Doc. E9–18285 Filed 8–3–09; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–R–2008–N0292; 80230–1265–0000–S3]

Klamath Marsh National Wildlife Refuge, Klamath County, OR

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments; draft comprehensive conservation plan/environmental assessment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a Draft Comprehensive Conservation Plan/Environmental Assessment (CCP/EA) for the Klamath Marsh National Wildlife Refuge for public review and comment. The CCP/EA, prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997, and in accordance with the National Environmental Policy Act of 1969, describes how the Service will manage the Refuge for the next 15 years. Draft compatibility determinations for several existing and proposed public uses are also available for review and public comment with the Draft CCP/EA.

DATES: Written comments must be received at the address below on or before Friday, September 18, 2009.

ADDRESSES: For more information on obtaining documents and submitting comments, see “Review and Comment” under **SUPPLEMENTARY INFORMATION**. For public meeting location see “Public Meetings.”

FOR FURTHER INFORMATION CONTACT: Mark Pelz, Chief, Refuge Planning, 2800 Cottage Way, W–1832, Sacramento, CA 95825, phone (916) 414–6500.

SUPPLEMENTARY INFORMATION: The National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–668ee), which amended the National Wildlife Refuge System Administration Act of 1966, requires us to develop a CCP for each national wildlife refuge. The purpose in developing a CCP is to provide refuge

managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, environmental education and interpretation.

We initiated the CCP/EA for the Klamath Marsh National Wildlife Refuge in February 2007. At that time and throughout the process, we requested, considered, and incorporated public scoping comments in numerous ways. Our public outreach has included a **Federal Register** notice of intent published on January 29, 2007, agency and Tribal scoping meetings, two public workshops, planning updates, and a CCP Web page. We received over 180 scoping comments during the 60-day public comment period.

Background

Klamath Marsh was established in 1958 and is located in south central Oregon on the east slope of the Cascade Mountain Range along the Williamson River. The Service owns approximately 40,960 acres within the 49,583-acre acquisition boundary. The Refuge protects one of the largest remaining natural freshwater marshes on the west coast. Other important habitats on the refuge include sedge meadow, grassland, riverine, riparian scrub, and ponderosa pine forest. The refuge protects habitat for a variety of unique species including greater sandhill cranes, yellow rails, Oregon spotted frogs, red-naped sapsuckers, pygmy nuthatches, bald eagles, beaver, and red band trout. The entire Refuge is located within the former reservation of the Klamath Tribes.

Alternatives

The Draft CCP/EA identifies and evaluates three alternatives for managing Klamath Marsh National Wildlife Refuge for the next 15 years. The alternative that appears to best meet the Refuge purposes is identified as the preferred alternative. The preferred alternative is identified based on the analysis presented in the Draft CCP/EA, which may be modified following the completion of the public comment period based on comments received from other agencies, Tribal

governments, non-governmental organizations, or individuals.

Under Alternative A, the no action alternative, we would continue to manage the Refuge as we have in the recent past. No major changes in habitat management would occur. The existing wildlife observation, photography, environmental education, and interpretation programs would remain unchanged.

Under Alternative B, (preferred alternative), the Service would restore the portion of the Williamson River and Big Spring Creek on the Refuge; substantially improve management of emergent marsh, meadows, ponderosa pine forest and aspen to increase habitat value for migratory birds and other wildlife; improve and expand visitor services by developing new trails, interpretive exhibits, an environmental education program, and a visitor contact station; maintain existing hunting and fishing programs with minor modifications; increase cultural resources protection; and recommend no units for wilderness designation. The Service would also revise and update the MOU with the Klamath Tribes regarding subsistence hunting and gathering.

Under Alternative C, the Service would restore the portions of the Williamson River and Big Springs Creek on the Refuge; improve management of emergent marsh, meadows, ponderosa pine forest and aspen using a more limited tool set (fire only for non-forested areas); minimally expand opportunities for non-consumptive public uses; eliminate public hunting; increase cultural resource protection; and recommend 11,165 acres for wilderness designation. The Service would also revise and update the MOU with the Tribes regarding subsistence hunting and gathering.

Public Meetings

The locations, dates, and times of public meetings will be listed in a planning update distributed to the project mailing list and posted on the Refuge Web site at <http://www.fws.gov/klamathbasinrefuges/KlamathMarshCCP/kmarshccp.html>.

Review and Comment

Copies of the Draft CCP/EA may be obtained by writing to the U.S. Fish and Wildlife Service, Attn: Mark Pelz, CA/NV Refuge Planning Office, 2800 Cottage Way, W-1832, Sacramento, CA 95825-1846. Copies of the Draft CCP/EA may be viewed at this address or at the Klamath National Wildlife Refuge, HC 63 Box 303, Chiloquin, OR 97624. The Draft CCP/EA will also be available for

viewing and downloading online at:

<http://www.fws.gov/klamathbasinrefuges/KlamathMarshCCP/kmarshccp.html>.

Comments on the Draft CCP/EA should be addressed to: Mark Pelz, Chief, Refuge Planning, 2800 Cottage Way, W-1832, Sacramento, CA 95825-1846. Comments may also be faxed to (916) 414-6497 or if you choose to submit comments via electronic mail, submit them to the following address: fw8plancomments@fws.gov.

At the end of the review and comment period for this Draft CCP/EA, comments will be analyzed by the Service and addressed in the Final CCP/EA. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: July 28, 2009.

Ren Lohofener,

Regional Director, Pacific Southwest Region, Sacramento, California.

[FR Doc. E9-18427 Filed 8-3-09; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Quarterly Status Report of Water Service, Repayment, and Other Water-Related Contract Negotiations

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given of contractual actions that have been proposed to the Bureau of Reclamation and are new, modified, discontinued, or completed since the last publication of this notice on June 24, 2009. This notice is one of a variety of means used to inform the public about proposed contractual actions for capital recovery and management of project resources and facilities consistent with section 9(f) of the Reclamation Project Act of 1939. Additional announcements of individual contract actions may be published in the **Federal Register** and in newspapers of general circulation in the areas determined by Reclamation to be affected by the proposed action.

ADDRESSES: The identity of the approving officer and other information

pertaining to a specific contract proposal may be obtained by calling or writing the appropriate regional office at the address and telephone number given for each region in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Michelle Kelly, Water and Environmental Resources Office, Bureau of Reclamation, PO Box 25007, Denver, Colorado 80225-0007; telephone 303-445-2888.

SUPPLEMENTARY INFORMATION: Consistent with section 9(f) of the Reclamation Project Act of 1939 and the rules and regulations published in 52 FR 11954, April 13, 1987 (43 CFR 426.22), Reclamation will publish notice of proposed or amendatory contract actions for any contract for the delivery of project water for authorized uses in newspapers of general circulation in the affected area at least 60 days prior to contract execution. Announcements may be in the form of news releases, legal notices, official letters, memorandums, or other forms of written material. Meetings, workshops, and/or hearings may also be used, as appropriate, to provide local publicity. The public participation procedures do not apply to proposed contracts for the sale of surplus or interim irrigation water for a term of 1 year or less. Either of the contracting parties may invite the public to observe contract proceedings. All public participation procedures will be coordinated with those involved in complying with the National Environmental Policy Act. Pursuant to the "Final Revised Public Participation Procedures" for water resource-related contract negotiations, published in 47 FR 7763, February 22, 1982, a tabulation is provided of all proposed contractual actions in each of the five Reclamation regions. When contract negotiations are completed, and prior to execution, each proposed contract form must be approved by the Secretary of the Interior, or pursuant to delegated or redelegated authority, the Commissioner of Reclamation or one of the regional directors. In some instances, congressional review and approval of a report, water rate, or other terms and conditions of the contract may be involved.

Public participation in and receipt of comments on contract proposals will be facilitated by adherence to the following procedures:

1. Only persons authorized to act on behalf of the contracting entities may negotiate the terms and conditions of a specific contract proposal.

2. Advance notice of meetings or hearings will be furnished to those

parties that have made a timely written request for such notice to the appropriate regional or project office of Reclamation.

3. Written correspondence regarding proposed contracts may be made available to the general public pursuant to the terms and procedures of the Freedom of Information Act, as amended.

4. Written comments on a proposed contract or contract action must be submitted to the appropriate regional officials at the locations and within the time limits set forth in the advance public notices.

5. All written comments received and testimony presented at any public hearings will be reviewed and summarized by the appropriate regional office for use by the contract approving authority.

6. Copies of specific proposed contracts may be obtained from the appropriate regional director or his designated public contact as they become available for review and comment.

7. In the event modifications are made in the form of a proposed contract, the appropriate regional director shall determine whether republication of the notice and/or extension of the comment period is necessary.

Factors considered in making such a determination shall include, but are not limited to (i) the significance of the modification, and (ii) the degree of public interest which has been expressed over the course of the negotiations. At a minimum, the regional director shall furnish revised contracts to all parties who requested the contract in response to the initial public notice.

Definitions of Abbreviations Frequently Used in This Document

ARRA American Recovery and Reinvestment Act of 2009
BCP Boulder Canyon Project Reclamation Bureau of Reclamation
CAP Central Arizona Project
CVP Central Valley Project
CRSP Colorado River Storage Project
FR Federal Register
IDD Irrigation and Drainage District
ID Irrigation District
M&I Municipal and Industrial
NMISC New Mexico Interstate Stream Commission
O&M Operation and Maintenance
P-SMBP Pick-Sloan Missouri Basin Program
PPR Present Perfected Right
RRA Reclamation Reform Act of 1982
SOD Safety of Dams
SRPA Small Reclamation Projects Act of 1956
USACE U.S. Army Corps of Engineers
WD Water District

Pacific Northwest Region: Bureau of Reclamation, 1150 North Curtis Road, Suite 100, Boise, Idaho 83706-1234, telephone 208-378-5344.

Modified Contract Actions

8. Greenberry ID, Willamette Basin Project, Oregon: Irrigation water service contract for approximately 10,000 acre-feet of project water.

10. Five irrigation water user entities, Rogue River Basin Project, Oregon: Long-term contracts for exchange of water service with five entities for the provision of up to 1,163 acre-feet of stored water from Applegate Reservoir (a USACE project) for irrigation use in exchange for the transfer of out-of-stream water rights from the Little Applegate River to instream flow rights with the State of Oregon for instream flow use. This item was mistakenly listed as completed in the May 9, 2008, FR.

Completed Contract Action

10. Six irrigation water user entities, Rogue River Basin Project, Oregon: Long-term contracts for exchange of water service with six entities for the provision of up to 4,141 acre-feet of stored water from Applegate Reservoir (a USACE project) for irrigation use in exchange for the transfer of out-of-stream water rights from the Little Applegate River to instream flow rights with the State of Oregon for instream flow use. This item was mistakenly listed as completed in the May 9, 2008, FR. One contract for up to 2,978 acre-feet of water has been executed.

Mid-Pacific Region: Bureau of Reclamation, 2800 Cottage Way, Sacramento, California 95825-1898, telephone 916-978-5250.

New Contract Actions

39. California Department of Fish and Game, CVP, California: Proposed renewal of a water service contract for the Department's San Joaquin Fish Hatchery. Contract would allow 35 cubic feet per second of continuous flow to pass through the Hatchery prior to it returning to the San Joaquin River.

40. Cachuma Operation and Maintenance Board, Cachuma Project, California: Amendment to SOD contract No. 01-WC-20-2030 to provide for increased SOD costs associated with Bradbury Dam.

41. Contractors from the Friant Division, CVP, California: Contracts to be negotiated and executed with existing Friant long-term contractors for the conversion from water service contracts entered into pursuant to subsections 9(c) and 9(e) of the Reclamation Projects Act of 1939 to

repayment contracts pursuant to subsection 9(d) of the Reclamation Projects Act of 1939. This action is intended to satisfy the mandate set forth in section 10010 of Title X of the Omnibus Public Land Management Act of 2009. Negotiations are scheduled to begin late July 2009.

Modified Contract Action

2. Contractors from the American River Division, Cross Valley Canal, San Felipe Division, West San Joaquin Division, Delta Division, and Elk Creek Community Services District; CVP; California: Renewal of 29 long-term water service contracts; water quantities for these contracts total in excess of 2.1M acre-feet. These contract actions will be accomplished through long-term renewal contracts pursuant to Public Law 102-575. Prior to completion of negotiation of long-term renewal contracts, existing interim renewal water service contracts may be renewed through successive interim renewal of contracts. Execution of long-term renewal contracts have been completed for the Friant, Shasta, and Trinity River Divisions and are nearly completed for the Delta Division. Long-term renewal contract execution is continuing for the other contractors.

Discontinued Contract Action

32. Cawelo WD and Lindsay-Strathmore ID, CVP, California: Long-term Warren Act contract for conveying nonproject water for a non-CVP contractor. This action is a duplicate item.

Lower Colorado Region: Bureau of Reclamation, PO Box 61470 (Nevada Highway and Park Street), Boulder City, Nevada 89006-1470, telephone 702-293-8192.

New Contract Actions

22. Clark County, BCP, Nevada: Agreement with Clark County for an annual diversion of up to 50 acre-feet of Colorado River water from Reclamation's Secretarial Reservation Entitlement for use on Reclamation land that is managed by Clark County and is part of the Laughlin Regional Heritage Greenway Train Project. Specifically, the water will be used for a natural bathing area (lagoon), construction, dust control, and riparian revegetation, which are all features of the Reclamation-approved Project.

23. ChaCha, LLC, Arizona, BCP: Partial assignment of the water delivery contract with ChaCha, LLC for transfer of ownership of 50 percent of the land within ChaCha LLC's contract service area. ChaCha LLC's 50 percent ownership will transfer to the following

entities (undivided interest): Befra Farming, LLC, a California limited liability company; R&R Almond Orchards, Inc., a California corporation; and XLNT, LLC, a California limited liability company.

Completed Contract Action

6. Chacha AZ, LLC, BCP, Arizona: Contract for 2,100 acre-feet per year of fourth priority water for agricultural purposes, as recommended by the Arizona Department of Water Resources. Contract executed on May 1, 2009.

Upper Colorado Region: Bureau of Reclamation, 125 South State Street, Room 6107, Salt Lake City, Utah 84138-1102, telephone 801-524-3864.

New Contract Actions

1. (g) Charles Weaver, Aspinall Storage Unit, CRSP: Mr. Weaver has requested a 40-year water service contract for 1 acre-foot of M&I water out of Blue Mesa Reservoir, which requires Mr. Weaver to present a Plan of Augmentation to the Division 4 Water Court.

33. Pine Glen, LLC, Mancos Project, Colorado: Pine Glen LLC has requested a new carriage contract to replace existing contract No. 14-06-400-4901, assignment No. 6. The new contract is the result of a property sale. Remaining interest in the existing assignment is for 0.56 cubic feet per second of nonproject water to be carried through Mancos Project facilities.

34. Navajo-Gallup Water Supply Project, New Mexico: Repayment contract with the City of Gallup for up to 7,500 acre-feet per year of M&I water. Contract terms to be consistent with the Northwestern New Mexico Rural Water Projects Act (Title X of Pub. L. 111-11).

35. Navajo-Gallup Water Supply Project, New Mexico: Repayment contract with the Jicarilla Apache Nation for up to 1,200 acre-feet per year of M&I water. Contract terms to be consistent with the Northwestern New Mexico Rural Water Projects Act (Title X of Pub. L. 111-11).

36. Northwestern New Mexico Rural Water Projects Act, New Mexico: Settlement contract with the Navajo Nation for up to 530,650 acre-feet per year of irrigation and M&I water. Contract terms to be consistent with the Northwestern New Mexico Rural Water Projects Act (Title X of Pub. L. 111-11).

37. Navajo-Gallup Water Supply Project, New Mexico: Cost-sharing agreement with the State of New Mexico. Contract terms to be consistent with the Northwestern New Mexico Rural Water Projects Act (Title X of Pub. L. 111-11).

Discontinued Contract Actions

1. (a) Camp Id-Ra-Ha-Je West Association, Aspinall Storage Unit, CRSP: Camp Id-Ra-Ha-Je West Association has requested a 40-year water service contract for 1 acre-foot of M&I water out of Blue Mesa Reservoir, which requires Camp Id-Ra-Ha-Je West Association to present a Plan of Augmentation to the Division 4 Water Court.

Completed Contract Actions

1. (e) Horse Meadows Home Owners Association, Aspinall Unit, CRSP: The Association has requested a 40-year water service contract for 1 acre-foot of M&I water out of Blue Mesa Reservoir, which requires the Association to present a Plan of Augmentation to the Division 4 Water Court. Contract was executed April 29, 2009.

1. (f) David Beaulieu, Aspinall Storage Unit, CRSP: Mr. Beaulieu has requested a 40-year water service contract for 1 acre-foot of M&I water out of Blue Mesa Reservoir, which requires Mr. Beaulieu to present a Plan of Augmentation to the Division 4 Water Court. Contract was executed April 1, 2009.

25. Florida Water Conservancy District, Florida Project, Colorado: The District has requested a long-term water service contract for 114 acre-feet of water for project purposes to be used in Plans of Augmentation and Substitute Water Supply Plans from the Florida Project. Contract was executed April 2, 2009.

28. Glen, Michael D, and Tambda Spencer; Mancos Project; Colorado: The parties have requested a new carriage contract to replace existing contract No. 02-WC-40-8290. Existing carriage contract is for 1 cubic foot per second of nonproject water to be carried through Mancos Project facilities. The new contract will add 2 cubic feet per second to the existing quantity for a total of 3 cubic feet per second. Contract was executed May 14, 2009.

31. City of Santa Fe and Reclamation: Contract to store up to 50,000 acre-feet of San Juan-Chama Project Water in Elephant Butte Reservoir for a 40-year maximum term. This action is a duplicate item.

Great Plains Region: Bureau of Reclamation, PO Box 36900, Federal Building, 316 North 26th Street, Billings, Montana 59101, telephone 406-247-7752.

New Contract Actions

45. Green Mountain Reservoir, Colorado-Big Thompson Project, Colorado: Consideration of a request for a long-term contract for the use of

excess capacity in Green Mountain Reservoir in the Colorado-Big Thompson Project.

46. Municipal Recreation Contract out of Granby Reservoir, Colorado-Big Thompson Project, Colorado: Water service contract for delivery of 5,412.5 acre-feet of water annually out of Lake Granby to the 15-Mile Reach.

47. Rocky Mountain National Park, Colorado-Big Thompson Project, Colorado: Amendment to the existing memorandum of understanding for project water.

48. Glen Elder ID; Glen Elder Unit, P-SMBP; Kansas: Intent to enter into a contract for repayment of extraordinary maintenance work on the spillway structure in accordance with the ARRA.

49. Mirage Flats ID, Mirage Flats Project, Nebraska: Request to amend contract to change billing date from May to July.

50. Glen Elder ID; Glen Elder Unit, P-SMBP; Kansas: Renewal of long-term water service contract.

51. State of Kansas Department of Wildlife and Parks; Glen Elder Unit, P-SMBP; Kansas: Reclamation is contemplating a contract for the remaining conservation storage in Waconda Lake.

Modified Contract Actions

3. Ruedi Reservoir, Fryingpan-Arkansas Project, Colorado: Second round water sales from the regulatory capacity of Ruedi Reservoir. Water service and repayment contracts for up to 17,000 acre-feet annually.

Discontinued Contract Actions

18. City of Golden, Colorado-Big Thompson Project, Colorado: Consideration of a request for a long-term agreement for power interference in the Colorado-Big Thompson Project.

Completed Contract Actions

6. Dickinson Parks and Recreation District; Dickinson Unit, P-SMBP; North Dakota: A temporary contract has been negotiated with the District for minor amounts of water from Dickinson Reservoir. Negotiate a long-term water service contract for minor amounts of water from Dickinson Reservoir. Contract was executed May 26, 2009.

26. Individual Irrigators; Canyon Ferry Unit, P-SMBP; Montana: Replace temporary 1-year contracts with long-term water service contracts for minor amounts of less than 1,000 acre-feet of irrigation water annually from the Missouri River below Canyon Ferry Dam. Contracts executed June 10, 2009.

Dated: July 2, 2009.

Roseann Gonzales,

Director, Policy and Program Services Denver Office.

[FR Doc. E9-18605 Filed 8-3-09; 8:45 am]

BILLING CODE 4310-MN-P

DEPARTMENT OF JUSTICE

[OMB Number 1103-NEW]

Office of Community Oriented Policing Services; Agency Information Collection Activities: Emergency Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: COPS Hiring Recovery Program (CHRP) Progress Report.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The emergency proposed information collection is published to obtain comments from the public and affected agencies.

The purpose of this notice is to allow for 60 days for public comment until October 5, 2009. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rebekah Whiteaker, Department of Justice Office of Community Oriented Policing Services, 1100 Vermont Avenue, NW., Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Emergency proposed collection; comments requested.

(2) *Title of the Form/Collection:* CHRP Progress Report.

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection: None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Law enforcement and public safety agencies that are recipients of COPS Hiring Recovery Program grants.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated that approximately 1,046 respondents can complete the report in an average of 10 minutes per calendar quarter.

(6) An estimate of the total public burden (in hours) associated with the collection: 697.333 total burden hours.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: July 30, 2009.

Lynn Bryant,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. E9-18578 Filed 8-3-09; 8:45 am]

BILLING CODE 4410-AT-P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public

and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed reinstatement of the "Current Population Survey (CPS) Displaced Worker, Job Tenure, and Occupational Mobility Supplement." A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before October 5, 2009.

ADDRESSES: Send comments to Carol Rowan, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue, NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202-691-5111. (This is not a toll free number.)

FOR FURTHER INFORMATION CONTACT: Carol Rowan, BLS Clearance Officer, 202-691-7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The CPS Displaced Worker, Job Tenure, and Occupational Mobility supplement is conducted biennially and was last collected in January 2008.

This supplement will gather information on workers who have lost or left their jobs because their plant or company closed or moved, there was insufficient work for them to do, or their position or shift was abolished. Data will be collected on the extent to which displaced workers received advance notice of job cutbacks or the closing of their plant or business. For those workers who have been reemployed, the supplement will gather data on the types of jobs they found and will compare current earnings with those from the lost job.

The incidence and nature of occupational changes in the preceding year will be queried. The survey also probes for the length of time workers (including those who have not been

displaced) have been with their current employer. Additional data to be collected include information on the receipt of unemployment compensation, the loss of health insurance coverage, and the length of time spent without a job.

Because this supplement is part of the CPS, the same detailed demographic information collected in the CPS will be available on respondents to the supplement. Comparisons will be possible across characteristics such as sex, race, age, and educational attainment of the respondent.

The information collected by this survey will be used to determine the size and nature of the population affected by job displacements and the needs and scope of programs serving adult displaced workers. It also will be used to assess employment stability by determining the length of time workers have been with their current employer and estimating the incidence of occupational change over the course of a year. Combining the questions on displacement, job tenure, and occupational mobility will enable analysts to obtain a more complete picture of employment stability.

II. Current Action

Office of Management and Budget clearance is being sought for the CPS Displaced Worker, Job Tenure, and Occupational Mobility Supplement. A reinstatement of this previously approved collection for which approval has expired is needed to provide the Nation with timely information about the size and characteristics of the population affected by job displacements as well as an assessment of occupational stability and change.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- 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 submissions of responses.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Agency: Bureau of Labor Statistics.

Title: CPS Displaced Worker, Job Tenure, and Occupational Mobility Supplement.

OMB Number: 1220-0104.

Affected Public: Individuals or households.

Total Respondents: 55,000.

Frequency: Biennially.

Total Responses: 55,000.

Average Time per Response: 8 minutes.

Estimated Total Burden Hours: 7,333 hours.

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintenance): \$0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 30th day of July 2009.

Darrin King,

Departmental Clearance Officer, U.S.

Department of Labor.

[FR Doc. E9-18577 Filed 8-3-09; 8:45 am]

BILLING CODE 4510-24-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0335]

Notice of Availability of Draft Interim Staff Guidance Document for Fuel Cycle Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: David Rahn, Senior Electrical/I&C Engineer, Technical Support Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20005-0001, Telephone: (301) 492-3115; Fax: (301) 492-3363; E-mail: David.Rahn@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC continues to prepare and issue Interim Staff Guidance (ISG)

documents for fuel cycle facilities and on the use of digital instrumentation and controls in nuclear facilities. These ISG documents provide clarifying guidance to the NRC staff when reviewing licensee integrated safety analyses, license applications or amendment requests, or other related licensing activities for fuel cycle facilities under 10 CFR Part 70. Draft DI&C-ISC-07, "Digital Instrumentation and Control Systems in Safety Applications at Fuel Cycle Facilities," Revision 0, is being prepared for use by NRC staff reviewers in the review of new license applications or amendments for fuel cycle facilities in conjunction with the NRC Digital Instrumentation and Control Project, and is now being issued for public review and comments.

II. Summary

The purpose of this notice is to notify the public of the availability for review and comments of DI&C-ISC-07, "Digital Instrumentation and Control Systems in Safety Applications at Fuel Cycle Facilities," Revision 0, which provides guidance to NRC staff when performing reviews regarding the use of digital instrumentation and controls in safety applications at fuel cycle facilities. Such reviews would be applicable to new license applications or amendment requests submitted pursuant to 10 CFR Part 70.

Upon receiving public comments, the NRC staff will evaluate the comments and make a determination to incorporate the comments, as appropriate. The NRC staff will incorporate the guidance from the approved ISG into a future revision to the standard review plan governing the performance of fuel cycle facility license application reviews.

DATES: Comments may be submitted by September 2, 2009. Comments received after this date will be considered, if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any one of the following methods. Please include Docket ID NRC-2009-0335 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the Federal rulemaking Web site Regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

Federal Rulemaking Web site: Go to: <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2009-0335. Address questions about NRC dockets by telephone: 301-492-3668; e-mail carol.gallagher@nrc.gov.

Mail comments to: Michael T. Lesar, Chief, Rulemaking and Directives Branch (RDB), Division of Administrative Services, Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to RDB at (301) 492-3446.

III. Further Information

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents created or received at the NRC after November 1, 1999. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>.

The ADAMS accession number for the document related to this notice is provided in the following table. If you do not have access to ADAMS or if there are problems in accessing the document located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr@nrc.gov.

Interim staff guidance	ADAMS accession number
DI&C—Interim Staff Guidance-07, Revision 0	ML091550599

This document may also be viewed electronically on the NRC's Public Web Site at <http://www.nrc.gov/reading-rm/doc-collections/isg/digital-instrumentation-ctrl.html> or on the public computers located at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC Public Document Room (PDR) reference staff at

1-800-397-4209, 301-415-4737, or by e-mail at pdr@nrc.gov.

Dated at Rockville, Maryland this 23rd day of July 2009.

For the Nuclear Regulatory Commission.

Marissa G. Bailey,

Director, Special Projects and Technical Support Directorate, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E9-18554 Filed 8-3-09; 8:45 am]

BILLING CODE 7590-01-P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards: Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Retraction of a Waiver from the Nonmanufacturer Rule for Product Service Code (PSC) 9130, Liquid Propellants—Petroleum Base, under North American Industry Classification System (NAICS) code 324110 (Petroleum Refineries).

SUMMARY: The U. S. Small Business Administration (SBA) is proposing the retraction of a class waiver from the non-manufacturer rule for PSC 9130, Liquid Propellants—Petroleum Base, NAICS 324110.

DATES: Comments must be submitted on or before August 21, 2009.

ADDRESSES: You may submit comments to Pamela M. McClam, Program Analyst, U.S. Small Business Administration, Office of Government Contracting, 409 3rd Street, SW., Suite 8800, Washington, DC 20416. A printout of approved class waivers can be found at http://www.sba.gov/aboutsba/sbaprograms/gc/programs/gc_waivers_nonmanufacturer.html.

FOR FURTHER INFORMATION CONTACT:

Pamela M. McClam, Program Analyst, by telephone at (202) 205-7408; by FAX at (202) 481-4783; or by e-mail at Pamela.McClam@sba.gov.

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act (Act), 15 U.S.C. 637(a)(17), requires that recipients of Federal contracts set aside for small businesses, service-disabled veteran-owned small businesses, or participants in SBA's 8(a) Business Development (BD) Program provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule. 13 CFR 121.406(b). Section 8(a)(17)(b)(iv) of the Act authorizes SBA

to waive the Nonmanufacturer Rule for any "class of products" for which there are no small business manufacturers or processors available to participate in the Federal market.

A class of products is defined based on the Office of Management and Budget's NAICS codes and the General Services Administration's Product and Service Code Directory. Within each six-digit NAICS code are subdivisions of products that can be considered for waiver. A request for a waiver of a class of products should refer to a specific subdivision, or statement of product, within a six-digit code in one of these manuals. A waiver of the Nonmanufacturer Rule does not waive the entire class of products under a specific NAICS code. The class waiver waives specific products within a subdivision within a NAICS code.

Any individual or organization (government agency, business, association, *etc.*) may request a waiver for a class of products. The request should be in writing, addressed to the Director for Government Contracting and should specifically state the class (or classes) of products for which the waiver is sought.

SBA is proposing to a retraction of the class waiver from the non-manufacturer rule for PSC 9130 (Liquid Propellants—Petroleum Base) under NAICS code 324110. The waiver from the non-manufacturer rule for PSC 9130 is being retracted based on information SBA received from the Defense Logistics Agency, Defense Energy Support Center (DESC), Fort Belvoir, VA. SBA's **Federal Register** Notice of Intent to grant a waiver of the Non-Manufacturer Rule for (PSC) 9130 (Liquid Propellants—Petroleum Base) was published on May 11, 2009. SBA finalized the waiver on June 8, 2009 (74 FR 27202). DESC was not aware of the notice until after the closing date for submission of comments. They have awarded prime contracts to, or received offers from, multiple small business refiners within the past 24 months.

Thus the SBA is proposing a retraction of the class waiver from the non-manufacturer rule for PSC 9130 (Liquid Propellants—Petroleum Base) under NAICS code 324110.

The public is invited to provide comments to SBA on the proposed retraction of the waiver within 15 days after date of publication in the **Federal Register**.

Authority: 15 U.S.C. 634.

Jim Gambardella,

(A) Director for Government Contracting.

[FR Doc. E9-18584 Filed 8-3-09; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

Small Business Size Standards: Waiver of the Nonmanufacturer Rule

AGENCY: U.S. Small Business Administration.

ACTION: Notice of intent to terminate the Nonmanufacturer Rule for radio telephones, (Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing) Product Service Code (PSC) 5805 under North American Industry Classification System 334220.

SUMMARY: The U.S. Small Business Administration (SBA) intends to terminate a waiver of the Nonmanufacturer Rule for radio telephones based on SBA's recent discovery of a small business manufacturer. Terminating this waiver will require recipients of contracts set aside for small businesses, service-disabled veteran-owned small businesses, or Participants in SBA's 8(a) Business Development (BD) Program to provide the products of small business manufacturers or processors on such contracts.

DATES: Comments and source information must be submitted August 19, 2009.

ADDRESSES: You may submit comments and source information to Edith G. Butler, Program Analyst, Small Business Administration, Office of Government Contracting, 409 3rd Street, SW., Suite 8800, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Ms. Edith G. Butler, by telephone at (202) 619-0422; by FAX at (202) 481-1788; or by e-mail at edith.butler@sba.gov.

SUPPLEMENTARY INFORMATION: Section 8(a)(17) of the Small Business Act (Act), and 15 U.S.C. 637(a)(17), and SBA's implementing regulations require that recipients of Federal contracts set aside for small businesses, service-disabled veteran-owned small businesses, or Participants in the SBA's 8(a) BD Program provide the product of a small business manufacturer or processor, if the recipient is other than the actual manufacturer or processor of the product. This requirement is commonly referred to as the Nonmanufacturer Rule. 13 CFR 121.406(b), 125.15(c). Section 8(a)(17)(b)(iv) of the Act authorizes SBA to waive the Nonmanufacturer Rule for any "class of products" for which there are no small business manufacturers or processors available to participate in the Federal market.

In order to be considered available to participate in the Federal market for a

class of products, a small business manufacturer must have submitted a proposal for a contract solicitation or received a contract from the Federal government within the last 24 months. The SBA defines "class of products" based on the NAICS. In addition, SBA uses PSCs to identify particular products within the NAICS code to which a waiver would apply.

SBA announced its decision to grant the waiver for radio telephones, in the **Federal Register** on July 20, 1998 63 FR 38742. SBA recently became aware of the existence of a small business manufacturer for this item. For this reason, SBA intends to terminate the waiver previously granted for radio telephones, identified under PSC 5805, and NAICS code 334220.

The public is invited to comment to SBA on the proposed termination of the waiver of the Nonmanufacturer Rule for this class of product specified. All comments by the public will be duly considered by SBA in determining whether to finalize its intent to terminate this class of product.

Dated: July 29, 2009.

James A. Gambardella,

Acting Director, Office of Government Contracting.

[FR Doc. E9-18590 Filed 8-3-09; 8:45 am]

BILLING CODE 8025-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213.

Extension:

Form 11-K; OMB Control No. 3235-0082; SEC File No. 270-101.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Form 11-K (17 CFR 249.311) is the annual report designed for use by employee stock purchase, savings and similar plans to comply with the reporting requirements under Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") (15 U.S.C. 78o(d)). Section 15(d) establishes a periodic reporting obligation for every

issuer of a class of securities registered under the Securities Act of 1933 (the "Securities Act") (15 U.S.C. 77a *et seq.*). Form 11-K provides employees of an issuer with financial information so that they can assess the performance of the investment vehicle or stock plan. Form 11-K is filed on occasion. The information collected must be filed with the Commission and is publicly available. Form 11-K takes approximately 30 burden hours per response and is filed by 2,000 respondents for a total of 60,000 burden hours.

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 control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or send an e-mail to Shagufta_Ahmed@omb.eop.gov; and (ii) Charles Boucher, Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson 6432 General Green Way, Alexandria, Virginia 22312; or send an e-mail to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 29, 2009.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-18559 Filed 8-3-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Extension of Existing Collection; Comment Request

Upon Written Request, Copies Available

From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213.

Extension:

Rule 204, OMB Control No. 3235-0647, SEC File No. 270-586.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection

of information to the Office of Management and Budget for extension and approval.

Rule 204 (17 CFR 242.204) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) requires that, subject to certain limited exceptions, if a participant of a registered clearing agency has a fail to deliver position at a registered clearing agency it must immediately close out the fail to deliver position by purchasing or borrowing securities by no later than the beginning of regular trading hours on the settlement day following the day the participant incurred the fail to deliver position. Rule 204 is intended to help further the Commission's goal of reducing fails to deliver by maintaining the reductions in fails to deliver achieved by the adoption of temporary Rule 204T, as well as other actions taken by the Commission. In addition, Rule 204 is intended to help further the Commission's goal of addressing abusive "naked" short selling in all equity securities.

Several provisions under Rule 204 will impose a "collection of information" within the meaning of the Paperwork Reduction Act.

I. Allocation Notification Requirement: It is estimated that the active broker-dealer respondents registered with the Commission incur an aggregate burden of 394,626 hours per year to comply with this provision of Rule 204.

II. Demonstration Requirement for Fails to Deliver on Long Sales: It is estimated that the active broker-dealer respondents registered with the Commission incur an aggregate burden of 270,063 hours per year to comply with this provision of Rule 204.

III. Pre-Borrow Notification Requirement: It is estimated that the active broker-dealer respondents registered with the Commission incur an aggregate burden of 397,152 hours per year to comply with this provision of Rule 204.

IV. Certification Requirement: It is estimated that the active broker-dealer respondents registered with the Commission incur an aggregate burden of 394,626 hours per year to comply with this provision of Rule 204.

V. Pre-Fail Credit Demonstration Requirement: It is estimated that the active broker-dealer respondents registered with the Commission incur an aggregate burden of 394,626 hours per year to comply with this provision of Rule 204.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the

Commission, including whether the information will have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Comments should be directed to Charles Boucher, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312 or send an e-mail to: PRA_Mailbox@sec.gov.

Dated: July 29, 2009.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-18560 Filed 8-3-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

In the Matter of Gulf Alternative Energy Corporation; Order of Suspension of Trading

July 31, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Gulf Alternative Energy Corporation (trading symbol: GAEC) because of questions regarding the accuracy and adequacy of information contained in press releases and on its website regarding the quality of the company's technology and the company's business prospects and agreements.

The Commission is of the opinion that the public interest and the protection of the investors require a suspension of trading in the securities of Gulf Alternative Energy Corporation.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT, July 31, 2009, through 11:59 p.m. EDT, on August 13, 2009.

By the Commission.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-18669 Filed 7-31-09; 4:15 pm]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60394; File No. SR-DTC-2009-13]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change Relating to Municipal Bonds Redemption Process

July 28, 2009.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ notice is hereby given that on July 15, 2009, The Depository Trust Company ("DTC") 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 primarily by DTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

DTC proposes to modify the timing when an issuer of certain municipal securities or its agent notifies DTC of a redemption or an advance refunding of such municipal securities.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DTC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In early 2008, the Association of Global Custodians ("AGC") and DTC formed a working group to explore issues associated with redemption announcements. Several meetings were

held in 2008 with participation from members of the AGC, The Securities Industry and Financial Markets Association, the agent community, DTC, and DTC's participants.

Among other things, the working group reviewed redemption announcement data for a six month period and discovered that many conventional municipal bond² issuers or their agents were notifying DTC of the redemption or refund later than the 30 day Publication Date period as required in DTC's rules. The working group then investigated the ramifications of this and concluded that if DTC were to amend the Publication Date from the current standard of "no fewer than 30 calendar days" prior to the redemption or advance refund to "no fewer than 20 calendar days" prior to the redemption or advance refund for conventional municipal bonds, DTC would still have sufficient time to process the redemption announcement and issuers and their agents would have more time to notify DTC of a redemption thereby making the redemption notification process more efficient. The working group presented this proposal to the American Bankers Association and to the National Association of Bond Lawyers and both organizations approved this recommendation.

Therefore, DTC proposes to amend Part V.A. of its Operational Arrangements to redefine the time frame for an issuer or its agent of a conventional municipal bond to notify DTC of a full or partial redemption or an advance refunding of part of such outstanding securities. Under the proposal, the issuer or agent will have to notify DTC at least two business days prior to the Publication Date, which will be redefined as "no fewer than 20 calendar days nor more than 60 calendar days prior to the redemption date or, in the case of an advance refunding, the date that the proceeds are deposited in escrow (and, in such cases, final notification must be received no later than 20 calendar days prior to the refunding date.)" DTC proposes that this new requirement would be effective October 1, 2009.

DTC states that the proposed rule change is consistent with the requirements of Section 17A of the Act³ and the rules and regulations thereunder because it modifies an existing DTC service in order to make

the redemption process for municipal bonds more efficient. As such it is a change to an existing service, which will not adversely affect the safeguarding of securities and funds in DTC's control or custody.

B. Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will have any impact or impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. DTC will notify the Commission of any written comments received by DTC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five 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 ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>) or
- Send an e-mail to rule-comments@sec.gov. Please include File No. SR-DTC-2009-13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File No. SR-DTC-2009-13. This file number

¹ 15 U.S.C. 78s(b)(1).

² A "conventional municipal bond" was defined as "a bond without any derivatives attached to it and no inherent features that would prevent a redemption announcement from being provided in a timely manner."

³ 15 U.S.C. 78q-1.

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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings also will be available for inspection and copying at DTC's principal office and DTC's Web site at (<http://www.dtc.org/impNtc/mor/index.html>). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-DTC-2009-13 and should be submitted on or before August 25, 2009.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.⁴

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E9-18558 Filed 8-3-09; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-60395; File No. SR-CHX-2009-10]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Add the Quote@CHX and Reprice@CHX Order Types to Brokerplex System

July 28, 2009.

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 July 23, 2009, Chicago Stock Exchange, Inc.

("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by CHX. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CHX proposes to amend its rules to allow Exchange-registered Institutional Brokers to enter two new order types, known as Quote@CHX and Reprice@CHX, when using the Brokerplex® order entry system. The text of this proposed rule change is available on the Exchange's Web site at (<http://www.chx.com>) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add Interpretations and Policies .04 to the Article 17 obligations of CHX-registered Institutional Brokers to permit the entry of two new order types within Brokerplex for Institutional Brokers to use when submitting orders to the CHX Matching System for display and potential execution. The new order types are known as "Quote@CHX" and "Reprice@CHX."

The Brokerplex system is an order entry and management system developed and operated by the Exchange for use on a non-exclusive basis by CHX-registered Institutional Brokers to receive and hold orders from their clients while seeking execution on the CHX or elsewhere in the National Market System. The Exchange seeks to add two new order types within Brokerplex for Institutional Brokers to use when submitting orders to the CHX

Matching System for display and potential execution.

In many instances, Institutional Brokers would like to display orders in the CHX Matching System when seeking trade execution rather than simply hitting bids or lifting offers already displayed in the marketplace. By doing so, they could achieve a level of price improvement for their customers. Rapidly changing quotes in today's market environment often make it difficult to successfully post a bid or offer, however, since a standard limit order entered by the Institutional Broker may lock or cross the National Best Bid or Offer ("NBBO") by the time that order entry is complete (by our rules, the Matching System automatically rejects orders in such circumstances).³

The new Quote@CHX order type would allow the Institutional Broker to submit an order to be priced within Brokerplex at a defined limit price which is one minimum price increment (normally 1 cent for most securities) from the relevant side of the National Best Bid or Offer ("NBBO") at the time of order submission. For buy orders, the relevant side of the NBBO is the offer; for sell orders it is the bid. The pricing of the Quote@CHX (and Reprice@CHX) order is done solely within Brokerplex and the order is then sent as a limit order by Brokerplex to the Matching System. For example, if the Institutional Broker has set the incremental offset at 1 cent and the NBBO was 20.10 x 20.13, a Quote@CHX buy order would be automatically priced and submitted by Brokerplex to the Matching System as a 20.12 limit order. The systematic pricing of the Quote@CHX (and Reprice@CHX) orders is non-dynamic, i.e., the order does not automatically reprice upon changes to the NBBO once it has been accepted by the Matching System.

The Reprice@CHX order type allows an Institutional Broker to change an existing limit order residing in the Matching System and replace it with an order generated in the same manner as a Quote@CHX order type. Submission of a Reprice@CHX order would generate an instruction to (1) cancel a limit order previously submitted by an Institutional Broker to the Matching System and (2) generate a new order to either buy or sell (priced by Brokerplex in the same manner as for Quote@CHX orders as described above) and send it to the Matching System as a limit order.

³ It is important to keep in mind that Institutional Brokers manually enter orders into the Matching System through Brokerplex and those orders are often competing for priority with system-generated orders of algorithmic order senders.

⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Generally, usage of an agency Quote@CHX or Reprice@CHX order by an Institutional Broker should be confined to situations in which it is handling a non-marketable or "not held" limit order on behalf of a customer.⁴ There may be limited circumstances in which it could be appropriate for an Institutional Broker handling a market order to submit a Quote@CHX (but not a Reprice@CHX) order. Institutional Brokers handling a customer limit order would be required to enter the limit price into Brokerplex when submitting a Quote@CHX or Reprice@CHX order. In pricing the Quote@CHX and Reprice@CHX orders, Brokerplex will reject any entries if the systematically-generated price would be outside the customer's specified limit price.

Our standard Matching System validations for locked and crossed markets would apply equally to these orders upon receipt. Neither the Quote@CHX nor Reprice@CHX order type would be available for Institutional Brokers submitting orders to destinations other than the CHX Matching System. The Matching System itself will not be eligible to receive these order types. As the owner and operator of the Brokerplex system, the Exchange would collect and maintain all of the order records relating to these two order types required by our rules, although the responsibility for the accurate entry of transaction-related information lies with the Brokerplex user.

Our belief is that these two order types will permit Institutional Brokers to enter displayable orders in a more efficient manner and avoid the delays associated with reentering a rejected order at a new price. This functionality is optional, so an Institutional Broker which does not want its order priced by Brokerplex can simply enter a traditional limit order.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general,⁵ and furthers the objectives of Section 6(b)(5) in particular,⁶ in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transaction in securities, to remove impediments and perfect the mechanisms of a free and open market, and, in general, to protect investors and

the public interest. In this case, providing Institutional Brokers with the ability to enter display-eligible orders on a more efficient basis protects investors and removes an impediment to a free and open market in that it improves the ability of Institutional Brokers to seek the best execution of the orders which they are handling.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to rule-comments@sec.gov. Please include File Number SR-CHX-2009-10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-CHX-2009-10. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR-CHX-2009-10 and should be submitted on or before August 25, 2009.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁷

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-18563 Filed 8-3-09; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding the FHWA's finding that Buy America waivers are not appropriate for the use of foreign hollow structural section (hollow structural section round A500, Grade C, 10.75 x 0.625 steel pipe) and one-inch diameter stainless steel anchor bolts (1 inch diameter stainless steel, F 593,

⁴ A "not held" order is one in which the Institutional Broker has been given price and time discretion by its customer. See Article 1, Rule 2(w).

⁵ 15 U.S.C. 78f(b).

⁶ 15 U.S.C. 78f(b)(5).

⁷ 17 CFR 200.30-3(a)(12).

Group 6, anchor bolts) for construction of projects by Contra Costa County Public Works, CA, and Vermont Agency of Transportation, respectively. Domestic sources of these materials were identified through FHWA's public notice process.

DATES: Since the Buy America waiver is not granted, there is no effective date for the waiver.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366-1562, or via e-mail at gerald.yakowenko@dot.gov. For legal questions, please contact Mr. Michael Harkins, FHWA Office of the Chief Counsel, (202) 366-4928, or via e-mail at michael.harkins@dot.gov. Office hours for the FHWA are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register's** home page at: <http://www.archives.gov> and the Government Printing Office's database at: <http://www.access.gpo.gov/nara>.

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding the FHWA's finding that Buy America waivers are not appropriate for the use of: (1) The hollow structural section for construction of Iron Horse Trail Pedestrian Overcrossing Project by Contra Costa County Public Works in California, and (2) one-inch diameter stainless steel anchor bolts for the construction of East Montpelier Bridge project #BRF 028-3(36) by the Vermont Agency of Transportation.

In accordance with Division K, section 130 of the "Consolidated Appropriations Act, 2008" (Pub. L. 110-161), the FHWA published the notices of intent to issue the waivers on its Web site for: (1) The hollow structural section (<http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=34>) on June 10, and (2)

the one-inch diameter stainless steel anchor bolts (<http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=35>) on June 15.

The FHWA received a comment from Independence Tube Corporation which claimed to have the capacity to manufacture the hollow structural section domestically. Further inquiries confirmed that the hollow structural section can be manufactured domestically. The FHWA received three comments indicating that the one-inch diameter stainless steel anchor bolts are available domestically. The Contra Costa County Public Works and Vermont Agency of Transportation have verified that the hollow structural section and the one-inch diameter stainless steel anchor bolts are available domestically; therefore, FHWA concludes that the materials are available domestically and that Buy America waivers are not appropriate for the hollow structural section and the one-inch diameter stainless steel anchor bolts.

In accordance with the provisions of section 117 of the SAFETEA-LU Technical Corrections Act of 2008 (Pub. L. 110-244, 122 Stat.1572), the FHWA is providing this notice as its finding that a waiver of Buy America requirements is not appropriate for these projects. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to the FHWA's Web site via the links provided to the California and Vermont waiver pages noted above.

Authority: 23 U.S.C. 313; Public Law 110-161, 23 CFR 635.410.

Issued on: July 29, 2009.

King W. Gee,

Associate Administrator for Infrastructure.

[FR Doc. E9-18607 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fuel Drain Valves

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of re-issuance of Technical Standard Order (TSO) C76, Fuel Drain Valves.

SUMMARY: This notice announces the re-issuance of TSO-C76, Fuel Drain Valves, telling manufacturers seeking TSO authorization (TSOA) or letter of design approval (LODA) what minimum performance standard (MPS) their Fuel

Drain Valve must first meet for approval and identification with the appropriate TSO markings. In the event that you feel a need to comment on the re-issuance of TSO-C76, please do so to the address listed below.

DATES: Comments must be received on or before September 3, 2009.

ADDRESSES: Send all comments regarding the re-issuance of the Fuel Drain Valve TSO to: Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, Technical Programs and Continued Airworthiness Branch, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024. *Attn.:* Jim Kabbara, AIR-120. You may hand deliver comments to: Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jim Kabbara, AIR-120, Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024. *Telephone:* (202) 385-6335; *Fax:* (202) 385-6475; *or via e-mail at:* jim.kabbara@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on the re-issuance of the TSO-C76 by submitting written data, views, or arguments to the above-specified address. Your comments should stipulate "Comments, re-issuance of TSO-C76." All comments received may be examined after the comment closing date by visiting Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024, weekdays except Federal holidays, between 8:30 a.m. and 4 p.m. The Director, Aircraft Certification Service, will consider all comments received on or before the closing date before issuing the final notice of re-issuance.

Background

This TSO is being re-issued in its entirety. We have cancelled TSO-C76a because the specific requirements that make up the minimum performance standard necessary to have the Fuel Drain Valves be marked as TOS approved, provided no technical value. Those requirements have resulted in manufacturers seeking TSO approval of their Fuel Drain Valves to experience difficulties in meeting the MPS. We have deemed the requirements to be

arbitrary, resulting in our re-issuing of the original TSO-C76.

Issued in Washington, DC, on July 30, 2009.

Susan J.M. Cabler,

Assistant Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. E9-18575 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fuel Drain Valves

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of cancellation of Technical Standard Order (TSO) C76a, Fuel Drain Valves.

SUMMARY: This notice announces the cancellation of TSO-C76a, Fuel Drain Valves. If you have reason to believe that this proposed action will negatively impact aviation safety, we would like to solicit your comments.

DATES: Comments must be received on or before September 3, 2009.

ADDRESSES: Send all comments regarding the cancelling of the Fuel Drain Valve TSO-C76a to: Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, Technical Programs and Continued Airworthiness Branch, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024. ATTN.: Jim Kabbara, AIR-120. You may hand deliver comments to: Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jim Kabbara, AIR-120, Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division, AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024. Telephone: (202) 385-6335; Fax: (202) 385-6475; or via e-mail at: jim.kabbara@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited:

Interested persons are invited to comment on the cancellation of TSO-C76a by submitting written data, views, or arguments to the above-specified address. Your comments should stipulate "Comments, cancellation of TSO-C76a." Comments received on or before the closing date may be examined by visiting Federal Aviation Administration, Aircraft Certification Service, Aircraft Engineering Division,

AIR-100, 950 L'Enfant Plaza, SW., 5th Floor, Washington, DC 20024, weekdays except Federal holidays, between 8:30 a.m. and 4 p.m. The Director, Aircraft Certification Service, will consider all comments received on or before the closing date before issuing the final notice of cancellation.

Background

Note 3 attachment to Table 2, Fuel Resistance and Extreme Temperature Test Schedule, is located in Appendix 1 of TSO-C76a, only appears in the "a" version. A subsequent review of the "a" revision of TSO-C76 determined that the revised temperature values contained in Note 3 were arbitrary and provides no technical value to the qualification of fuel drain valves, nor will the testing to those temperature values provide an increase in the operational safety of the fuel drain valve. Therefore, we are taking this opportunity to cancel TSO-C76a.

Issued in Washington, DC, on July 30, 2009.

Susan J.M. Cabler,

Assistant Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. E9-18576 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[NHTSA-06-24175]

Insurer Reporting Requirements; Reports Under 49 U.S.C. on Section 33112(c)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of Availability.

SUMMARY: This notice announces publication by NHTSA of the annual insurer report on motor vehicle theft for the 2003 reporting year. Section 33112(h) of Title 49 of the U.S. Code, requires this information to be compiled periodically and published by the agency in a form that will be helpful to the public, the law enforcement community, and Congress. As required by section 33112(c), this report provides information on theft and recovery of vehicles; rating rules and plans used by motor vehicle insurers to reduce premiums due to a reduction in motor vehicle thefts; and actions taken by insurers to assist in deterring thefts.

ADDRESSES: Interested persons may obtain a copy of this report or read background documents by going to

<http://regulations.dot.gov> at any time or to Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 am and 5 pm, Monday through Friday, except Federal Holidays. Requests should refer to Docket No. 2006-24175.

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 1200 New Jersey Ave., SE., Washington, DC 20590. Ms. Ballard's telephone number is (202) 366-0846. Her fax number is (202) 493-2990.

SUPPLEMENTARY INFORMATION: The Motor Vehicle Theft Law Enforcement Act of 1984 (Theft Act) was implemented to enhance detection and prosecution of motor vehicle theft (Pub. L. 98-547). The Theft Act added a new Title VI to the Motor Vehicle Information and Cost Savings Act, which required the Secretary of Transportation to issue a theft prevention standard for identifying major parts of certain high-theft lines of passenger cars. The Act also addressed several other actions to reduce motor vehicle theft, such as increased criminal penalties for those who traffic in stolen vehicles and parts, curtailment of the exportation of stolen motor vehicles and off-highway mobile equipment, establishment of penalties for dismantling vehicles for the purpose of trafficking in stolen parts, and development of ways to encourage decreases in premiums charged to consumers for motor vehicle theft insurance.

This notice announces publication by NHTSA of the annual insurer report on motor vehicle theft for the 2003 reporting year. Section 33112(h) of Title 49 of the U.S. Code, requires this information to be compiled periodically and published by the agency in a form that will be helpful to the public, the law enforcement community, and Congress. As required by section 33112(h), this report focuses on the assessment of information on theft and recovery of motor vehicles, comprehensive insurance coverage and actions taken by insurers to reduce thefts for the 2003 reporting period.

Section 33112 of Title 49 requires subject insurers or designated agents to report annually to the agency on theft and recovery of vehicles, on rating rules and plans used by insurers to reduce premiums due to a reduction in motor vehicle thefts, and on actions taken by insurers to assist in deterring thefts. Rental and leasing companies also are required to provide annual theft reports to the agency. In accordance with 49

CFR Part 544.5, each insurer, rental and leasing company to which this regulation applies must submit a report annually not later than October 25, beginning with the calendar year for which they are required to report. The report would contain information for the calendar year three years previous to the year in which the report is filed. The report that was due by October 25, 2006 contains the required information for the 2003 calendar year. Interested persons may obtain a copy of individual insurer reports for CY 2003 by contacting the U.S. Department of Transportation, Docket Management, 1200 New Jersey Avenue, SE., West Building, Room W12-140 ground level, Washington, DC 20590-001. Requests should refer to Docket No. 2006-24175.

The annual insurer reports provided under section 33112 are intended to aid in implementing the Theft Act and fulfilling the Department's requirements to report to the public the results of the insurer reports. The first annual insurer report, referred to as the Section 612 Report on Motor Vehicle Theft, was prepared by the agency and issued in December 1987. The report included theft and recovery data by vehicle type, make, line, and model which were tabulated by insurance companies and rental and leasing companies. Comprehensive premium information for each of the reporting insurance companies was also included. This report, the eighteenth, discloses the same subject information and follows the same reporting format.

Issued on: July 28, 2009.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. E9-18566 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2009-33]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or

omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before August 24, 2009.

ADDRESSES: You may send comments identified by Docket Number FAA-2009-0598 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://www.regulations.gov> and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202-493-2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477-78).

Docket: To read background documents or comments received, go to <http://www.regulations.gov> at any time or to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kenna Sinclair, ANM-113, (425) 227-1556, FAA, Transport Airplane Directorate, 1601 Lind Ave., SW., Renton, Washington 98057-3356; or Ralen Gao, ARM-200, (202) 267-3168, FAA, Office of Rulemaking, 800 Independence Ave., SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on July 30, 2009.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2009-0598.

Petitioner: Bombardier.

Section of 14 CFR Affected: 14 CFR 26.

Description of Relief Sought: The petitioner seeks relief from part 26 for its Bombardier CL-600-1A11, CL-600-2A12 and CL-600-2B16 airplanes. These airplanes' maximum payload capacities and passenger capacities are below those specified for transport category airplanes. However, since these models are on the same Type Certification Data Sheet (TCDS) as the original Bombardier Model CL-600, they are subject to the part 26 rule.

[FR Doc. E9-18600 Filed 8-3-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY

Treasury Inspector General for Tax Administration; Privacy Act of 1974: Computer Matching Program

AGENCY: Treasury Inspector General for Tax Administration, Treasury.

ACTION: Notice.

SUMMARY: Pursuant to 5 U.S.C. 552a, the Privacy Act of 1974, as amended, notice is hereby given of the agreement between the Treasury Inspector General for Tax Administration (TIGTA) and the Internal Revenue Service (IRS) concerning the conduct of TIGTA's computer matching program.

DATES: *Effective Date:* September 3, 2009.

ADDRESSES: Comments or inquiries may be mailed to the Treasury Inspector General for Tax Administration, Attn: Office of Chief Counsel, 1125 15th Street, NW., Washington, DC 20005, or via electronic mail to Counsel.Office@tigta.treas.gov.

FOR FURTHER INFORMATION CONTACT:

Office of Chief Counsel, Treasury Inspector General for Tax Administration, (202) 622-4068.

SUPPLEMENTARY INFORMATION: TIGTA's computer matching program assists in the detection and deterrence of fraud, waste, and abuse in the programs and operations of the IRS and related entities as well as protects against attempts to corrupt or interfere with tax administration. TIGTA's computer matching program is also designed to proactively detect and to deter criminal and administrative misconduct by IRS

employees. Computer matching is the most feasible method of performing comprehensive analysis of data.

Name of Source Agency: Internal Revenue Service.

Name of Recipient Agency: Treasury Inspector General for Tax Administration.

Beginning and Completion Dates:

This program of computer matches is expected to commence on September 1, 2009, but not earlier than the fortieth day after copies of the Computer Matching Agreement are provided to the Congress and OMB unless comments dictate otherwise. The program of computer matches is expected to conclude on March 31, 2011.

Purpose: This program is designed to deter and detect fraud, waste, and abuse in Internal Revenue Service programs and operations, to investigate criminal and administrative misconduct by IRS employees, and to protect against attempts to corrupt or threaten the IRS and/or its employees.

Authority: The Inspector General Act of 1978, 5 U.S.C. App. 3, and Treasury Order 115-01.

Categories of Individuals Covered: Current and former employees of the Internal Revenue Service as well as individuals and entities about whom information is maintained in the systems of records listed below.

Categories of Records Covered: Included in this program of computer matches are records from the following Treasury or Internal Revenue Service systems.

- a. Treasury Payroll and Personnel System [Treasury/DO .001]
- b. Treasury Child Care Tuition Assistance Records [Treasury/DO .003]
- c. Treasury Financial Management Systems [Treasury/DO .009]
- d. Integrated Financial Management and Revenue System [Treasury/DO .210]
- e. Correspondence Files and Correspondence Control Files [Treasury/IRS 00.001]
- f. Correspondence Files: Inquiries About Enforcement Activities [Treasury/IRS 00.002]
- g. Taxpayer Advocate Service and Customer Feedback and Survey Records System [Treasury/IRS 00.003]
- h. Employee Complaint and Allegation Referral Records [Treasury/IRS 00.007]
- i. Third Party Contact Records [Treasury/IRS 00.333]
- j. Volunteer Records [Treasury/IRS 10.555]
- k. Annual Listing of Undelivered Refund Checks [Treasury/IRS 22.003]
- l. File of Erroneous Refunds [Treasury/IRS 22.011]
- m. Foreign Information System (FIS) [Treasury/IRS 22.027]
- n. Individual Microfilm Retention Register [Treasury/IRS 22.032]
- o. Subsidiary Accounting Files [Treasury/IRS 22.054]
- p. Automated Non-Master File (ANMF) [Treasury/IRS 22.060]
- q. Information Return Master File (IRMF) [Treasury/IRS 22.061]
- r. Electronic Filing Records [Treasury/IRS 22.062]
- s. CADE Individual Master File (IMF) [Treasury/IRS 24.030]
- t. CADE Business Master File (BMF) [Treasury/IRS 24.046]
- u. Audit Underreporter Case File [Treasury/IRS 24.047]
- v. Acquired Property Records [Treasury/IRS 26.001]
- w. Lien Files [Treasury/IRS 26.009]
- x. Offer in Compromise (OIC) File [Treasury/IRS 26.012]
- y. Trust Fund Recovery Cases/One Hundred Percent Penalty Cases [Treasury/IRS 26.013]
- z. Record 21, Record of Seizure and Sale of Real Property [Treasury/IRS 26.014]
- aa. Taxpayer Delinquent Accounts (TDA) Files [Treasury/IRS 26.019]
- bb. Taxpayer Delinquency Investigation (TDI) Files [Treasury/IRS 26.020]
- cc. Identification Media Files System for Employees and Others Issued IRS ID [Treasury/IRS 34.013]
- dd. Security Clearance Files [Treasury/IRS 34.016]
- ee. National Background Investigations Center Management Information System [Treasury/IRS 34.022]
- ff. IRS Audit Trail and Security Records System [Treasury/IRS 34.037]
- gg. General Personnel and Payroll Records [Treasury/IRS 36.003]
- hh. Practitioner Disciplinary Records [Treasury/IRS 37.007]
- ii. Enrolled Agents Records [Treasury/IRS 37.009]
- jj. Examination Administrative File [Treasury/IRS 42.001]
- kk. Audit Information Management System (AIMS) [Treasury/IRS 42.008]
- ll. Compliance Programs and Projects Files [Treasury/IRS 42.021]
- mm. Anti-Money Laundering/Bank Secrecy Act (BSA) and Form 8300 Records [Treasury/IRS 42.031]
- nn. Appeals Centralized Data System [Treasury/IRS 44.003]
- oo. Criminal Investigation Management Information System [Treasury/IRS 46.002]
- pp. Treasury Enforcement Communications System (TECS) Criminal Investigation Division [Treasury/IRS 46.022]
- qq. Automated Information Analysis System [Treasury/IRS 46.050]
- rr. Tax Exempt/Government Entities (TE/GE) Case Management Records [Treasury/IRS 50.222]
- ss. Employee Protection System Records [Treasury/IRS 60.000]

tt. Chief Counsel Automated System Environment (CASE) Records [Treasury/IRS 90.016]

Dated: July 28, 2009.

Melissa Hartman,

Acting Deputy Assistant Secretary for Privacy and Treasury Records.

[FR Doc. E9-18580 Filed 8-3-09; 8:45 am]

BILLING CODE 4810-04-P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: StarNet Insurance Company

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. I to the Treasury Department Circular 570, 2009 Revision, published July 1, 2009, at 74 FR 31536.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874-6850.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued under 31 U.S.C. 9305 to the following company:

StarNet Insurance Company (NAIC # 40045). BUSINESS ADDRESS: 475 Steamboat Road, Greenwich, CT 06830. PHONE: (203) 542-3800.

UNDERWRITING LIMITATION b/: \$10,963,000. SURETY LICENSES C/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, MI, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. INCORPORATED IN: Delaware.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570 ("Circular"), 2009 Revision, to reflect this addition.

Certificates of Authority expire on June 30th each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (see 31 CFR part 223). A list of qualified companies is published annually as of July 1st in the Circular, which outlines details as to the underwriting limitations, areas in which companies are licensed to transact surety business, and other information.

The Circular may be viewed and downloaded through the Internet at <http://www.fms.treas.gov/c570>.

Questions concerning this Notice may be directed to the U.S. Department of

the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: July 24, 2009.

Rose M. Miller,

Acting Director, Financial Accounting and Services Division.

[FR Doc. E9-18336 Filed 8-3-09; 8:45 am]

BILLING CODE 4810-35-M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-New (21-0842)]

Agency Information Collection (Pre-Discharge Compensation Claim) Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted

below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 3, 2009.

ADDRESSES: Submit written comments on the collection of information through <http://www.Regulations.gov> or to VA's OMB Desk Officer, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395-7316. Please refer to "OMB Control No. 2900-New (21-0842)" in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-7485, FAX (202) 273-0443 or e-mail denise.mclamb@va.gov. Please refer to "OMB Control No. 2900-New (21-0842)."

SUPPLEMENTARY INFORMATION:

Title: Pre-Discharge Compensation Claim, VA Form 21-0842.

OMB Control Number: 2900-New (21-0842).

Type of Review: New collection.

Abstract: The Pre-Discharge Compensation Claim form will be used by service members to file claims under the Benefits Delivery at Discharge or Quick Start programs. VA will use the data collected as the required certification statement needed from claimants to confirm that the information they provided is true and correct.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 26, 2009, at page 24902.

Affected Public: Individuals or households.

Estimated Annual Burden: 40,250.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 161,000.

Dated: July 30, 2009.

By direction of the Secretary

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. E9-18627 Filed 8-3-09; 8:45 am]

BILLING CODE 8320-01-P



Federal Register

**Tuesday,
August 4, 2009**

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 872

**Dental Devices: Classification of Dental
Amalgam, Reclassification of Dental
Mercury, Designation of Special Controls
for Dental Amalgam, Mercury, and
Amalgam Alloy; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2008-N-0163; Formerly Docket No. 2001N-0067]

RIN 0910-AG21

Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying dental amalgam into class II, reclassifying dental mercury from class I to class II, and designating a special control to support the class II classifications of these two devices, as well as the current class II classification of amalgam alloy. The three devices are now classified in a single regulation. The special control for the devices is a guidance document entitled, "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy." This action is being taken to establish sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the devices.

DATES: This rule is effective November 2, 2009.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 2606, Silver Spring, MD 20993-0002, 301-796-6276.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

1. Review of Scientific Evidence
 - a. Evidence Related to the Population Age Six and Older
 - i. Air Monitoring Standards for Elemental Mercury Vapor
 - ii. Biological Monitoring Standards for Urine Mercury
 - iii. Clinical Studies
- b. Evidence Related to Special Populations
 - i. Potentially Sensitive Subpopulations (Developing Fetuses, Breastfed Infants, and Children Under Age Six)
 - ii. Dental Professionals
 - iii. Individuals with Mercury Allergies

2. Rationale for Special Controls

- a. Risk of Exposure to Mercury
 - i. Specific Labeling Recommendations
 - ii. Information for Use Recommendation
 - iii. Performance Test Recommendation
- b. Risk of Allergic Response Including Adverse Tissue Reaction
 - i. Specific Labeling Recommendations
 - ii. Performance Test Recommendation
 - c. Risk of Mercury Contamination
 - d. Risk of Mechanical Failure
 - i. Specific Labeling Recommendation
 - ii. Performance Test Recommendation
 - e. Risk of Corrosion
 - i. Specific Labeling Recommendation
 - ii. Performance Test Recommendation
 - f. Risk of Improper Use
- B. Statutory Authority
- C. Regulatory History of the Devices
 1. Regulatory Status
 2. Proposed Rule
3. Scientific Information, Safety Assessments, and Adverse Event Reports Regarding Dental Amalgam
 - a. Information and Assessments Discussed in the Proposed Rule
 - b. Information and Assessments That Have Become Available Since Publication of the Proposed Rule
 - i. Life Sciences Research Office (LSRO) Report
 - ii. White Paper and Addendum Scientific Reviews
 - c. Adverse Event Reports
- II. Development of the Final Rule
- III. Comments and FDA's Responses
 - A. Classification
 - B. Banning
 - C. Mercury Content and Toxicity
 - D. Patient Information
 - E. Alternative Materials
 - F. Need for Public Hearings
 - G. Accusations of FDA Bias
 - H. Preemption
 - I. Environmental Concerns
- IV. Environmental Impact
- V. Analysis of Impacts
 - A. Introduction
 - B. Summary of Economic Impacts
 - C. Objective and Need of the Final Rule
 - D. Risk
 - E. Baseline in the Absence of the Final Rule
 - F. The Final Rule
 - G. Costs of the Final Rule
 1. Manufacturing Costs
 - a. Testing Costs
 - b. Labeling Costs Associated With the Final Rule
 - c. Increased Manufacturing Costs
 2. Costs of FDA Regulatory Oversight
 3. Total Costs
 - H. Potential Public Health Effects of the Final Rule
 - I. Alternatives to the Final Rule
 1. No New Regulatory Action
 2. Class II But With Other Special Controls
 3. Reclassification to Class III
 4. Ban the Use of Mercury in Dental Restorations
 - J. Regulatory Flexibility Analysis
- VI. Federalism
- VII. The Paperwork Reduction Act of 1995
- VIII. References

I. Background

The following section provides an overview of the final rule, applicable statutory authority for classifying devices, the regulatory history of these dental devices, scientific information and safety assessments involving the devices, and the development of this rule.

A. Overview

Dental amalgam is a metallic restorative material that is used for direct filling of carious lesions or structural defects in teeth. It is a combination of mercury (liquid) and amalgam alloy (powder), which is composed primarily of silver, tin, and copper.

As discussed in detail in this preamble, this final rule classifying dental amalgam reflects FDA's careful consideration of the valid scientific evidence related to dental amalgam's benefits, which include its effectiveness as a restorative material, strength, and durability, and its potential risks, which include those related to the release of low levels of mercury vapor. FDA is required by statute to classify devices (21 U.S.C. 360c). This final rule classifies the device "dental amalgam" into class II and reclassifies the device "dental mercury" (hereinafter "mercury") from class I to class II. Importantly, the rule also establishes special controls for dental amalgam, mercury, and amalgam alloy (mercury and amalgam alloy are combined to form dental amalgam). Special controls are established to provide a reasonable assurance of safety and effectiveness for class II devices and are in addition to the general controls already applicable to any device.¹ This rule designates a special controls guidance document with performance data and labeling recommendations as the special controls for dental amalgam.

The Agency has determined that class II with special controls is the appropriate classification for dental amalgam after evaluating the valid scientific evidence related to dental amalgam, including comprehensive reviews of the scientific literature and safety assessments. Based on its review of this scientific evidence, FDA made the two findings it is required by law to make when classifying a device (21 CFR

¹ General controls are specifically identified in the statute and include requirements such as adverse event reporting and good manufacturing practices. General controls are applicable to any class of device. Special controls are controls identified and designated by the Agency as controls in addition to the general controls that apply to a specific device to address the specific risks to health of that device.

860.7(d)(1): First, FDA found that, when subject to the general controls of the act and the designated special control, the probable benefits to health from the use of the device for its intended use and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. Second, FDA found that, when subject to the general controls of the act and the designated special control, the scientific evidence adequately demonstrates the absence of unreasonable risk of illness or injury associated with the intended use of dental amalgam.

In developing this final rule, FDA reviewed scientific evidence and also considered the classification recommendation of the Dental Products Panel (Ref. 1), which concluded that there are no major risks associated with encapsulated dental amalgam, when used as directed, but recognized there is a small population of patients who may experience allergic hypersensitive reactions to the materials in the device. The Panel also noted that improper use exposes dental professionals to risks associated with mercury toxicity, with improper storage, trituration, and handling contributing to this risk.

As part of its assessment, FDA considered the important public health benefits of dental amalgam and the advantages it presents as a restorative material.

Dental amalgam has been used since the 1890s.² Millions of patients have received dental amalgam restorations to treat dental caries.³

A dentist's decision concerning the use of a particular restorative material is complex, involving factors related to the tooth, the patient, the clinician and the properties of the restorative materials. The dentist must, among other considerations, take into account the patient's age, caries history, oral hygiene, ability to maintain a dry field, degree of tooth destruction and the necessity to perform a procedure quickly and efficiently due to a patient's ability to cooperate. Specific clinical situations may limit the restoration options. Dental amalgam provides advantages in that it may be placed quickly in a wet field while providing high strength, durability, longevity, and marginal integrity, features that may help prevent recurrent decay. Dental amalgams are typically used:

- In stress-bearing areas and in small to moderate sized cavities in posterior teeth;
- In teeth with severe destruction;
- As a foundation for cast-metal, metal-ceramic and ceramic restorations;
- When a patient's commitment to oral hygiene is poor; and/or
- When moisture control is problematic.

Dental amalgam may provide benefits over other dental restorative materials because amalgam fillings offer a broad range of applicability in clinical situations, ease of use and relative insensitivity to variations in handling technique and oral conditions (Refs. 3–7).

FDA also considered the potential risks of dental amalgam. Dental amalgam is a combination of elemental mercury (liquid) and amalgam alloy (powder), which is composed primarily of silver, tin, and copper. FDA's assessment focused on the risks associated with the presence of mercury in the device.

Mercury is a toxic metal that exists naturally in several forms in the environment: Elemental metallic mercury, inorganic mercury (ionic salt forms), and methylmercury (Ref. 70, Ref. 69). Elemental metallic mercury is highly volatile and releases mercury vapor. This form of mercury has a well-studied toxicity profile and its toxicity is dependent on dose and exposure conditions. The toxicokinetics and adverse effects associated with mercury vapor are different from those associated with methylmercury. These differences include route of exposure (mercury vapor is inhaled while methylmercury is ingested), percent of dose that is absorbed (80% in the case of mercury vapor; 95% in the case of methylmercury), and toxicity profiles (Ref. 69, Ref. 70).

Dental amalgam releases low levels of mercury vapor, with higher amounts released with mastication and gum chewing (Ref. 3). Higher levels of exposure to elemental mercury vapor are also associated with placement and removal of dental amalgams. For example, urinary mercury concentrations in 43 children ages 5 to 7 years before and after amalgam placement (1–4 teeth filled) were $3.04 \pm 1.42 \mu\text{g Hg/L}$ ($2.34 \mu\text{g Hg/g Cr}$) and $4.20 \pm 1.60 \mu\text{g Hg/L}$ ($3.23 \mu\text{g Hg/g Cr}$), respectively (Ref. 8). Removal of amalgams resulted in an increase in urinary mercury; values were $1.8 \pm 1.2 \mu\text{g Hg/L}$ ($1.4 \mu\text{g Hg/g Cr}$) before removal compared to $2.8 \pm 2.1 \mu\text{g Hg/L}$ ($2.2 \mu\text{g/g Cr}$) at 10 days post-removal (Ref. 9).

After inhalation, approximately 70–80% of a mercury vapor dose is

absorbed by the lung, enters the systemic circulation, distributes to several organ systems in varying amounts, and excretion occurs generally via the urinary route (Ref. 70). Because of its high lipid solubility, mercury vapor readily diffuses into erythrocytes and is oxidized by the catalase-hydrogen peroxide complex to divalent mercuric ion (Hg^{2+}) (Ref. 70). Despite this rapid oxidation and intracellular localization, a fraction of the elemental mercury dose crosses the blood-brain barrier. Once inside cells, mercury vapor is also oxidized to mercuric ions (Hg^{2+}) that are unable to diffuse back across the cell membrane (Ref. 70). The mercuric ion is believed to be the proximate toxic species responsible for the adverse health effects of inhaled mercury vapor. The mercuric ion has a biological half-life of two months (Ref. 69, Ref. 70).

While mercury toxicity has been demonstrated in a variety of organ systems in laboratory studies, the central nervous system (CNS) and the kidneys are both target organs sensitive to mercury vapor (Ref. 69).

The first signs of mercury vapor toxicity at high doses are subtle effects on the nervous system, such as changes in nerve conduction, slight tremor, abnormalities in electroencephalography (EEG) patterns, and changes in motor functions, cognitive functions, and behavior. (Ref. 69, Ref. 70). With progressively higher exposures, these effects become more pronounced and include prominent tremor, ataxia (incoordination), memory loss, psychological distress, irritability, excitability, depression, and gingivitis (inflammation of the gums) (Refs. 69, 70).

Mercury also accumulates in the kidneys. Adverse renal effects can range from reversible proteinuria (protein in the urine) to irreversible nephrotic syndrome, depending on the degree of exposure to mercury vapor (Ref. 69, Ref. 70).

In addition to crossing the blood-brain barrier, mercury vapor has been shown in animal studies to cross the placenta and reach the fetal brain (Ref. 48, Ref. 44) is also able to cross the placenta and reach the fetal brain. Inorganic mercury, most likely in the form of Hg^{2+} , is found in breast milk after maternal exposure to mercury vapor and, therefore, may be present in breastfed infants (Ref. 55). Because maternal exposure to mercury vapor from dental amalgam may lead to prenatal and postnatal exposure of offspring, FDA considered the potential health effects of dental amalgam on developing fetuses and breastfed infants.

² Earlier prototypes were available beginning in the 1830s.

³ Over 50 million dental amalgam restorations are placed per year in the United States (Ref. 2).

1. Review of Scientific Evidence

As already noted, this rule and the special controls guidance reflect FDA's evaluation of the valid scientific evidence related to the use of dental amalgam in the population age six and older and in potentially sensitive subpopulations (developing fetuses, breastfed infants, and children under age six). The White Paper (Ref. 10) and Addendum (Ref. 11) referenced in this rule include more details regarding FDA's examination.⁴ These documents are included as references and are available on FDA's Web site.

In developing the White Paper and Addendum, FDA drew from the expertise of other groups⁵ that had previously conducted reviews related to the potential health effects of dental amalgam. FDA's approach was to build upon these reviews, rather than to duplicate the work other groups had already undertaken. FDA reviewed more than 200 scientific articles, published from 1997 to 2008, on the potential health effects of dental amalgam. In addition to considering these studies, FDA also considered information and assessments reviewed in the proposed rule, and other risk assessments developed since the publication of the proposed rule, including the 2004 Life Sciences Research Office (LSRO) Report (Ref. 13).⁶ In an effort to determine if any very recent articles would have an impact on FDA's analysis, a literature search was conducted for 2008–July 2009 (even though FDA had already reviewed studies published through October 2008). Three databases (PubMed, Biosis, and Embase) were searched with key words, such as mercury, toxicity, mercury vapor, adverse effect, dental, *etc.* Several studies from this search had already been reviewed in the FDA Addendum to the White Paper. After review of the total of 70 abstracts from the search, FDA determined that no studies have been published in 2008–2009 that

would change FDA conclusions about the health effects of dental amalgam.

FDA also considered the fact that dental amalgam is a commonly used device with a low frequency of adverse events reported to the Agency. FDA received 141 adverse event reports related to dental amalgam from 1988 to 2008. It is estimated that over one billion amalgam restorations were placed during this time period. The majority of the dental amalgam adverse event reports submitted to FDA were anecdotal, lacked specific details, and were often reported years after placement of the restoration, making it difficult for the Agency to perform a causal analysis.

An overview of the available evidence and FDA's conclusions follows.

a. Evidence Related to the Population Age Six and Older

i. Air Monitoring Standards for Elemental Mercury Vapor

The Agency for Toxic Substance and Disease Registry (ATSDR) has established a Minimal Risk Level (MRL)⁷ for elemental mercury vapor at 0.2 µg/m³. The Environmental Protection Agency (EPA) has established a Reference Concentration (RfC)⁸ for elemental mercury vapor at 0.3 µg/m³. These reference values were derived using a standard risk assessment approach employing uncertainty factors, including an uncertainty factor to account for variability in sensitivity of the human population. They are considered to represent chronic or lifetime inhalation exposures that are free from adverse health outcomes and protective of human health for all individuals, including potentially sensitive populations such as children prenatally or postnatally exposed to mercury vapor (Refs. 14, 15).⁹

⁷ ATSDR defines a Minimal Risk Level (MRL) as follows: "An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure."

* * * [MRLs] are set below levels that, based on current information, might cause adverse health effects in the people most sensitive to such substance induced effects" (<http://www.atsdr.cdc.gov/mrls/>).

⁸ EPA defines a Reference Concentration (RfC) as follows: "An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL [No Observed Adverse Event Level], LOAEL [Lowest Observed Adverse Event Level], or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used" (http://www.epa.gov/ncea/iris/help_gloss.htm#r).

⁹ After considering a large body of literature, ATSDR derived the MRL for elemental mercury

Using widely accepted values for the respiratory rate and tidal volume in individuals at various ages, the following ventilation rates were calculated: 16.2 m³/day for the average adult; 7.6 m³/day for the average five-year-old child; and 5.8 m³/day for the average one-year-old child.¹⁰

from a study of 26 workers exposed to low levels of mercury (0.026 mg/m³) in three industrial settings for an average of 15.3 years (range 1–41 years) (Ref. 16). Urinary mercury concentrations for this study averaged 11.3 µmol/mol creatinine (Cr) (approximately 20.1 µg/g Cr; 26.1 µg/L urine). Continuous exposure was taken into account by converting workplace exposures of 8 hr/day-5 days/week into exposures of 24 hr/day-7 days/week. Uncertainty factors (UFs) were used in deriving the MRL included variability in sensitivity to mercury within the human population (UF = 10) and the use of a lowest observed adverse effect level (LOAEL)—in this study, increased average velocity of naturally occurring hand tremors—instead of a no observed adverse effect level (NOAEL). In deriving the MRL, the ATSDR applied a less conservative uncertainty factor for the LOAEL (UF = 3), an approach commonly used when the endpoint is determined to be a less serious effect. In total, an uncertainty factor of 30 was applied. Application of the exposure conversions and uncertainty factors yielded a tolerable mercury vapor intake concentration of 0.2 µg/m³ for chronic inhalation exposure. The derivation of the ATSDR MRL for chronic exposure to mercury vapor also considered supporting evidence from several more recent studies that showed effect levels and adverse outcomes similar to those reported in Fawer *et al.* (Ref. 16), including Ngim *et al.* (Ref. 17) and Piikivi and Tolonen (Ref. 18). (See ATSDR, Ref. 14) EPA derived its RfC for chronic inhalation exposure to mercury vapor using the same occupational exposure study (Fawer *et al.*, Ref. 16) and supporting studies (including Ngim *et al.* (Ref. 17) and Piikivi and Tolonen, (Ref. 18) used by ATSDR in deriving the MRL for chronic mercury vapor exposure (Ref. 15). EPA conducts periodic screening level reviews for chemicals and in 2002 decided that the RfC for mercury vapor would remain unchanged (Ref. 15).

¹⁰ These ventilation rates were calculated as follows, using standard physiological parameters from several sources and handbooks (Refs. 19 and 20) *Adult*: The tidal volume per kilogram body weight in adults is 10.7 mL/kg. The weight of the average adult is 70 kg. Given these two values, the tidal volume of the average adult is 750 mL. The respiratory rate of the average adult is 12–15 breaths/minute. At a rate of 15 breaths/minute, the average adult would have a respiratory minute volume of 11.25 L/min. Given that there are 1,440 minutes/day and 1 m³/1000 L, this would result in a ventilation rate of 16.2 m³/day. *Five-year-old child*: The tidal volume per kilogram body weight in five-year-old children is 10.7 mL/kg. The weight of the average five-year-old child is 20 kg. Given these two values, the tidal volume of the average five-year-old child is 217 mL. The respiratory rate of the average five-year-old child is 21–25 breaths/minute. At a rate of 25 breaths/minute, the average five-year-old child would have a respiratory minute volume of 5.3 L/min. Given that there are 1440 minutes/day and 1 m³/1000 L, this would result in a ventilation rate of 7.6 m³/day. *One-year-old child*: The tidal volume per kilogram body weight in one-year-old children is 10 mL/kg. The weight of the average one-year-old child is 10 kg. Given these two values, the tidal volume of the average one-year-old child is 100 mL. The respiratory rate of the average one-year-old child is 40 breaths/minute. At a rate of 40 breaths/minute, the average one-year-old child would have a respiratory minute volume of 4 L/min. Given that there are 1440 minutes/day and

⁴ FDA decided to conduct this comprehensive review of the literature and prepare the Addendum rather than revise the White Paper.

⁵ These groups included the U.S. Public Health Service and the Environmental Health Policy Committee's Working Group on Dental Amalgam (Refs. 3, 12).

⁶ The LSRO report examined studies published from 1996 through 2003. In conducting its review, LSRO engaged an independent panel of academic experts in the fields of immunotoxicology, immunology, and allergy; neurobehavioral toxicology and neurodevelopment; pediatrics; developmental and reproductive toxicology; toxicokinetics and modeling; occupational health and epidemiology; pathology; and general toxicology. (Ref. 13)

At these ventilation rates, chronic exposure at the level of the MRL would result in an estimated dose of mercury vapor of 3.2 µg/day in the average adult, 1.5 µg/day in the average five-year-old child, and 1.2 µg/day in the average one-year-old child. Chronic exposure at the level of the RfC would result in an estimated dose of mercury vapor of 4.9 µg/day in the average adult, 2.3 µg/day in the average five-year-old child, and 1.7 µg/day in the average one-year-old child.

ATSDR assumes a slightly higher ventilation rate of 20 m³/day for the average adult (Ref. 14). At this ventilation rate, chronic exposure at the level of the MRL would result in an estimated dose of elemental mercury vapor of 4 µg/day in the average adult. Chronic exposure at the level of the RfC would result in an estimated dose of elemental mercury vapor of 6 µg/day in the average adult.

The U.S. Public Health Service (PHS) reviewed several studies estimating the daily dose of elemental mercury from dental amalgam (Ref. 3). In some of the studies, investigators measured the mercury concentration of intraoral and exhaled air in small populations of individuals with and without amalgams. In these studies, estimates of the daily dose of mercury from dental amalgams ranged from 1–29 µg/day. However, the reliability of these studies is questionable. Problems have been cited with the instruments used to measure mercury vapor in the oral cavity. Questions have also been raised about whether the small size of the oral cavity is appropriate for accurately measuring vapor concentrations, and about how to control for variable factors such as the dilution of vapor with inhaled air within the oral cavity and inhalation/exhalation rates, analytical quality control, and differences in sampling methodology (Ref. 20). According to PHS, the best estimates of daily intake of mercury from dental amalgam restorations have come from measurements of mercury in blood among subjects with and without amalgam restorations, and subjects before and after amalgams were removed. For adults, these estimates range from 1–5 µg/day.

The World Health Organization (WHO) also reviewed several studies estimating the daily dose of elemental mercury from dental amalgam (Ref. 21). WHO found that values generally in the range of 1–5 µg/day were estimated in the U.S. adult population, which is consistent with the PHS determination.

WHO noted three studies that made higher estimates of the daily dose. The highest estimate that WHO reports was a dose of 12 µg/day, for middle-aged individuals with approximately 30 amalgam surfaces (Ref. 22).

According to these estimates, the daily dose of mercury from dental amalgam is generally expected to be in the same range as the daily dose that would result from chronic exposure at the level of the MRL (4 µg/day) or the RfC (6 µg/day) in adults. Moreover, exceeding these protective reference levels does not necessarily mean that any adverse effects will occur (Refs. 14–15). FDA assumes that the daily dose from amalgam in children under six years old is below those in adults since children under six years old have fewer and smaller teeth and lower ventilation rates as compared to adults.

Given that the MRL and the RfC were derived to be protective and are set below air mercury concentrations associated with observed adverse health effects,¹¹ chronic exposure at these levels would not generally be expected to produce such effects. Chronic exposure to air mercury concentrations several times higher than the MRL and the RfC would also generally not be expected to result in adverse effects, because of the conservative approach of incorporating uncertainty factors in the derivation of these reference levels.¹² Moreover, both the MRL and the RfC assume lifetime chronic exposure. FDA has taken a conservative approach by applying these reference levels to children, who have experienced less than a full lifetime of exposure.

ii. Biological Monitoring Standards for Urine Mercury Occupational Studies

Several studies have assessed the risk of adverse health effects in workers occupationally exposed to high doses of mercury vapor. Strong correlations have been found between daily, time-weighted air concentrations, adverse health outcomes, and urinary mercury levels in workers (Refs. 14, 21).

Based on a number of occupational studies, the American Conference of

Government Industrial Hygienists (ACGIH) has determined that the biological threshold for preclinical changes for central nervous system and kidney effects is 50 µg Hg/g Cr (Ref. 24).¹³ However, occupational studies published since 1996 report that increases in urinary levels of early biomarkers predictive of renal injury have been observed at urinary mercury concentrations of 16–28 µg Hg/g Cr (Refs. 25–28).

Studies of Amalgam Bearers

Studies of large cohorts indicate that urinary mercury concentrations in individuals without dental amalgam restorations are approximately 0.5–0.6 µg Hg/g Cr in adults (Refs. 29, 30) and 0.5–2 µg Hg/g Cr in children, aged 6–17 (Refs. 31, 32).

Studies of adults with dental amalgam restorations have found a positive correlation between the number of dental amalgam restorations in the mouth and urinary mercury concentration. In a study of 1,626 women, aged 16–49, urinary mercury concentrations ranged from 0.83–1.25 µg Hg/g Cr (Ref. 29). The average urinary mercury concentration for the 75 percent of the women who had 12 amalgam surfaces or less was reported to be 0.81 µg Hg/g Cr. In a study of 550 adults, aged 30–49, urinary mercury concentrations ranged from 0.75–2.9 µg Hg/g Cr in individuals with 1–46 amalgam surfaces (Ref. 33). In one study of 1,127 men, aged 40–78, with dental amalgam restorations, 47 percent of the participants had a urinary mercury concentration less than 1.5 µg Hg/g Cr, and 1.3 percent of the participants had urinary mercury concentrations over 12 µg Hg/g Cr (Ref. 30). A urinary mercury concentration of 1.9 µg Hg/g Cr was reported for men with approximately 20 amalgam surfaces. Based on the study's analysis, an individual with 60 amalgam surfaces would be expected to have a urinary mercury concentration of 4–5 µg Hg/g Cr.

Studies have also assessed urinary mercury concentrations in amalgam-bearing children age six or older. Two prospective studies assessed urinary mercury concentrations in children age six and older after placement of dental amalgam restorations. In a seven-year study of children ages eight to ten at

¹¹ As described in Footnote 9, ATSDR used a total uncertainty factor of 30 to derive the MRL.

¹² As discussed by EPA in their Staff Paper on Risk Assessment Principles and Practices, "EPA risk assessments tend towards protecting public and environmental health by preferring an approach that does not underestimate risk in the face of uncertainty and variability. In other words, EPA seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated." See EPA 2004, An Examination of EPA Risk Assessment Principles and Practices, EPA/100/B-04/001 available at: <http://www.epa.gov/osa/pdfs/ratf-final.pdf>.

¹³ Given that 50 µg Hg/g Cr is the threshold urinary mercury concentration associated with preclinical nervous and renal system effects, ACGIH recommends that the urinary mercury concentration of occupationally exposed individuals not exceed 35 µg Hg/g Cr. This urinary mercury concentration is associated with chronic occupational exposure of a healthy worker to an air concentration of 25 µg Hg/m³.

1 m³/1000 L, this would result in a ventilation rate of 5.8 m³/day.

baseline, the highest average urinary mercury concentration reported during the study period was 3.2 µg Hg/g Cr (Ref. 31); this level occurred during the second year of the follow-up and progressively declined through year seven. The subjects had an average total of 19 amalgam surfaces at the end of the study period. In a five-year study of children ages six to ten at baseline, average urinary mercury concentrations were 0.9 µg Hg/g Cr (range 0.1–5.7) five years after dental amalgam placement (Ref. 34). The subjects had an average total of 12 amalgam surfaces at the end of the study period. The highest outlier in this study had a reported urinary mercury concentration of 10.5 µg Hg/g Cr. Children from the composite restoration-only group averaged 0.6 µg Hg/g Cr (range 0.1–2.9). In a study of 60 children aged 4–8 years (Ref. 89), those with amalgam restorations had higher urinary mercury concentrations (1.4 µg Hg/g Cr) compared to those without amalgams (0.436 µg Hg/g Cr).

The urinary mercury concentrations generally observed in adults and children age six and older with dental amalgam restorations is approximately one order of magnitude less than the threshold levels associated with preclinical neurological and renal health effects in persons occupationally exposed to mercury vapor. Reported high outliers in adults and children age six and older are also below this threshold level.

FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

iii. Clinical Studies

In order to assess potential health effects of mercury exposure from dental amalgam in the population age six and older, FDA reviewed studies evaluating neurological and renal outcomes. Studies of persons occupationally exposed to mercury vapor are also helpful for assessing risks of potential toxicity in the population age six and older from exposure to mercury vapors released from dental amalgams because occupationally-exposed individuals are exposed to higher mercury levels than those associated with dental amalgams.

Neurological Effects

Occupational Studies

In a study of chloralkali workers and age-matched controls evaluated twice at five years apart, no correlations were found between multiple neurobehavioral (motor and cognitive) and tremor tests and mercury vapor

exposure (Ref. 35). Performance on only one test, the Digital Symbol Test, showed improvement when subjects were tested five years later after exposure ceased suggesting that these individuals experienced some neurological toxicity while still being exposed to mercury at the time of the initial testing. Those subjects who demonstrated improvement had the highest inorganic mercury blood concentrations.¹⁴

In another study, 38 chloralkali workers with average urinary mercury concentration of 9 µg Hg/g Cr were compared with non-exposed controls (average urinary mercury concentration 2 µg/g Cr (Ref. 36)). No differences in results of multiple neurobehavioral tests were observed between the two groups.

Studies of Amalgam Bearers

Studies have shown a lack of association between amalgam exposure and neuropsychological and neurobehavioral deficits. In a retrospective study of 550 adults, no significant associations between neuropsychological function and indices of cumulative amalgam exposure over many years were found (Ref. 33). In a report evaluating 1,127 men (Ref. 37), no effects on tremor, coordination, gait, strength, sensation, muscle stretch, or peripheral neuropathy were associated with amalgam exposure.

It has been suggested that exposure to mercury vapor from dental amalgam may be linked to various neurological or neurodegenerative diseases, such as Parkinson's disease, Alzheimer's disease, multiple sclerosis, amyotrophic lateral sclerosis, and autism. There is a paucity of studies that evaluate a link between dental amalgam and these conditions.

In one study, regional brain levels of mercury were determined at autopsy in subjects with Alzheimer's disease and controls (Ref. 38). Brain mercury levels did not correlate with the number of amalgams and there were no differences between the Alzheimer's disease and control groups with respect to number of amalgams. In another study, the mean number of dental amalgam surfaces and urinary mercury concentrations for Alzheimer's disease patients were not

different from those of control patients (Ref. 39). In a study of aging and Alzheimer's disease evaluating 129 Catholic nuns, aged 75–102, no effect of dental amalgam number and surfaces was observed for eight tests of cognitive function (Ref. 38). These findings do not support the hypothesis that mercury from dental amalgam plays a role in the pathogenesis of Alzheimer's disease.

Several reports of results from prospective clinical studies of dental amalgam numbers (Refs. 31, 32, 34, and 40) found no neurological deficits in children who first received dental amalgam restorations at ages six to ten and were followed for five or seven years.

FDA concludes that the existing data support a finding that exposures to mercury vapor at levels associated with dental amalgams do not result in neurological deficits, tremors, peripheral neuropathies, or Alzheimer's Disease in the population age six and older. Although the existing clinical data on purported links between dental amalgam and other neurological or neurodegenerative diseases, such as Parkinson's Disease are limited, FDA concludes that, in light of the air monitoring and biological monitoring evidence described above, there is information from which to determine that general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness.

Renal Effects

The kidneys accumulate the highest organ concentration of mercury (as Hg²⁺) following exposure to mercury vapor. The concentration of mercury in the kidney has been associated with the number of dental amalgams (Refs. 41, 42).

Animal Studies

Renal mercury concentrations increased in proportion to increasing mercury vapor exposure concentrations in rats (Refs. 43, 44). Pregnant rats exposed to high concentrations of mercury vapor through gestation exhibited increases in two biomarkers of renal injury at gestation day 15, but no changes were observed for three other biomarkers at any time evaluated during gestation (Ref. 44).

Occupational Studies

Numerous occupational studies of mercury vapor exposure indicate that effects on the kidney begin to manifest when urinary mercury concentrations reach or exceed 50 µg Hg/g creatinine (Ref. 24). However, occupational studies published since 1996 report that increases in urinary levels of early

¹⁴ The authors noted that "[w]hen summarizing the available evidence, one could suggest that long-term neurobehavioral effects on a group basis may occur when the average [urinary mercury] concentration has been in the range of 30–40 nmol/mmol Cr [53.1–70.8 µg Hg/g Cr] or higher, but not when the average [urinary mercury] concentration has been lower than 10 nmol/mmol Cr [17.7 µg Hg/g Cr]."

biomarkers predictive of renal injury have been observed at urinary mercury concentrations of 16–28 µg Hg/g creatinine. In a study of chloralkali workers exposed to mercury vapor for 13 years (mean urinary mercury concentrations of 16.5 µg/g Cr), no significant differences in urinary biomarkers of renal function were found between the exposed and non-exposed groups (Ref. 45). Urinary biomarkers of renal function may be reversible upon cessation of exposure at the levels of exposure in this study. In several occupational studies of exposed workers (Refs. 25–28), increases in urinary N-acetylglucosaminidase (NAG), a preclinical renal biomarker, were correlated with urinary mercury concentrations of 16–28 µg Hg/g Cr. In another study, 38 chloralkali workers with average urinary mercury concentration of 9 µg Hg/g Cr were compared with non-exposed controls (average urinary mercury concentration 2 µg Hg/g Cr (Ref. 36)). No differences in renal expression as measured by multiple preclinical urinary biomarkers were observed between the two groups.

Studies of Amalgam Bearers

Two prospective amalgam trials in children age six and older demonstrated that kidney injury is not associated with exposure to dental amalgam. In the New England trial (Ref. 46) groups of children had amalgam or composite restorations placed at ages 6–8 and were followed for 5 years. Results showed that, although microalbuminuria levels were higher in the amalgam treatment group, the levels of three other biomarkers of kidney injury were not different between the amalgam versus composite restoration groups. The authors of the study noted that they were unable to determine whether the increase in microalbuminuria was related to treatment or may have occurred by chance, since albuminuria may be caused by strenuous physical exercise, urinary tract infections, or other conditions with fever, or be related to orthostatic proteinuria (Ref. 46). In another children's prospective trial (Casa Pia), groups of children had amalgam or composite restorations placed at ages 6–10 and were followed for 7 years. There were no differences between the amalgam and composite groups with respect to the urinary excretion of microalbumin or albumin (Ref. 31), a biomarker of renal glomerular injury, and GST-alpha and GST-pi, two biomarkers of renal proximal and distal tubule injury, respectively (Ref. 47).

FDA concludes that the data from these studies support a finding that

exposures to mercury vapor at levels associated with dental amalgams do not result in renal damage in the population age six and older. The conclusions from studies of amalgam mercury exposure and neurological and renal endpoints are supported by independent investigations by other scientific bodies, such as the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which stated in 2007 that "no risks of adverse systemic effects exist and the current use of dental amalgam does not pose a risk of systemic disease" (Ref. 6).

In light of the evidence from air monitoring, biological monitoring, and clinical studies, FDA concludes that exposures to mercury vapor from dental amalgam are not associated with adverse health effects in the population age six and older.

b. Evidence Related to Special Populations

i. Potentially Sensitive Subpopulations (Developing Fetuses, Breastfed Infants, and Children Under Age Six)

Fetal Development

Elemental mercury is transported through the placenta, which results in fetal exposure with the potential for subsequent developmental toxicity in offspring.

Animal Studies

FDA reviewed several well-conducted studies designed to assess high-level mercury vapor exposure on developmental effects in pregnant animals and their offspring. High levels of maternal mercury vapor exposure were associated with the accumulation of mercury in fetal tissues. In one study (Ref. 48), no effects were observed on peripheral, somatosensory, auditory, or visual neurological functions in offspring of rats exposed to mercury vapor prenatally. In another study, prenatal exposure of pregnant rats was associated with adverse effects on fetal development only in cases where maternal exposure to mercury vapor was so high that it became toxic to the mother (leading to decreased maternal body weight, which can directly alter fetal development) (Ref. 44). The 2004 Life Sciences Research Office (LSRO) Report (Ref. 13) reviewed several studies of exposure of pregnant squirrel monkeys to high concentrations of mercury vapor. Although mercury accumulated in brain tissues *in utero*, only modest effects were observed on learning, motor function, and adaptive behaviors. In all of the aforementioned studies, maternal mercury vapor

exposures were considerably higher than those estimated for individuals with dental amalgam restorations.

Occupational Studies

Very few available studies have evaluated the effects of elemental mercury exposure on pregnancy outcomes in humans. Although mercury has the ability to cross the placental barrier, the limited human data do not demonstrate an association between exposure to the mercury in dental amalgam and adverse reproductive outcomes such as low birth weight babies or increased rates of miscarriage. In a retrospective study (Ref. 49), no strong association or clear dose-response relationship between occupational exposure to chemical agents or restorative materials and the risk of miscarriage was observed. A slight but non-significant increase in risk was found for exposure to some acrylate compounds, mercury amalgam, solvents and disinfectants leading the authors to conclude that they could not rule out the possibility of a slightly increased risk of miscarriage among exposed dental workers. In a study of female factory workers exposed to a median concentration of 90 µg Hg/m³ (maximum 600 µg/m³), no significant differences in stillborn or miscarriage rates were observed between exposed and unexposed subjects (Ref. 50). The mercury vapor concentrations to which these workers were exposed were over an order of magnitude higher than those associated with dental amalgam.

Studies in Amalgam Bearers

Very few well-controlled animal studies or human epidemiological studies have evaluated the potential effect of low-level mercury vapor exposure on fetal development, especially at exposures experienced by dental amalgam bearers. In one retrospective study (Ref. 51), no association was found between the number of amalgam fillings in women and low birth weight of their babies. However, there is limited clinical information concerning the effects of prenatal exposure from maternal sources of mercury vapor at relevant concentrations.

Although the data are limited, FDA concludes that the existing data do not suggest that fetuses are at risk for adverse health effects due to maternal exposure to mercury vapors from dental amalgam. As described earlier in this document, maternal exposures are likely to increase temporarily when new dental amalgams are inserted or existing dental amalgam restorations are removed.

Breastfed Infants

Mercury present in the mother's body is transmitted to her infant through breast milk. Maternal exposure to elemental mercury vapor would be expected to affect the concentration of inorganic mercury in breast milk.

The EPA has set a Reference Dose (RfD)¹⁵ for oral exposure to inorganic mercury at 0.3 µg Hg/kg/day (Ref. 52). This value represents the daily exposure to inorganic mercury that is likely to be without an appreciable risk of deleterious health effects during a lifetime. Reference values are derived to be protective against adverse health effects in sensitive subpopulations, such as developing fetuses and children.

Seven studies reviewed in the 2004 Life Sciences Research Office Report evaluated concentrations of total mercury in breast milk. In some of the reviewed studies, the number of amalgams correlated with the concentration of total mercury in breast milk (Refs. 53, 54, 55). However, the LSRO report concluded from its review that inorganic mercury absorption through breast milk is not a significant source of mercury exposure to infants (Ref. 13).

One study (Ref. 56) determined the concentration of breast milk mercury attributable to dental amalgam. In this study, the concentration of mercury in subjects with dental amalgam restorations was subtracted from the level in subjects without dental amalgam restorations. The level of mercury attributable to amalgam was 0.09 µg Hg/L (Addendum, p. 13). A standard value used in risk assessment for daily breast milk consumption is 0.85 L/day. Based on this value, the typical daily dose of inorganic mercury from breastfeeding in an individual with dental amalgam restorations would be 0.075 µg Hg/day. For a 5 kg infant, the daily exposure to inorganic mercury from breastfeeding would be 0.015 µg Hg/kg/day.

The estimated concentration of mercury in breast milk attributable to dental amalgam exposure is low and is an order of magnitude below the health-based exposure reference value for oral exposure to inorganic mercury

established to protect the health of adults and children.

FDA concludes that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgams.

Children Under Six Years of Age¹⁶

No clinical studies have evaluated the effects of mercury vapor exposure from dental amalgam in children under six years of age. FDA assumes that the daily dose of mercury from amalgams in children less than six years old would not be higher than the estimated daily dose for adults (1–5 µg/day). FDA expects that the daily dose in children will be lower than the estimated dose for adults since children less than six have fewer and smaller teeth and lower ventilation rates, as compared to adults. The MRL and the RfC are derived using a conservative approach by applying uncertainty factors, and therefore are protective against adverse health effects, in populations including potentially sensitive subpopulations such as young children. Therefore, chronic exposure at these or slightly higher levels would not generally be expected to produce adverse health effects, suggesting that these children are not at risk for adverse health effects from mercury vapor released from dental amalgams.

Summary

Based on comparisons between the expected daily dose in these potentially sensitive subpopulations and the MRL and RfC, the exposure estimated from breast milk in breastfed infants, and clinical studies, we would not expect to see any adverse health effects in these subpopulations from mercury vapors released from dental amalgam. However, the data regarding risk in these subpopulations is not as robust as in adults due to the absence of measured urinary mercury concentrations and limited clinical data in these subpopulations.

ii. Dental Professionals

Dentists and their staff may be exposed to mercury vapor in the workplace during the preparation, placement, and removal of dental amalgams. As noted by the Dental Products Panel, improper use of dental amalgam exposes dental professionals to risks associated with mercury toxicity. Improper storage, trituration, and handling contribute to this risk (Ref. 1).

Dental professionals are generally exposed to lower levels of mercury vapor than those that have been reported in industrial settings, and they have urinary mercury concentrations approaching those observed in non-occupationally-exposed populations.

Several studies, primarily from one laboratory group, provide the most information about the potential health effects of low-level mercury exposure among dental professionals. In four of these studies, mean urinary mercury concentrations in dentists and hygienists ranged from 0.9 to 3 µg Hg/L (–0.7 to 2.3 µg Hg/g Cr) and were associated with some neurobehavioral effects. In a fourth study which pooled results from six earlier studies, urine mercury concentrations ranged from less than 1 µg Hg/L (–0.8 µg Hg/g Cr) to greater than 50 µg Hg/L (–38 µg Hg/g Cr). A significant weakness of these studies was that no non-mercury-exposed dental professionals were evaluated; therefore, the effect of exposure to other chemicals in the workplace (gases, organic solvents) cannot be ruled out. Nor was a non-dental workplace control group studied, which would have been informative about effects of the dental work environment in general. The neurobehavioral measures reported in several studies of dentist/dental assistant populations as being significantly correlated with mercury exposure (urine mercury levels) have not been shown in some cases to be similarly affected in other occupationally-exposed groups where urinary mercury concentrations were much higher (e.g., chloralkali workers) than in the dental professional cohorts.

In one study (Ref. 57), 34 dentists and 15 hygienists exposed to mercury vapor in the workplace (mean number of amalgams placed was 16.1) were chelated to allow assessment of recent mercury exposure (pre-chelation) and body burden from longer-term exposures (post-chelation). Mean urinary mercury concentrations for each group were: 0.9 ± 0.5 µg Hg/L (0.7 µg Hg/g Cr) before chelation; 9.1 ± 6.9 µg Hg/L (7 µg Hg/g Cr) after chelation. Subtle but statistically significant associations were demonstrated for recent exposure (pre-chelation) and measures of mood, motor function and cognition, and mercury body burden (post-chelation) was associated with symptoms, mood, and motor function. Chelation of mercury in dental professionals suggests that the mercury body burden in this population of workers is much greater than indicated solely by pre-chelation urinary mercury levels.

¹⁵ EPA defines a Reference Dose (RfD) as follows: "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL [no observed adverse effect level], LOAEL [lowest observed adverse effect level], or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used" (http://www.epa.gov/ncea/iris/help_gloss.htm#r).

¹⁶ Table 4 of this final rule (section V), "Projected Amalgam Restorations for Specific Populations" projects for 2009 that total amalgam in children under age 6 will be 2.6 million.

Another study (Ref. 58) 230 dentists (data pooled from six previous studies) had urinary mercury concentrations ranging from less than 1 µg Hg/L (~0.8 µg Hg/g Cr) to greater than 50 µg Hg/L (~38 µg Hg/g Cr); 50% subjects had urine concentrations less than 3 µg Hg/L (~2 µg Hg/g Cr) and 30% had concentration greater than 20 µg Hg/L (~15 µg Hg/g Cr). Dentists stratified into three urine mercury concentration groups: Less than 1 µg Hg/L (~0.8 µg Hg/g Cr), 1–20 µg Hg/L (~0.8–15 µg Hg/g Cr) and greater than 20 µg Hg/L (~15 µg Hg/g Cr). An association of urine mercury concentrations to a hand steadiness test was highly significant; however, associations with motor function tests were not significant.

Two studies (Refs. 59, 60) evaluated 194 dentists (average exposure of 26 years; average amalgam surfaces = 16; urine mercury = 3.32 ± 4.87 µg/L, ~2.6 µg/g Cr) and 233 hygienists (average exposure of 15 years; average amalgam surfaces = 12; urine mercury = 1.98 ± 2.29 µg/L, ~1.48 µg/g Cr) for neurological effects. No effects were observed on verbal intelligence and reaction time. Significant correlations with urine mercury concentrations were found on 9 measures in dentists and 8 measures in hygienists, including visual discrimination, hand steadiness, finger tapping and trail making tests. A weakness of the study was that no non-mercury-exposed dental professionals were studied; therefore, the effect of exposure to other chemicals in the workplace (gases, organic solvents) cannot be ruled out. Nor was a non-dental workplace control group studied, which would have been informative about effects of the dental work environment in general.

FDA concludes that existing data indicate that dental professionals are generally not at risk for mercury toxicity except when dental amalgams are improperly used, stored, triturated, or handled.

iii. Individuals With Mercury Allergies

Some individuals are hypersensitive or allergic to mercury and/or other metals. FDA reviewed several epidemiological and case studies related to the effects of mercury vapor exposure from dental amalgam on allergic individuals.

According to some of the studies that were reviewed, some patients develop adverse tissue reactions such as dermatological conditions or lesions of the skin, mouth, and tongue as a result of exposure to dental amalgam (Ref. 61, 62). In mercury-allergic individuals, clinical improvements were reported after dental amalgam restorations were

removed. Other studies reported that dental amalgam may exacerbate pre-existing autoimmune disease in mercury-allergic individuals (Refs. 63, 64). After dental amalgam restorations were removed, the health status of these patients reportedly improved.

FDA concludes that existing data indicate that certain individuals with a pre-existing hypersensitivity or allergy to mercury may be at risk for adverse health effects from mercury vapor released from dental amalgam.

2. Rationale for Special Controls

In light of the above information, FDA has identified the following as the potential risks to health associated with the use of dental amalgam devices, requiring the establishment of special controls: (1) Exposure to mercury; (2) allergic response including adverse tissue reaction; (3) contamination; (4) mechanical failure; (5) corrosion; and (6) improper use. FDA is establishing a special controls guidance document that includes recommendations to address these risks as follows.

a. Risk of Exposure to Mercury

As discussed above, dental amalgam releases mercury vapor and is associated with a risk of human exposure to this vapor. The special controls to address this risk are recommendations for: (i) Specific labeling, (ii) an information for use statement, and (iii) a performance test for mercury vapor release.

i. Specific Labeling Recommendation

The special controls guidance recommends the following specific labeling:

- WARNING: CONTAINS MERCURY.
- Warning: May be harmful if vapors are inhaled.
- Precaution: Use with adequate ventilation.
- Precaution: Store in a cool, well ventilated place.
- Contains []% mercury by weight.

The recommended warning about the presence of mercury in a dental amalgam device and the recommended disclosure of mercury content by weight will alert dental professionals of the potential for exposure to mercury vapor and will remind them of the need for protective measures, such as the use of gloves when handling the device. The recommended precautions about the need for adequate ventilation and the need to store in a cool, well ventilated place will encourage professionals to ensure there is adequate ventilation when in proximity to the device and to use a vacuum pump and adequate ventilation during placement of dental amalgams to minimize the amount of

mercury vapor that they or their patients may inhale.

ii. Information for Use Recommendation

Dental amalgam has been and remains one of the most commonly used restorative materials in dentistry. In the recent past the use of dental amalgam has gradually declined due to the improved properties of composite resin materials. Although amalgam has been used successfully for many years, the risks associated with this device have been controversial. Some scientists, professional groups, clinicians and patient advocacy groups have expressed concern about the potential hazards to health arising from mercury vapor release from amalgam restorations. Other groups of scientists, clinicians, and professional organizations have disagreed with these concerns. These opposing viewpoints were voiced at the 2006 FDA joint panel meeting (Ref. 66).

In order for dentists to make appropriate treatment decisions with their patients, it is important to provide information to help dentists understand the complexities of the science related to dental amalgam and its mercury content.

FDA recommends the inclusion of an "information for use" statement in dental amalgam labeling as a special control:

Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability.¹⁷ Dental amalgam also releases low levels of mercury vapor, a chemical that at high exposure levels is well-documented to cause neurological and renal adverse health effects.¹⁸ Mercury vapor concentrations are highest immediately after placement and removal of dental amalgam but decline thereafter.

Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older. In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.¹⁹

¹⁷ Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation; Public Health Service, U.S. Department of Health and Human Services, January 1993.

¹⁸ Liu, J. et al., "Toxic effects of metals," *Casarett & Doull's Toxicology: The Basic Science of Poisons*, Chapter 23, pp. 931–979, McGraw-Hill Medical, New York, New York, 2008.

Clarkson, T.W. et al., "The Toxicology of Mercury and Its Chemical Compounds," *Critical Reviews in Toxicology*, Vol. 36, pp. 609–662, 2006.

¹⁹ De Rouen, T. et al., "Neurobehavioral Effects of Dental Amalgam in Children, A Randomized Clinical Trial," *Journal of the American Medical Association*, Vol. 295, 1784–1792, No. 15, April, 19, 2006.

The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) and the Environmental Protection Agency (EPA) have established levels of exposure for mercury vapor that are intended to be highly protective against adverse health effects, including for sensitive subpopulations such as pregnant women and their developing fetuses, breastfed infants, and children under age six.²⁰ Exceeding these levels does not necessarily mean that any adverse effects will occur.

FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

Taking into account factors such as the number and size of teeth and respiratory volumes and rates, FDA estimates that the estimated daily dose of mercury in children under age six with dental amalgams is lower than the estimated daily adult dose. The exposures to children would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.

In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse

health effects from the breast milk of women exposed to mercury vapors from dental amalgam."

The purpose of this labeling recommendation is address potential misunderstandings about the risk of exposure to mercury from the device and to help dental professionals plan appropriate treatment recommendations for their patients by providing them with FDA's assessment of the most current, best available evidence regarding potential risks to health from mercury vapor released from dental amalgams.

iii. Performance Test Recommendation

The special controls guidance recommends a performance test to determine the amount of mercury vapor released by a dental amalgam device during corrosion (ng/cm² in 4 hrs).

Dental amalgam releases the highest levels of mercury vapor when it corrodes (Ref. 65). By measuring the amount of mercury vapor released during corrosion, the recommended performance test will quantify the highest levels of vapor release that can be expected from a dental amalgam device. The results of this test will enable FDA, through a premarket notification (510(k)) submission, to determine if these levels are acceptable and are comparable to legally marketed devices.²¹

b. Risk of Allergic Response Including Adverse Tissue Reaction

Dental amalgam is associated with a risk of adverse tissue reaction, particularly in individuals with a mercury allergy, who may experience additional allergic reactions. The special controls to address this risk are recommendations for: (i) Specific labeling and (ii) a performance test for biocompatibility.

i. Specific Labeling Recommendation

The special controls guidance recommends the following specific labeling:

■ **Contraindication:** Do not use in persons with a known mercury allergy.

The recommended contraindication is designed to prevent exposure and resultant adverse tissue reactions in allergic individuals.

ii. Performance Test Recommendation

The special controls guidance recommends a performance test to assess the biocompatibility of a dental amalgam device. Specifically, the

guidance recommends that devices be tested in conformance with the following consensus standard: "ISO 7405:1997(E), Dentistry—Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials."

Biocompatibility refers to the appropriate interaction between the device and the human body, and the minimization of risk of rejection or toxicity. Conformance to the recommended consensus standard will minimize the potential of a dental amalgam device to cause toxic or injurious effects by ensuring that the device will have the appropriate biological response for its intended use.

c. Risk of Mercury Contamination

When the mercury used to form dental amalgam is contaminated with impurities, such as oil, water, or other foreign matter, the amalgam may not harden properly. This may cause the device to be less effective. The special control to address this risk is a recommendation for a quality control test.

The special controls guidance recommends a quality control test for the production of dental amalgam devices. Specifically, the guidance recommends that devices be tested in conformance with the ISO 24234:2004(E) consensus standard. This standard includes quality control procedures for mercury, setting specific guidelines for visually inspecting mercury during production and observing its pouring characteristics. Among other things, this standard describes what visual signs indicate that a mercury sample is contaminated and therefore unsuitable for dental amalgam.

The recommended quality control test will ensure that the mercury used in dental amalgam devices is free from contamination.

d. Risk of Mechanical Failure

If a dental amalgam device is not sufficiently strong, it will not be able to withstand the force of regular chewing. As a result, it may fracture and require replacement. The special controls to address the risk of mechanical failure are recommendations for (i) specific labeling and (ii) a performance test.

i. Specific Labeling Recommendation

The special controls guidance recommends the following specific labeling:

■ **Compressive strength (MPa) @ 24 hrs.**

■ **Dimensional change during hardening (%).**

■ **Trituration time (s).**

Bellinger, D.C. *et al.*, "Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial," *Journal of the American Medical Association*, Vol. 295, No. 15, April 19, 2006, 1775–1783, 2006.

Barregard, L. *et al.*, "Renal Effects of Dental Amalgam in Children: The New England Children's Amalgam Trial," *Environmental Health Perspectives*, Volume 116, 394–399, No. 3, March 2008.

Woods, J.S. *et al.*, "Biomarkers of Kidney Integrity in Children and Adolescents with Dental Amalgam Mercury Exposure: Findings from the Casa Pia Children's Amalgam Trial," *Environmental Research*, Vol. 108, pp. 393–399, 2008.

Lauterbach, M. *et al.*, "Neurological Outcomes in Children with and Without Amalgam-Related Mercury Exposure: Seven Years of Longitudinal Observations in a Randomized Trial," *Journal of the American Dental Association*, Vol. 139, 138–145, February 2008.

²⁰ Agency for Toxic Substances and Disease Registry (ATSDR) and Research Triangle Institute, *Toxicological profile for mercury*, U.S. Dept. of Health and Human Services, Public Health Service, Atlanta, Georgia, 1999.

United States Environmental Protection Agency (EPA), "Integrated Risk Information System (IRIS) Screening-Level literature Review"—Mercury, elemental, 2002.

²¹ Dental amalgam devices currently on the market must also be in conformance with the special controls guidance.

■ Working time (min).

The recommended labeling will ensure that dental professionals are aware of the key physical properties of a dental amalgam device. This information will be useful in helping the professional decide if the device is suitable for an intended application.

ii. Performance Test Recommendation

The special controls guidance recommends that dental amalgam devices be tested in conformance with the ISO 24234:2004(E) performance standard. This standard calls for evaluation of the following physical properties:

- Complete chemical composition.
- Compressive strength (MPa) @ 1 hr.
- Compressive strength (MPa) @ 24 hrs.
- Maximum creep (%).
- Dimensional change during hardening (%).
- Particle size distribution (μ) and shape, *i.e.*, spherical, irregular, *etc.*
- Trituration time (s).
- Working time (min).

The recommended performance test will evaluate key physical properties of dental amalgam devices that could affect their function. Analysis of these properties will enable FDA, through a premarket notification (510(k)) submission, to determine if a device has physical properties that are acceptable and are comparable to legally marketed devices.

e. Risk of Corrosion

Dental amalgam devices may corrode under certain conditions, including when they are placed in direct contact with other metals. If a dental amalgam device corrodes, it will lose its strength and will need to be replaced. Corrosion also increases the amount of mercury vapor a dental amalgam device releases. The special controls to address the risk of corrosion are recommendations for: (i) Specific labeling and (ii) a performance test for corrosion potential.

i. Specific Labeling Recommendation

The special controls guidance recommends the following specific labeling:

■ **Precaution:** Do not place the device in direct contact with other types of metals.

This labeling precaution recommendation will alert dental professionals of a potential material incompatibility between dental amalgam and other metal restoratives that may be present in the mouth, such as stainless steel, titanium, base metal alloys, and noble metal alloys. It will help ensure that a dental amalgam

device is not placed in contact with a metal that will cause the device to corrode.

ii. Performance Test Recommendation

The special controls guidance recommends that dental amalgam devices be tested to assess their corrosion potential. Specifically, the guidance recommends that dental amalgam devices be tested in conformance with the ISO 24234:2004(E) performance standard. This standard calls for an evaluation of corrosion byproducts, identifying the type and amount of substances leached from the device when corrosion occurs.

The recommended performance test will provide information about what chemical products could be expected to be leached if the device were to corrode. This information will enable FDA, through a premarket notification (510(k)) submission, to determine if the device is acceptable and is comparable to legally marketed devices.

f. Risk of Improper Use

“Improper use” of a device can result from misuse of the device. The special controls to address the risk of improper use are recommendations for specific labeling.

The special controls guidance recommends the following specific labeling:

■ **Contraindication:** Do not use in persons with a known mercury allergy.

■ **Precaution:** Single-use only.

The recommended labeling contraindication will alert dental professionals of situations in which the use of a dental amalgam device is not recommended, such as in patients with a known mercury allergy. The recommended labeling precaution will inform dental professionals that a dental amalgam device is not intended to be reused.

B. Statutory Authority

FDA regulates devices, including dental devices, under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), and the act’s implementing regulations (parts 800 through 898 (21 CFR parts 800 through 898)). The Medical Device Amendments of 1976 (Pub. L. 94–295) amended the act to add premarket review authority and other authorities related to devices. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I devices, which are subject to general controls; class II

devices, which are subject to general and “special” controls; and class III devices, for which premarket approval applications generally must be submitted.

General controls include requirements for registration, listing, adverse event reporting, and good manufacturing practice (section 513(a)(1)(A) of the act). Special controls are controls that, in addition to general controls, are applicable to a class II device to help provide reasonable assurance of that device’s safety and effectiveness (section 513(a)(1)(B) of the act). Under the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. The Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629) broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act). The premarket approval requirements specify data and information that must be provided to FDA to obtain approval of a class III device (section 515 of the act (21 U.S.C. 360e)).

Devices that were in commercial distribution before the enactment of the Medical Device Amendments of 1976 (May 28, 1976) are commonly referred to as “preamendments devices.” Under section 513 of the act, FDA classifies preamendments devices according to the following steps: (1) FDA receives a recommendation from a device classification panel (an FDA advisory committee); (2) FDA publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA publishes a final regulation. FDA has classified most preamendments devices under these procedures.

Section 513(e) of the act governs reclassification of preamendments devices. This section provides that FDA may reclassify a device by rulemaking based upon “new information.” FDA may initiate reclassification under section 513(e) or an interested person

may petition FDA to reclassify a preamendments device. The term “new information,” as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (DC Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966)).

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in “medical science.” (See *Upjohn v. Finch*, supra, 422 F.2d at 951). Whether data before the agency are past or new data, the “new information” to support reclassification under section 513(e) must be “valid scientific evidence,” as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (DC Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (DC Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices (§ 860.7). For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the act (21 U.S.C. 360j(c)).

C. Regulatory History of the Devices

1. Regulatory Status

Dental amalgam²² is a metallic restorative material that has been used for direct filling of carious lesions or structural defects in teeth since the 1890s.²³ It is a combination of two devices, mercury²⁴ (liquid) and amalgam alloy (powder), which is composed primarily of silver, tin, and

copper. At the time FDA proposed to classify mercury and amalgam alloy, the devices were most commonly marketed individually in tablet/sachet or bulk form to be prepared by mixing the two devices in a dentist’s office, although the devices were also available in an already combined predosed, encapsulated form. Since the mid-1980s, the device has been marketed most frequently in the predosed, encapsulated form.

FDA classified mercury and amalgam alloy separately in accordance with the classification procedures for preamendments devices. In 1980, FDA published a proposed rule to classify amalgam alloy into class II, based on the recommendation of a device classification panel (Dec. 30, 1980, 45 FR 85979), and finalized the classification of amalgam alloy into class II in the **Federal Register** of August 12, 1987 (52 FR 30099). Although FDA proposed classifying mercury into class II, in the **Federal Register** of August 12, 1987 (52 FR 30089) FDA issued a final rule classifying mercury into class I. FDA explained that it believed that the general controls of the act, particularly the requirement that the device bear adequate directions for use, were sufficient to provide reasonable assurance of the safety and effectiveness of the device and to address the risk of rare allergic reactions among patients as well as the risk of toxicity among dental health professionals.

FDA did not classify dental amalgam at the time it classified its two components, mercury and amalgam alloy. However, in accordance with its customary practice regarding regulation of devices composed of two or more devices, FDA has regulated the predosed, encapsulated form of dental amalgam in accordance with the requirements applicable to its component with the highest classification, i.e., amalgam alloy. Accordingly, dental amalgam devices entering the market have been regulated as class II devices under 21 CFR 872.3050, amalgam alloy.

2. Proposed Rule

In the **Federal Register** of February 20, 2002 (67 FR 7620), FDA published a proposed rule entitled “Dental Devices: Classification of Dental Amalgam and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy.” The proposed rule was based on the recommendation of the device advisory panel, information submitted in citizen petitions requesting the agency to take various actions with respect to the devices, a substantial

amount of scientific data, and the results of several government safety assessments related to the devices (Refs. 3, 4, 12).

The Dental Products Panel²⁵ (the Panel) unanimously recommended that FDA classify dental amalgam in its encapsulated form into class II (Ref. 1). The Panel concluded that there are no major risks associated with encapsulated dental amalgam, when used as directed, but recognized there is a small population of patients who may experience allergic hypersensitive reactions to the materials in the device. The Panel also noted that improper use of the device exposes professionals to risks associated with mercury toxicity. To address these risks, the Panel recommended that the device be subject to voluntary performance standards, voluntary testing guidelines, and requirements that the device be used only on the written or oral authorization of a licensed practitioner, and only by persons with training or expertise in its use.

The proposed rule included the following actions: (1) Classify encapsulated dental amalgam into class II (special controls); (2) amend the class II classification for amalgam alloy by designating special controls; and (3) reclassify mercury from class I (general controls) to class II (special controls). In the 2002 proposed rule, FDA identified risks to health associated with the use of dental amalgam, mercury, and amalgam alloy that it believed required the imposition of special controls that, in conjunction with the general controls of the act, would provide reasonable assurance of the safety and effectiveness of the device. The risks identified were mercury toxicity associated with the improper use of dental amalgam and allergic reactions in a small subpopulation of individuals. To mitigate these risks, FDA proposed a labeling guidance and compliance with recognized consensus standards as special controls for these devices. FDA proposed that all three devices be subject to the same special control guidance document, “Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling,” dated February 20, 2002, as well as the following consensus standards, as relevant: (1) International Standards Organization (ISO) 1559:1995 Dental Materials-Alloys for Dental Amalgam, and (2) American National Standards Institute/American Dental Association (ANSI/ADA) Specification

²² “Dental amalgam,” as it is referred to in this final rule, is a device that is a combination of two component devices, mercury and amalgam alloy.

²³ Earlier prototypes were available from the 1830s.

²⁴ FDA is no longer using the term “dental mercury,” but instead is using “mercury,” to more accurately reflect the fact that the mercury used in dental amalgam is elemental mercury.

²⁵ A panel of FDA’s Center for Devices and Radiological Health Medical Devices Advisory Committee.

No. 6–1987 for Dental Mercury. The comment period on the proposed rule was reopened on July 17, 2002 (67 FR 46941), and again on April 28, 2008 (73 FR 22877), to permit additional opportunities for public comment (Docket No. FDA–2008–N–0163).

3. Scientific Information, Safety Assessments, and Adverse Event Reports Regarding Dental Amalgam

a. Information and Assessments Discussed in the Proposed Rule

Before issuing the proposed rule, FDA carefully examined extensive information related to the safety and effectiveness of dental amalgam. This information included a comprehensive safety assessment of dental amalgam performed by the U.S. Public Health Service (PHS), U.S. government research related to dental amalgam, studies and other information submitted in citizen petitions to the agency, several national and international comprehensive reviews of scientific information about the risks and benefits of the device, comprehensive safety assessments of dental products that contain mercury by international health organizations and foreign countries, and the scientific literature reviewed by the Panel. *See* 67 FR 7621–7625 (Feb. 20, 2002).

b. Information and Assessments That Have Become Available Since Publication of the Proposed Rule

i. Life Sciences Research Office (LSRO) Report

In 2004, the Trans-agency Working Group on the Health Effects of Dental Amalgam completed a comprehensive review of approximately 300 peer-reviewed studies of dental amalgam and mercury vapor published from 1996 through 2003 (LSRO report) (Ref. 13). The project was completed under contract by Life Sciences Research Office, Inc. (LSRO), and was funded by the National Institutes of Health (NIH), in cooperation with FDA, the Centers for Disease Control and Prevention (CDC), and the Office of the Chief Dental Officer of the Public Health Service. In conducting the review, LSRO engaged an independent panel of experts from academia in the fields of immunotoxicology, immunology, and allergy; neurobehavioral toxicology and neurodevelopment; pediatrics; developmental and reproductive toxicology; toxicokinetics and modeling; occupational health and epidemiology; pathology; and general toxicology. The LSRO report concluded that there is little evidence to support claims of a causal relationship between mercury fillings and human health problems,

such as kidney or cognitive dysfunction; neurodegenerative disease, specifically Alzheimer's disease or Parkinson's disease; or autoimmune disease (Refs. 13, 67). The report also identified important data gaps, including whether low-level mercury vapor results in neurotoxicity, whether low-level in utero exposure to mercury vapor affects the developing brain, and whether occupational exposure to mercury vapor affects reproductive and/or pregnancy outcomes.

ii. White Paper and Addendum Scientific Reviews

In an effort to assess whether peer-reviewed literature published since FDA's 1997 safety assessment of dental amalgam (Ref. 12) presented new information on the potential health risks of dental amalgam, FDA's National Center for Toxicological Research (NCTR) prepared a White Paper review (Ref. 10). Rather than duplicate previous extensive reviews of the scientific literature by U.S. government agencies and international organizations, NCTR chose to build on the previous reviews and conducted an in-depth evaluation of 34 primary research articles that were chosen for their scientific merit, relevance, and potential to provide the most significant current information regarding the potential health risks associated with exposure to mercury in dental amalgam. The conclusion in the draft White Paper was that the peer-reviewed scientific information published since 1997 was consistent with FDA's previous assessment that, except for persons with rare allergic or hypersensitivity reactions, individuals with dental amalgam restorations do not experience adverse effects from the device.

On September 6 and 7, 2006, FDA presented the findings of the White Paper in draft to a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee (the 2006 Panel). At that time, FDA also opened a docket related to the meeting to facilitate public submission of information regarding the potential health risks of mercury in dental amalgam (Docket No. FDA–2006–N–0543 (formerly 2006N–0352)).

The 2006 Panel heard from numerous public speakers, and then deliberated and made recommendations on a series of questions FDA had posed on its draft White Paper (Ref. 66). The committee concluded that FDA's draft White Paper had significant limitations, such as the fact that the literature search used a single database (PubMed), the Paper did not satisfactorily explain how the

scientific references were chosen,²⁶ and it failed to identify significant gaps in the scientific knowledge, particularly with respect to exposure limits and possible health risks for sensitive subpopulations. The majority of the 2006 Panel voted that it could not find the conclusions of the draft White Paper to be "reasonable" in light of these limitations. In their closing comments, the panelists provided individual recommendations, including the individual (not consensus) recommendations that FDA consider labeling requirements related to the use of dental amalgam in pregnant women and small children, that manufacturers be required to provide information to patients to ensure that they understand that the devices contain mercury, and that the Federal government (public health agencies) research the effects of dental amalgam mercury on reproductive health and developing fetuses.

In response to the deliberations and recommendations of the 2006 Panel, FDA conducted a more comprehensive review of the scientific literature in an Addendum to the White Paper (Ref. 11). In total, more than 200 scientific articles, including 33 case studies, were considered in the White Paper and its Addendum.²⁷

The conclusions of the Addendum generally confirmed the conclusions of the White Paper and previous assessments by other organizations and agencies regarding the potential health risks presented by the presence of mercury in dental amalgam. More specifically, the articles and case studies reviewed in the Addendum to the White Paper were consistent with the conclusion in earlier government safety assessments (Refs. 3, 4, 12) that exposures to mercury vapor from dental amalgam are not associated with adverse health effects in the population age six and older (*see also* section I.A.). As discussed in the Addendum, FDA also concluded that prospective clinical studies of dental amalgam published to date (Refs. 31, 32, 34, 40, 46, 47, 68) found no neurological deficits in children who first received dental amalgam restorations at ages six to ten and were followed for five or seven years. FDA concluded, however, that the clinical data are limited regarding certain subpopulations (pregnant

²⁶ Appendix A of the draft White Paper did list the inclusion and exclusion criteria for identification of relevant studies.

²⁷ FDA decided to conduct this comprehensive review of the literature and prepare the Addendum rather than revise the White Paper. FDA finalized the White Paper with the addition of the Addendum.

women and their developing fetuses, and children under the age of six, including breastfed infants).

c. Adverse Event Reports

As part of FDA's effort to determine the appropriate regulatory controls to provide reasonable assurance of the safety and effectiveness of dental amalgam, FDA reviewed all adverse event reports submitted to MedWatch for dental amalgam devices through 2008. The review identified 141 reports, dating back to 1988, including 102 reports of injuries, 12 reports of malfunctions, 26 miscellaneous complaints, and 1 misreported death.²⁸ The large majority of the injury reports were submitted voluntarily by individual patients. The malfunction reports were submitted primarily by health professionals and two reports were submitted by manufacturers.

The malfunction reports described problems with encapsulated amalgam such as product shrinkage, inaccurate powder to liquid ratios, and capsule leaking. There were also some reports of mercury spills as a result of mixing (trituration) amalgam capsules.

The injury reports described a wide array of conditions and symptoms that individual patients believed to be caused by their dental amalgam fillings. The conditions and symptoms reported included fatigue, headaches, joint pain, brain "fog," depression, neuropathy, rheumatoid arthritis, hypothyroidism, visual impairments, hearing loss, allergies, kidney damage, attention deficit disorder, irritable bowel syndrome, seizures, abnormal menstrual cycle, weight loss, and developmental problems, such as autism, attention deficit hyperactivity disorder, and unidentified congenital defects. Several reporters stated that they experienced relief from their symptoms when their amalgam fillings were removed, while others stated that their symptoms did not appear until after their fillings were removed.

The great majority of the adverse event reports submitted to FDA regarding dental amalgam are anecdotal and lack specific details, such as when symptoms first appeared, how they progressed, and what may have caused onset or relief of certain symptoms. In addition, the reports frequently were not made until years after the events occurred. Because of these factors, FDA is unable to assess the relationship of

the reported adverse effects with the device. FDA notes, however, that the number of adverse event reports it has received regarding dental amalgam is quite low in light of the device's long history of use in tens of millions of dental restorations in the United States each year.²⁹

II. Development of the Final Rule

In developing this final rule, FDA considered the comments and information submitted in response to the proposed rule, the scientific reviews, studies, and safety assessments described above, and its analysis of the adverse event reports submitted. The final rule and the special controls guidance document are consistent with the proposed regulation, although they reflect several changes made in response to the comments and information received. As proposed, the final rule classifies dental amalgam into class II, reclassifies mercury from class I to class II, and designates a special control for dental amalgam, mercury, and amalgam alloy. However, the final rule classifies the three devices together in a single regulation and uses the term "mercury" instead of "dental mercury."

The special controls guidance document specifically revises the draft special controls guidance document as follows:

- Includes recommendations related to the updated relevant consensus standards, rather than designating these standards as separate special controls.
- Includes recommendations regarding device composition, performance data, warnings, and labeling precautions.
- Recommends a contraindication against use in persons with a known mercury allergy.
- Recommends that the labeling include an information for use (IFU) statement.
- Updates recommendations regarding performance testing to be included in 510(k) submissions to include strength, creep, dimensional change, particle shape and distribution, corrosion products, and amount of mercury vapor released.
- Replaces the recommendation that each ingredient of the device be listed in the labeling with the recommendation that the primary ingredients be listed, and that the labeling state that the device contains mercury.
- Replaces the recommendation that the labeling warn that the device

contains zinc with the recommendation that the labeling warn that the device contains mercury. FDA believes that the effects of zinc on the expansion of dental amalgam are well understood and that a warning that the device contains zinc is not necessary to provide a reasonable assurance of the safety and effectiveness of the device. In contrast, as discussed in section I.A., FDA recommends that the device bear a warning that the device contains mercury because FDA believes such a warning is necessary to provide a reasonable assurance of safety and effectiveness because of the potential risks to health of exposure to mercury and toxicity and adverse tissue reaction.

- Deletes recommendations regarding packaging and handling because FDA has concluded that these recommendations are not necessary to provide a reasonable assurance of the safety and effectiveness of the device.

In this final rule, FDA is designating a special controls guidance document (described in section I.A.) that, along with the general controls under the act, will provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the special controls guidance. Following the effective date of this final rule, any firm submitting a 510(k) premarket notification for dental amalgam, as well as any firm currently marketing the device, must address the risks to health identified in the special controls guidance document. Firms marketing or intending to market mercury or amalgam alloy must address the risks to health identified in the special controls guidance document that apply to those devices.

When a guidance document is established as a special control by rulemaking, manufacturers are required to address the issues identified in the guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness. If a manufacturer proposes to use a means other than the recommendations set forth in the special controls guidance, it is required to demonstrate that the alternative means provides equivalent assurances of safety and effectiveness.

III. Comments and FDA's Responses

As stated previously, in addition to the comment period provided when the proposed rule was issued in 2002, FDA reopened the comment period on the rule in July 2002 and again in April 2008. Altogether, FDA received more than 1,400 comments on the proposed

²⁸ The death report appears to have been misclassified because it was self-reported (an actual death had not occurred). This report attributes symptoms of joint pain, neurological spasms, a compromised immune system, and a variety of other physical symptoms to dental amalgam.

²⁹ FDA estimates that dental amalgam has been used in approximately one billion restorations between 1988 and 2008.

rule and the draft special controls guidance document. The commenters included consumers, health professionals, industry, academia, State and Federal agencies, professional societies, and organizations. Because of the intertwined nature of the documents and the significant duplication of comments, FDA is summarizing and responding to the comments it received on both the proposed rule and the draft special controls guidance document in this preamble.³⁰

In the 2008 **Federal Register** notice reopening the comment period on the proposed rule, FDA requested comments supported by empirical data and scientific evidence on specific topics relating to the classification of the devices and the special controls that should apply to them if they were classified into class II. FDA requested comments on whether the proposed special controls (materials and labeling) would provide reasonable assurance of the safety and effectiveness of the devices if they were placed in class II, and on whether the proposed special controls guidance document should be revised in light of the recommendations and discussions of the 2006 Panel. FDA also sought information related to the agency's analysis of the benefits and costs of the various regulatory options for classifying the devices, including the number of annual procedures in which the devices are used, trends in the use of various restorative devices, information regarding alternatives to dental amalgam, how labeling describing the risks in certain populations might affect demand, how such risks should be communicated, information regarding the current level of mercury to which patients and professionals are exposed, and whether that exposure might be reduced by using alternatives to dental amalgam.

A. Classification

(Comment) FDA received many comments regarding the appropriate classification of these devices. The comments generally did not distinguish among dental amalgam, mercury, and amalgam alloy, treating them as one device, dental amalgam. Many comments urged the agency to classify the device into class III (premarket approval), frequently stating safety concerns. For example, some

commentators urged the agency to classify dental amalgam into class III because, as a class III device, "[it would be] presumed as unsafe and needing to be proven safe before general use can be allowed" and that "it should be placed in class III where manufacturers are forced to prove that it is safe, not the class II where it can continue to be grandfathered." Others believed the device should be classified into class II because there is sufficient information to establish special controls for the device that would provide reasonable assurance of its safety and effectiveness. One comment stated that special controls were unnecessary because it believed that the general controls of the act are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(Response) FDA has determined that class II with a designated special controls guidance document will provide a reasonable assurance of safety and effectiveness for dental amalgam. In reaching this determination, FDA made the findings required by § 860.7(d)(1) that, first, when subject to the general controls of the act and the designated special control, and when accompanied by warnings against unsafe use in individuals who are allergic to mercury, the probable benefits to health from use of the device outweigh any probable risks. Second, FDA has determined that, when subject to the general controls of the act and the designated special control, valid scientific evidence demonstrates the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

FDA classifies devices in accordance with the statutory criteria in section 513 of the act. As provided in section 513, class I devices are devices for which the general controls of the act are sufficient to provide reasonable assurance of safety and effectiveness. Class II devices are devices for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls that, along with the general controls of the act, will provide such assurance. Class III devices are devices for which premarket approval is necessary to provide reasonable assurance of safety and effectiveness.

As stated above, FDA relies on valid scientific evidence in making determinations regarding classification. Valid scientific evidence is defined as "evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-

documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use." § 860.7(c)(2). Consistent with the regulation, FDA does not rely on isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, or unsubstantiated opinions. The valid scientific evidence to support classification of a device may vary according to, among other things, the existence and adequacy of warnings and restrictions, and the extent of experience with use of the device. § 860.7(c)(2).

The standard for determining whether there is reasonable assurance that a device is safe is described in § 860.7(d)(1).³¹ According to that section, "[t]here is reasonable assurance that a device is safe when it can be determined, based on valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use."

In determining the appropriate classification of dental amalgam, FDA has relied on valid scientific evidence, including, as described in detail in section I.A., several comprehensive reviews of the scientific literature and safety assessments, air monitoring standards for mercury vapor, biological monitoring standards for urine mercury, and clinical studies. Based on its review of this information, FDA concludes that exposures to mercury vapor from dental amalgam are not associated with adverse health effects in the population age six and older. With respect to potentially sensitive populations, *i.e.*, fetuses, breastfed infants, and children under six years of age, FDA would not expect to see any adverse health effects in these subpopulations from mercury vapors released from dental amalgam, although clinical data are limited. These conclusions are supported by

³⁰ FDA also received more than 1,800 comments to the docket for the 2006 Panel meeting on dental amalgam (Docket No. 2006N-0352), which had been established to permit persons to comment and provide information on the issues and questions raised at the meeting. FDA reviewed and considered those comments in finalizing this regulation.

³¹ There is no question regarding the effectiveness of the device. It is undisputed that the device has been used effectively in millions of dental restorations over 100 years.

independent investigations by other scientific bodies, such as the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which stated in 2007 (Ref. 6) that "no risks of adverse systemic effects exist and the current use of dental amalgam does not pose a risk of systemic disease."

Consistent with the regulation defining valid scientific evidence, in determining the appropriate classification of dental amalgam, FDA has considered the device's long history of use in tens of millions of procedures in the United States each year, as well as the information available regarding that use. FDA has also considered the adequacy of warnings and the fact that the device is a prescription device and, therefore, available to patients only with the involvement of a health care provider. Finally, FDA has considered the probable benefits to health from use of the device, such as its strength, marginal integrity, suitability for large occlusal surfaces, durability, ease of placement, and low failure and complication rates.

FDA recognizes that dental amalgam releases low levels of mercury, and that there are scientific data showing mercury vapor, at high enough exposures, to be a neurotoxicant and nephrotoxicant. FDA also recognizes that certain individuals are allergic to mercury. In addition, there is very limited to no clinical information available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed. FDA believes that, in order to provide reasonable assurance of the safety of dental amalgam, it is important that dentists are informed that the device contains mercury, that it is contraindicated against use in persons with a known allergy to mercury, and that the labeling include an information for use statement discussing the benefits, risks, and scientific study information.

FDA has concluded that general controls alone are not sufficient to address the identified risks to health presented by dental amalgam and thus provide reasonable assurance of its safety and effectiveness. FDA has also determined that premarket approval is not necessary to provide such assurance because there is sufficient information to establish special controls that, in conjunction with the general controls under the act, will provide reasonable assurance of the safety and effectiveness of the device. Specifically, FDA has concluded that the recommendations in the special controls guidance document,

including the recommended labeling statements, along with the general controls of the act, are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

In accordance with § 860.7(d)(1), FDA has also concluded that, when subject to the general controls of the act and the designated special control, and when accompanied by warnings against unsafe use in individuals who are allergic to mercury, the probable benefits to health from use of the device outweigh any probable risks. Finally, FDA has determined that, when subject to the general controls of the act and the designated special control, valid scientific evidence demonstrates the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(Comment) Some comments were opposed to "FDA reclassifying mercury-encapsulated amalgam dental fillings as a class II," stating that "FDA is moving quickly to approve mercury."

(Response) These comments reflect a misunderstanding of the device classification process. Mercury, amalgam alloy, and dental amalgam are legally marketed preamendments devices. As explained above, preamendments devices are subject to specific classification procedures. In 1987, FDA classified mercury and amalgam alloy through notice and comment rulemaking, as required by the statute. Although FDA did not classify dental amalgam (the combination of those two devices) at that time, the device has been regulated in accordance with the requirements applicable to its component with the highest classification, *i.e.*, amalgam alloy. In 2002, the agency issued a proposed rule to classify dental amalgam. Consistent with that proposed rule, FDA is now classifying the device into class II subject to a special control that, along with the general controls under the act, will provide reasonable assurance of its safety and effectiveness. Thus, this rule does not constitute an "approval" for marketing, but rather establishes additional regulatory controls for the device.

(Comment) One comment stated that dental amalgam should be regulated as a class III device because it is an implant.

(Response) FDA disagrees with the comment. As explained in the **Federal Register** of December 30, 1980 (45 FR 85962 at 85964), FDA does not consider restorative materials placed in the teeth, such as dental amalgam, to be

implants.³² Moreover, even if the devices were considered to be implants, FDA would not be required to classify them into class III. In accordance with section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) and 21 CFR 860.93, an implant may be classified into class I or class II if FDA determines that premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness. As stated above, FDA has made this determination with respect to dental amalgam.

B. Banning

(Comment) Some comments stated that dental amalgam should be banned because it is poisonous and not safe for use in dentistry. Other comments requested that dental amalgam be banned for children 18 and under, women of childbearing age, pregnant women, nursing mothers, and persons with compromised immune systems and kidney problems. Some comments suggested that FDA employ the "precautionary principle" adopted by other countries to protect these populations. In contrast, other comments noted that no scientific study or assessment has found a causal link between dental amalgam and adverse health effects in either the general population or in any sensitive subpopulation, and that the device has been used safely for many years in millions of dental restorations.

(Response) As discussed in detail above, FDA disagrees that the levels of mercury released from dental amalgam contribute to adverse health outcomes or is unsafe for use in dentistry when used with appropriate occupational health controls for dental offices. FDA recognizes that certain countries, *e.g.*, Norway, Sweden, and Denmark, have banned dental amalgam, adopting a "precautionary principle" approach (taking preventive action despite uncertainty regarding the need for such action). However, FDA regulates devices, like dental amalgam, in accordance with the requirements of the act. As explained above, in accordance with the statutory criteria for classifying devices, FDA has concluded that there is sufficient information from which to establish special controls that, along with the general controls of the act, will provide reasonable assurance of the

³² The classification panel identified a dental implant as "a device that is surgically placed into, or in opposition to, the maxilla or mandible and which protrudes through the mucosa of the oral cavity" (45 FR 85964). Dental restorative materials such as amalgam do not protrude through the mucosa of the oral cavity and, therefore, are not considered implants.

safety and effectiveness of the device. Specifically, FDA has determined that the risks to health presented by dental amalgam can be addressed through the general controls of the act in conjunction with the recommendations in the special controls guidance document. Because of this determination, FDA disagrees with comments suggesting that the device should be banned.

C. Mercury Content and Toxicity

(Comment) One comment stated that the labeling of the device should disclose the fact that it contains mercury, citing to a recent poll showing that 76 percent of Americans do not know that the primary component of amalgam fillings is mercury. Another comment stated that the amount of mercury vapor released from dental amalgam also should be disclosed.

(Response) FDA agrees that the labeling of the device should disclose the fact that it contains mercury. Accordingly, the special controls guidance recommends that the labeling include a warning that the device contains mercury and disclose the total mercury content (% by mass). FDA has concluded that labeling disclosing the amount of mercury vapor released from the device would not provide useful information because the mercury vapor released in a clinical setting varies among patients and is dependent on several variables, such as age and wear of the restoration, as well as the diet and chewing habits of the patient. FDA believes, however, the recommended warning about the presence of mercury in a dental amalgam device and the recommended disclosure of mercury content by weight will alert dental professionals of the potential for exposure to mercury vapor and will remind them of the need for protective measures, such as the use of gloves when handling the device. The recommended precaution about the need for adequate ventilation will encourage professionals to use a vacuum pump and adequate ventilation during placement of dental amalgams to minimize the amount of mercury vapor that they or their patients may inhale. Moreover, FDA is recommending that, to establish substantial equivalence to a legally marketed device in a 510(k) premarket notification, manufacturers conduct a test showing that the amount of mercury vapor released due to corrosion is acceptable when evaluated using an FDA-recognized standard or an equivalent method of evaluating the amount of mercury vapor released due to corrosion.

(Comment) Several comments were submitted in response to FDA's request for information on the current level of exposure to the mercury in dental amalgam for patients and dental professionals. One comment stated that dental amalgams release 0.53 micrograms of mercury per surface per day, resulting in an uptake into the blood stream of 0.081 micrograms of mercury per surface per day, well below the World Health Organization (WHO) Acceptable Daily Intake (ADI) levels of 40 micrograms/day or 300 micrograms/day for demonstrable health effects to the most sensitive individual. Another comment stated that dental amalgam fillings release 4 to 22 micrograms/cm² per day, that those amounts are increased further by galvanism, heat, or chewing, and that data show an average of 60 micrograms of mercury are excreted daily in the feces of the average patient with amalgam fillings. Another comment stated that the average urinary mercury concentrations in children (age six and older) with amalgam fillings range from 0.1 to 5.7 micrograms/gram creatinine, as compared to 0.1 to 2.9 micrograms/gram creatinine for children with composite fillings. Another comment stated that health screenings of dental professionals from 1997–2007 found an average urinary mercury concentration of approximately 2.5 micrograms/L and that this level is within the range of the urinary mercury concentration found in individuals who are not exposed to mercury in their occupations. Finally, one comment stated that there are 0.2 micrograms of mercury in the breathing zone of dentists during placement and removal of amalgam.

(Response) FDA agrees with the comments that the current level of exposure to mercury in dental amalgam, for patients with restorations and dental professionals exposed occupationally, is below the accepted threshold levels for the most subtle health effects and is consistent with the conclusions of previous safety assessments (Refs. 3, 6, 12, 13) that the mercury in dental amalgam does not present a risk to health for the population age six and older. While the fact that dental amalgam releases mercury vapor has been known for a long time, it is difficult to make accurate estimates of the amount of mercury released from amalgam and subsequent absorption of mercury in the body using an air monitoring approach. These difficulties account for the disparate range of values reported in the literature, some of which are noted in the comment above. Because of the difficulties noted in

determining a robust estimate of daily dose of mercury resulting from monitoring of mercury vapor in the oral cavity, as discussed in section I.A., FDA is primarily relying on a consensus estimate of 1–5 µg/day for adults (Refs. 3, 22).

FDA also recognizes that good dental hygiene practices, such as the use of vacuum pumps and chair-side traps, have greatly reduced the level of mercury to which dental professionals are exposed. Nevertheless, because dental amalgam releases mercury vapor and is associated with a risk of human exposure to this vapor, and because some individuals have a known allergy to mercury, FDA is recommending that the labeling warn that the device contains mercury, contain a precaution that it should be used with proper ventilation, and include a contraindication against use in persons with a known allergy to mercury.

(Comment) A few comments stated that dental amalgam fillings contribute to the majority of the mercury body burden in the general population and that urinary mercury concentrations are not measures of mercury body burden, but rather represent a combination of the amount of mercury to which an individual has been exposed and his or her ability to excrete mercury. The comments added that 90 percent of mercury is excreted from the body through the fecal route, and that low urinary mercury concentrations are not an accurate predictor of mercury exposure. Some comments stated that data obtained from autopsies demonstrate that high mercury levels are present in the brain and kidneys, despite dental amalgam mercury exposure levels being below safety limits. A few comments noted that mercury passes through both the umbilical cord and the blood/brain barrier.

(Response) FDA recognizes that dental amalgam contributes to the majority of the body burden of mercury for many people not occupationally exposed to mercury (Ref. 22). FDA recognizes that urine and feces are major routes of mercury excretion, but also recognizes that which excretion route predominates is dependent on the mercury species. The “90% mercury excreted by the fecal route” relates to excretion of organic methylmercury, and this high percent is not the case for inorganic forms of mercury, where the urinary route predominates, especially in the case of chronic mercury vapor exposure (Refs. 14, 69, 70). The amount of mercury excreted into feces is not a well-accepted index of exposure to elemental mercury vapor. Further, the

correlation of fecal mercury levels, mercury vapor exposure, and adverse health effects has not been reliably established, as has been shown for urinary mercury concentrations. Fecal mercury concentrations might increase during removal of dental amalgams due to swallowing amalgam particles. Fecal levels might also be elevated from dietary exposure to methylmercury, which undergoes extensive enterohepatic recycling between the GI tract and liver biliary excretion system.

FDA disagrees with the comment that urinary mercury concentrations are not accurate measures of inorganic mercury, including mercury vapor, exposure. In fact, FDA and other public health agencies, such as ATSDR (Ref. 14), and WHO (Refs. 21, 22), consider urinary mercury concentrations to be the most accurate and widely used biomarker for assessing the absorbed dose that results from chronic mercury vapor exposure. For example, in a number of occupational studies, strong correlations have been found between daily, time-weighted air concentrations (which are considerably higher than exposures to dental amalgam mercury) and urinary mercury concentrations in workers (Refs. 14, 21). In studies evaluating dental amalgam mercury exposure, urinary mercury concentrations have been shown to be proportional to the number of amalgam restorations and/or surfaces in the mouth.

FDA is aware that, in autopsy studies, mercury has been found to accumulate in the brain. However, it is difficult to draw conclusions from autopsy studies regarding a potential association between exposure to dental amalgam and adverse health outcomes without information concerning the individual's lifetime history of exposure to mercury from fish and other environmental sources. Similarly, even in cases attempting to find an association, meaningful conclusions could not be drawn between neurodegenerative disorders, the number of dental amalgams, and the amount of accumulated mercury, because it is possible that damaged neuronal cells in patients with neurodegenerative disorders are able to accumulate more mercury than healthy cells (Ref. 70).

In response to the comments noting that mercury passes through both the umbilical cord, FDA agrees that mercury vapor has the ability to cross the placental barrier. As discussed in detail in section I.A., FDA found that the limited human data do not demonstrate an association between exposure to the mercury in dental amalgam and adverse reproductive outcomes such as low birth weight babies or increased rates of

miscarriage. Moreover, FDA also reviewed several well-conducted studies designed to assess high-level mercury vapor exposure on developmental effects in pregnant animals and their offspring. In one study no effects were observed on peripheral, somatosensory, auditory, or visual neurological functions in offspring of rats exposed to mercury vapor prenatally (Ref. 48). In another study, prenatal exposure of pregnant rats was associated with adverse effects on fetal development only in cases where maternal exposure to mercury vapor was so high that it became toxic to the mother (leading to decreased maternal body weight) (Ref. 44). More details are provided in section I.A.

(Comment) One comment stated that mercury in dental amalgam is more toxic than mercury in fish.

(Response) The form of mercury in dental amalgam (mercury vapor) is different from the form of mercury in fish (methylmercury). These two types of mercury differ in terms of kinetic behavior, mechanism of action, exposure routes, and tissue targets. For the purpose of classifying dental amalgam, FDA is addressing only the form of mercury in that device. As discussed in detail above, FDA disagrees that the levels of mercury released from dental amalgam are unsafe.

(Comment) A few comments stated that toxic/allergic reactions to mercury in dental amalgam may produce autoimmune conditions such as lichen planus lesions, eczema, pustulosis, and dermatitis, and often play a role in the pathogenesis of periodontal disease.

(Response) After reviewing 23 case studies and several epidemiological studies in the Addendum to the White Paper and conclusions from other reviews, FDA concluded that various dermatological conditions or lesions of the skin, mouth, and tongue were attributed to direct or indirect contact with dental amalgam, and may have been related to a pre-existing hypersensitivity or allergy to mercury and/or other metals. To help ensure that the device is not used in patients who are allergic to mercury, FDA is recommending that the labeling of the device contain a warning that the device contains mercury and a contraindication against use in persons with a known allergy to mercury.

FDA disagrees that the mercury from dental amalgam plays a role in the pathogenesis of periodontal disease. Based on its review of the scientific literature on this subject (Refs. 71–75), FDA has concluded that the mercury in dental amalgam is not an etiological or

aggravating agent for the initiation, propagation, or aggravation of any form of periodontitis.

(Comment) Several comments suggested that the mercury in dental amalgam causes or contributes to chronic neurological or neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease, and autism.

(Response) FDA discusses in detail in section I.A the available clinical information related to these diseases and its conclusions. In addition to the studies discussed in section I.A., and explained in the White Paper and Addendum reports (Refs. 10, 11), no evidence of neurodegenerative diseases have been reported in occupational cohorts exposed to much higher levels of mercury vapor in the workplace compared to the low levels in non-occupational groups with exposure from amalgams.

(Comment) One comment claimed that dental amalgam may cause kidney damage in children, as evidenced by a recent clinical trial (New England) (Ref. 46) that showed that children with amalgam restorations had higher levels of microalbuminuria (protein in urine), which is a marker of kidney injury, than children with non-amalgam restorations.

(Response) FDA disagrees with this comment. FDA reviewed the New England trial (Ref. 46) in the Addendum to the White Paper and concluded that, although microalbuminuria levels were higher in the amalgam treatment group, the levels of three other biomarkers of kidney injury were not different between the amalgam versus composite restoration groups. The authors of the study noted that they were unable to determine whether the increase in microalbuminuria was related to treatment or may have occurred by chance, since albuminuria may be caused by strenuous physical exercise, urinary tract infections, or other conditions with fever, or be related to orthostatic proteinuria (Ref. 46). However, in another children's prospective trial (Casa Pia), there were no differences between the amalgam and composite groups with respect to the urinary excretion of microalbumin or albumin (Ref. 31), a biomarker of renal glomerular injury, and GST-alpha and GST-pi, two biomarkers of renal proximal and distal tubule injury, respectively (Ref. 47) (*see also* section I.A).

D. Patient Information

(Comment) Several comments stated that FDA should require dentists to inform their patients that dental

amalgam contains mercury, and to advise them of the risks and benefits of the device, as well as the various restoration choices available to them. Many comments expressed concern that the labeling information would be provided only to dentists and not to patients. Several comments suggested that informed consent should be obtained from patients before they are treated with the device.

(Response) As a preliminary matter, FDA believes the comments that suggested that "informed consent" be obtained before patients receive dental amalgam were not using the term as it is used in 21 CFR part 50, which applies to the protection of human subjects in clinical investigations (for example, investigations of devices that have not been cleared or approved for marketing). Rather, these comments appear to be concerned about ensuring that patients are informed about the risks, benefits, and alternatives to dental amalgam.

FDA recognizes that selection of an appropriate restorative material for an individual patient, and hence an appropriate treatment plan, is a complex matter that requires the expertise of the dental professional. In selecting the appropriate restorative material for an individual patient, the dentist routinely considers many factors, such as the patient's oral health, the material properties of the various options, and the patient's medical history, including whether the patient has a known allergy to mercury.

FDA believes that the recommended labeling statements in the special controls guidance document will provide dentists with important information that will improve their understanding of the devices and help them make appropriate treatment decisions with their patients. In addition, FDA notes that dental amalgam is a prescription device and, therefore, patients cannot receive the device without the involvement of a learned intermediary, the dental professional. Based on the reasons described above, FDA has concluded that it is not necessary to require that dentists provide this information to patients in order to provide reasonable assurance of the safety and effectiveness of the device.

E. Alternative Materials

Several comments were submitted in response to FDA's request for information on the relative costs and replacement lives of dental amalgam and alternative materials, particularly composite resins.

(Comment) With respect to cost, one comment stated that composites cost 46

percent more than equivalent amalgam restorations and are more likely to fail, resulting in the need for crowns on large surfaces. Another comment stated that alternative materials cost 20 percent more than amalgam restorations. One commenter stated that data from 2007 indicate that the average fee submitted to insurance companies for one to four or more surfaces of dental amalgam ranged from \$107 to \$186, while the average submitted fee for composite resins ranged from \$135 to \$242 for the same surfaces. One comment stated that amalgam remains the best choice for deeper carious lesions of the posterior teeth and for patients seeking effective, lower cost dentistry.

(Response) FDA agrees that, in general, composite resin restorations are more costly than dental amalgam restorations.

(Comment) FDA received conflicting comments on the durability of composite resins versus dental amalgam. Some comments stated that composite resins are inferior to amalgam with respect to durability, stiffness, wear resistance, marginal stability, and service life, and that they must be replaced more frequently. One comment stated that amalgam fillings can last for 35 years, while composites need to be replaced every 5 years. In contrast, other comments stated that amalgam is inferior to composites. For example, one comment stated that amalgam-filled teeth have a tendency to crack more frequently than composite-filled teeth, inevitably leading to more expensive restorations, such as crowns. The commenter stated further that composite resins better preserve the structural integrity of the tooth because they do not expand and because less natural tooth structure is removed in preparation for their placement. Other comments stated that the service lives of composite resins and dental amalgam are equivalent. One comment stated that the process for placing composite restorations is technique-sensitive and, if done properly, a composite restoration can last as long as an amalgam restoration.

(Response) FDA believes that the durability of dental restorations is dependent on many factors related to material properties, the type and size of the restoration, the dentist's skill, and patient use. According to the literature, the two primary reasons dental restorations fail are secondary caries (as the result of marginal leakage) and fracture. Studies have shown higher secondary caries rates for composite resins, but equivalent fracture rates for composite and amalgam restorations (Ref. 76).

F. Need for Public Hearings

(Comment) FDA received many comments on the proposed rule in 2002 requesting the agency to hold a public hearing or advisory committee meeting on dental amalgam, noting that dental amalgam had not been discussed in an FDA public meeting since 1994. Many comments requested that individual consumers, consumer advocacy organizations, and scientists and health professionals opposed to the use of dental amalgam be included in such a meeting.

(Response) FDA believes the concerns expressed by these comments were addressed in 2006 when FDA held a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous Drugs Advisory Committee. One of the principal purposes of that meeting was to provide a transparent, public forum where all parties might share information. The panelists at the meeting were selected from a wide range of disciplines and interests, including neurology, dentistry, toxicology, statistics, epidemiology, and consumer advocacy. The 2006 meeting included an opportunity for the public to provide presentations, and a docket was opened to permit additional information to be submitted to the agency (Docket No. FDA-2008-N-0163). The 2006 Panel listened to presentations from more than 50 members of the public and FDA's presentation of its White Paper. At the conclusion of the meeting, the 2006 Panel provided individual and panel recommendations to the agency.

G. Accusations of FDA Bias

(Comment) Several comments accused FDA of being biased in this rulemaking in support of the continued use of dental amalgam. The comments stated that the agency is too closely aligned with the interests of professional dental organizations and, as a result, has unfairly discounted evidence regarding the health risks presented by dental amalgam.

(Response) FDA disagrees with the comments suggesting that it has been biased in its approach to regulating these devices. This final rule and the special controls guidance document reflect FDA's careful and impartial consideration of all the comments and information it has received, the scientific information and safety assessments discussed previously, the White Paper and Addendum reports, and the adverse event reports submitted regarding these devices.

FDA has been proactive in obtaining as much information as practicable

regarding the safety of these devices. As described previously, FDA has undertaken or supported several safety assessments since the early 1990s regarding dental amalgam. In 2006, in an effort to ensure a transparent, public forum for discussion, FDA convened a joint committee of panelists with diverse backgrounds, including neurology and toxicology experts, to consider FDA's most recent review of the scientific literature related to dental amalgam (the White Paper) as well as presentations from members of the public. In response to the recommendations of the 2006 Panel, FDA updated its White Paper in the Addendum report.

(Comment) Some comments suggested that FDA did not consider the report on mercury by the Agency for Toxic Substances and Disease Registry, and that FDA ignored the toxicological and adverse health effects identified in Toxicological Profiles for Mercury, which was published by the U.S. Department of Health and Human Services.

(Response) FDA disagrees with the comments. FDA reviewed and evaluated both of these reports in preparing the White Paper (Ref. 10).

H. Preemption

(Comment) FDA received several comments requesting the agency to explain the preemptive effect of this rule on state requirements involving dental amalgam and on the tort liability of dentists.

(Response) FDA has imposed a special control to address the risks of exposure to mercury, toxicity and adverse tissue reaction, corrosion and mechanical failure, and improper use presented by these devices. This special control creates "requirements" for the manufacturer's labeling and other aspects of dental amalgam devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997). With respect to the tort liability of dentists, the special control in this rule requires manufacturers to properly inform dentists about dental amalgam in the labeling, but does not impose any requirements on dentists. Dental amalgam is a prescription device, and properly informed dentists will be able to make the most appropriate treatment decisions for their patients, taking individual concerns into account. FDA does not intend to regulate the practice of dentistry. State consumer protection laws that concern the practice of dentistry, not manufacturer labeling, are

therefore not implicated by this final rule. *See* Cal. Bus. & Prof. Code §§ 1648.10–1648.20 (requiring dentists to provide factual information to patients about dental amalgam); Maine (32 M.R.S. § 1094–C) (same); N.H. R.S.A. § 317–A:38 (same); N.Y. C.L.S. E.C.L. § 27–0926 (precluding dentists from using mercury in dentistry unless it is encapsulated for environmental reasons).

I. Environmental Concerns

(Comment) Many comments stated that dental amalgam should not be used because it is a toxic metal that pollutes the environment and frequently referenced concerns related to water and air pollution. Several comments stated, in general, that FDA has never prepared an Environmental Assessment for dental amalgam and should do so considering mercury is a bioaccumulative toxicant. One comment specifically addressed FDA requirements under the National Environmental Policy Act of 1969 (NEPA). The comment stated that FDA has a statutory duty to prepare an Environmental Impact Statement (EIS) or, at a minimum, an Environmental Assessment (EA) before promulgating any final action relating to the classification of dental amalgam, reclassification of mercury or the issuance of a special control. Moreover, the comment characterized the categorical exclusion in 21 CFR 25.34(b) as being "overbroad" and seemed to fault FDA for not finding extraordinary circumstances in the context of this rulemaking. The comment cited to *Louisiana v. Lee*, 758 F.2d 1081 (5th Cir. 1985), *cert. denied*, 475 U.S. 1044 (1986) as support for its assertion that an FDA action to classify or reclassify dental mercury devices does not perpetuate the status quo and has significant effects. The comment suggests that FDA must evaluate the continued introduction of mercury into the environment attributable to dental devices.

(Response) Under the National Environmental Policy Act of 1969 (NEPA), all Federal agencies must assess the environmental impact of any "major Federal action" they take (42 U.S.C. 4332(C)). A regulation to classify or reclassify a device constitutes a major Federal action under NEPA (*see* 40 CFR 1508.18). The Council on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA and issued regulations on procedural requirements of NEPA (40 CFR Parts 1500–1508). CEQ directs Federal agencies to adopt procedures, as necessary, to supplement the CEQ regulations (40 CFR 1507.3).

FDA promulgated its supplemental NEPA regulations in 21 CFR Part 25.

For major Federal actions "significantly affecting the quality of the human environment," an agency must prepare an Environmental Impact Statement (EIS) (*see id.*; 40 CFR 1501.4; 21 CFR 25.22). If the action "may" have such a significant environmental effect, an agency must prepare an Environmental Assessment (EA) to provide sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact (FONSI) (40 CFR 1501.3; 21 CFR 25.20).

However, agencies can establish categorical exclusions for categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required (*see* 40 CFR 1508.4). FDA promulgated such an exclusion, under 21 CFR 25.34(b), for agency actions that classify or reclassify a device and that may include the establishment of a special control, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes. FDA considered the application of this categorical exclusion to its classification/reclassification decision in this final rule, and to the establishment of the special control for mercury, amalgam alloy, and dental amalgam. (Ref. 77) Consistent with its NEPA obligations, the agency considered whether there were any extraordinary circumstances that would preclude its reliance on this categorical exclusion for this final rule (agency procedures must "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect" (40 CFR 1508.4; *see also* 21 CFR 25.21)). The agency determined that the action it is taking in this final rule is appropriately categorically excluded under 21 CFR 25.34(b).

These comments reflect a misunderstanding of the action FDA is taking in this final rule and its obligations under NEPA for such action. The comments presume that FDA has a general obligation under NEPA, in the context of promulgating this final rule, to assess the impacts of mercury on the environment and the effects of any continued introduction of mercury attributable to dental devices. FDA disagrees with such a presumption, particularly where there is "no reasonably close causal relationship" between the actions in the final rule and such general impacts. *DOT v. Public Citizen*, 541 U.S. 752, 767 (2004)

(rejecting a “but for” causal relationship as sufficient to require agency environmental review under NEPA) (citation omitted)). The comments ignore the scope of the action FDA is taking in this final rule and the categorical exclusion that applies to it.

Specifically, FDA is classifying dental amalgam into class II, reclassifying mercury from class I to class II, and designating a special control to support the class II classifications of dental amalgam, mercury, and amalgam alloy (currently classified as class II). The action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. This action does not constitute a decision to permit any individual’s particular use of any of these devices in the market. It simply provides a classification regulation establishing sufficient regulatory controls that will provide reasonable assurance of safety and effectiveness as to the particular class of these devices. The introduction into interstate commerce of amalgam alloy, mercury, or dental amalgam requires FDA clearance under section 510(k) of the act (21 U.S.C. 360(k)). An FDA decision to clear a device under section 510(k) of the act would be a “major Federal action” (as defined in 40 CFR 1508.18) and would be independent of FDA’s action in this final rule. Thus, FDA would evaluate, independent of this final rule, its obligations under NEPA for a decision to clear a particular use of amalgam alloy, mercury, or dental amalgam in the context of a 510(k) submission. Such a decision is not before the agency in this final rule. Manufacturers currently or intending to market amalgam alloy, mercury, or dental amalgam are expected to comply with the requirements of special controls and address the issues of safety and effectiveness identified in the special controls guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness, on or before effective date of rule (see the **DATES** section of this document).

Further, the reference in the comment to *Louisiana v. Lee* is misplaced. In that case, the court vacated a lower court’s judgment and remanded the case for more careful review to ascertain whether an environmental assessment and finding of no significant impact by the United States Army Corps of Engineers was reasonable. 758 F.2d 1081 at 1086. To the extent the comment likens the issuance of permits that would allow for continued dredging

of the Louisiana Gulf Coast area to a decision on a classification, the comparison is not on point. As previously stated, this final rule does not constitute a decision on a particular submission to “permit” any particular introduction into the environment of any of these devices.

FDA appropriately focuses its environmental review in this final rule on its action to classify, reclassify, and establish a special control for amalgam alloy, mercury, and dental amalgam. FDA disagrees, as one comment asserts, that FDA is required to prepare an environmental assessment or an environmental impact statement under NEPA for this final rule. FDA has evaluated the application of the existing categorical exclusion in 21 CFR 25.34(b) to the actions it is taking in this final rule and concludes, based on the reasons set forth below, that it is proper to rely on that categorical exclusion for this final rule.

In 1985, FDA finalized a categorical exclusion in 21 CFR 25.24(e)(2) for the “classification or reclassification of a device under Part 860” (50 FR 16635 at 16661; April 26, 1985). FDA identified this as a class of actions that would not result in the production or distribution of any substance, and therefore, would not result in the introduction of any substance into the environment. (44 FR 71742 at 71745; December 11, 1979). In other words, changing the classification of a device from, e.g., class I to class II, would not, by itself, result in the introduction of any substance into the environment. Therefore, such an action would not normally require the preparation of an environmental assessment (44 FR 71742 at 71745; December 11, 1979). In 2005, FDA expanded the categorical exclusion for the classification and reclassification of devices to include, within its scope, an action that establishes special controls, if such action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes (70 FR 69276; November 15, 2005). Thus, FDA would evaluate the application of the categorical exclusion for classification and reclassification decisions that include the establishment of special controls on a case-by-case basis to determine whether its action would result in increases in the existing levels of use or changes to the intended use of the device or its substitutes. FDA does not consider such a categorical exclusion to be “overbroad” as one comment asserts.

FDA has determined that its action to classify dental amalgam, reclassify dental mercury, and to establish a

special control are all within the scope of the categorical exclusion in 21 CFR 25.34(b). This final rule reclassifies mercury from the lower risk class I to the higher risk class II and classifies dental amalgam as class II. The final rule does not change the requirements in place prior to this final rule and that remain in effect after this final rule publishes, e.g., premarket review and general controls. The change in classification alone does not result in the introduction of any substance into the environment, does not increase the existing levels of use, and does not change the intended use of these devices or their substitutes (Ref. 77).

In addition, FDA undertook a careful review of the special control designated by this final rule to determine whether the special control would increase the existing levels of use or change the intended use of amalgam alloy, mercury, and dental amalgam or their substitutes. (Ref. 77) FDA has determined that the labeling recommendations in the special controls guidance imposed by the final rule would not result in increases in the existing levels of use of the devices or changes in the intended use of the devices or their substitutes. (Ref. 77) The labeling statements should help ensure that dentists are more fully informed regarding the devices. We have no basis to suggest or expect that the labeling recommendations would result in any increase in use of these devices or changes in the intended use of the devices or their substitutes.

Further, FDA has determined that testing recommendations would not result in increases in the existing levels of use of the devices or changes in the intended use of the devices or their substitutes. (Ref. 77) None of the tests require additional specimens of dental amalgam, amalgam alloy, or mercury. The test for mercury requires only visual inspection, which can be performed using current inventory, i.e., without the need for any additional mercury for the test. The tests for dental amalgam and amalgam alloy, required by the final rule and that were not routinely performed prior to the final rule, would require approximately 2.2 grams per product, which can be obtained from material used for a previous non-destructive test already routinely performed or from inventory needed for all testing. To the extent a manufacturer elects to procure additional product for the test, the amount is not significant. (Ref. 77) Moreover, the possibility a manufacturer would even elect to procure additional material for such tests is speculative. FDA found that its

action in this final rule to classify dental amalgam into class II, reclassify mercury from class I to class II, and to establish a special control for dental amalgam, mercury, and amalgam alloy does not significantly affect the quality of the human environment and that there are no extraordinary circumstances (Ref. 77). (See also, *Utah Envtl. Cong. v. Bosworth*, 443 F.3d 732 (10th Cir. 2006) (stating an extraordinary circumstance exists “only where a proposed action ‘may have a significant environmental effect.’”) (citations omitted)). Based on FDA’s review, it concludes that this final rule is appropriately categorically excluded under 21 CFR 25.34(b), and therefore, does not require an environmental assessment or an environmental impact statement.

(Comment) Some comments suggested that dental amalgam manufacturers should provide an environmental impact statement to prove that dental amalgams are environmentally safe.

(Response) Under 21 CFR 25.40, FDA generally requires an applicant to prepare an environmental assessment for any action that is not categorically excluded. FDA would determine, for each 510(k) submission the agency may receive, what environmental documents may be necessary to comply with the agency’s obligations under NEPA.

IV. Environmental Impact

The agency has considered the environmental effects of this final rule and has determined under categorical exclusion 21 CFR 25.34(b) 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 (Ref. 77).

V. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this final rule is a not an economically significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the relatively minor direct costs to entities attributable to this final rule, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandates that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator of the Gross Domestic Product. FDA does not expect this final rule to result in a 1-year expenditure that could exceed this amount.

B. Summary of Economic Impacts

The final rule classifies dental amalgam into class II, reclassifies mercury from class I to class II, and designates a special control to support the class II classifications of these two devices, as well as the current class II classification of amalgam alloy. Today’s action classifies the three devices in a single regulation. The special control for the devices is a guidance document entitled “Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy,” which includes labeling recommendations as well as quality control procedures.

Conforming to the special control will require few additional resources at the manufacturing stage as well as costs to FDA for administering the final regulation. Some dentists may consider the information-for-use statement, along with many other factors, when making treatment decisions for their patients. A small number of dentists may use dental amalgam for some patients for whom they may not have used the device previously, and decide not to use the device for other patients for whom they may have used the device. However, any change away from use of dental amalgam is likely to result in negative public health outcomes (delayed dental treatments or increased costs of treatment). While there would be a decrease in mercury exposure, there is no evidence that there would be any reduction in adverse effects associated with mercury. Conversely, any change

towards use of dental amalgam is likely to result in positive public health outcomes or decreased costs of treatment.

C. Objective and Need of the Final Rule

The purpose of this final rule is to classify dental amalgam, reclassify mercury, and designate a special control to support the class II classification of dental amalgam, mercury, and amalgam alloy as required by section 513 of the act. The special control for the device is a guidance document with composition and performance data, biocompatibility, and labeling recommendations. One of the labeling recommendations is the following information for use:

Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability.³³ Dental amalgam also releases low levels of mercury vapor, a chemical that at high exposure levels is well-documented to cause neurological and renal adverse health effects.³⁴ Mercury vapor concentrations are highest immediately after placement and removal of dental amalgam but decline thereafter.

Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older. In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.³⁵

The developing neurological systems in fetuses and young children may be more

³³ Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation; Public Health Service, U.S. Department of Health and Human Services, January 1993.

³⁴ Liu, J. et al., “Toxic effects of metals,” *Casarett & Doull’s Toxicology: The Basic Science of Poisons*, Chapter 23, pp. 931–979, McGraw-Hill Medical, New York, New York, 2008.

Clarkson, T.W. et al., “The Toxicology of Mercury and Its Chemical Compounds,” *Critical Reviews in Toxicology*, Vol. 36, pp. 609–662, 2006.

³⁵ De Rouen, T. et al., “Neurobehavioral Effects of Dental Amalgam in Children: A Randomized Clinical Trial,” *Journal of the American Medical Association*, Vol. 295, 1784–1792, No. 15, April 19, 2006.

Bellinger, D.C. et al., “Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial,” *Journal of the American Medical Association*, Vol. 295, No. 15, April 19, 2006, 1775–1783, 2006.

Barregard, L. et al., “Renal Effects of Dental Amalgam in Children: The New England Children’s Amalgam Trial,” *Environmental Health Perspectives*, Volume 116, 394–399, No. 3, March 2008.

Woods, J.S. et al., “Biomarkers of Kidney Integrity in Children and Adolescents With Dental Amalgam Mercury Exposure: Findings From the Casa Pia Children’s Amalgam Trial,” *Environmental Research*, Vol. 108, pp. 393–399, 2008.

Lauterbach, M. et al., “Neurological Outcomes in Children With and Without Amalgam-Related Mercury Exposure: Seven Years of Longitudinal Observations in a Randomized Trial,” *Journal of the American Dental Association*, Vol. 139, 138–145, February 2008.

sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) and the Environmental Protection Agency (EPA) have established levels of exposure for mercury vapor that are intended to be highly protective against adverse health effects, including for sensitive subpopulations such as pregnant women and their developing fetuses, breastfed infants, and children under age six.³⁶ Exceeding these levels does not necessarily mean that any adverse effects will occur.

FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

Taking into account factors such as the number and size of teeth and respiratory volumes and rates, FDA estimates that the estimated daily dose of mercury in children under age six with dental amalgams is lower

than the estimated daily adult dose. The exposures to children would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.

In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam.

The guidance also recommends that the labeling of dental amalgam and mercury devices include warnings about potential exposure to mercury, including: "WARNING: CONTAINS MERCURY" and "harmful if vapors are inhaled." The labeling recommendations also include the following contraindication: "Do not use in persons with a known mercury allergy." In addition, the special controls guidance document includes recommendations regarding composition and performance data, and biocompatibility testing.

The need for this regulation stems from the current poor distribution of accurate information about exposure to

mercury (Hg) through dental amalgam. The special control imposed by this final rule will ensure that dentists are reminded that dental amalgam contains mercury, and will provide them with FDA's assessment of the most current, best available information regarding use of the device in various patient groups.

D. Risk

Mercury poisoning is a disease caused by exposure to mercury or its compounds. The most common exposure is to organic mercury through fish consumption. Elemental mercury may be inhaled or absorbed through the skin and is used for dental restorations as amalgam. Toxic effects of mercury, depending on the level of exposure, include damage to the brain, kidneys, and lungs, with symptoms that include sensory impairment, disturbed sensation, and lack of coordination. Elemental mercury is primarily associated with neurologic toxicity (Ref. 78), although most cases do not have any noticeable physiological effects. Table 2 of this document shows reported elemental mercury exposures and treatments for 2005–2007.

TABLE 1—ELEMENTAL MERCURY EXPOSURES AND TREATMENT OUTCOMES

Year	Number of reported exposures	Number seeking treatment	No adverse outcome	Minor adverse outcome	Moderate adverse outcome	Major adverse outcome	Death
2005	2,786	909	747	99	55	6	2
2006	2,336	854	767	66	20	1	0
2007	2,319	672	576	55	38	3	0
Total	7,441	2,435	2,090	220	113	10	2
Percentage	100.0	85.83	9.03	4.64	0.41	0.08

Source: American Association of Poison Control Centers (Refs. 79, 80, and 81).

Dental amalgam has not been shown to cause mercury poisoning and no data show a causal effect of dental amalgam for any adverse health effects (except in a small number of patients with a known allergy to mercury). Dental amalgam does contain mercury, although in quantities much smaller than those associated with the adverse outcomes summarized in table 2 of this document.

Dental amalgam has been used to restore decayed teeth since the 1890s in the United States, although early prototypes were available from the 1830s. Amalgam is an alloy that is about 50% mercury (usually combined with silver, tin, or copper) and is one of

several potential materials used to treat dental caries. Over the last 15 years (1993–2008), we estimate that approximately 900 million restorations have been performed using dental amalgam, although the annual number of all restorations, as well as amalgam restorations, has been decreasing (*see* Section V.E). According to Delta Dental Insurance (Ref. 82), the typical amalgam restoration has 1.8 surfaces (a "surface" is a measure of exposed surface of the restoration). Research has indicated that each surface of an amalgam restoration releases approximately 0.534 µg Hg/day (Ref. 83). With a baseline of 900 million amalgams and 1.8 surfaces per amalgam, we estimate 865 million µg Hg/day were

released by amalgams (900 million amalgams × 1.8 surfaces per amalgam × 0.534 µg Hg/day per surface) during 2008.

We are unable to estimate possible changes in exposure to mercury that may result from this rule. Dentists may use dental amalgam for some patients for whom they may not have used the device previously, and decide not to use the device for other patients for whom they may have used the device. However, any change away from use of dental amalgam is likely to result in negative public health outcomes (delayed dental treatments or increased costs of treatment); while there would be a decrease in mercury exposure,

³⁶ Agency for Toxic Substances and Disease Registry (ATSDR) and Research Triangle Institute, *Toxicological Profile for Mercury*, U.S. Dept. of

Health and Human Services, Public Health Service, Atlanta, Georgia, 1999.

United States Environmental Protection Agency (EPA), "Integrated Risk Information System (IRIS) Screening-Level literature Review"—Mercury, elemental, 2002.

there is no evidence that there would be any reduction in adverse effects associated with mercury. Conversely, any change toward use of dental amalgam is likely to result in positive public health outcomes (fewer delayed dental treatments or decreased costs of treatment).

E. Baseline in the Absence of the Final Rule

During 2008, there were an estimated 154.1 million dental restorations in the United States (Ref. 84). This number represents a decrease of almost 12 million restorations from 2005, with the decrease associated with better dental care. We assume that recent trends to

reduce the use of dental amalgam as a restorative material will continue as patients and dentists take advantage of improved alternative materials for restorative and cosmetic purposes. Table 2 of this document shows projected annual restorations and annual amalgam restorations expected for the 15-year evaluation period.

TABLE 2—PROJECTED ANNUAL DENTAL RESTORATIONS

[In millions]

Evaluation year	Total U.S. population	Total restoration	Amalgam restorations	Other restorations
2009	307.2	149.0	50.5	98.5
2010	310.2	145.0	49.0	96.0
2011	313.2	141.0	47.6	93.5
2012	316.3	137.2	46.2	91.0
2013	319.3	133.4	44.8	88.5
2014	322.4	129.7	43.5	86.2
2015	325.5	126.1	42.2	83.9
2016	328.7	122.6	41.0	81.6
2017	331.8	119.1	39.8	79.4
2018	335.0	115.8	38.6	77.2
2019	338.2	112.5	37.5	75.0
2020	341.4	109.4	36.4	72.9
2021	344.6	106.3	35.4	70.9
2022	347.8	103.3	34.4	68.9
2023	351.0	100.3	33.4	67.0

The population of the United States is projected to increase at an annual rate of about 0.9 percent over this period and dental restorations as a whole, as well as amalgam restorations, are expected to decrease by about 1.9 percent per year. This projection is based on the expected age distribution of the population as reported by the Census Bureau and historical rates of restorations by age-cohort. For example, the population between the ages of 0–4 was about 20.3 million in 2005, during which year 3,339,000 restorations were conducted for this age cohort, for an average of 0.16 restorations per capita. The Census Bureau projected that there will be about 20.9 million in the population aged 0–4 in 2009. Using the per capita rate of restorations, we expect there to be 3,344,000 restorations for this age group. The distributions of restoration by material and by age groups were summed for each year to result in the

estimates shown in table 2 of this document.

As an approximation of the total number of patients in specific populations who might be expected to be more vulnerable to mercury (pregnant women and their fetuses, children under the age of six, including those who are breastfed), we use the total number of pregnant and lactating women and children under six as the targeted or special populations in this analysis. According to the Agency for Toxic Substances and Disease Registry (Ref. 85), very young children are more sensitive to mercury than adults. Mercury in a mother's body can pass to the fetus and may accumulate there (Ref. 85), and a nursing infant may be exposed to inorganic mercury through breast milk. Because of these sensitivities, we projected dental amalgam restorations for children under the age of 6, as well as for pregnant and

lactating females ages 15–44 based on reporting from the American Dental Association (ADA) and projections from the Bureau of Census. The number of pregnant women was obtained from the National Center of Health Statistics for 2004 (Ref. 86). The rate of pregnancy among women between the ages of 15 and 44 for 2004 (0.1036) was used to project future annual pregnancies. Approximately two-thirds of all live births breast feed at least once (Ref. 87). Therefore, we have estimated that two-thirds of the previous years' live births account for lactating women. The number of children under the age of 6 was obtained from Census projections. We could not obtain information on the potential number of other affected sub-populations but believe they could reasonably be accounted for in these projections, which include practically all the affected persons. Table 3 of this document shows these projections.

TABLE 3—PROJECTED AMALGAM RESTORATIONS FOR SPECIFIC POPULATIONS

[In millions]

Evaluation year	Number of pregnant and lactating women	Total children under the age of 6	Total amalgam restorations	Total amalgam in pregnant and lactating women	Total amalgam in children under 6	Total amalgam restorations in sensitive sub-populations
2009	9.22	25.1	50.5	1.8	2.6	4.4
2010	9.23	25.3	49.0	1.8	2.5	4.3
2011	9.27	25.5	47.6	1.7	2.5	4.2
2012	9.29	25.7	46.2	1.6	2.4	4.0
2013	9.32	26.0	44.8	1.6	2.3	3.9

TABLE 3—PROJECTED AMALGAM RESTORATIONS FOR SPECIFIC POPULATIONS—Continued
[In millions]

Evaluation year	Number of pregnant and lactating women	Total children under the age of 6	Total amalgam restorations	Total amalgam in pregnant and lactating women	Total amalgam in children under 6	Total amalgam restorations in sensitive sub-populations
2014	9.37	26.2	43.5	1.5	2.3	3.8
2015	9.41	26.4	42.2	1.5	2.2	3.7
2016	9.44	26.7	41.0	1.4	2.1	3.5
2017	9.49	26.9	39.8	1.4	2.1	3.5
2018	9.55	27.1	38.6	1.3	2.0	3.3
2019	9.62	27.2	37.5	1.3	2.0	3.3
2020	9.70	27.4	36.4	1.3	1.9	3.2
2021	9.78	27.6	35.4	1.2	1.8	3.0
2022	9.93	27.7	34.4	1.2	1.8	3.0
2023	10.04	27.9	33.4	1.2	1.7	2.9

Because the annual use of dental amalgam for restorations is expected to continue to decrease, the exposures of these sub-populations to amalgam are also expected to decrease along with exposures in the population age six and older. We model the expected contribution per day of amalgam for the evaluation period in table 4 of this document. These projections are based on the decreasing number of amalgam restorations expected as replacements. During the period 1993–2008, according to data supplied by the ADA, approximately 60 million annual restorations used amalgam for a total of 900 million current amalgam restorations in place. In the absence of the final rule, we project only 50.5 million new amalgam restorations during 2009, down from 60 million from 1993, resulting in only 890.5 million amalgam restorations for the entire population (900 million restorations in place + 50.5 new restorations during year 1 – 60 million restorations from 1993). Therefore, the daily potential exposure to mercury vapor originating from dental amalgam is expected to decrease gradually in the absence of the final rule.

TABLE 4—PROJECTED TOTAL μg Hg PER DAY FROM DENTAL AMALGAM IN THE ABSENCE OF THE FINAL RULE
[In millions]

Evaluation year	Number of amalgam restorations in place	Number of annual amalgam restorations	Micrograms (μg) of mercury (Hg) per day
2009	890.5	50.5	856
2010	879.5	49.0	845
2011	867.1	47.6	833
2012	853.3	46.2	820
2013	838.1	44.8	806
2014	821.6	43.5	790
2015	803.8	42.2	772

TABLE 4—PROJECTED TOTAL μg Hg PER DAY FROM DENTAL AMALGAM IN THE ABSENCE OF THE FINAL RULE—Continued
[In millions]

Evaluation year	Number of amalgam restorations in place	Number of annual amalgam restorations	Micrograms (μg) of mercury (Hg) per day
2016	784.8	41.0	754
2017	764.6	39.8	735
2018	743.2	38.6	714
2019	720.7	37.5	693
2020	697.1	36.4	670
2021	672.5	35.4	646
2022	646.9	34.4	622
2023	620.3	33.4	596

Table 4 of this document includes estimates of projected levels of mercury per day associated with the expected number of amalgams in place. Each amalgam is assumed to have 1.8 surfaces and release 0.534 μg Hg per day per surface.

F. The Final Rule

This final rule will classify dental amalgam as class II, reclassify mercury from class I to class II, and designate a special control to support the class II classifications of these class II devices, as well as the current class II classification of amalgam alloy. All three devices will now be classified in a single regulation. Under Class II, these devices will be subject to a special control. In this case, we are designating as the special control a guidance document (with composition and performance data, biocompatibility testing, and labeling recommendations). The guidance document provides for some increased testing requirements that will ensure the composition of the amalgam as well as labeling recommendations. Specific additional

tests in the guidance document include particle size distribution assays and corrosion testing that are not typically currently conducted by manufacturers. The labeling recommendations include a warning that dental amalgam contains mercury and provide information for use explaining that, although there are very limited to no clinical information available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed, the estimated concentration of mercury in breastmilk attributable to dental amalgam exposure is low and is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. The estimated daily dose of mercury in children under age 6 with dental amalgams is also low and at or below the ATSDR and EPA protective reference levels.

G. Costs of the Final Rule

FDA is required by statute to classify devices (21 U.S.C. 360c). This final rule classifies dental amalgam into Class II and reclassifies dental mercury (hereinafter “mercury”) from Class I to Class II. Importantly, the rule also establishes special controls for dental amalgam, mercury, and amalgam alloy (mercury and amalgam alloy are combined to form dental amalgam).

The costs of the final rule are the costs of complying with and administering the special control (including testing and labeling costs, and FDA administration costs).

The special controls guidance referenced in this final rule recommends that dental amalgam, mercury, and amalgam alloy be subject to periodic assays to demonstrate physical properties. Two of these assays are not routinely conducted and, consequently, would constitute additional expenses. In addition, the

special controls guidance recommends that the labeling state that the device contains mercury, that it should not be used in persons with a known allergy to mercury, and that data are limited regarding long term outcomes in certain populations. These labeling revisions are also additional requirements for manufacturers.

1. Manufacturing Costs

a. Testing Costs

FDA records indicate the final rule will affect 50 separate products manufactured by 16 companies. These companies are classified in the Dental Equipment and Supplies Industry (NAICS 339114) by the Census of Manufacturers (NAICS is the North American Industry Classification System).

The special controls guidance document that is part of this final rule includes two recommended quality control assays that are not routinely conducted by manufacturers. These assays are particle size distribution testing and corrosion products identification. While some of the 16 manufacturers may use in-house laboratories to conduct these tests, if additional equipment is needed they are more likely to use contract laboratories. Discussions with contract laboratories showed that estimated costs for conducting assays of these types ranged between \$35 and \$150 per test with a typical test costing approximately \$75.

It is unclear how frequently these tests would be conducted. The current guidance recommends that tests be conducted once before marketing. However, we expect manufacturers to test each of their 50 marketed products at least once per year to ensure product quality. Therefore, the expected annual cost of conducting these additional tests

equals \$7,500 per year (50 products times 2 tests times \$75).

b. Labeling Costs Associated With the Final Rule

The recommended labeling controls included in this final rule will result in enhanced labeling for dental amalgam devices. Specifically, the guidance recommends that the labeling for this product state that the device contains mercury, that it should not be used in persons with a known allergy to mercury, and that current scientific evidence indicates there is no connection between the device and adverse events in the population age six and older. The label also informs dentists that the clinical data are limited regarding long term outcomes in certain patients who might be expected to be more sensitive to the effects of mercury.

We expect that each of the 50 products currently marketed will develop a new label that includes this information. The cost of developing new artwork, label design, regulatory review, production, and application was estimated based on a labeling cost model developed by the Eastern Research Group (Ref. 88) and updated to 2008. Overall, the cost of developing a new label using these guidelines is estimated to be approximately \$2,000 per label. Each of the 50 products marketed by 16 manufacturers is expected to have a revised label due to this requirement and result in a total one-time labeling cost of \$100,000 (50 products times \$2,000).

c. Increased Manufacturing Costs

The total increased manufacturing costs of this final rule are \$107,500 in the first evaluation year and \$7,500 per year thereafter. The present value over 15 years is \$186,600 (3 percent discount

rate) or \$161,800 (7 percent discount rate).

2. Costs of FDA Regulatory Oversight

Although FDA currently regulates dental amalgam, the reclassification from this final rule is likely to increase oversight. Label review will likely be more rigorous and inspections will entail review of more testing data. Any reviews of marketing applications will be more rigorous and there are likely to be increases in the number of marketing applications submitted for review (although we have not estimated any such increase). In addition, FDA can anticipate additional interest in these products, which will probably require resources to respond to consumer and media requests for information. These activities are not likely to consume more than 30 minutes of full-time equivalent (FTEs) per product per year, or approximately 26 hours of resources. The estimated cost of an FDA FTE is approximately \$130,000 per year, or about \$64.75 per hour. (This estimate includes salary, benefits, overhead, and support). Therefore, the increased use of FDA resources due to the final rule is only approximately \$1,700 per year (26 hours times \$64.75). The present values of 15 years of this cost equal \$20,300 (using 3 percent annual discount rate) and \$15,500 (using 7 percent annual discount rate).

3. Total Costs

Table 5 of this document shows the estimated present value of costs and the annualized costs of the final rule by type. Testing costs and the costs of FDA administration are annual recurring costs. While the present values of these costs differ by discount rate, the annualized costs are not affected by discount rates.

TABLE 5—PRESENT VALUE AND ANNUALIZED COSTS OF FINAL RULE

	Present value at 3 percent	Present value at 7 percent	Annualized value at 3 percent	Annualized value at 7 percent
Labeling Cost	\$100,000	\$100,000	\$8,400	\$10,100
Testing Cost	89,500	68,300	7,500	7,500
Cost of FDA Administration	20,300	15,500	1,700	1,700
Total Cost	209,800	183,800	17,600	19,300

H. Potential Public Health Effects of the Final Rule

The recommended information for use statement will provide dentists with current information to help them make treatment decisions for their patients. We expect that dentists will consider that information, along with other

factors, when making treatment decisions for their patients. Dentists may use dental amalgam for some patients for whom they may not have used the device previously, and decide not to use the device for other patients for whom they may have used the device. However, any change away from

use of dental amalgam is likely to result in negative public health outcomes (delayed dental treatments or increased costs of treatment); while there would be a decrease in mercury exposure, there is no evidence that there would be any reduction in adverse effects associated with mercury. Conversely,

any change toward use of dental amalgam is likely to result in positive public health outcomes (fewer delayed dental treatments or decreased costs of treatment).

I. Alternatives to the Final Rule

The principal regulatory alternatives considered were as follows: (1) No new regulatory action, (2) Class II but with other special controls, (3) reclassification to Class III, and (4) ban the use of mercury in dental restorations.

1. No New Regulatory Action

No new regulatory action is the projected baseline we use to estimate the effects of the other options. By

definition, there are no costs or public health effects associated with the baseline.

2. Class II But With Other Special Controls

This alternative would retain Class II but calls for different special controls. While deciding the type of special controls best suited for this device, we considered many different options. For example, we considered a labeling requirement that would require dentists to inform patients of the presence of mercury in dental amalgam and discuss treatment options and a special controls guidance document with labeling recommendations. Whatever the special controls in this alternative, the result

would be that patients would get direct information that would include the presence of mercury in amalgam. The costs of this alternative would include the opportunity costs both dentists and patients of discussing treatment options, costs of alternative restorative materials, potentially delayed or deferred treatments, the cost of periodic testing by manufacturers, and the cost of FDA administration. There would be an expected reduction in mercury exposure and some potential reduction in anxiety for patients who would choose alternative materials with this information and after consultation with dentists. The costs and effects of this alternative are shown in table 6 of this document.

TABLE 6—PRESENT VALUE AND ANNUALIZED EFFECTS OF ALTERNATIVE LABELING

	Present value—3%	Present value—7%	Annualized value—3%	Annualized value—7%
Costs (In millions)	\$2,433 to \$6,563	\$1,932 to \$4,948	\$208 to \$550	\$212 to \$543.
Reduced Mercury Exposures (in million of µg Hg per day)	0 to 153.2	0 to 109.5	0 to 12.8	0 to 12.0.
Delayed Dental Treatments	0 to 990,000	0 to 813,000	0 to 83,000	0 to 89,000.

The ranges shown in Table 6 show the uncertainty of how patients and dentists may be expected to react to information and differences in the durability of alternative materials. The estimates and ranges shown in table 6 include the effects of the higher costs of alternative materials, ranges of expected useful life of alternative materials, opportunity costs of dentists providing counseling, opportunity costs of patients, different durations of counseling, different expected reactions by patients to the information that amalgam contains mercury (based on market response of tuna consumers), and ranges of estimates of price elasticities of demand for dental services. The ranges are shown to address a wide range of potential alternative special controls that we did not select.

3. Reclassification to Class III

Class III classification of these products would require that manufacturers obtain premarket

approval for dental amalgam, mercury, and amalgam alloy. The most likely effect of this alternative would be that marketers would choose to withdraw their products from the market rather than incur the costs and resources necessary to collect safety and effectiveness data to support premarket approval applications. The effects of this regulatory alternative are probably equivalent to a ban on the use of mercury in restorations and should be equal to the estimated impacts discussed for Alternative 4.

4. Ban the Use of Mercury in Dental Restorations

Another alternative is to ban dental amalgam. The ban would not give consumers a choice with respect to the use of dental amalgam. All consumers would be forced to use alternative materials or defer treatment for dental caries. The costs and effects of a ban are shown in tables 7 and 8 of this document. While the estimated number

of delayed dental caries treatments that may result from a ban are not included in table 7, we consider them to represent negative public health effects. Any delay in dental treatment would likely lead to further deterioration and patient discomfort. However, there are no empirical data to suggest how long a delay in treatment would typify the response to a ban or what the social costs of delayed (or avoided) dental treatment would be. This negative public health outcome should be considered an additional non-quantified cost. The annualized public health effects appear equal for both discount rates due to rounding to the nearest hundred thousand. The difference in annualized treatment delays shown in Table 6 is a reflection of the differing responses to prices and alternative special controls. The totality of a potential ban removes most of the variability of response to regulation and reduces differences arising from different discount rates.

TABLE 7—COSTS OF A BAN

[In millions]

	Present value—3%	Present value—7%	Annualized value—3%	Annualized value—7%
Total costs assuming durable alternative material	\$33,224.0	\$25,867.0	\$3,784.2	\$2,840.2
Total costs assuming alternative materials have ten-year replacement life ...	63,953.8	44,714.7	5,359.3	4,909.7

TABLE 8—POTENTIAL PUBLIC HEALTH EFFECTS OF A BAN

	Present value—3%	Present value—7%	Annualized value—3%	Annualized value—7%
Reduced Mercury Exposure	*688.6	*525.5	*57.7	*57.7
Delayed Caries Treatments (in millions)	27.1	21.0	2.3	2.3

* Million µg Hg per day.

J. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the relatively minor costs to manufacturing entities attributable to this final rule, the agency believes that the final rule will not have a significant economic impact on a substantial number of small manufacturing entities.

FDA records indicate the final rule will affect 50 separate products manufactured by 16 domestic companies. These companies are classified in the Dental Equipment and Supplies Industry (NAICS 339114) by the Census of Manufacturers. The affected industry (NAICS 339114; Dental Equipment and Supplies) is typified by small entities. Only about 35 of the approximately 875 establishments in the entire industry employ more than 100 workers. According to the Small Business Administration Size Standards, any entity with fewer than 500 employees is considered small in this industry. We therefore conclude that the manufacturing 16 companies affected by this final rule will be small businesses. The formal costs per company, however, are relatively small. The annualized costs of developing new required and recommended labeling and conducting additional assays to ensure product quality are not significant for a substantial number of small entities. The annualized costs per firm, \$750 using a 3-percent discount rate or \$865 using a 7-percent discount rate, are not significant. (These annualized costs are based on an average of 3.125 products per company). The average value of shipments for establishments in this industry with fewer than five employees was \$244,100 according the Census of Manufacturers. The annualized costs of the final rule represent less than 0.5% of the annual value of shipments. We certify that there will not be a significant economic impact on a substantial number of small entities.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies

to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k; *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).

In this rulemaking, FDA has determined that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices, and that there is sufficient information to establish special controls to provide such assurance. FDA has therefore imposed special controls to address the risks of exposure to mercury, allergic reaction including adverse tissue reaction, contamination, mechanical failure, corrosion, and improper use. These special controls create “requirements” for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

The preemptive effects are the result of existing law set forth in the statute as interpreted in decisions of the United States Supreme Court. FDA therefore has not sought separate comment on the preemptive effect of this action because it is not seeking independently to preempt state law beyond the effects of 21 U.S.C. 360k or existing case law.

VII. The Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 have been approved

under control number 0910–0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR 820 have been approved under OMB control number 0910–0073.

VIII. References

1. Transcript from Meeting of the Food and Drug Administration Dental Products (Advisory) Panel, December 3, 1993, and transcript from Meeting of the Food and Drug Administration Dental Products (Advisory) Panel, June 29, 1994.
2. Beazoglu, T. *et al.*, Economic Impact of Regulating the Use of Amalgam Restorations, Public Health Reports, September–October 2007, Volume 122.
3. Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation; Public Health Service, U.S. Department of Health and Human Services, January 1993.
4. Update Statement by the U.S. Public Health Service on the Safety of Dental Amalgam, September 1, 1995.
5. Review and Analysis of the Literature on the Potential Adverse Health Effects of Dental Amalgam, Life Sciences Research Office, July 2004.
6. The Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users—Preliminary Report, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), European Commission, Health and Consumer Protection DG, 2007.
7. Bernardo, M. *et al.*, “Survival and Reasons for Failure of Amalgam Versus Composite Posterior Restorations Placed in a Randomized Clinical Trial,” *Journal of the American Dental Association*, Vol. 138, pp. 775–783, June 2007.
8. Khordi-Mood M., *et al.*, “Urinary mercury excretion following amalgam filling in children,” *Journal of Toxicology, Clinical Toxicology*, Vol. 39 (7), pp. 701–705, 2001.
9. Berglund, A. *et al.*, “Mercury vapor release from dental amalgam in patients with symptoms allegedly caused by amalgam fillings,” *European Journal of Oral Science*, Vol. 104, pp. 56–63, 1996.
10. FDA Update/Review of Potential Adverse Health Risks Associated with Exposure to Mercury in Dental Amalgam, National Center for Toxicological Research, Food and Drug Administration, August 2006. (FDA Draft White Paper)

11. Addendum to FDA Draft White Paper, Addendum Review in Response to Advisory Panel Comments and Recommendations, July 2009. (The 2006 Draft White Paper and the 2009 Addendum constitute the final White Paper.)
12. Dental Amalgam and Alternative Restorative Materials: An Update Report to the Environmental Health Policy Committee, September 1997.
13. Review and Analysis of the Literature on the Potential Adverse Health Effects of Dental Amalgam, Life Sciences Research Office, July 2004.
14. Agency for Toxic Substances and Disease Registry (ATSDR) and Research Triangle Institute, *Toxicological profile for mercury*, U.S. Dept. of Health and Human Services, Public Health Service, Atlanta, Georgia, 1999.
15. United States Environmental Protection Agency (EPA), "Integrated Risk Information System (IRIS) Screening-Level literature Review"—Mercury, elemental, 2002.
16. Fawer R.F. *et al.*, "Measurement of hand tremor induced by industrial exposure to metallic mercury," *British Journal of Industrial Medicine*, Vol. 40, pp. 204–208, 1983.
17. Ngim C.H. *et al.*, "Chronic neurobehavioral effects of elemental mercury in dentists," *British Journal of Industrial Medicine*, Vol. 49, pp. 782–790, 1992.
18. Piikivi L. *et al.*, "EEG findings in chloralkali workers subjected to low long term exposure to mercury vapour," *British Journal of Industrial Medicine*, 1989; 46:30–35.
19. Pinkerton KE, Joad JP (2006) "Influence of air pollution on respiratory health during perinatal development," *Clin Exp Pharmacol Physiol* 33:269–272.
20. ICRP (1994), "Human respiratory tract model for radiological protection," (Ann Int Comm Rad Protect, Vol. 24).
21. World Health Organization, "Inorganic Mercury," *Environmental Health Criteria Document 118*, Geneva, Switzerland, 1991.
22. World Health Organization, "Elemental Mercury and Inorganic Mercury Compounds: Human health effects," *Concise International Chemical Assessment Document (CICAD) 50*, Geneva, Switzerland, 2003.
23. Skare, I. *et al.*, "Human exposure to mercury and silver released from dental amalgam restorations," *Archives of Environmental Health*, Vol. 49, pp. 384–394, 1994.
24. American Conference of Governmental Industrial Hygienists, "Mercury, All forms except alkyl," *Chemical Substances*, 7th Edition, pp. 1–13, ACGIH, Cincinnati, OH 2001.
25. Ellingsen, D.G. *et al.*, "Renal and immunologic markers for chloralkali workers with low exposure to mercury vapor," *Scand. J. Work Environ. Health*, Vol. 26, pp. 427–435, 2000.
26. Roels, H.A. *et al.*, "Usefulness of biomarkers of exposure to inorganic mercury, lead, or cadmium in controlling occupational and environmental risks of nephrotoxicity," *Renal Failure*, Vol. 21, pp. 251–262, 1999.
27. Boogaard, P.J. *et al.*, "Effects of exposure to elemental mercury on the nervous system and the kidneys of workers producing natural gas," *Archives of Environmental Health*, Vol. 51, pp. 108–115, 1996.
28. Mandic, L. *et al.*, "Change in the isoenzyme profiles of urinary N-acetyl- β -D-glucosaminidase in workers exposed to mercury," *Toxicol. Ind. Health*, Vol. 18, pp. 207–214, 2002.
29. Dye *et al.*, "Urinary mercury concentrations associated with dental restorations in adult women aged 16–49 years: United States, 1999–2000," *Occupational and Environmental Medicine*, Vol. 62, pp. 368–375, 2005.
30. Kingman, A. *et al.*, "Mercury concentrations in urine and whole blood associated with amalgam exposure in a U.S. military population," *Journal of Dental Research*, Vol. 77, pp. 461–471, 1998.
31. De Rouen, T. *et al.*, "Neurobehavioral Effects of Dental Amalgam in Children: A Randomized Clinical Trial," *Journal of the American Medical Association*, Vol. 295, 1784–1792, 2006.
32. Bellinger, D.C. *et al.*, "A Dose-Effect Analysis of Children's Exposure to Dental Amalgam and Neuropsychological Function: The New England Children's Amalgam Trial," *Journal of the American Dental Association*, Vol. 138, 1210–1216, 2007.
33. Factor-Litvak, P. *et al.*, "Mercury derived from dental amalgams and neuropsychologic function," *Environmental Health Perspectives*, Vol. 111, pp. 719–723, 2003.
34. Bellinger, D.C. *et al.*, "Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial," *Journal of the American Medical Association*, Vol. 295, 1775–1783, 2006.
35. Bast-Pettersen R. *et al.*, "A neurobehavioral study of chloralkali workers after the cessation of exposure to mercury vapor," *Neurotoxicology*, Vol. 26(3), pp. 427–437, 2005.
36. Camerino, D. *et al.*, "Evaluation of the neurotoxic and nephrotoxic effects following long-term exposure to metallic mercury in employed at a chlorine/sodium-hydroxide plant," *Med. Lav*, Vol. 93, pp. 238–250, 2002.
37. Kingman, A. *et al.*, "Amalgam exposure and neurological function," *Neurotoxicology*, Vol. 26, pp. 241–255, 2005.
38. Saxe S.R. *et al.*, "Alzheimer's disease, dental amalgam, and mercury," *Journal of the American Dental Association*, Vol. 130, pp. 191–199, 1999.
39. Fung F. *et al.*, "Neurotoxicity of mercury in dental amalgam," *Journal of the American Medical Association*, Vol. 296 (12), pp. 1462–1463, 2006.
40. Lauterbach, M. *et al.*, "Neurological Outcomes in Children with and Without Amalgam-Related Mercury Exposure: Seven Years of Longitudinal Observations in a Randomized Trial," *Journal of the American Dental Association*, Vol. 139, 138–145, 2008.
41. Barregard, L. *et al.*, "Tissue levels of mercury determined in a deceased worker after occupational exposure," *International Archives Occupational Environmental Health*, Vol. 72, pp. 169–173, 1999.
42. Maas, C. *et al.*, "Study on the significance of mercury accumulation in the brain from dental amalgam fillings through direct mouth-nose-brain transport," *Zentralbl. Hyg. Umweltmed*, Vol. 198, pp. 275–291, 1996.
43. Davis, B.J. *et al.*, "Mercury Vapor and Female Reproductive Toxicity," *Toxicological Sciences*, Vol. 59, pp. 291–296, 2001.
44. Morgan, D.L. *et al.*, "Disposition of Inhaled Mercury Vapor in Pregnant Rats: Maternal Toxicity and Effects on Developmental Outcome," *Toxicological Sciences*, Vol. 66, pp. 261–273, 2002.
45. Efskind J. *et al.*, "Renal function of chloralkali workers after the cessation of exposure to mercury vapor," *Scand. J. Work. Environ. Health*, Vol. 32 (3), pp. 241–249, 2006.
46. Barregard, L. *et al.*, "Renal Effects of Dental Amalgam in Children: The New England Children's Amalgam Trial," *Environmental Health Perspectives*, Volume 116, 394–399, 2008.
47. Woods, J.S. *et al.*, "Biomarkers of Kidney Integrity in Children and Adolescents with Dental Amalgam Mercury Exposure: Findings from the Casa Pia Children's Amalgam Trial," *Environmental Research*, Vol. 108, pp. 393–399, 2008.
48. Herr, D.W. *et al.*, "Evaluation of Sensory Evoked Potentials in Long Evans Rats Gestationally Exposed to Mercury Vapor," *Toxicological Sciences*, Vol. 82, pp. 193–206, 2004.
49. Lindbohm, M.L. *et al.*, "Occupational exposure in dentistry and miscarriage," *Occupational Environmental Medicine*, Vol. 64 (2), pp. 127–133, 2007.
50. Elghany, N.A. *et al.*, "Occupational exposure to inorganic mercury vapour and reproductive outcomes," *Occupational Medicine*, Vol. 47 (6), pp. 333–336, 1997.
51. Hujoel, P.P. *et al.*, "Mercury exposure from dental filling placement during pregnancy and low birth weight risk," *American Journal of Epidemiology*, Vol. 161(8), pp. 734–740, 2005.
52. United States Environmental Protection Agency (EPA), "Integrated Risk Information System (IRIS) Screening-Level literature Review"—Mercuric chloride, 2002.
53. Drexler, H. *et al.*, "The mercury concentration in breast milk resulting from amalgam fillings and dietary habits," *Environmental Research*, Vol. 77, pp. 124–129, 1998.
54. Drasch, G. *et al.*, "Mercury in human colostrum and early breast milk. Its dependence on dental amalgam and other factors," *J. Trace Elem. Med. Biol.*, Vol. 12, pp. 23–27, 1998.
55. Oskarsson A. *et al.*, "Total and inorganic mercury in breast milk in relation to fish

- consumption and amalgam in lactating women," *Archives of Environmental Health*, Vol. 51 (3), pp. 234–241, 1996.
56. Vimy M.J. *et al.*, "Mercury from maternal "silver" tooth fillings in sheep and human breast milk: A source of neonatal exposure," *Biol. Trace Elem. Res.*, Vol. 56 (2), pp. 143–152, 1997.
 57. Echeverria, D. *et al.*, "Neurobehavioral effects from exposure to dental amalgam Hg⁰: new distinctions between recent exposure and Hg body burden," *The FASEB Journal*, Vol. 12, pp. 971–980, 1998.
 58. Bittner, A.C., *et al.*, "Behavioral effects of low-level exposure to Hg⁰ among dental professionals: a cross-study evaluation of psychomotor effects," *Neurotoxicology and Teratology*, Vol. 20 (4), pp. 429–439, 1998.
 59. Echeverria, D. *et al.*, "Chronic low-level mercury exposure, BDNF polymorphism, and associations with cognitive and motor function," *Neurotoxicology and Teratology*, Vol. 27, pp. 781–796, 2005.
 60. Echeverria, D. *et al.*, "The association between a genetic polymorphism of coproporphyrinogen oxidase, dental mercury exposure and neurobehavioral response in humans," *Neurotoxicology and Teratology*, Vol. 28, pp. 39–48, 2006.
 61. Kanerva L. *et al.*, "A multicenter study of patch test reactions with dental screening series," *Amer. J. Contact. Dermat.*, Vol. 12 (2), pp. 83–87, 2001.
 62. Laeijendecker R. *et al.*, "Oral lichen planus and allergy to dental amalgam restorations," *Archives of Dermatology*, Vol. 140 (12), pp. 1434–1438, 2004.
 63. Prochazkova J. *et al.*, "The beneficial effect of amalgam replacement on health in patients with autoimmunity," *Neuro. Endocrinol. Lett.*, Vol. 25 (3), pp. 211–218, 2004.
 64. Yaqob A. *et al.*, "Metal-specific lymphocyte reactivity is downregulated after dental metal replacement," *Neuro. Endocrinol. Lett.*, Vol. 27 (1–2), pp. 189–197, 2006.
 65. Dodes, J., "The amalgam controversy," *Journal of the American Dental Association*, Vol. 132, pp. 348–356, 2001.
 66. Transcript from Joint Meeting of Dental Products Panel and Central Nervous System Drugs Advisory Committee, September 6 and 7, 2006.
 67. Brownawell, A.M. *et al.*, "The Potential Adverse Health Effects of Dental Amalgam," *Toxicological Reviews*, 24(1):1–10, 2005.
 68. Woods, J.S. *et al.*, "The Association between Genetic Polymorphisms of Coproporphyrinogen Oxidase and an Atypical Porphyrinogenic Response to Mercury Exposure in Humans," *Toxicology and Applied Pharmacology*, Vol. 206, pp. 113–120, 2005.
 69. Liu, J. *et al.*, "Toxic effects of metals," *Casarett & Doull's Toxicology: The Basic Science of Poisons*, Chapter 23, pp. 931–979, McGraw-Hill Medical, New York, New York, 2008.
 70. Clarkson, T.W. *et al.*, "The Toxicology of Mercury and Its Chemical Compounds," *Critical Reviews in Toxicology*, Vol. 36, pp. 609–662, 2006.
 71. McCullough, M.J. *et al.*, "Local Adverse Effects of Amalgam Restorations," *International Dental Journal*, Vol. 58, pp. 3–9, 2008.
 72. Prochazkova, J.J. *et al.*, "HLA-Association in Patients with Intolerance to Mercury and other Metals in Dental Materials," *Disease Markers*, Vol. 16, pp. 135–138, 2000.
 73. Henriksson, E. *et al.*, "Healing of Lichenoid Reactions Following Removal of Amalgam. A Clinical Follow-Up," *Journal of Clinical Periodontology*, Vol. 22, pp. 287–94, 1995.
 74. Swartzendruber, D.E., "The Possible Relationship Between Mercury from Dental Amalgam and Diseases. I: Effects within the Oral Cavity," *Medical Hypotheses*, Vol. 41, pp. 31–34, 1993.
 75. Sibley, R.L., "The Relationship Between Mercury from Dental Amalgam and Oral Cavity Health," *Annals of Dentistry*, Vol. 49, pp. 6–10, 1990.
 76. Bernardo, M. *et al.*, "Survival and Reasons for Failure of Amalgam Versus Composite Posterior Restorations Placed in a Randomized Clinical Trial," *Journal of the American Dental Association*, Vol. 138, pp. 775–783, June 2007.
 77. Review of the Agency's Analysis of its NEPA obligations for the Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy, July 2009.
 78. Diner, B.M. *et al.*, "Mercury Toxicity"; <http://emedicine.medscape.com/article/819872-overview>; December 11, 2007.
 79. Lai, M.W. *et al.*, "2005 Annual Report of the American Association of Poison Control Center's National Poisoning and Exposure Database," *Clinical Toxicology*, Vol. 44:8, pp. 803–932, 2006.
 80. Bronstein, A.C. *et al.*, "2006 Annual Report of the American Association of Poison Control Center's National Poisoning Data System," *Clinical Toxicology*, Vol. 45:8, pp. 815–917, 2007.
 81. Bronstein, A.C. *et al.*, "2007 Annual Report of the American Association of Poison Control Center's National Poisoning Data System," *Clinical Toxicology*, Vol. 46:10, pp. 927–1057, 2008.
 82. Delta Dental Plans Association, Comment 0169, Docket No. FDA–2008–N–0163; July 24, 2008.
 83. Jones, D.W., "Exposure and Absorption and the Crucial Question of Limits for Mercury," *Journal of Canadian Dental Association*, Vol. 65, pp. 788–792, 1999.
 84. American Dental Association, "Survey of Dental Practice—Dental Services," 2006.
 85. U.S. Agency for Toxic Substances and Disease Registry, "ToxFAQs for Mercury," U.S. Department of Health and Human Services, April 1999.
 86. Ventura, S.J. *et al.*; Estimated Pregnancy Rates by Outcome for the United States, 1990–2004; National Vital Statistics Reports; April 14, 2008; 56:15:1–28.
 87. American Academy of Pediatrics; Breastfeeding and the Use of Human Milk; *Pediatrics* 2005; 115; 496–506.
 88. Eastern Research Group; "Preliminary Estimates: Labeling and Related Testing Costs for Medical Glove Manufacturers," Memorandum, January 18, 1999.
 89. Levy, M. *et al.*, "Childhood urine mercury excretion: Dental amalgam and fish consumption as exposure factors," *Environmental Research*, Vol. 64, pp. 283–290, 2004.

List of Subjects in 21 CFR Part 872

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

§ 872.3050 [Removed]

■ 2. Remove § 872.3050.

■ 3. Add § 872.3070 to subpart D to read as follows:

§ 872.3070 Dental amalgam, mercury, and amalgam alloy.

(a) *Identification.* Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy." See § 872.1(e) for the availability of this guidance document.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18447 Filed 7–29–09; 4:15 pm]

BILLING CODE P



Federal Register

**Tuesday,
August 4, 2009**

Part III

Department of Housing and Urban Development

**Proposed Fair Market Rents for the
Housing Choice Voucher Program and
Moderate Rehabilitation Single Room
Occupancy Program Fiscal Year 2010;
Notice**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5328-N-01]

Proposed Fair Market Rents for the Housing Choice Voucher Program and Moderate Rehabilitation Single Room Occupancy Program Fiscal Year 2010

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice of Proposed Fiscal Year (FY) 2010 Fair Market Rents (FMRs) and request for comments on FMR methodology.

SUMMARY: Section 8(c)(1) of the United States Housing Act of 1937 (USHA) requires the Secretary to publish FMRs periodically, but not less than annually, adjusted to be effective on October 1 of each year. Today's notice proposes FMRs for FY 2010 to be used: to determine payment standard amounts for the Housing Choice Voucher program, to determine initial renewal rents for some expiring project-based Section 8 contracts, and to determine initial rents for housing assistance payment (HAP) contracts in the Moderate Rehabilitation Single Room Occupancy program. Other programs may require use of FMRs for other purposes. The proposed FY 2010 FMR areas are based on current Office of Management and Budget (OMB) metropolitan area definitions and include HUD modifications that were first used in the determination of FY 2006 FMR areas. OMB changes to the metropolitan area definitions through November 2008 are incorporated. Three Micropolitan areas that became Metropolitan Statistical Areas (MSA) are included here as HUD Metropolitan Statistical Areas without modification.¹ Proposed FY 2010 FMRs are based on 2000 Census data updated with more current survey data. For FY 2010, FY 2009 FMRs are updated using 2007 American Community Survey (ACS) data and more recent Consumer Price Index (CPI) rent and utility indexes. HUD continues to use ACS data in different ways according to how many two-bedroom standard-quality and recent-mover sample cases are available in the FMR area or its Core-Based Statistical Area (CBSA).

HUD is considering reforms and several changes to the methodology for

calculating FMRs that are not reflected in these proposed FMRs. HUD will publish a separate **Federal Register** notice describing and depicting examples of the effects of a number of reforms and improvements to the methodology for estimating Fair Market Rents and requesting public comment. In this notice, HUD is seeking public comments suggesting items for consideration in the subsequent notice.

DATES: *Comment Due Date:* September 2, 2009.

ADDRESSES: Interested persons are invited to submit comments regarding HUD's estimates of the FMRs, as published in this notice, to the Office of General Counsel, Rules Docket Clerk, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410-0001. Communications should refer to the above docket number and title and should contain the information specified in the "Request for Comments" section.

Submission of Hard Copy Comments. To ensure that the information is fully considered by all of the reviewers, each commenter that is submitting hard-copy comments, by mail or hand delivery, is requested to submit two copies of its comments to the address above, one addressed to the attention of the Rules Docket Clerk and the other addressed to the attention of the Economic and Market Analysis Division staff in the appropriate HUD field office. Due to security measures at all Federal agencies, submission of comments by mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that any comments submitted by mail be sent at least 2 weeks in advance of the public comment deadline.

Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the <http://www.regulations.gov> Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that Web site to submit comments electronically.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Comments. All comments and communications submitted to HUD will be available, without charge, for public inspection and copying between 8 a.m. and 5 p.m. weekdays, at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202-708-3055 (this is not a toll-free number). Copies of all comments submitted are available for inspection and downloading at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For technical information on the methodology used to develop FMRs or for a listing of all FMRs, please call the HUD USER information line at 800-245-2691 or access the information on the HUD Web site at <http://www.huduser.org/datasets/fmr.html>. FMRs are listed at the 40th or 50th percentile in Schedule B. For informational purposes, 40th percentile recent-mover rents for the areas with 50th percentile FMRs will be provided in the HUD FY 2010 FMR documentation system at <http://www.huduser.org/datasets/fmr/fmrs/index.asp?data=fmr10>.

Questions related to use of FMRs or voucher payment standards should be directed to the respective local HUD program staff. Questions on how to conduct FMR surveys or concerning further methodological explanations may be addressed to Marie L. Lihn or Lynn A. Rodgers, Economic and Market Analysis Division, Office of Economic Affairs, Office of Policy Development and Research, telephone number 202-708-0590. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800-877-8339. (Other than the HUD USER information line and TDD numbers, telephone numbers are not toll free.)

SUPPLEMENTARY INFORMATION:

I. Background

Section 8 of the USHA (42 U.S.C. 1437f) authorizes housing assistance to aid lower-income families in renting safe and decent housing. Housing assistance payments are limited by FMRs established by HUD for different geographic areas. In the Housing Choice Voucher program, the FMR is the basis for determining the "payment standard amount" used to calculate the maximum monthly subsidy for an assisted family (see 24 CFR 982.503). In general, the FMR for an area is the

¹ These areas are: Cape Girardeau-Jackson, MO-IL MSA (comprised of Alexander County, IL; Bollinger County, MO; and Cape Girardeau County, MO); Manhattan, KS MSA (comprised of Geary County, Pottawatomie County, and Riley County, KS); Mankato-North Mankato, MN MSA (comprised of Blue Earth County and Nicollet County, MN).

amount that would be needed to pay the gross rent (shelter rent plus utilities) of privately-owned, decent, and safe rental housing of a modest (non-luxury) nature with suitable amenities. In addition, all rents subsidized under the Housing Choice Voucher program must meet reasonable rent standards. The interim rule published on October 2, 2000 (65 FR 58870), established 50th-percentile FMRs for certain areas.

Electronic Data Availability: This **Federal Register** notice is available electronically from the HUD User page at <http://www.huduser.org/datasets/fmr.html>. **Federal Register** notices also are available electronically at <http://www.gpoaccess.gov/fr/index.html>, the U.S. Government Printing Office Web site. Complete documentation of the methodology and data used to compute each area's proposed FY 2010 FMRs is available at <http://www.huduser.org/datasets/fmr/fmrs/index.asp?data=fmr10>.

II. Procedures for the Development of FMRs

Section 8(c) of the USHA requires the Secretary of HUD to publish FMRs periodically, but not less frequently than annually. Section 8(c) states, in part, as follows:

Proposed fair market rentals for an area shall be published in the **Federal Register** with reasonable time for public comment, and shall become effective upon the date of publication in final form in the **Federal Register**. Each fair market rental in effect under this subsection shall be adjusted to be effective on October 1 of each year to reflect changes based on the most recent available data trended so the rentals will be current for the year to which they apply, of rents for existing or newly constructed rental dwelling units, as the case may be, of various sizes and types in this section.

HUD's regulations at 24 CFR 888 provide that HUD will develop proposed FMRs, publish them for public comment, provide a public comment period of at least 30 days, analyze the comments, and publish final FMRs. (See 24 CFR 888.115.)

In addition, HUD's regulations at 24 CFR 888.113 set out procedures for HUD to assess whether areas are eligible for FMRs at the 50th percentile. Minimally qualified areas are reviewed each year, unless not qualified to be reviewed. Areas are not qualified to be reviewed if they have been made a 50th-percentile area within the last 3 years or have lost 50th-percentile status for failure to deconcentrate within the last 3 years. Twelve FMR areas, listed below, were reviewed for proposed FY 2010 FMRs.

CURRENT OR POTENTIAL FMR AREAS REVIEWED FOR ELIGIBILITY AS FY 2010 50TH-PERCENTILE FMR AREAS

Baltimore-Towson, MD MSA	
Bergen-Passaic, NJ HMFA ²	
Dallas, TX HMFA	
Fort Lauderdale, FL HMFA	
Grand Rapids-Wyoming, MI HMFA	
New Haven-Meriden, CT HMFA	
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA	
Providence-Fall River, RI-MA HMFA	
Sacramento—Arden-Arcade—Roseville, CA HMFA	
San Diego-Carlsbad-San Marcos, CA MSA	
Washington-Arlington-Alexandria, DC-VA-MD HMFA	
West Palm Beach-Boca Raton, FL HMFA	

² HMFA is an acronym for HUD Metro FMR Area, which is an MSA subarea, or the remaining portions of an MSA after subareas have been determined.

Six of the 12 areas eligible for review become or remain 50th percentile areas: The Baltimore-Towson, MD MSA; the Fort Lauderdale, FL HMFA; the Grand Rapids-Wyoming, MI HMFA; the New Haven-Meriden, CT HMFA; and the Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA; and the West Palm Beach-Boca Raton, FL HMFA. Grand Rapids did not meet the concentration-of-tenants criterion in FY 2009, but now meets it and is designated a 50th-percentile area for FY 2010. Fort Lauderdale, FL HMFA; and the West Palm Beach-Boca Raton, FL HMFA continue to meet the criteria for 50th percentile status and have made progress in the deconcentration of tenants, so they will remain 50th percentile areas for another 3 years.

The Baltimore-Towson, MD MSA; the New Haven-Meriden, CT HMFA; and the Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA have large PHAs operating within their jurisdiction under HUD's Moving to Work (MTW) program. MTW reporting requirements differ from non-MTW agencies and have limited HUD's ability to evaluate some metropolitan areas' eligibility for 50th percentile FMRs. Reporting by the MTW agencies in these three metropolitan areas has improved such that HUD is now able to assess the criteria for eligibility for 50th percentile FMRs and determine that they now qualify. Under current program rules, these six areas will not have their 50th percentile FMR status reevaluated until FY 2013.

Six of the 12 areas eligible for review fail to qualify for the 50th-percentile FMR program for FY 2010. Of these six areas, one area, San Diego-Carlsbad-San Marcos, CA MSA, no longer qualifies for the 50th-percentile FMR program

because, based on current tenant data, less than 25 percent of the tenant-based rental program participants reside in the 5 percent of census tracts in the metropolitan area with the largest number of program participants (the concentration-of-tenants test). Three areas with FY 2009 40th-percentile FMRs that were evaluated for FY 2010 50th-percentile FMRs also fail the concentration-of-tenants test: The Providence-Fall River, RI-MA HMFA; the Bergen-Passaic, NJ HMFA; and the Sacramento—Arden-Arcade—Roseville, CA HMFA. These areas will be reviewed next year; if this concentration changes, they may be made 50th-percentile areas for the FY 2011 FMRs.

Voucher tenants in the Dallas, TX HMFA have not materially deconcentrated over its 3-year eligibility period for a 50th percentile FMR. Deconcentration of tenants is the primary objective of the 50th-percentile program, and failure to make progress on the deconcentration of tenants over a 3-year period disqualifies an otherwise eligible area for 3 years. This area is not currently eligible for reevaluation until the FY 2013 FMRs. HUD solicits public comments on this aspect of the 50th percentile regulation.

The Washington-Arlington-Alexandria, DC-VA-MD HMFA still does not meet the minimum reporting criteria of 85 percent of resident records after an extensive search for useable data on assisted tenants. The District of Columbia Housing Authority is encouraged to submit to HUD by the end of the comment period any additional tenant data available in order to improve the reporting rate for the metropolitan area in which they operate. The Washington-Arlington-Alexandria, DC-VA-MD HMFA will be re-evaluated for 50th percentile FMR status in time for publication of the final FY 2010 FMRs based on all additional data submitted or refinements of analysis of data already at HUD based on comments from the PHAs. Please contact Lynn Rodgers at lynn.a.rodgers@hud.gov for specific data requirements.

Ten current 50th-percentile FMR areas were not evaluated this year because they have not completed 3 years of program participation since their last review. These 10 areas, listed below, continue in FY 2010 as 50th-percentile FMR areas. They will be up for review again in computation of the FY 2012 FMRs:

FY 2009 50TH-PERCENTILE FMR AREAS NOT SLATED FOR ELIGIBILITY EVALUATION AND CONTINUING WITH 50TH-PERCENTILE FMRS IN FY 2010

Albuquerque, NM MSA
Bradenton-Sarasota-Venice, FL MSA
Chicago-Naperville-Joliet, IL HMFA
Denver-Aurora, CO MSA
Hartford-West Hartford-East Hartford, CT
HMFA
Houston-Baytown-Sugar Land, TX HMFA
Kansas City, MO-KS, HMFA
Milwaukee-Waukesha-West Allis, WI MSA
Richmond, VA HMFA
Tacoma, WA HMFA

In total, 16 areas will be 50th-percentile areas for FY 2010, the 10 areas listed above and the six that passed review this year: Baltimore, Fort Lauderdale, Grand Rapids, New Haven, Philadelphia, and West Palm Beach.

III. FMR Methodology

This section provides a brief overview of how the FY 2010 FMRs are computed. For complete information on how FMR areas are determined, and on how each area's FMRs are derived, see the online documentation at: <http://www.huduser.org/datasets/fmr/fmrs/index.asp?data=fmr10>.

The FY 2010 FMRs are based on current OMB metropolitan area definitions and standards that were first used in the FY 2006 FMRs. OMB changes to the metropolitan area definitions through November 2008 are incorporated. As of November 2008, three micropolitan areas were redefined as metropolitan areas: Cape Girardeau-Jackson, MO-IL MSA; Manhattan KS MSA; and Mankato-North Mankato, MN MSA.

A. Data Sources—2000 Census, the American Community Survey, and the Consumer Price Index

As in all post-FY 2006 FMR publications, FY 2010 FMRs start with base rents generated using Census 2000 long-form survey data. They are updated with American Community Survey (ACS) data and Bureau of Labor Statistics Consumer Price Index (CPI) data. FY 2010 FMRs are FY 2009 FMRs updated by replacing the CPI data used for FY 2009 FMRs with ACS 2007 survey data and updated CPI data. Specifically, the FY 2009 rent (as of date: April 2009) is deflated to June 2006 by dividing it by 18 months of CPI data representing June 2006 through December 2007 inflation, and the usual 15-month trend factor. This June 2006 rent is the best and most recent rent estimate available using only ACS

survey data and eliminating all other update data. It is this rent that will be updated with additional ACS data and new CPI data.

In order to preserve additional information gathered by HUD through random digit dialing (RDD) surveys, areas surveyed after June 2007 are updated separately, the details of which can be found at the Web site listed above.

B. Updates from 2006 to 2007—2007 ACS

ACS survey data continues to be applied to areas based on the type of area (CBSA, metropolitan subarea, or nonmetropolitan county), the amount of survey data available, and the reliability of the survey estimates. Both 1- and 3-year ACS 2007 data are used to update June 2006 rents. All areas are updated with the change from 2006 to 2007 in State or metropolitan one-year standard-quality median rents. In a methodological update from previous years' estimates intended to minimize fluctuations in rents due to survey error, these rent changes are tested for statistical significance³

$$Z = \frac{EST_1 - EST_2}{\sqrt{(SE_1^2 + SE_2^2)}}$$

before being applied to 2006 rents. Any State or metropolitan level change that is not statistically significant is not applied; that is, the updated 2007 rent is the same as the 2006 rent. Metropolitan level rent changes are used for CBSA areas and subareas that have more than 200 standard quality cases in 2006 and 2007. All other areas are updated with State-level rent changes. For subareas, State and CBSA change factors continue to be selected based on which factor brings the subarea rent closer to the CBSA-wide rent. Subareas that have 200 or more local standard-quality survey observations are updated with their local area update factor.

After all areas have been updated with a standard-quality median rent change, local areas with estimates that reflect more than 200 one-year recent-mover cases are evaluated further. If the updated rent is outside the confidence interval of the ACS recent-mover estimate, the updated rent is replaced with the ACS recent-mover rent estimate. In areas without 200 or more one-year ACS recent-mover observations, but with 200 or more 3-

year ACS recent mover observations, the 3-year estimate⁴ is used if it is statistically different from the updated 2007 rent based on the standard-quality median rent change. This process creates a June 2007 rent.

C. Updates from 2007 to 2008

ACS 2007 data updates the June 2006 rents used in the FY 2009 FMRs forward by 12 months to June 2007. Six months of 2007 and 12 months of 2008 CPI rent and utilities price index data are used to update the June 2007 rents to the end of 2008. Local CPI data are used for FMR areas with at least 75 percent of their population within Class A metropolitan areas covered by local CPI data. Census region CPI data are used for FMR areas in Class B and C size metropolitan areas and nonmetropolitan areas without local CPI update factors.

D. Updates from 2008 to 2010

The national 1990 to 2000 average annual rent increase trend of 1.03 is applied to end-of-2008 rents for 15 months, to derive the proposed FY 2010 FMRs.

The area-specific data and computations used to calculate proposed FY 2010 FMRs and FMR area definitions can be found at <http://www.huduser.org/datasets/fmr/fmrs/index.asp?data=fmr10>.

E. Bedroom Rent Adjustments

FMR estimates are calculated for two-bedroom units. This generally is the most common size of rental units and, therefore, the most reliable to survey and analyze. After each Decennial Census, rent relationships between two-bedroom units and other unit sizes are calculated and used to set FMRs for other units. This is done because it is much easier to update two-bedroom estimates and to use pre-established cost relationships with other bedroom sizes than it is to develop independent FMR estimates for each bedroom size. This was last done using 2000 Census data. A publicly releasable version of the data file used for the derivations of rent ratios is available at <http://www.huduser.org/datasets/fmr/CensusRentData/index.html>.

Adjustments were made using 2000 Census data to establish rent ratios for areas with local bedroom-size intervals above or below what are considered reasonable ranges or where sample sizes

³ The change is considered statistically significant if $Z > 1.645$ where [see equation above] and EST_1 = ACS 2007 Estimate, EST_2 = ACS 2006 Estimate, SE_1 = Standard Error of Estimate 1, and SE_2 = Standard Error of Estimate 2.

⁴ The recent-mover estimate from the 3-year data includes all those who moved in the most recent 24-month period. That means that no 2005 survey data are included in this 3-year recent-mover classification, and the likelihood of having a valid (with 200 or more cases) 3-year recent-mover rent is lower for these estimates.

are inadequate to accurately measure bedroom rent differentials. Experience has shown that highly unusual bedroom ratios typically reflect inadequate sample sizes or peculiar local circumstances that HUD would not want to utilize in setting FMRs (*e.g.*, luxury efficiency apartments that rent for more than typical one-bedroom units). Bedroom interval ranges were established based on an analysis of the range of such intervals for all areas with large-enough samples to permit accurate bedroom ratio determinations. The range requirements used were: efficiency FMRs to fall between 0.65 and 0.83 of the two-bedroom FMR; one-bedroom FMRs must be between 0.76 and 0.90 of the two-bedroom FMR; three-bedroom FMRs must be between 1.10 and 1.34 of the two-bedroom FMR; and four-bedroom FMRs must be between 1.14 and 1.63 of the two-bedroom FMR. Bedroom rents for a given FMR area were then adjusted if the differentials between bedroom-size FMRs were inconsistent with normally observed patterns (*i.e.*, efficiency rents were not allowed to be higher than one-bedroom rents, and four-bedroom rents were not allowed to be lower than three-bedroom rents).

The rents for three-bedroom and larger units are further adjusted to continue to reflect HUD's policy to set higher rents for these units than would result from using unadjusted market rents. This adjustment is intended to increase the likelihood that the largest families, who have the most difficulty in leasing units, will be successful in finding eligible program units. The adjustment adds bonuses of 8.7 percent to the unadjusted three-bedroom FMR estimates and adds 7.7 percent to the unadjusted four-bedroom FMR estimates. The FMRs for unit sizes larger than four bedrooms are calculated by adding 15 percent to the four-bedroom FMR for each extra bedroom. For example, the FMR for a five-bedroom unit is 1.15 times the four-bedroom FMR, and the FMR for a six-bedroom unit is 1.30 times the four-bedroom FMR. FMRs for single-room occupancy units are 0.75 times the zero-bedroom (efficiency) FMR.

For low-population, nonmetropolitan counties with small 2000 Census samples of recent-mover rents, Census-defined county group data were used to determine rents for each bedroom size. This adjustment was made to protect against unrealistically high or low FMRs due to insufficient sample sizes. The areas covered by this estimation method had less than the HUD standard of 200 two-bedroom, Census-tabulated observations.

IV. Manufactured Home Space Surveys

The FMR used to establish payment standard amounts for the rental of manufactured home spaces in the Housing Choice Voucher program is 40 percent of the FMR for a two-bedroom unit. HUD will consider modification of the manufactured home space FMRs where public comments present statistically valid survey data showing the 40th-percentile manufactured home space rent (including the cost of utilities) for the entire FMR area.

All approved exceptions to these rents that were in effect in FY 2008 were updated to FY 2010 using the same data used to estimate the Housing Choice Voucher program FMRs, if the respective FMR area's definition remained the same. If the result of this computation was higher than 40 percent of the new two-bedroom rent, the exception remains and is listed in Schedule D. The FMR area definitions used for the rental of manufactured home spaces are the same as the area definitions used for the other FMRs. Areas with definitional changes that previously had manufactured housing space rental exception FMRs are requested to submit new surveys to justify higher-than-standard space rental FMRs, if they believe higher-space rental allowances are needed.

V. Request for Public Comments

HUD seeks public comments on FMR levels for specific areas. Comments on FMR levels must include sufficient information (including local data and a full description of the rental housing survey methodology used) to justify any proposed changes. Changes may be proposed in all or any one or more of the unit-size categories on the schedule. Recommendations and supporting data must reflect the rent levels that exist within the entire FMR area.

For the supporting data, HUD recommends the use of professionally conducted RDD telephone surveys to test the accuracy of FMRs for areas where there is a sufficient number of Section 8 units, to justify the survey cost of approximately \$35,000 to \$50,000. Areas with 2,000 or more program units usually meet this cost criterion, and areas with fewer units may meet it if actual rents for two-bedroom units are significantly different from the FMRs proposed by HUD.

PHAs in nonmetropolitan areas may, in certain circumstances, conduct surveys of groups of counties. HUD must approve all county-grouped surveys in advance. PHAs are cautioned that the resulting FMRs will not be identical for the counties surveyed; each

individual FMR area will have a separate FMR based on the relationship of rents in that area to the combined rents in the cluster of FMR areas. In addition, PHAs are advised that counties where FMRs are based on the combined rents in the cluster of FMR areas will not have their FMRs revised, unless the grouped survey results show a revised FMR above the combined rent level.

PHAs that plan to use the RDD survey technique should obtain a copy of the appropriate survey guide. Larger PHAs should request HUD's survey guide entitled "Random Digit Dialing Surveys: A Guide to Assist Larger Public Housing Agencies in Preparing Fair Market Rent Comments." Smaller PHAs should obtain the guide entitled "Rental Housing Surveys: A Guide to Assist Smaller Public Housing Agencies in Preparing Fair Market Rent Comments." These guides are available from HUD USER at 800-245-2691, or from HUD's Web site, in Microsoft Word or Adobe Acrobat format, at: <http://www.huduser.org/datasets/fmr.html>.

Other survey methodologies are acceptable in providing data to support comments, if the survey methodology can provide statistically reliable, unbiased estimates of the gross rent. Survey samples, preferably, should be randomly drawn from a complete list of rental units for the FMR area. If this is not feasible, the selected sample must be drawn to be statistically representative of the entire rental housing stock of the FMR area. Surveys must include units at all rent levels and be representative by structure type (including single-family, duplex, and other small rental properties), age of housing unit, and geographic location. The Decennial Census should be used as a means of verifying if a sample is representative of the FMR area's rental housing stock.

Most surveys cover only one- and two-bedroom units, which has statistical advantages. If the survey is statistically acceptable, HUD will estimate FMRs for other bedroom sizes using ratios based on the Decennial Census. A PHA or contractor that cannot obtain the recommended number of sample responses after reasonable efforts should consult with HUD before abandoning its survey; in such situations, HUD may find it appropriate to relax normal sample-size requirements.

HUD will consider increasing manufactured home space FMRs where public comment demonstrates that 40 percent of the two-bedroom FMR is not adequate. In order to be accepted as a basis for revising the manufactured home space FMRs, comments must

include a pad rental survey of the mobile home parks in the area, identify the utilities included in each park's rental fee, and provide a copy of the applicable public housing authority's utility schedule.

Accordingly, the Fair Market Rent Schedules, which will not be codified in 24 CFR part 888, are proposed to be amended as shown in the Appendix to this notice:

Dated: July 28, 2009.

Raphael W. Bostic,

Assistant Secretary for Policy Development and Research.

Fair Market Rents for the Housing Choice Voucher Program

Schedules B and D—General Explanatory Notes

1. Geographic Coverage

a. *Metropolitan Areas*—FMRs are market-wide rent estimates that are intended to provide housing opportunities throughout the geographic area in which rental-housing units are in direct competition. HUD is using the metropolitan CBSAs, which are made up of one or more counties, as defined by the Office of Management and Budget (OMB), with some modifications. HUD is generally assigning separate FMRs to the component counties of CBSA Micropolitan Areas.

b. *Modifications to OMB Definitions*—Following OMB guidance, the estimation procedure for the FY 2010 proposed FMRs incorporates the current OMB definitions of metropolitan areas based on the CBSA standards as implemented with 2000 Census data, but makes adjustments to the definitions to separate subparts of these areas where

FMRs or median incomes would otherwise change significantly if the new area definitions were used without modification. In CBSAs where subareas are established, it is HUD's view that the geographic extent of the housing markets are not yet the same as the geographic extent of the CBSAs, but may become so in the future as the social and economic integration of the CBSA component areas increases. Modifications to metropolitan CBSA definitions are made according to a formula as described below.

Metropolitan area CBSAs (referred to as MSAs) may be modified to allow for subarea FMRs within MSAs based on the boundaries of old FMR areas (OFAs) within the boundaries of new MSAs. (OFAs are the FMR areas defined for the FY 2005 FMRs. Collectively they include 1999-definition MSAs/Primary Metropolitan Statistical Areas (PMSAs), metro counties deleted from 1999-definition MSAs/PMSAs by HUD for FMR purposes, and counties and county parts outside of 1999-definition MSAs/PMSAs referred to as nonmetropolitan counties.) Subareas of MSAs are assigned their own FMRs when the subarea 2000 Census Base Rent differs by at least 5 percent from (*i.e.*, is at most 95 percent or at least 105 percent of) the MSA 2000 Census Base Rent, or when the 2000 Census Median Family Income for the subarea differs by at least 5 percent from the MSA 2000 Census Median Family Income. MSA subareas, and the remaining portions of MSAs after subareas have been determined, are referred to as HMFAs to distinguish these areas from OMB's official definition of MSAs.

The specific counties and New England towns and cities within each

State in MSAs and HMFAs are listed in Schedule B.

2. Bedroom Size Adjustments

Schedule B shows the FMRs for zero-bedroom through four-bedroom units. The FMRs for unit sizes larger than four bedrooms are calculated by adding 15 percent to the four-bedroom FMR for each extra bedroom. For example, the FMR for a five-bedroom unit is 1.15 times the four-bedroom FMR, and the FMR for a six-bedroom unit is 1.30 times the four-bedroom FMR. FMRs for single-room-occupancy (SRO) units are 0.75 times the zero-bedroom FMR.

3. Arrangement of FMR Areas and Identification of Constituent Parts

a. The FMR areas in Schedule B are listed alphabetically by metropolitan FMR area and by nonmetropolitan county within each State. The exception FMRs for manufactured home spaces in Schedule D are listed alphabetically by State.

b. The constituent counties (and New England towns and cities) included in each metropolitan FMR area are listed immediately following the listings of the FMR dollar amounts. All constituent parts of a metropolitan FMR area that are in more than one State can be identified by consulting the listings for each applicable State.

c. Two nonmetropolitan counties are listed alphabetically on each line of the non-metropolitan county listings.

d. The New England towns and cities included in a nonmetropolitan county are listed immediately following the county name.

BILLING CODE 4210-67-P

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

ALABAMA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Anniston-Oxford, AL MSA.....	426	471	585	773	909	Calhoun
Auburn-Opelika, AL MSA.....	421	502	647	851	874	Lee
Birmingham-Hoover, AL HMFA.....	593	659	735	933	960	Bibb, Blount, Jefferson, St. Clair, Shelby
Chilton County, AL HMFA.....	398	550	612	769	881	Chilton
Columbus, GA-AL MSA.....	550	579	663	882	1044	Russell
Decatur, AL MSA.....	467	524	603	789	818	Lawrence, Morgan
Dothan, AL HMFA.....	415	488	553	707	808	Geneva, Houston
Florence-Muscle Shoals, AL MSA.....	490	493	598	762	945	Colbert, Lauderdale
Gadsden, AL MSA.....	387	489	594	761	786	Etowah
Henry County, AL HMFA.....	350	482	536	641	660	Henry
Huntsville, AL MSA.....	517	563	665	910	999	Limestone, Madison
Mobile, AL MSA.....	580	620	700	917	1082	Mobile
Montgomery, AL MSA.....	552	653	735	975	1287	Autauga, Elmore, Lowndes, Montgomery
Tuscaloosa, AL MSA.....	483	558	723	929	958	Greene, Hale, Tuscaloosa
Walker County, AL HMFA.....	496	497	596	744	813	Walker

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Baldwin.....	534	643	764	1013	1160	Barbour.....	448	449	539	667	687
Bullock.....	397	449	550	659	710	Butler.....	397	449	550	659	710
Chambers.....	445	483	536	727	750	Cherokee.....	464	465	560	667	688
Choctaw.....	444	469	536	680	908	Clarke.....	348	481	536	642	942
Clay.....	446	448	536	662	825	Cleburne.....	450	452	542	664	827
Coffee.....	427	487	552	755	969	Conecuh.....	444	469	536	680	908
Coosa.....	435	481	536	726	815	Covington.....	446	447	536	731	754
Crenshaw.....	397	449	550	659	710	Cullman.....	464	478	560	753	774
Dale.....	414	478	536	774	939	Dallas.....	355	493	547	690	740
DeKalb.....	400	425	536	713	733	Escambia.....	445	451	536	668	822
Fayette.....	352	407	536	781	943	Franklin.....	349	452	536	723	941
Jackson.....	445	482	536	683	941	Lamar.....	359	445	536	716	940
Macon.....	398	428	552	736	761	Marengo.....	445	473	536	694	713
Marion.....	348	407	536	681	942	Marshall.....	473	507	572	772	851
Monroe.....	445	483	536	742	820	Perry.....	445	473	536	694	713
Pickens.....	359	445	536	716	940	Pike.....	427	460	536	688	710
Randolph.....	446	448	536	662	825	Sunter.....	359	458	536	716	940
Talladega.....	454	455	545	735	961	Tallapoosa.....	429	439	538	759	881
Washington.....	444	469	536	680	908	Wilcox.....	444	469	536	680	908
Winston.....	358	407	536	642	660						

ALASKA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
--	------	------	------	------	------	-----------------------------------

Anchorage, AK HMFA.....	723	822	1031	1485	1808	Anchorage
Fairbanks, AK MSA.....	653	785	1004	1454	1535	Fairbanks North Star
Matanuska-Susitna Borough, AK HMFA.....	660	769	981	1395	1694	Matanuska-Susitna

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

ALASKA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Aleutians East.....									
815	926	1174	1451	1496	Aleutians West.....				
933	1168	1418	1696	2490	Bristol Bay.....				
686	847	1057	1484	1671	Dillingham.....				
686	847	1057	1484	1671	Juneau.....				
615	703	855	1171	1501	Ketchikan Gateway.....				
Kodiak Island.....									
785	920	1210	1739	1840	Lake and Peninsula.....				
817	1050	1205	1454	1498	North Slope.....				
815	926	1174	1451	1496	Prince of Wales-Outer Ketchikan.				
780	899	1073	1563	1883	Skagway-Hoonah-Angoon.....				
686	847	1057	1484	1671	Valdez-Cordova.....				
Southeast Fairbanks.....									
815	926	1174	1451	1496	Wrangell-Petersburg.....				
815	926	1174	1451	1496	Yukon-Koyukuk.....				

ARIZONA

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Flagstaff, AZ MSA.....					Coconino				
820	975	1102	1417	1787	Mohave				
Lake Havasu City-Kingman, AZ MSA.....					Maricopa, Pinal				
615	676	788	1090	1216	Yavapai				
Phoenix-Mesa-Scottsdale, AZ MSA.....					Pima				
654	762	919	1338	1567	Yuma				
Prescott, AZ MSA.....									
683	706	891	1298	1337					
Tucson, AZ MSA.....									
540	635	815	1174	1240					
Yuma, AZ MSA.....									
574	678	810	1149	1408					

NONMETROPOLITAN COUNTIES

0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Apache.....									
433	530	627	870	1102	Cochise.....				
554	649	854	1173	1208	Graham.....				
526	585	734	1009	1141	La Paz.....				
516	552	728	981	1162	Santa Cruz.....				

ARKANSAS

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Fayetteville-Springdale-Rogers, AR HMFA.....					Benton, Madison, Washington				
497	524	655	954	981	Crawford, Sebastian				
Fort Smith, AR-OK HMFA.....					Franklin				
394	447	557	742	808	Grant				
Franklin County, AR HMFA.....					Garland				
335	438	515	653	797	Craighead				
Grant County, AR HMFA.....					Faulkner, Lonoke, Perry, Pulaski, Saline				
433	446	545	789	813					
Hot Springs, AR MSA.....									
402	499	621	775	799					
Jonesboro, AR HMFA.....									
469	489	564	794	818					
Little Rock-North Little Rock-Conway, AR HMFA.....									
540	614	684	916	945					

Memphis, TN-MS-AR HMF.	648	705	783	1043	1076	Crittenden
Pine Bluff, AR MSA.	398	472	592	710	842	Cleveland, Jefferson, Lincoln
Poinsett County, AR HMF.	335	433	515	685	820	Poinsett
Texarkana, TX-Texarkana, AR MSA.	501	506	623	760	827	Miller

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

ARKANSAS continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Arkansas.....	393	414	515	748	769	Ashley.....	400	414	544
Baxter.....	394	458	554	745	939	Boone.....	435	436	524
Bradley.....	383	389	515	639	677	Calhoun.....	333	462	515
Carroll.....	451	452	543	685	954	Chicot.....	383	389	515
Clark.....	410	416	535	690	710	Clay.....	415	417	515
Cleburne.....	467	468	561	769	987	Columbia.....	337	433	519
Conway.....	428	441	515	709	771	Cross.....	430	431	518
Dallas.....	333	462	515	656	835	Desha.....	383	389	515
Drew.....	368	473	568	714	996	Fulton.....	410	411	515
Greene.....	334	465	515	753	776	Hempstead.....	403	451	528
Hot Spring.....	429	430	515	675	696	Howard.....	393	457	515
Independence.....	358	426	515	666	723	Izard.....	410	411	515
Jackson.....	347	455	515	727	749	Johnson.....	334	458	515
Lafayette.....	406	465	534	639	764	Lawrence.....	336	411	515
Lee.....	366	414	515	686	798	Little River.....	406	465	534
Logan.....	335	433	515	736	824	Marion.....	427	429	515
Mississippi.....	362	404	529	698	842	Monroe.....	428	430	515
Montgomery.....	399	464	584	734	756	Nevada.....	406	465	534
Newton.....	429	430	517	667	750	Ouachita.....	333	464	515
Phillips.....	427	431	515	671	692	Pike.....	406	465	534
Polk.....	428	464	515	670	814	Pope.....	387	415	537
Prairie.....	428	430	515	645	666	Randolph.....	335	419	515
St. Francis.....	436	452	528	745	925	Scott.....	428	430	515
Searcy.....	429	430	517	667	750	Sevier.....	430	444	515
Sharp.....	428	430	515	656	678	Stone.....	410	411	515
Union.....	440	463	529	686	890	Van Buren.....	335	391	515
White.....	442	443	532	722	743	Woodruff.....	428	430	515
Yell.....	425	449	515	706	728				

CALIFORNIA

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Bakersfield, CA MSA.....	622	670	799	1155	1384	Kern			
Chico, CA MSA.....	594	706	852	1201	1434	Butte			
El Centro, CA MSA.....	606	685	845	1163	1481	Imperial			
Fresno, CA MSA.....	646	711	840	1222	1316	Fresno			
Hanford-Corcoran, CA MSA.....	639	680	790	1152	1388	Kings			
Los Angeles-Long Beach, CA HMFA.....	943	1137	1420	1907	2295	Los Angeles			

Madera-Chowchilla, CA MSA.....	642	674	860	1250	1289	Madera
Merced, CA MSA.....	577	658	799	1139	1330	Merced
Modesto, CA MSA.....	715	790	930	1334	1540	Stanislaus
Napa, CA MSA.....	927	1040	1350	1867	2121	Napa
Oakland-Fremont, CA HMFA.....	963	1162	1377	1867	2312	Alameda, Contra Costa
Orange County, CA HMFA.....	1183	1336	1594	2256	2597	Orange

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

CALIFORNIA continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Oxnard-Thousand Oaks-Ventura, CA MSA.....	1053	1162	1479	2119	2424	Ventura
Redding, CA MSA.....	584	680	827	1207	1454	Shasta
Riverside-San Bernardino-Ontario, CA MSA.....	854	940	1108	1559	1818	Riverside, San Bernardino
Sacramento-Arden-Arcade-Roseville, CA HMFA.....	749	852	1039	1499	1719	El Dorado, Placer, Sacramento
Salinas, CA MSA.....	868	977	1122	1585	1661	Monterey
San Benito County, CA HMFA.....	797	1080	1201	1702	2107	San Benito
San Diego-Carlsbad-San Marcos, CA MSA.....	945	1082	1324	1883	2326	San Diego
San Francisco, CA HMFA.....	1144	1406	1760	2350	2483	Marin, San Francisco, San Mateo
San Jose-Sunnyvale-Santa Clara, CA HMFA.....	1032	1196	1438	2068	2276	Santa Clara
San Luis Obispo-Paso Robles, CA MSA.....	805	952	1160	1690	1739	San Luis Obispo
Santa Barbara-Santa Maria-Goleta, CA MSA.....	1005	1122	1259	1658	1892	Santa Barbara
Santa Cruz-Watsonville, CA MSA.....	1076	1270	1656	2383	2456	Santa Cruz
Santa Rosa-Petaluma, CA MSA.....	850	1034	1306	1853	2167	Sonoma
Stockton, CA MSA.....	673	768	947	1300	1637	San Joaquin
Vallejo-Fairfield, CA MSA.....	980	1055	1210	1696	2090	Solano
Visalia-Porterville, CA MSA.....	517	578	672	961	987	Tulare
Yolo, CA HMFA.....	813	861	1052	1533	1631	Yolo
Yuba City, CA MSA.....	550	620	763	1110	1188	Sutter, Yuba

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Alpine.....	642	720	918	1309	1348	Amador.....	692	812	1065	1547	1594
Calaveras.....	707	708	851	1241	1368	Colusa.....	644	647	841	1086	1476
Del Norte.....	632	640	828	1206	1243	Glenn.....	552	566	745	969	995
Humboldt.....	586	686	903	1295	1434	Inyo.....	581	608	791	1152	1359
Lake.....	580	680	885	1282	1428	Lassen.....	563	660	867	1261	1299
Mariposa.....	642	720	918	1309	1348	Mendocino.....	646	797	969	1323	1700
Modoc.....	558	617	807	1150	1194	Mono.....	756	911	1163	1593	2043
Nevada.....	726	848	1117	1613	1963	Plumas.....	575	673	887	1294	1558
Sierra.....	679	791	1044	1479	1831	Siskiyou.....	501	601	769	1094	1127
Tehama.....	524	596	778	1130	1358	Trinity.....	568	596	782	1073	1190
Tuolumne.....	624	742	959	1325	1366						

COLORADO

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Boulder, CO MSA.....	729	844	1059	1544	1851	Boulder
Colorado Springs, CO HMFA.....	561	630	795	1134	1342	El Paso
*Denver-Aurora-Broomfield, CO MSA.....	638	728	921	1308	1524	Adams, Arapahoe, Broomfield, Clear Creek, Denver, Douglas,
						Elbert, Gilpin, Jefferson, Park

Fort Collins-Loveland, CO MSA.....	572	686	832	1211	1412	Larimer
Grand Junction, CO MSA.....	583	584	701	1021	1234	Mesa
Greeley, CO MSA.....	533	565	691	1008	1189	Weid
Pueblo, CO MSA.....	490	516	678	888	1005	Pueblo
Teller County, CO HMFA.....	575	673	885	1289	1552	Teller

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

COLORADO continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES							
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR			
Alamosa.....	428	530	588	799	1033	Archuleta.....	524	616	775	942	1217	
Baca.....	450	528	588	837	904	Bent.....	468	483	588	771	947	
Chaffee.....	436	549	669	975	1004	Cheyenne.....	468	483	588	771	947	
Conejos.....	450	528	588	837	904	Costilla.....	450	528	588	837	904	
Crowley.....	468	483	588	771	947	Custer.....	466	545	718	1005	1157	
Delta.....	512	523	616	845	871	Dolores.....	523	613	710	940	1213	
Eagle.....	868	1013	1333	1677	2290	Fremont.....	415	495	636	913	1046	
Garfield.....	889	1012	1122	1385	1426	Grand.....	520	594	755	1099	1132	
Gunnison.....	538	591	768	1063	1349	Hinsdale.....	656	827	999	1244	1753	
Huerfano.....	450	528	588	837	904	Jackson.....	583	674	748	964	1164	
Kiowa.....	468	483	588	771	947	Kit Carson.....	468	483	588	771	947	
Lake.....	656	827	999	1244	1753	La Plata.....	574	701	802	1125	1281	
Las Animas.....	400	530	588	758	783	Lincoln.....	468	483	588	771	947	
Logan.....	460	462	588	766	886	Mineral.....	656	827	999	1244	1753	
Moffat.....	534	583	732	960	1285	Montezuma.....	459	537	620	740	989	
Montrose.....	441	578	670	889	1102	Morgan.....	498	539	601	801	967	
Otero.....	459	485	588	814	838	Ouray.....	656	827	999	1244	1753	
Phillips.....	468	483	588	771	947	Pitkin.....	917	1072	1410	1958	2476	
Prowers.....	451	529	588	797	1034	Rio Blanco.....	583	674	748	964	1164	
Rio Grande.....	451	528	588	853	906	Routt.....	676	800	1040	1244	1826	
Saguache.....	450	528	588	837	904	San Juan.....	523	613	710	940	1213	
San Miguel.....	706	848	1083	1579	1627	Sedgwick.....	468	483	588	771	947	
Summit.....	758	891	1165	1659	2045	Washington.....	468	483	588	771	947	
Yuma.....	468	483	588	771	947							
CONNECTICUT												
METROPOLITAN FMR AREAS					Components of FMR AREA within STATE							
Bridgeport, CT HMFA.....					833	1076	1283	1533	1862	Fairfield County towns of Bridgeport town, Easton town,		
town,										Fairfield town, Monroe town, Shelton town, Stratford town,		
Colchester-Lebanon, CT HMFA.....					739	868	1139	1362	1406	Trumbull town		
town										New London County towns of Colchester town, Lebanon town		
Danbury, CT HMFA.....					1033	1254	1591	1904	2361	Fairfield County towns of Bethel town, Brookfield town,		
Redding town,										Danbury town, New Fairfield town, Newtown town,		

*Hartford-West Hartford-East Hartford, CT HMFA....	748	896	1095	1315	1633	Ridgefield town, Sherman town Hartford County towns of Avon town, Berlin town, Bloomfield town, Bristol town, Burlington town, East Granby town, East Hartford town, East Windsor town, Enfield town, Farmington town, Glastonbury town, Hartford town, Hartland town, Manchester town, Marlborough town, New Britain town, Newington town, Plainville town, Rocky Hill town, Simsbury town, Southington town, South Windsor town, Suffield town, West Hartford town, Wethersfield town, Windsor town, Windsor Locks town
--	-----	-----	------	------	------	--

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

CONNECTICUT continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
town,						Middlesex County towns of Chester town, Cromwell
Portland town						Durham town, East Haddam town, East Hampton town, Haddam town, Middlefield town, Middletown town, Tolland County towns of Andover town, Bolton town, Columbia town, Coventry town, Ellington town, Hebron Mansfield town, Somers town, Stafford town, Tolland Union town, Vernon town, Willington town
town,						New Haven County towns of Ansonia town, Beacon Falls
town,	909	1054	1179	1501	1648	Derby town, Milford town, Oxford town, Seymour town
Milford-Ansonia-Seymour, CT HMFA.....						New Haven County towns of Bethany town, Branford
*New Haven-Meriden, CT HMFA.....	862	978	1181	1414	1616	Cheshire town, East Haven town, Guilford town,
town,						Madison town, Meriden town, New Haven town,
Hamden town,						North Branford town, North Haven town, Orange town, Wallingford town, West Haven town, Woodbridge town
Norwich-New London, CT HMFA.....	740	878	1016	1244	1374	New London County towns of Bozrah town, East Lyme
town,						Franklin town, Griswold town, Groton town, Ledyard
town,						Lisbon town, Lyme town, Montville town, New London
town,						North Stonington town, Norwich town, Old Lyme town, Preston town, Salem town, Sprague town, Stonington
town,						Voluntown town, Waterford town
Southern Middlesex County, CT HMFA.....	870	916	1166	1496	1706	Middlesex County towns of Clinton town, Deep River
town,						Essex town, Killingworth town, Old Saybrook town, Westbrook town
Stamford-Norwalk, CT HMFA.....	1183	1440	1800	2345	2833	Fairfield County towns of Darien town, Greenwich
town,						New Canaan town, Norwalk town, Stamford town, Weston
town,						Westport town, Wilton town
Waterbury, CT HMFA.....	616	796	947	1134	1180	New Haven County towns of Middlebury town, Naugatuck
town,						Prospect town, Southbury town, Waterbury town,
Wolcott town						

NONMETROPOLITAN COUNTIES					Towns within nonmetropolitan counties				
0 BR	1 BR	2 BR	3 BR	4 BR					
Litchfield County, CT.....	668	870	1027	1319	1483	Barkhamsted town, Bethlehem town, Bridgewater town, Canaan town, Colebrook town, Cornwall town, Goshen			
town,						Harwinton town, Kent town, Litchfield town, Morris			
town,						New Hartford town, New Milford town, Norfolk town, North Canaan town, Plymouth town, Roxbury town, Salisbury town, Sharon town, Thomaston town,			
Torrington town,						Warren town, Washington town, Watertown town,			
Windham County, CT.....	617	747	899	1131	1200	Winchester town, Woodbury town			
town,						Ashford town, Brooklyn town, Canterbury town, Chaplin			
Plainfield town,						Eastford town, Hampton town, Killingly town,			
town,						Pomfret town, Putnam town, Scotland town, Sterling			
						Thompson town, Windham town, Woodstock town			
DELAWARE									
METROPOLITAN FMR AREAS	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE			
Dover, DE MSA.....	696	757	838	1096	1472	Kent			

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

DELAWARE continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
*Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA...	803	915	1095	1339	1615	New Castle

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Sussex.....	640	697	774	1059	1090						

DISTRICT OF COLUMBIA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Washington-Arlington-Alexandria, DC-VA-MD HMFA....	1061	1198	1364	1745	2285	District of Columbia

FLORIDA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Baker County, FL HMFA.....	382	529	588	860	883	Baker
*Bradenton-Sarasota-Venice, FL MSA.....	871	953	1147	1465	1609	Manatee, Sarasota
Cape Coral-Fort Myers, FL MSA.....	837	903	1029	1398	1440	Lee
Deltona-Daytona Beach-Ormond Beach, FL MSA.....	652	762	948	1226	1262	Volusia
*Fort Lauderdale, FL HMFA.....	1010	1130	1358	1878	2385	Broward
Fort Walton Beach-Crestview-Destin, FL MSA.....	655	767	863	1259	1383	Okaloosa
Gainesville, FL MSA.....	663	731	833	1218	1255	Alachua, Gilchrist
Jacksonville, FL HMFA.....	682	776	903	1133	1299	Clay, Duval, Nassau, St. Johns
Lakeland-Winter Haven, FL MSA.....	620	684	788	999	1173	Polk
Miami-Miami Beach-Kendall, FL HMFA.....	878	994	1206	1542	1803	Miami-Dade
Naples-Marco Island, FL MSA.....	918	1052	1185	1473	1533	Collier
Ocala, FL MSA.....	655	675	792	1040	1071	Marion
Orlando-Kissimmee, FL MSA.....	847	921	1052	1317	1551	Lake, Orange, Osceola, Seminole
Palm Bay-Melbourne-Titusville, FL MSA.....	636	778	916	1234	1376	Brevard
Palm Coast, FL MSA.....	699	806	1014	1420	1514	Flagler
Panama City-Lynn Haven-Panama City Beach, FL MSA..	675	711	815	1126	1252	Bay
Pensacola-Ferry Pass-Brent, FL MSA.....	662	720	799	1158	1401	Escambia, Santa Rosa
Port St. Lucie, FL MSA.....	763	765	969	1281	1320	Martin, St. Lucie
Punta Gorda, FL MSA.....	683	715	928	1355	1630	Charlotte
Sebastian-Vero Beach, FL MSA.....	628	757	966	1203	1237	Indian River
Tallahassee, FL HMFA.....	687	764	943	1258	1295	Gadsden, Jefferson, Leon
Tampa-St. Petersburg-Clearwater, FL MSA.....	714	793	959	1215	1467	Hernando, Hillsborough, Pasco, Pinellas
Wakulla County, FL HMFA.....	646	701	780	1026	1058	Wakulla
*West Palm Beach-Boca Raton, FL HMFA.....	910	1066	1259	1780	1834	Palm Beach

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Bradford.....	422	585	649	804	829	Calhoun.....	545	546	654	824	940

Citrus.....	583	634	702	1019	1226	Columbia.....	508	587	694	866	1217
DeSoto.....	573	586	689	831	855	Dixie.....	485	530	588	734	818
Franklin.....	544	545	654	823	937	Glades.....	603	642	730	891	952
Gulf.....	545	546	654	824	940	Hamilton.....	485	530	588	734	818
Hardee.....	573	621	689	845	869	Hendry.....	547	654	729	876	1081

FLORIDA continued

NONMETROPOLITAN COUNTIES										NONMETROPOLITAN COUNTIES										NONMETROPOLITAN COUNTIES									
0	BR	1	BR	2	BR	3	BR	4	BR	0	BR	1	BR	2	BR	3	BR	4	BR	0	BR	1	BR	2	BR	3	BR	4	BR
Highlands.....	618	621	744	963	1150				Holmes.....	519	552	626	814	855															
Jackson.....	414	532	592	733	855				Lafayette.....	485	530	588	734	818															
Levy.....	507	543	611	780	803				Liberty.....	545	546	654	824	940															
Madison.....	545	546	654	824	940				Monroe.....	910	1108	1365	1986	2127															
Okeechobee.....	616	637	742	999	1029				Putnam.....	515	558	620	744	766															
Sumter.....	489	531	590	775	1036				Suwannee.....	390	530	588	741	812															
Taylor.....	554	601	668	799	821				Union.....	506	582	654	865	892															
Walton.....	609	628	735	908	936				Washington.....	392	445	588	843	867															
GEORGIA																													
METROPOLITAN FMR AREAS																													
0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE																													
Albany, GA MSA.....	516	550	646	867	895	Baker, Dougherty, Lee, Terrell, Worth																							
Athens-Clarke County, GA MSA.....	552	614	770	1026	1058	Clarke, Madison, Oconee, Oglethorpe																							
Atlanta-Sandy Springs-Marietta, GA HMPA.....	757	820	912	1110	1211	Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta,																							
Gwinnett,						Dawson, Dekalb, Douglas, Fayette, Forsyth, Fulton,																							
Pike,						Heard, Henry, Jasper, Newton, Paulding, Pickens,																							
Augusta-Richmond County, GA-SC MSA.....	533	578	649	869	914	Rockdale, Spalding, Walton																							
Brunswick, GA MSA.....	517	562	624	889	1096	Burke, Columbia, McDuffie, Richmond																							
Butts County, GA HMPA.....	424	566	654	954	1136	Butts																							
Chattanooga, TN-GA MSA.....	537	568	669	824	968	Catoosa, Dade, Walker																							
Columbus, GA-AL MSA.....	550	579	663	882	1044	Chattahoochee, Harris, Marion, Muscogee																							
Dalton, GA HMPA.....	527	573	634	784	808	Whitfield																							
Gainesville, GA MSA.....	720	755	871	1070	1240	Hall																							
Haralson County, GA HMPA.....	456	478	548	798	967	Haralson																							
Hinesville-Fort Stewart, GA HMPA.....	522	567	631	888	1010	Liberty																							
Lamar County, GA HMPA.....	495	497	596	786	1046	Lamar																							
Long County, GA HMPA.....	465	505	562	770	794	Long																							
Macon, GA MSA.....	542	588	654	806	840	Bibb, Crawford, Jones, Twiggs																							
Meriwether County, GA HMPA.....	485	491	585	706	727	Meriwether																							
Monroe County, GA HMPA.....	522	568	630	755	780	Monroe																							
Murray County, GA HMPA.....	494	533	594	710	731	Murray																							
Rome, GA MSA.....	498	508	655	804	830	Floyd																							
Savannah, GA MSA.....	676	732	815	1082	1117	Bryan, Chatham, Effingham																							
Valdosta, GA MSA.....	532	534	642	871	898	Brooks, Echols, Lanier, Lowndes																							
Warner Robins, GA MSA.....	590	600	713	1035	1190	Houston																							
NONMETROPOLITAN COUNTIES																													
0 BR 1 BR 2 BR 3 BR 4 BR NONMETROPOLITAN COUNTIES																													

Appling.....	454	494	548	668	688	Atkinson.....	455	476	548	698	795
Bacon.....	455	476	548	698	795	Baldwin.....	427	515	639	763	787
Banks.....	474	513	569	691	982	Ben Hill.....	360	464	554	670	689
Berrien.....	449	450	548	679	700	Bleckley.....	385	449	548	678	777
Bulloch.....	505	522	619	743	763	Calhoun.....	455	493	548	703	864
Camden.....	564	565	681	991	1195	Candler.....	454	494	548	668	688
Charlton.....	455	476	548	698	795	Chattooga.....	357	437	548	657	956

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

GEORGIA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Clay.....	455	493	548	703	864	Clinch.....	455	476	548	698	795
Coffee.....	454	470	548	682	835	Colquitt.....	456	492	548	656	825
Cook.....	455	465	548	745	963	Crisp.....	455	459	548	692	713
Decatur.....	407	473	623	745	828	Dodge.....	432	434	548	733	754
Dooly.....	455	471	548	691	933	Early.....	455	493	548	703	864
Elbert.....	455	475	548	688	710	Emanuel.....	358	415	548	668	854
Evans.....	454	494	548	668	688	Fannin.....	371	516	572	685	821
Franklin.....	474	513	569	691	982	Gilmer.....	537	581	648	855	1032
Glascok.....	393	416	548	656	770	Gordon.....	537	541	695	831	858
Grady.....	356	492	548	760	785	Greene.....	455	475	548	688	710
Habersham.....	541	544	651	780	1143	Hancock.....	455	475	548	688	710
Hart.....	455	493	548	654	961	Irwin.....	455	482	548	695	848
Jackson.....	565	613	682	829	1082	Jeff Davis.....	454	494	548	668	688
Jefferson.....	393	437	548	656	770	Jenkins.....	393	416	548	656	770
Johnson.....	413	506	564	729	761	Laurens.....	455	495	548	736	893
Lincoln.....	455	475	548	688	710	Lumpkin.....	481	625	742	1002	1111
Macon.....	455	471	548	691	933	Miller.....	423	492	548	686	818
Mitchell.....	357	453	548	657	912	Montgomery.....	415	486	548	733	838
Morgan.....	493	494	609	729	750	Peach.....	497	498	601	860	905
Pierce.....	455	476	548	698	795	Polk.....	450	501	611	753	778
Pulaski.....	415	486	548	797	837	Putnam.....	413	418	548	796	819
Quitman.....	455	493	548	703	864	Rabun.....	539	559	649	837	1009
Randolph.....	455	493	548	703	864	Schley.....	455	471	548	691	933
Screven.....	393	416	548	656	770	Seminole.....	423	492	548	686	818
Stephens.....	366	508	564	675	697	Stewart.....	455	493	548	703	864
Sumter.....	429	482	592	709	1040	Talbot.....	525	526	635	782	805
Taliaferro.....	455	475	548	688	710	Tattall.....	456	493	548	723	791
Taylor.....	455	471	548	691	933	Telfair.....	415	486	548	733	838
Thomas.....	503	545	606	778	1064	Tift.....	478	518	574	733	847
Toombs.....	356	493	548	763	845	Towns.....	539	559	649	833	1009
Treutlen.....	415	486	548	733	838	Troup.....	525	531	666	842	870
Turner.....	455	482	548	695	848	Union.....	539	559	649	833	1009
Upson.....	386	523	595	711	732	Ware.....	454	490	548	702	737
Warren.....	455	475	548	688	710	Washington.....	393	451	548	670	770
Wayne.....	392	444	548	723	962	Webster.....	455	471	548	691	933
Wheeler.....	415	486	548	733	838	White.....	480	599	665	839	1010
Wilcox.....	415	486	548	733	838	Wilkes.....	455	475	548	688	710

Wilkinson.....	413	506	564	729	761	
HAWAII						
METROPOLITAN FMR AREAS				0 BR	1 BR	2 BR
Honolulu, HI MSA.....				1191	1397	1704
						2473
						2767
						Counties of FMR AREA within STATE
						Honolulu

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

HAWAII continued

NONMETROPOLITAN COUNTIES		0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES		0 BR	1 BR	2 BR	3 BR	4 BR
Hawaii.....		818	982	1102	1554	1703	Kalawao.....		982	1132	1330	1681	1914
Kauai.....		943	1062	1399	1756	1911	Maui.....		1207	1337	1555	2081	2228

IDAHO

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS		0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	
Boise City-Nampa, ID HMFA.....		516	611	721	1048	1115	Ada, Boise, Canyon, Owyhee	
Coeur d'Alene, ID MSA.....		564	609	733	1066	1192	Kootenai	
Gem County, ID HMFA.....		500	606	673	979	1007	Gem	
Idaho Falls, ID MSA.....		480	505	645	884	1110	Bonneville, Jefferson	
Lewiston, ID-WA MSA.....		494	513	642	912	1111	Nez Perce	
Logan, UT-ID MSA.....		491	530	663	889	1098	Franklin	
Pocatello, ID MSA.....		412	479	617	892	1045	Bannock, Power	

NONMETROPOLITAN COUNTIES

NONMETROPOLITAN COUNTIES		0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES		0 BR	1 BR	2 BR	3 BR	4 BR
Adams.....		482	503	633	857	1021	Bear Lake.....		411	474	606	861	1016
Benewah.....		554	564	708	1012	1043	Bingham.....		415	460	590	812	838
Blaine.....		801	870	966	1372	1693	Bonner.....		560	588	721	1020	1050
Boundary.....		554	564	708	1012	1043	Butte.....		459	491	627	887	1053
Canas.....		491	537	670	883	945	Caribou.....		411	474	606	861	1016
Cassia.....		491	537	670	883	945	Clark.....		459	491	627	887	1053
Clearwater.....		490	507	628	906	1046	Custer.....		459	491	627	887	1053
Elmore.....		418	487	641	813	995	Fremont.....		459	491	627	887	1053
Gooding.....		491	537	670	883	945	Idaho.....		479	513	676	808	956
Jerome.....		491	537	670	883	945	Latah.....		493	515	622	907	1049

Lemhi.....		459	491	627	887	1053	Lewis.....		490	507	628	906	1046
Lincoln.....		491	537	670	883	945	Madison.....		457	458	588	854	929
Minidoka.....		381	502	588	779	801	Oneida.....		411	474	606	861	1016
Payette.....		415	500	635	804	1050	Shoshone.....		486	487	588	774	820
Teton.....		459	491	627	887	1053	Twin Falls.....		443	538	682	879	1040
Valley.....		482	503	633	857	1021	Washington.....		482	503	633	857	1021

ILLINOIS

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS		0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	
Bloomington-Normal, IL MSA.....		515	569	718	960	1200	McLean	
Bond County, IL HMFA.....		406	434	563	819	963	Bond	
Cape Girardeau-Jackson, MO-IL MSA.....		388	442	577	746	917	Alexander	

Champaign-Urbana, IL MSA.....	493	599	705	885	1215	Champaign, Ford, Piatt
*Chicago-Naperville-Joliet, IL HMFA.....	790	903	1015	1240	1402	Cook, DuPage, Kane, Lake, McHenry, Will
Danville, IL MSA.....	389	465	599	717	761	Vermilion
Davenport-Moline-Rock Island, IA-IL MSA.....	463	516	650	829	864	Henry, Mercer, Rock Island
DeKalb County, IL HMFA.....	578	653	858	1113	1365	Dekalb
Decatur, IL MSA.....	407	485	615	820	846	Macon

ILLINOIS continued

METROPOLITAN FMR AREAS										Counties of FMR AREA within STATE										
0 BR	1 BR	2 BR	3 BR	4 BR						0 BR	1 BR	2 BR	3 BR	4 BR						
Grundy County, IL HMTA.....										582	682	894	1126	1515	Grundy					
Kankakee-Bradley, IL MSA.....										520	566	747	969	1038	Kankakee					
Kendall County, IL HMTA.....										819	820	985	1385	1500	Kendall					
Macoupin County, IL HMTA.....										514	515	619	771	799	Macoupin					
Peoria, IL MSA.....										470	556	692	891	1012	Marshall, Peoria, Stark, Tazewell, Woodford					
Rockford, IL MSA.....										497	560	710	929	956	Boone, Winnebago					
Springfield, IL MSA.....										437	514	664	867	967	Menard, Sangamon					
St. Louis, MO-IL HMTA.....										572	621	771	993	1039	Calhoun, Clinton, Jersey, Madison, Monroe, St. Clair					
NONMETROPOLITAN COUNTIES										0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES					
Adams.....										367	435	563	731	755	Brown.....	365	444	563	752	775
Bureau.....										398	463	611	753	825	Carroll.....	428	484	609	758	780
Cass.....										445	477	563	716	738	Christian.....	368	471	563	727	851
Clark.....										364	508	563	819	846	Clay.....	369	460	563	752	773
Coles.....										389	498	599	845	1052	Crawford.....	367	434	563	740	776
Cumberland.....										390	485	586	780	1028	De Witt.....	463	464	566	739	865
Douglas.....										380	477	586	834	860	Edgar.....	366	428	563	708	730
Edwards.....										459	467	563	741	817	Effingham.....	495	496	597	754	797
Fayette.....										467	480	563	779	803	Franklin.....	364	447	563	699	988
Fulton.....										391	467	563	720	893	Gallatin.....	459	467	563	741	817
Greene.....										387	431	566	717	753	Hamilton.....	459	467	563	741	817
Hancock.....										470	471	563	677	700	Hardin.....	459	467	563	741	817
Henderson.....										388	454	563	711	850	Iroquois.....	419	465	563	708	830
Jackson.....										381	465	586	798	993	Jasper.....	365	453	563	741	762
Jefferson.....										480	493	588	740	762	Jo Daviess.....	442	473	563	750	774
Johnson.....										459	467	563	741	817	Knox.....	388	454	597	793	817
La Salle.....										465	502	661	834	1073	Lawrence.....	365	428	563	749	772
Lee.....										405	498	598	798	929	Livingston.....	418	513	645	770	802
Logan.....										483	484	599	795	911	McDonough.....	379	447	563	722	944
Marion.....										410	471	563	720	793	Mason.....	365	463	563	791	816
Massac.....										468	469	563	820	846	Montgomery.....	468	469	563	675	836
Morgan.....										397	461	608	755	819	Moultrie.....	376	444	578	728	884
Ogle.....										479	511	670	876	936	Perry.....	365	477	563	680	874
Pike.....										365	446	563	757	780	Pope.....	459	467	563	741	817
Pulaski.....										459	467	563	741	817	Putnam.....	381	445	586	741	810
Randolph.....										367	427	563	746	915	Richland.....	419	508	563	675	928
Saline.....										367	472	563	762	988	Schuyler.....	365	446	563	757	780
Scott.....										387	431	566	717	753	Shelby.....	467	468	563	734	830

Stephenson.....	422	494	651	779	803	Union.....	468	470	563	690	857
Wabash.....	459	467	563	741	817	Warren.....	366	428	563	703	801
Washington.....	390	446	563	723	745	Wayne.....	365	443	563	717	738
White.....	459	467	563	741	817	Whiteside.....	431	507	625	774	795
Williamson.....	368	430	563	811	836						

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

INDIANA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Countries of FMR AREA within STATE
Anderson, IN MSA.....	563	564	678	872	908	Madison
Bloomington, IN HMFA.....	479	555	677	962	994	Monroe
Carroll County, IN HMFA.....	410	481	631	830	855	Carroll
Cincinnati-Middleton, OH-KY-IN HMFA.....	473	560	726	972	1009	Dearborn, Franklin, Ohio
Columbus, IN MSA.....	651	652	783	960	1027	Bartholomew
Elkhart-Goshen, IN MSA.....	537	599	740	930	975	Elkhart
Evansville, IN-KY HMFA.....	435	508	632	780	848	Posey, Vanderburgh, Warrick
Fort Wayne, IN MSA.....	472	502	627	782	804	Allen, Wells, Whitley
Gary, IN HMFA.....	537	669	816	975	1006	Lake, Newton, Porter
Gibson County, IN HMFA.....	490	492	588	752	1034	Gibson
Greene County, IN HMFA.....	456	457	588	853	882	Greene
Indianapolis, IN HMFA.....	548	635	754	976	1032	Boone, Brown, Hamilton, Hancock, Hendricks, Johnson, Marion,
Jasper County, IN HMFA.....	593	595	739	964	993	Morgan, Shelby
Kokomo, IN MSA.....	542	548	696	887	913	Jasper
Lafayette, IN HMFA.....	538	636	781	1017	1163	Howard, Tipton
Louisville, KY-IN HMFA.....	499	577	684	956	1015	Benton, Tippecanoe
Michigan City-La Porte, IN MSA.....	465	537	682	906	932	Clark, Floyd, Harrison
Muncie, IN MSA.....	556	568	687	925	971	LaPorte
Owen County, IN HMFA.....	499	501	600	760	1054	Delaware
Putnam County, IN HMFA.....	554	555	668	798	900	Owen
South Bend-Mishawaka, IN HMFA.....	535	595	716	919	946	Putnam
Sullivan County, IN HMFA.....	381	447	588	703	724	St. Joseph
Terre Haute, IN HMFA.....	416	474	610	752	866	Sullivan
Washington County, IN HMFA.....	447	500	588	723	963	Clay, Vermillion, Vigo

	0 BR	1 BR	2 BR	3 BR	4 BR
Blackford.....	497	500	599	762	824
Clinton.....	517	548	670	837	878
Daviess.....	489	492	588	765	938
DeKalb.....	478	511	649	892	917
Fayette.....	398	492	611	809	832
Fulton.....	497	516	599	846	872
Henry.....	528	530	635	817	913
Jackson.....	544	545	663	852	1034
Jefferson.....	432	463	610	730	903
Knox.....	409	466	588	728	908
LaGrange.....	535	536	643	775	860
Marshall.....	460	530	659	869	896
Miami.....	382	449	588	856	923

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR
Adams.....	489	530	588	769	907
Cass.....	423	456	599	763	787
Crawford.....	419	478	588	727	770
Decatur.....	560	563	676	876	903
Dubois.....	391	469	601	820	844
Fountain.....	432	519	588	787	823
Grant.....	509	510	616	777	907
Huntington.....	454	541	640	799	967
Jay.....	382	468	588	797	832
Jennings.....	419	495	647	784	1079
Kosciusko.....	441	514	676	860	1001
Lawrence.....	421	498	649	776	798
Martin.....	419	462	588	724	847

INDIANA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES								
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR				
Starke.....	503	531	607	802	844	Steuben.....			486	554	728	878	903
Switzerland.....	458	496	653	818	912	Union.....			411	502	634	789	815
Wabash.....	384	447	588	804	916	Warren.....			413	508	636	782	908
Wayne.....	415	488	612	830	856	White.....			441	609	676	808	1141
IOWA													
METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE								
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR				
Ames, IA MSA.....	558	589	728	1042	1233	Story							
Benton County, IA HMFA.....	355	419	547	681	912	Benton							
Bremer County, IA HMFA.....	359	442	551	660	892	Bremer							
Cedar Rapids, IA HMFA.....	429	499	658	932	1059	Linn							
Davenport-Moline-Rock Island, IA-IL MSA.....	463	516	650	829	864	Scott							
Des Moines-West Des Moines, IA MSA.....	506	604	737	944	1052	Dallas, Guthrie, Madison, Polk, Warren							
Dubuque, IA MSA.....	411	442	581	781	851	Dubuque							
Iowa City, IA HMFA.....	488	582	734	1069	1251	Johnson							
Jones County, IA HMFA.....	455	456	547	767	790	Jones							
Omaha-Council Bluffs, NE-IA HMFA.....	540	614	766	1023	1052	Harrison, Mills, Pottawattamie							
Sioux City, IA-NE-SD MSA.....	429	504	661	832	857	Woodbury							
Washington County, IA HMFA.....	361	435	553	706	848	Washington							
Waterloo-Cedar Falls, IA HMFA.....	412	507	606	744	911	Black Hawk, Grundy							
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES								
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR				
Adair.....	374	416	547	667	746	Adams.....			374	416	547	667	746
Allamakee.....	388	427	547	709	754	Appanoose.....			355	415	547	691	757
Audubon.....	409	420	547	719	753	Boone.....			408	492	627	816	878
Buchanan.....	454	455	547	706	725	Buena Vista.....			426	430	563	676	775
Butler.....	388	427	547	709	754	Calhoun.....			433	434	547	703	735
Carroll.....	371	432	570	680	701	Cass.....			408	498	626	767	826
Cedar.....	387	427	563	728	788	Cerro Gordo.....			413	459	604	750	771
Cherokee.....	409	420	547	719	753	Chickasaw.....			388	427	547	709	754
Clarke.....	374	427	561	672	748	Clay.....			355	415	547	664	832
Clayton.....	388	427	547	709	754	Clinton.....			355	416	547	697	796
Crawford.....	409	432	547	719	753	Davis.....			374	416	547	667	746
Decatur.....	374	416	547	667	746	Delaware.....			387	427	563	728	788
Des Moines.....	424	463	587	738	831	Dickinson.....			354	438	547	692	959
Emmet.....	385	415	547	670	786	Fayette.....			388	427	547	709	754
Floyd.....	384	415	547	684	705	Franklin.....			395	435	547	699	733
Freemont.....	408	498	626	767	826	Greene.....			409	420	547	719	753

Hamilton.....	425	426	547	689	720	Hancock.....	395	435	547	699	733
Hardin.....	468	470	562	672	715	Henry.....	460	462	553	791	815
Howard.....	388	427	547	709	754	Humboldt.....	433	434	547	703	735
Ida.....	409	420	547	719	753	Iowa.....	423	447	555	726	749
Jackson.....	387	427	563	728	788	Jasper.....	426	465	611	777	811

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

IOWA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Jefferson.....	457	465	550	692	842	Keokuk.....	374	416	547
Kossuth.....	395	435	547	699	733	Lee.....	399	464	547
Louisa.....	419	469	580	751	794	Lucas.....	374	416	547
Lyon.....	385	415	547	670	786	Mahaska.....	404	458	584
Marion.....	408	501	626	773	796	Marshall.....	417	484	604
Mitchell.....	395	435	547	699	733	Monona.....	409	420	547
Monroe.....	374	416	547	667	746	Montgomery.....	408	498	626
Muscataine.....	417	515	640	788	849	O'Brien.....	385	415	547
Osceola.....	385	415	547	670	786	Page.....	353	416	547
Palo Alto.....	385	415	547	670	786	Plymouth.....	453	455	547
Pocahontas.....	433	434	547	703	735	Poweshiek.....	381	445	585
Ringgold.....	374	416	547	667	746	Sac.....	409	420	547
Shelby.....	408	498	626	767	826	Sioux.....	444	451	547
Tama.....	423	447	555	726	749	Taylor.....	374	416	547
Union.....	374	416	547	667	746	Van Buren.....	374	416	547
Wapello.....	390	453	598	713	743	Wayne.....	374	416	547
Webster.....	416	424	550	761	785	Winnebago.....	395	435	547
Winneshie.....	356	416	547	711	963	Worth.....	395	435	547
Wright.....	433	434	547	703	735				

KANSAS

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Franklin County, KS HMFA.....	530	658	838	896	Franklin				
*Kansas City, MO-KS HMFA.....	605	726	834	1128	Johnson, Leavenworth, Linn, Miami, Wyandotte				
Lawrence, KS MSA.....	561	576	741	1082	Douglas				
Manhattan, KS MSA.....	435	502	609	848	Geary, Pottawatomie, Riley				
St. Joseph, MO-KS MSA.....	376	464	577	726	Doniphan				
Sumner County, KS HMFA.....	367	431	567	763	Sumner				
Topeka, KS MSA.....	491	535	655	831	Jackson, Jefferson, Osage, Shawnee, Wabaunsee				
Wichita, KS HMFA.....	435	487	640	819	Butler, Harvey, Sedgwick				

NONMETROPOLITAN COUNTIES

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Allen.....	426	431	566	750	816	Anderson.....	409	455	566
Atchison.....	448	499	611	890	1073	Barber.....	368	434	566
Barton.....	367	443	566	752	974	Bourbon.....	410	436	566
Brown.....	448	499	611	890	1073	Chase.....	395	431	566
Chautauqua.....	409	455	566	729	794	Cherokee.....	472	489	566

Cheyenne.....	424	430	566	724	745	Clark.....	493	498	606	738	809
Clay.....	442	485	596	765	942	Cloud.....	442	450	569	747	772
Coffey.....	395	431	566	720	743	Comanche.....	368	434	566	737	869
Cowley.....	378	462	566	717	738	Crawford.....	404	473	622	838	934
Decatur.....	424	430	566	724	745	Dickinson.....	368	429	566	681	840

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

KANSAS continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Edwards.....	368	434	566	737	869	Elk.....	409	455	566	729	794
Ellis.....	408	462	608	841	880	Ellsworth.....	442	450	569	747	772
Finney.....	501	501	647	785	995	Ford.....	521	522	628	773	826
Gove.....	424	430	566	724	745	Graham.....	424	430	566	724	745
Grant.....	493	498	606	738	809	Gray.....	493	498	606	738	809
Greeley.....	493	498	606	738	809	Greenwood.....	395	431	566	720	743
Hamilton.....	493	498	606	738	809	Harper.....	368	434	566	737	869
Haskell.....	493	498	606	738	809	Hodgeman.....	493	498	606	738	809
Jewell.....	442	450	569	747	772	Kearny.....	493	498	606	738	809
Kingman.....	368	434	566	737	869	Kiowa.....	368	434	566	737	869
Labette.....	368	440	566	767	789	Lane.....	493	498	606	738	809
Lincoln.....	442	450	569	747	772	Logan.....	424	430	566	724	745
Lyon.....	368	431	566	756	895	McPherson.....	471	472	566	741	762
Marion.....	395	431	566	720	743	Marshall.....	442	485	596	765	942
Meade.....	493	498	606	738	809	Mitchell.....	442	450	569	747	772
Montgomery.....	405	453	566	696	867	Morris.....	442	485	596	765	942
Morton.....	493	498	606	738	809	Nemaha.....	448	499	611	890	1073
Neosho.....	367	441	566	674	990	Ness.....	493	498	606	738	809
Norton.....	424	430	566	724	745	Osborne.....	424	430	566	724	745
Ottawa.....	442	450	569	747	772	Pawnee.....	368	434	566	737	869
Phillips.....	424	430	566	724	745	Pratt.....	368	431	566	734	865
Rawlins.....	424	430	566	724	745	Reno.....	406	451	592	811	835
Republic.....	442	450	569	747	772	Rice.....	411	449	568	753	776
Rooks.....	424	430	566	724	745	Rush.....	368	434	566	737	869
Russell.....	424	430	566	724	745	Saline.....	471	473	622	829	853
Scott.....	493	498	606	738	809	Seward.....	427	525	607	745	903
Sheridan.....	424	430	566	724	745	Sherman.....	417	430	566	710	732
Smith.....	424	430	566	724	745	Stafford.....	368	434	566	737	869
Stanton.....	493	498	606	738	809	Stevens.....	493	498	606	738	809
Thomas.....	421	430	566	719	741	Trego.....	424	430	566	724	745
Wallace.....	424	430	566	724	745	Washington.....	442	450	569	747	772
Wichita.....	493	498	606	738	809	Wilson.....	409	454	566	727	792
Woodson.....	409	455	566	729	794						

KENTUCKY

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Bowling Green, KY MSA.....	462	552	671	894	1054	Edmonson, Warren
Cincinnati-Middletown, OH-KY-IN HMA.....	473	560	726	972	1009	Boone, Bracken, Campbell, Gallatin, Kenton, Pendleton
Clarksville, TN-KY HMA.....	550	572	664	960	988	Christians, Trigg
Elizabethtown, KY MSA.....	426	475	573	815	1003	Hardin, Larue
Evansville, IN-KY HMA.....	435	508	632	780	848	Henderson, Webster
Grant County, KY HMA.....	448	541	688	847	949	Grant

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

KENTUCKY continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Huntington-Ashland, WV-KY-OH MSA.....	414	490	588	725	749	Boyd, Greenup
Lexington-Fayette, KY MSA.....	492	591	729	980	1010	Bourbon, Clark, Fayette, Jessamine, Scott, Woodford
Louisville, KY-IN HMFA.....	499	577	684	956	1015	Bullitt, Henry, Jefferson, Oldham, Spencer, Trimble
Meade County, KY HMFA.....	475	476	570	731	820	Meade
Nelson County, KY HMFA.....	406	490	593	864	935	Nelson
Owensboro, KY MSA.....	415	461	607	842	892	Daviess, Hancock, McLean
Shelby County, KY HMFA.....	567	568	686	903	930	Shelby

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Adair.....	384	426	507	618	690	Allen.....	332	431	507	677	876
Anderson.....	489	522	690	998	1190	Ballard.....	415	459	566	725	817
Barren.....	349	409	530	661	728	Bath.....	396	429	530	662	684
Bell.....	333	455	507	605	742	Boyle.....	425	470	618	740	764
Breathitt.....	421	442	507	630	659	Breckinridge.....	414	416	535	715	737

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Butler.....	454	538	655	861	887	Caldwell.....	421	422	507	642	729
Calloway.....	504	505	607	748	1066	Carlisle.....	415	459	566	725	817
Carroll.....	499	500	621	821	892	Carter.....	330	440	510	607	687
Casey.....	384	426	507	618	690	Clay.....	329	455	507	605	623
Clinton.....	384	426	507	618	690	Crittenden.....	421	422	507	662	752

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Cumberland.....	384	426	507	618	690	Elliott.....	443	444	535	680	804
Estill.....	421	422	507	648	854	Fleming.....	396	429	530	662	684
Floyd.....	384	430	507	665	767	Franklin.....	500	530	698	946	973
Fulton.....	415	459	566	725	817	Garrard.....	428	478	574	685	1005
Graves.....	407	409	507	605	738	Grayson.....	422	423	507	661	776

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Green.....	382	423	507	613	684	Harlan.....	420	452	507	624	788
Harrison.....	436	438	573	751	776	Hart.....	377	412	507	647	753
Hickman.....	415	459	566	725	817	Hopkins.....	420	421	507	636	889
Jackson.....	420	442	507	613	631	Johnson.....	331	431	507	692	711
Knott.....	421	442	507	634	659	Knox.....	332	401	507	715	739

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Laurel.....	421	456	507	623	851	Lawrence.....	329	384	507	677	698
Lee.....	421	442	507	634	659	Leslie.....	421	442	507	634	659
Letcher.....	421	442	507	630	659	Lewis.....	396	429	530	662	684
Lincoln.....	366	501	555	664	878	Livingston.....	420	421	507	652	741
Logan.....	449	487	542	742	822	Lyon.....	494	502	596	773	801

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
McCracken.....	380	478	587	787	811	McCreary.....	421	455	507	654	671
Madison.....	436	462	592	835	979	Magoffin.....	421	425	507	624	652
Marion.....	414	416	535	715	737	Marshall.....	454	456	549	715	931
Martin.....	421	425	507	624	652	Mason.....	342	437	528	770	884

Menifee.....	396	429	530	662	684	Mercer.....	462	492	558	735	865
Metcalfe.....	377	412	507	647	753	Monroe.....	377	412	507	647	753
Montgomery.....	407	475	626	747	770	Morgan.....	396	429	530	662	684
Muhlenberg.....	418	419	507	644	661	Nicholas.....	520	520	681	834	919
Ohio.....	419	445	507	672	738	Owen.....	554	632	722	972	1266

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

KENTUCKY continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Owsley.....	421	442	507	634	659	Perry.....	421	443	507
Pike.....	430	431	519	623	641	Powell.....	384	485	593
Pulaski.....	360	399	507	626	663	Robertson.....	396	429	530
Rockcastle.....	420	442	507	613	631	Rowan.....	446	494	550
Russell.....	384	426	507	618	690	Simpson.....	454	533	701
Taylor.....	334	456	507	654	858	Todd.....	494	502	596
Union.....	447	448	540	657	691	Washington.....	414	416	535
Wayne.....	332	405	507	657	677	Whitley.....	387	408	537
Wolfe.....	421	442	507	634	659				
LOUISIANA									
METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Alexandria, LA MSA.....					478	517	616	801	824
Baton Rouge, LA HMFA.....					630	686	792	1010	1110
Livingston, Louisiana									
Feliciania									
Houma-Bayou Cane-Thibodaux, LA MSA.....					530	534	663	871	993
Iberville Parish, LA HMFA.....					470	471	567	768	791
Lafayette, LA MSA.....					553	634	703	902	1144
Lake Charles, LA MSA.....					517	583	709	875	1232
Monroe, LA MSA.....					470	532	661	877	905
New Orleans-Metairie-Kenner, LA MSA.....					758	840	982	1261	1303
Charles,									
Shreveport-Bossier City, LA MSA.....					535	615	719	912	941
St. John the Baptist, St. Tammany									
Caddo, De Soto									
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Acadia.....	441	441	537	679	779	Allen.....	445	447	537
Assumption.....	505	506	608	742	762	Avoyelles.....	347	473	537
Beauregard.....	459	471	554	807	971	Bienville.....	495	504	596
Caldwell.....	424	453	537	679	758	Catahoula.....	407	439	537
Claiborne.....	495	504	596	712	780	Concordia.....	407	439	537
East Carroll.....	424	453	537	679	758	Evangeline.....	444	446	537
Franklin.....	424	453	537	679	758	Iberia.....	510	523	617
Jackson.....	424	453	537	679	758	Jefferson Davis.....	446	447	537
La Salle.....	407	439	537	680	823	Lincoln.....	530	547	637
Madison.....	424	453	537	679	758	Morehouse.....	457	459	571

Natchitoches.....	518	519	622	745	962	Red River.....	495	504	596	712	780
Richland.....	424	453	537	679	758	Sabine.....	495	504	596	712	780
St. James.....	515	601	737	904	932	St. Landry.....	351	420	537	725	771
St. Mary.....	489	498	598	782	807	Tangipahoa.....	466	542	682	817	970
Tensas.....	424	453	537	679	758	Vermillion.....	447	448	537	736	761
Vernon.....	440	484	537	780	931	Washington.....	446	450	537	715	737
Webster.....	433	434	549	740	764	West Carroll.....	424	453	537	679	758
Winn.....	446	483	537	677	721						

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MAINE

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
Bangor, ME HMFA.....	542	632	806	1024	1157	Penobscot County towns of Bangor city, Brewer city, Eddington town, Glenburn town, Hampden town, Hermon
town,						Holden town, Kenduskeag town, Milford town, Old Town
city,						Orono town, Orrington town,
Cumberland County, ME (part) HMFA.....	591	705	909	1085	1391	Penobscot Indian Island Reservation, Veazie town Cumberland County towns of Baldwin town, Bridgton
town,						Brunswick town, Harpswell town, Harrison town,
Naples town,						New Gloucester town, Pownal town, Sebago town
Lewiston-Auburn, ME MSA.....	447	560	684	867	960	Androscoggin County towns of Auburn city, Durham
town,						Greene town, Leeds town, Lewiston city, Lisbon town, Livermore town, Livermore Falls town, Mechanic Falls
town,						Minot town, Poland town, Sabattus town, Turner town, Wales town
Penobscot County, ME (part) HMFA.....	554	555	667	834	1023	Penobscot County towns of Alton town, Argyle UT, Bradford town, Bradley town, Burlington town, Carmel
town,						Carroll plantation, Charleston town, Chester town, Clifton town, Corinna town, Corinth town, Dexter
town,						Dixmont town, Drew plantation, East Central
Penobscot UT,						East Millinocket town, Edinburg town, Enfield town, Etna town, Exeter town, Garland town, Greenbush
town,						Howland town, Hudson town, Kingman UT, Lagrange
town,						Lakeville town, Lee town, Levant town, Lincoln town, Lowell town, Mattawamkeag town, Maxfield town,
Medway town,						Millinocket town, Mount Chase town, Newburgh town, Newport town, North Penobscot UT, Passadumkeag town, Patten town, Plymouth town, Prentiss UT, Sebobeis
plantation,						Springfield town, Stacyville town, Stetson town,
Twombly UT,						Webster plantation, Whitney UT, Winn town, Woodville
town						

Portland, ME HMFA.....	721	856	1109	1397	1497	Cumberland County towns of Cape Elizabeth town, Casco town,
Island town,						Cumberland town, Falmouth town, Freeport town, Frye Island town, Gorham town, Gray town, Long North Yarmouth town, Portland city, Raymond town, Scarborough town, South Portland city, Standish town,
town,						Westbrook city, Windham town, Yarmouth town York County towns of Buxton town, Hollis town, Limington town, Old Orchard Beach town
Sagadahoc County, ME HMFA.....	714	715	857	1034	1484	Sagadahoc County towns of Arrowsic town, Bath city, Bowdoin town, Bowdoinham town, Georgetown town,
Perkins UT,						Phippsburg town, Richmond town, Topsham town, West Bath town,
York County, ME (part) HMFA.....	653	678	862	1031	1126	Woolwich town York County towns of Acton town, Alfred town, Arundel town,
town,						Biddeford city, Cornish town, Dayton town, Kennebunk town,
Lyman town,						Kennebunkport town, Lebanon town, Limerick town, Newfield town, North Berwick town, Ogunquit town, Parsonsfield town, Saco city, Sanford town,
Shapleigh town,						Waterboro town, Wells town
York-Kittery-South Berwick, ME HMFA.....	838	843	1011	1472	1604	York County towns of Berwick town, Eliot town, Kittery town,
						South Berwick town, York town

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MAINE continued

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	Towns within nonmetropolitan counties
Aroostook County, ME.....	422	520	623	813	896	Allagash town, Amity town, Ashland town, Bancroft town, Blaine town, Bridgewater town, Caribou city, Cary plantation, Castle Hill town, Caswell town, Central Aroostook UT, Chapman town, Connor UT, Crystal town, Cyr plantation, Dyer Brook town, Eagle Lake town, Easton town, Fort Fairfield town, Fort Kent town, Frenchville town, Garfield plantation, Glenwood plantation, Grand Isle town, Hamlin town, Hammond town, Haynesville town, Hersey town, Hodgdon town, Houlton town, Island Falls town, Limestone town, Linneus town, Littleton town, Ludlow town, Macwahoc plantation, Madawaska town, Mapleton town, Mars Hill town, Masardis town, Merrill town, Moro plantation, Nashville plantation, New Canada town, New Limerick town, New Sweden town, Northwest Aroostook UT, Oakfield town, Orient town, Oxbow plantation, Penobscot Indian Island Reservation, Perham town, Portage Lake town, Presque Isle city, Reed plantation, St. Agatha town, St. Francis town, St. John Sherman town, Smyrna town, South Aroostook UT, Square Lake UT, Stockholm town, Van Buren town, Wade town, Wallagrass town, Washburn town, Westfield town, Westmanland town, Weston town, Winterville plantation, Woodland town
Franklin County, ME.....	523	564	687	820	1065	Avon town, Carrabassett Valley town, Carthage town, Chesterville town, Coplin plantation, Dallas plantation, East Central Franklin UT, Eustis town, Farmington town, Industry town, Jay town, Kingfield town, Madrid town,

UT,						New Sharon town, New Vineyard town, North Franklin
town,						Phillips town, Rangeley town, Rangeley plantation,
						Sandy River plantation, South Franklin UT, Strong
						Temple town, Weld town, West Central Franklin UT,
						Wilton town, Wyman UT
Hancock County, ME.....	571	658	766	1079	1110	Amherst town, Aurora town, Bar Harbor town, Blue Hill
town,						Brooklin town, Brooksville town, Bucksport town,
						Castine town, Central Hancock UT, Cranberry Isles
town,						Dedham town, Deer Isle town, Eastbrook town, East
Hancock UT,						Ellsworth city, Franklin town, Frenchboro town,
						Gouldsboro town, Great Pond town, Hancock town,
Lamoine town,						Mariaville town, Mount Desert town, Northwest Hancock
UT,						Orland town, Osborn town, Otis town, Penobscot town,
						Sedgwick town, Sorrento town, Southwest Harbor town,
						Stonington town, Sullivan town, Surry town,
						Swans Island town, Tremont town, Trenton town, Verona
town,						Waltham town, Winter Harbor town
Kennebec County, ME.....	452	542	675	921	984	Albion town, Augusta city, Belgrade town, Benton
town,						Chelsea town, China town, Clinton town, Farmingdale
town,						Fayette town, Gardiner city, Hallowell city.
Litchfield town,						Manchester town, Monmouth town, Mount Vernon town,
town,						Oakland town, Pittston town, Randolph town, Readfield

MAINE continued

NONMETROPOLITAN COUNTIES

Towns within nonmetropolitan counties

Rome town, Sidney town, Unity UT, Vassalboro town, Vienna town, Waterville city, Wayne town, West Windsor town, Winslow town, Winthrop town	517	683	780	1056	1218	Appleton town, Camden town, Criehaven UT, Cushing Friendship town, Hope town, Isle au Haut town, Matinicus Isle plantation, North Haven town, Owls Rockland city, Rockport town, St. George town, South Thomaston town, Thomaston town, Union town, Vinalhaven town, Warren town, Washington town
Alna town, Boothbay town, Boothbay Harbor town, Bristol town, Damariscotta town, Dresden town, Hibberts gore, Jefferson town, Monhegan plantation, Newcastle town, Nobleboro town, Somerville town, South Bristol town, Southport town, Waldoboro town, Westport town, Whitefield town, Wiscasset town	625	671	809	977	1007	Andover town, Bethel town, Brownfield town, Buckfield Byron town, Canton town, Denmark town, Dixfield town, Fryeburg town, Gilead town, Greenwood town, Hanover Hartford town, Hebron town, Hiram town, Lincoln Lovell town, Magalloway plantation, Mexico town, Newry town, North Oxford UT, Norway town, Otisfield Oxford town, Paris town, Peru town, Porter town, Roxbury town, Rumford town, South Oxford UT, Stoneham Stow town, Sumner town, Sweden town, Upton town, Waterford town, West Paris town, Woodstock town
Abbot town, Atkinson town, Beaver Cove town, Bowerbank town, Brownville town, Dover-Foxcroft town, Greenville town, Guilford town, Kingsbury plantation, Lake View plantation, Medford town, Milo town, Monson Northeast Piscataquis UT, Northwest Piscataquis UT,	542	618	765	971	1039	Abbot town, Atkinson town, Beaver Cove town, Bowerbank town, Brownville town, Dover-Foxcroft town, Greenville town, Guilford town, Kingsbury plantation, Lake View plantation, Medford town, Milo town, Monson Northeast Piscataquis UT, Northwest Piscataquis UT,

town,						Parkman town, Sangerville town, Sebec town, Shirley town,
Willimantic town						Southeast Piscataquis UT, Wellington town,
Somerset County, ME.....	435	539	639	902	957	Anson town, Athens town, Bingham town, Brighton plantation,
plantation,						Cambridge town, Canaan town, Caratunk town, Central Somerset UT, Cornville town, Dennistown
plantation,						Detroit town, Embden town, Fairfield town, Harmony town,
town,						Hartland town, Highland plantation, Jackman town, Madison town, Mercer town, Moose River town, Moscow
town,						New Portland town, Norridgewock town, Northeast
Somerset UT,						Northwest Somerset UT, Palmyra town, Pittsfield town, Pleasant Ridge plantation, Ripley town, St. Albans
town,						Seboomook Lake UT, Skowhegan town, Smithfield town, Solon town, Starks town, The Forks plantation, West Forks plantation
Waldo County, ME.....	608	652	787	965	1026	Belfast city, Belmont town, Brooks town, Burnham town,
town,						Frankfort town, Freedom town, Islesboro town, Jackson
town,						Knox town, Liberty town, Lincolnville town, Monroe
town,						Montville town, Morrill town, Northport town, Palermo
town,						Prospect town, Searsmont town, Searsport town,

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MAINE continued

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	
Towns within nonmetropolitan counties						

town,						Stockton Springs town, Swanville town, Thorndike
Washington County, ME.....	523	565	674	835	911	Troy town, Unity town, Waldo town, Winterport town
Calais city,						Addison town, Alexander town, Baileyville town, Baring plantation, Beals town, Beddington town, Centerville town, Charlotte town, Cherryfield town, Codyville plantation, Columbia town, Columbia Falls
town,						Cooper town, Crawford town, Cutler town, Danforth
town,						Deblois town, Dennysville town, East Central
Washington UT,						East Machias town, Eastport city, Grand Lake Stream plantation, Harrington town, Jonesboro town, Jonesport town, Lubec town, Machias
town,						Machiasport town, Marshfield town, Meddybemps town, Milbridge town, Northfield town, North Washington UT, Passamaquoddy Indian Township Reservation, Passamaquoddy Pleasant Point Reservation, Pembroke
town,						Perry town, Princeton town, Robbinston town, Roque Bluffs town, Steuben town, Talmadge town, Topsfield town, Vanceboro town, Waite town, Wesley
town,						Whiting town, Whitneyville town

MARYLAND

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	
Counties of FMR AREA within STATE						

*Baltimore-Towson, MD HMFA.....	887	1002	1203	1545	1908	Anne Arundel, Baltimore, Carroll, Harford, Howard, Queen Anne's, Baltimore city
Columbia city, MD HMFA.....	1287	1339	1553	2111	2458	Columbia city
Cumberland, MD-WV MSA.....	414	501	588	793	926	Allegany
Hagerstown, MD HMFA.....	539	619	791	1141	1178	Washington
*Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA..	803	915	1095	1339	1615	Cecil
Salisbury, MD HMFA.....	573	712	837	1037	1189	Wicomico
Somerset County, MD HMFA.....	565	601	708	877	1151	Somerset
Washington-Arlington-Alexandria, DC-VA-MD HMFA....	1061	1198	1364	1745	2285	Calvert, Charles, Frederick, Montgomery, Prince George's

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0	BR	1	BR	2	BR	3	BR	4	BR
Caroline.....	642	663	776	1049	1078	Dorchester.....	483	580	739
Garrett.....	403	499	620	800	1060	Kent.....	722	723	870
St. Mary's.....	812	842	1097	1441	1898	Talbot.....	751	753	906
Worcester.....	689	716	830	1212	1290				
MASSACHUSETTS									
METROPOLITAN FMR AREAS					Components of FMR AREA within STATE				
Barnstable Town, MA MSA.....					779	913	1201	1433	1478
Bourne town,					Barnstable County towns of Barnstable Town city,				
town,					Brewster town, Chatham town, Dennis town, Eastham				
town,					Falmouth town, Harwich town, Mashpee town, Orleans				
Wellfleet town,					Provincetown town, Sandwich town, Truro town,				

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MASSACHUSETTS continued

METROPOLITAN FMR AREAS

0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
					Yarmouth town
Berkshire County, MA (part) HMFA.....	618	694	801	1097	1128
					Berkshire County towns of Alford town, Becket town, Clarkburg town, Egremont town, Florida town, Great Barrington town, Hancock town, Monterey town, Mount Washington town, New Ashford town, New Marlborough town, North Adams city, Otis town, Sandisfield town, Savoy town, Sheffield town, Washington town, West Stockbridge town, Williamstown
Peru town,					
Tyringham town,					
town,					Windsor town
Boston-Cambridge-Quincy, MA-NH HMFA.....	1090	1156	1357	1623	1783
town,					Essex County towns of Amesbury town, Beverly city, Danvers town, Essex town, Gloucester city, Hamilton Ipswich town, Lynn city, Lynnfield town, Manchester-by-the-Sea town, Marblehead town, Nahant town, Newbury town, Newburyport city, Peabody Rockport town, Rowley town, Salem city, Salisbury Saugus town, Swampscott town, Topsfield town, Wenham Middlesex County towns of Acton town, Arlington town, Ashby town, Ashland town, Ayer town, Bedford town, Belmont town, Boxborough town, Burlington town, Cambridge city, Carlisle town, Concord town, Everett Framingham town, Holliston town, Hopkinton town, Lexington town, Lincoln town, Littleton town, Malden Marlborough city, Maynard town, Medford city, Natick town, Newton city, North Reading town, Sherborn town, Shirley town, Somerville city, Stow town, Sudbury town, Townsend town, Wakefield Waltham city, Watertown city, Wayland town, Weston Wilmington town, Winchester town, Woburn city
Middleton town,					
city,					
town,					
town					
city,					
Hudson town,					
city,					
Melrose city,					
Reading town,					
Stoneham town,					
town,					
town,					

town,	Norfolk County towns of Bellingham town, Braintree			
town,	Brookline town, Canton town, Cohasset town, Dedham			
town,	Dover town, Foxborough town, Franklin city, Holbrook			
town,	Medfield town, Medway town, Millis town, Milton			
town,	Needham town, Norfolk town, Norwood town, Plainville			
town,	Quincy city, Randolph town, Sharon town, Stoughton			
town,	Walpole town, Wellesley town, Westwood town,			
Weymouth town,	Wrentham town			
	Plymouth County towns of Carver town, Duxbury town,			
town,	Hanover town, Hingham town, Hull town, Kingston			
Plymouth town,	Marshfield town, Norwell town, Pembroke town,			
	Rockland town, Scituate town, Wareham town			
	Suffolk County towns of Boston city, Chelsea city,			
	Revere city, Winthrop town			
Brockton, MA HMFA.....	974	1014	1277	1527 1914
town,	Norfolk County towns of Avon town			
	Plymouth County towns of Abington town, Bridgewater			
	Brockton city, East Bridgewater town, Halifax town,			
Mattapoisett town,	Hanson town, Lakeville town, Marion town,			
	Middleborough town, Plympton town, Rochester town,			
	West Bridgewater town, Whitman town			
Eastern Worcester County, MA HMFA.....	725	810	1066	1274 1871
town,	Worcester County towns of Berlin town, Blackstone			
town,	Bolton town, Harvard town, Hopedale town, Lancaster			

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MASSACHUSETTS continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
Southborough town,						Mendon town, Milford town, Millville town,
Easton-Raynham, MA HMFA.....	848	1124	1307	1563	2260	Upton town
Fitchburg-Leominster, MA HMFA.....	706	811	1017	1245	1353	Bristol County towns of Easton town, Raynham town
city,						Worcester County towns of Ashburnham town, Fitchburg
Franklin County, MA (part) HMFA.....	623	726	900	1201	1450	Gardner city, Leominster city, Lunenburg town,
town,						Templeton town, Westminster town, Winchendon town
town,						Franklin County towns of Ashfield town, Bernardston
town,						Buckland town, Charlemont town, Colrain town, Conway
Northfield town,						Deerfield town, Erving town, Gill town, Greenfield
town,						Hawley town, Heath town, Leverett town, Leyden town,
						Monroe town, Montague town, New Salem town,
						Orange town, Rowe town, Shelburne town, Shutesbury
Lawrence, MA-NH HMFA.....	761	968	1171	1398	1442	Warwick town, Wendell town, Whately town
						Essex County towns of Andover town, Boxford town,
						Georgetown town, Groveland town, Haverhill city,
						Lawrence city, Merrimac town, Methuen city,
						North Andover town, West Newbury town
Lowell, MA HMFA.....	843	1009	1297	1549	1699	Middlesex County towns of Billerica town, Chelmsford
town,						Dracut town, Dunstable town, Groton town, Lowell
city,						Pepperell town, Tewksbury town, Tyngsborough town,
						Westford town
New Bedford, MA HMFA.....	587	753	861	1031	1391	Bristol County towns of Acushnet town, Dartmouth
town,						Fairhaven town, Freetown town, New Bedford city
Pittsfield, MA HMFA.....	583	681	845	1086	1119	Berkshire County towns of Adams town, Cheshire town,
town,						Dalton town, Hinsdale town, Lanesborough town, Lee
						Lenox town, Pittsfield city, Richmond town,
Stockbridge town						
Providence-Fall River, RI-MA HMFA.....	751	836	963	1151	1419	Bristol County towns of Attleboro city, Fall River
city,						North Attleborough town, Rehoboth town, Seekonk
town,						
Springfield, MA HMFA.....	610	726	922	1104	1281	Somerset town, Swansea town, Westport town
						Franklin County towns of Sunderland town

town,							Hampden County towns of Agawam city, Blandford town, Brimfield town, Chester town, Chicopee city, East Longmeadow town, Granville town, Hampden town, Holland town, Holyoke city, Longmeadow town, Ludlow
town,							Monson town, Montgomery town, Palmer town, Russell
Wales town,							Southwick town, Springfield city, Tolland town,
town							Westfield city, West Springfield town, Wilbraham
town,							Hampshire County towns of Amherst town, Belchertown
city,							Chesterfield town, Cummington town, Easthampton
town,							Goshen town, Granby town, Hadley town, Hatfield
							Huntington town, Middlefield town, Northampton city, Pelham town, Plainfield town, Southampton town, South Hadley town, Ware town, Westhampton town, Williamsburg town, Worthington town
Taunton-Mansfield-Norton, MA HMFA.....	732	924	1128	1384	1493		Bristol County towns of Berkley town, Dighton town, Mansfield town, Norton town, Taunton city
Western Worcester County, MA HMFA.....	567	780	874	1043	1340		Worcester County towns of Athol town, Hardwick town, Hubbardston town, New Braintree town, Petersham
town,							Phillipston town, Royalston town, Warren town
Worcester, MA HMFA.....	708	814	991	1185	1257		Worcester County towns of Auburn town, Barre town,

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MASSACHUSETTS continued

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Components of FMR AREA within STATE

Clinton town,

Boylston town, Brookfield town, Charlton town,

town,

Douglas town, Dudley town, East Brookfield town,
Grafton town, Holden town, Leicester town, Milbury

Brookfield town,

Northborough town, Northbridge town, North

town,

Oakham town, Oxford town, Paxton town, Princeton

town,

Rutland town, Shrewsbury town, Southbridge town,
Spencer town, Sterling town, Sturbridge town, Sutton

city

Uxbridge town, Webster town, Westborough town,
West Boylston town, West Brookfield town, Worcester

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR Towns within nonmetropolitan counties

Dukes County, MA..... 936 1188 1414 1690 1742 Aquinnah town, Chilmark town, Edgartown town, Gosnold
town,Nantucket County, MA..... 1096 1516 1683 2013 2073 Oak Bluffs town, Tisbury town, West Tisbury town
Nantucket town

MICHIGAN

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Ann Arbor, MI MSA..... 649 728 886 1115 1147 Washtenaw

Barry County, MI HMFA..... 438 552 675 973 1071 Barry

Battle Creek, MI MSA..... 488 560 685 834 859 Calhoun

Bay City, MI MSA..... 450 504 612 817 841 Bay

Cass County, MI HMFA..... 479 548 606 803 933 Cass

Detroit-Warren-Livonia, MI HMFA..... 584 665 796 952 981 Lapeer, Macomb, Oakland, St. Clair, Wayne

Flint, MI MSA..... 525 554 665 824 850 Genesee

*Grand Rapids-Wyoming, MI HMFA..... 582 622 749 956 1001 Kent

Holland-Grand Haven, MI MSA..... 613 623 748 1035 1118 Ottawa

Ionia County, MI HMFA..... 467 541 660 790 880 Ionia

Jackson, MI MSA..... 509 568 678 843 868 Jackson

Kalamazoo-Portage, MI MSA..... 527 562 683 908 947 Kalamazoo, Van Buren

Lansing-East Lansing, MI MSA..... 565 614 760 963 1044 Clinton, Eaton, Ingham

Livingston County, MI HMFA..... 709 748 880 1269 1544 Livingston

Monroe, MI MSA..... 634 637 766 1000 1102 Monroe

Muskegon-Norton Shores, MI MSA..... 454 474 615 813 836 Muskegon

	0 BR	1 BR	2 BR	3 BR	4 BR		0 BR	1 BR	2 BR	3 BR	4 BR
Newaygo County, MI HMPA.....	515	544	621	840	864	Newaygo					
Niles-Benton Harbor, MI MSA.....	478	535	653	799	1025	Berrien					
Saginaw-Saginaw Township North, MI MSA.....	471	539	680	815	837	Saginaw					
NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Alcona.....	415	480	588	792	838	Alger.....	389	493	588	725	816
Allegan.....	487	587	704	882	946	Alpena.....	465	527	588	812	898
Antrim.....	506	507	612	851	1073	Arenac.....	467	493	588	787	871
Baraga.....	389	493	588	725	816	Benzie.....	626	627	760	949	977
Branch.....	486	518	682	818	841	Charlevoix.....	531	575	637	916	945
Cheboygan.....	410	476	588	790	830	Chippewa.....	386	480	593	719	805

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MICHIGAN continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Clare.....	431	447	588	792	816	Crawford.....	409	476	593	782	828
Delta.....	407	486	588	774	820	Dickinson.....	382	465	588	709	966
Emmet.....	445	548	683	921	974	Gladwin.....	467	493	588	787	871
Gogebic.....	406	485	588	719	855	Grand Traverse.....	641	642	805	1054	1087
Gratiot.....	490	492	588	784	876	Hillsdale.....	410	504	601	845	924
Houghton.....	418	489	588	764	876	Huron.....	489	492	588	780	947
Iosco.....	480	509	588	855	887	Iron.....	406	485	588	719	855
Isabella.....	488	527	588	846	924	Kalkaska.....	502	545	605	734	757
Keweenaw.....	406	485	588	719	855	Lake.....	450	492	588	770	926
Leelanau.....	626	627	760	949	977	Lenawee.....	445	558	685	874	954
Luce.....	406	496	588	771	841	Mackinac.....	386	480	594	716	781
Manistee.....	467	483	634	759	851	Marquette.....	381	495	588	740	804
Mason.....	382	449	588	770	846	Mecosta.....	427	508	615	817	1078
Menominee.....	489	490	588	776	1034	Midland.....	475	541	667	919	982
Missaukee.....	450	540	637	837	920	Montcalm.....	452	524	599	809	834
Montmorency.....	409	474	593	781	827	Oceana.....	426	493	588	711	759
Ogenaw.....	452	475	588	760	840	Ononagon.....	406	485	588	719	855
Osceola.....	488	489	588	805	1014	Oscoda.....	415	480	588	792	838
Otsego.....	478	559	735	881	926	Presque Isle.....	415	480	588	792	838
Roscommon.....	488	490	588	764	940	St. Joseph.....	483	538	635	784	879
Sanilac.....	490	528	588	828	851	Schoolcraft.....	406	496	588	771	841
Shiawassee.....	417	513	639	880	981	Tuscola.....	421	481	610	732	875
Wexford.....	408	540	629	832	917						
MINNESOTA											
METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE						
Duluth, MN-WI MSA.....					409	499	629	790	1006	Carlton, St. Louis	
Fargo, ND-MN MSA.....					416	494	628	906	1048	Clay	
Grand Forks, ND-MN MSA.....					403	506	621	787	1069	Polk	
La Crosse, WI-MN MSA.....					412	483	635	843	1035	Houston	
Mankato-North Mankato, MN MSA.....					504	587	682	951	1103	Blue Earth, Nicollet	
Minneapolis-St. Paul-Bloomington, MN-WI MSA.....					628	741	899	1177	1322	Anoka, Carver, Chisago, Hennepin, Isanti, Ramsey,	
Rochester, MN HMFA.....					610	651	855	1109	1158	Scott, Sherburne, Washington, Wright	
St. Cloud, MN MSA.....					502	553	662	936	1087	Dodge, Olmsted	
Wabasha County, MN HMFA.....					418	465	596	746	1047	Benton, Stearns	
										Wabasha	

MINNESOTA

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0	BR	1	BR	2	BR	3	BR	4	BR
Aitkin.....	421	495	650	811	878	Becker.....	381	452	588
Beltrami.....	408	482	613	843	1076	Big Stone.....	381	464	588
Brown.....	435	495	594	711	731	Cass.....	382	488	588
Chippewa.....	450	490	588	703	726	Clearwater.....	411	464	588
Cook.....	382	485	588	737	759	Cottonwood.....	430	470	588

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MINNESOTA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Crow Wing.....	435	509	671	861	1007	Douglas.....	415	494	621	900	984
Faribault.....	430	470	588	750	784	Fillmore.....	404	487	607	792	994
Freeborn.....	382	447	588	701	924	Goodhue.....	470	551	724	922	997
Grant.....	381	464	588	751	777	Hubbard.....	411	464	588	742	1031
Itasca.....	398	492	613	742	870	Jackson.....	430	470	588	750	784
Kanabec.....	452	530	696	869	939	Kandiyohi.....	473	485	602	811	836
Kitson.....	387	463	588	749	877	Koochiching.....	382	488	588	741	763
Lac qui Parle.....	450	490	588	703	726	Lake.....	382	485	588	737	759
Lake of the Woods.....	411	464	588	742	1031	Le Sueur.....	522	539	649	903	932
Lincoln.....	450	490	588	703	726	Lyon.....	448	503	619	772	794
McLeod.....	546	547	678	971	1002	Mahnomen.....	411	464	588	742	1031
Marshall.....	387	463	588	749	877	Martin.....	487	489	588	854	880
Meeker.....	471	522	606	792	814	Mille Lacs.....	487	501	660	818	908
Morrison.....	393	468	605	724	1062	Mower.....	393	461	588	730	753
Murray.....	430	470	588	750	784	Nobles.....	387	485	588	780	804
Norman.....	387	463	588	749	877	Otter Tail.....	383	456	588	717	739
Pennington.....	384	452	588	743	811	Pine.....	471	511	660	862	890
Pipestone.....	430	470	588	750	784	Pope.....	381	464	588	751	777
Red Lake.....	387	463	588	749	877	Redwood.....	450	490	588	703	726
Renville.....	471	491	606	792	814	Rice.....	572	597	786	939	1092
Rock.....	430	470	588	750	784	Roseau.....	382	453	588	733	858
Sibley.....	471	491	606	792	814	Steele.....	457	555	701	882	1150
Stevens.....	382	480	588	709	957	Swift.....	381	464	588	751	777
Todd.....	424	477	589	711	945	Traverse.....	381	464	588	751	777
Wadena.....	424	477	589	711	945	Waseca.....	421	495	650	777	813
Watonwan.....	430	470	588	750	784	Wilkin.....	381	464	588	751	777
Winona.....	429	507	661	914	1159	Yellow Medicine.....	450	490	588	703	726
MISSISSIPPI											
METROPOLITAN FMR AREAS											
					0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	
Gulfport-Biloxi, MS MSA.....					686	727	849	1106	1137	Hancock, Harrison, Stone	
Hattiesburg, MS MSA.....					463	528	628	914	944	Forrest, Lamar, Perry	
Jackson, MS HMFA.....					601	679	788	948	977	Copiah, Hinds, Madison, Rankin	
Marshall County, MS HMFA.....					368	460	568	829	855	Marshall	
Memphis, TN-MS-AR HMFA.....					648	705	783	1043	1076	DeSoto	
Pascagoula, MS MSA.....					588	673	808	1113	1193	George, Jackson	
Simpson County, MS HMFA.....					469	496	567	679	981	Simpson	

MISSISSIPPI

METROPOLITAN FMR AREAS

0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
686	727	849	1106	1137	Hancock, Harrison, Stone
463	528	628	914	944	Forrest, Lamar, Perry
601	679	788	948	977	Copiah, Hinds, Madison, Rankin
368	460	568	829	855	Marshall
648	705	783	1043	1076	DeSoto
588	673	808	1113	1193	George, Jackson
469	496	567	679	981	Simpson

Tate County, MS HMFA.....	468	542	603	845	1059	Tate
Tunica County, MS HMFA.....	513	617	790	949	1164	Tunica

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MISSISSIPPI continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Adams.....	372	515	572	686	982	Alcorn.....	448	483	539	749	948
Amite.....	431	484	539	652	741	Attala.....	442	455	539	722	904
Benton.....	491	549	609	731	750	Bolivar.....	440	497	572	686	1006
Calhoun.....	442	455	539	722	904	Carroll.....	364	408	539	715	749
Chickasaw.....	407	500	586	702	738	Choctaw.....	442	455	539	722	904
Claiborne.....	448	449	539	676	792	Clarke.....	449	499	573	750	776
Clay.....	447	448	539	785	810	Coahoma.....	459	475	626	748	1099
Covington.....	448	449	539	676	792	Franklin.....	431	484	539	652	741
Greene.....	409	438	539	704	741	Grenada.....	420	461	539	759	903
Holmes.....	455	526	586	701	734	Humphreys.....	364	408	539	715	749
Issaquena.....	455	526	586	701	734	Itawamba.....	349	476	539	712	841
Jasper.....	424	458	539	648	689	Jefferson.....	448	449	539	676	792
Jefferson Davis.....	448	449	539	676	792	Jones.....	364	423	539	710	733
Kemper.....	449	499	573	750	776	Lafayette.....	483	571	704	843	868
Lauderdale.....	454	509	597	820	846	Lawrence.....	448	449	539	676	792
Leake.....	424	458	539	648	689	Lee.....	490	511	589	804	906
Leflore.....	350	410	539	716	842	Lincoln.....	393	485	539	739	946
Lowndes.....	472	484	567	824	849	Marion.....	424	481	539	708	805
Monroe.....	447	476	539	674	721	Montgomery.....	442	455	539	722	904
Neshoba.....	349	471	539	641	943	Newton.....	449	499	573	750	776
Noxubee.....	453	470	547	749	799	Oktibbeha.....	429	521	634	826	850
Panola.....	349	484	539	646	744	Pearl River.....	558	559	670	818	1153
Pike.....	447	485	539	709	731	Pontotoc.....	447	448	539	733	754
Prentiss.....	350	408	539	646	666	Quitman.....	440	471	555	665	834
Scott.....	448	476	539	645	695	Sharkey.....	455	526	586	701	734
Smith.....	424	458	539	648	689	Sunflower.....	391	481	539	768	792
Tallahatchie.....	364	408	539	715	749	Tippah.....	447	486	539	702	874
Tishomingo.....	350	455	539	677	700	Union.....	366	509	564	675	817
Walthall.....	431	484	539	652	741	Warren.....	548	602	672	803	827
Washington.....	372	485	572	742	908	Wayne.....	409	438	539	704	741
Webster.....	442	455	539	722	904	Wilkinson.....	431	484	539	652	741
Winston.....	407	500	586	702	738	Yalobusha.....	442	455	539	722	904
Yazoo.....	446	473	539	644	665						

MISSOURI

METROPOLITAN FMR AREAS

0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
------	------	------	------	------	-----------------------------------

Bates County, MO HMFA.....	366	430	562	789	815	Bates
Calloway County, MO HMFA.....	442	446	564	770	794	Callaway
Cape Girardeau-Jackson, MO-IL MSA.....	388	442	577	746	917	Bollinger, Cape Girardeau
Columbia, MO MSA.....	429	513	637	927	1034	Boone, Howard
Dallas County, MO HMFA.....	336	437	517	706	728	Dallas
Jefferson City, MO HMFA.....	398	438	569	806	896	Cole, Osage

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MISSOURI continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Joplin, MO MSA.....	374	449	572	728	749	Jasper, Newton
*Kansas City, MO-KS HMFA.....	605	726	834	1128	1187	Caldwell, Cass, Clay, Clinton, Jackson, Lafayette, Platte,
McDonald County, MO HMFA.....	416	417	522	743	767	Ray
Moniteau County, MO HMFA.....	341	399	526	636	848	Moniteau
Polk County, MO HMFA.....	343	401	527	768	881	Polk
Springfield, MO HMFA.....	404	477	610	869	993	Christian, Greene, Webster
St. Joseph, MO-KS MSA.....	376	464	577	726	861	Andrew, Buchanan, DeKalb
St. Louis, MO-IL HMFA.....	572	621	771	993	1039	Sullivan city part of Crawford, Franklin, Jefferson, Lincoln,
Washington County, MO HMFA.....	396	462	518	682	760	St. Charles, St. Louis, Warren, St. Louis city
NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES
Adair.....	375	435	574	754	833	Atchison.....
Audrain.....	428	430	517	652	829	Barry.....
Barton.....	336	424	517	626	687	Benton.....
Butler.....	428	429	517	717	766	Camden.....
Carroll.....	453	454	573	719	802	Carter.....
Cedar.....	336	400	517	717	743	Chariton.....
Clark.....	381	392	517	640	754	Cooper.....
Crawford.....	337	427	517	688	907	Dade.....
Daviess.....	415	416	517	644	797	Dent.....
Douglas.....	382	428	517	684	793	Dunklin.....
Gasconade.....	367	399	517	647	824	Gentry.....
Grundy.....	415	416	517	644	797	Harrison.....
Henry.....	375	435	574	689	709	Hickory.....
Holt.....	415	416	517	644	797	Howell.....
Iron.....	380	428	562	718	831	Johnson.....
Knox.....	381	392	517	640	754	Laclede.....
Lawrence.....	429	430	517	704	812	Lewis.....
Linn.....	381	392	517	640	754	Livingston.....
Macon.....	418	419	517	619	665	Madison.....
Maries.....	387	421	517	682	867	Marion.....
Mercer.....	415	416	517	644	797	Miller.....
Mississippi.....	362	394	517	682	787	Monroe.....
Montgomery.....	341	399	526	676	695	Morgan.....
New Madrid.....	368	423	517	690	710	Nodaway.....

Oregon.....	382	428	517	684	793	Ozark.....	382	428	517	684	793
Pemiscot.....	337	395	517	650	669	Perry.....	386	420	550	659	967
Pettis.....	453	454	588	733	878	Phelps.....	384	414	519	718	884
Pike.....	336	393	518	678	741	Pulaski.....	446	481	535	777	851
Putnam.....	381	392	517	640	754	Ralls.....	341	399	526	676	695
Randolph.....	350	412	539	683	703	Reynolds.....	429	430	517	719	772

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MISSOURI continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Ripley.....	429	430	517	719	772	St. Clair.....	336	400	517	717	743
Ste. Genevieve.....	380	428	562	718	831	St. Francois.....	449	452	543	758	789
Saline.....	345	404	531	689	808	Schuyler.....	381	392	517	640	754
Scotland.....	381	392	517	640	754	Scott.....	430	431	540	673	796
Shannon.....	382	428	517	684	793	Shelby.....	381	392	517	640	754
Stoddard.....	401	416	517	705	762	Stone.....	384	447	590	773	851
Sullivan.....	381	392	517	640	754	Taney.....	492	493	623	743	946
Texas.....	408	430	517	712	820	Vernon.....	361	429	519	727	749
Wayne.....	429	430	517	719	772	Worth.....	415	416	517	644	797
Wright.....	379	397	517	652	672						
MONTANA											
METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE						
Billings, MT MSA.....			420	499	645	870	1047	Carbon, Yellowstone			
Great Falls, MT MSA.....			383	461	591	799	962	Cascade			
Missoula, MT MSA.....			496	571	721	934	1118	Missoula			
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Beaverhead.....	464	540	710	919	1113	Big Horn.....	439	456	588	729	777
Blaine.....	389	464	588	784	895	Broadwater.....	414	475	603	815	876
Carter.....	477	495	588	793	843	Chouteau.....	389	464	588	784	895
Custer.....	383	532	588	856	886	Daniels.....	477	495	588	793	843
Dawson.....	477	495	588	793	843	Deer Lodge.....	414	475	603	815	876
Fallon.....	477	495	588	793	843	Fergus.....	429	447	588	712	759
Flathead.....	418	513	645	912	1118	Gallatin.....	472	562	731	976	1281
Garfield.....	477	495	588	793	843	Glacier.....	389	464	588	784	895
Golden Valley.....	477	495	588	793	843	Granite.....	414	475	603	815	876
Hill.....	382	471	588	848	900	Jefferson.....	414	475	603	815	876
Judith Basin.....	389	464	588	784	895	Lake.....	492	494	599	807	870
Lewis and Clark.....	445	509	636	923	953	Liberty.....	389	464	588	784	895
Lincoln.....	400	491	614	850	952	McCone.....	477	495	588	793	843
Madison.....	464	540	710	919	1113	Meagher.....	464	540	710	919	1113
Mineral.....	496	561	704	903	1080	Musselshell.....	477	495	588	793	843
Park.....	441	515	677	810	1070	Petroleum.....	477	495	588	793	843
Phillips.....	477	495	588	793	843	Pondera.....	389	464	588	784	895
Powder River.....	477	495	588	793	843	Powell.....	414	475	603	815	876
Prairie.....	477	495	588	793	843	Ravalli.....	470	512	657	861	1018

Richland.....	477	495	588	793	843	Roosevelt.....	477	495	588	793	843
Rosebud.....	437	454	588	726	773	Sanders.....	400	491	614	850	952
Sheridan.....	477	495	588	793	843	Silver Bow.....	425	457	588	769	841
Stillwater.....	477	495	588	793	843	Sweet Grass.....	477	495	588	793	843
Teton.....	389	464	588	784	895	Toole.....	389	464	588	784	895

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

MONTANA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Treasure.....	477	495	588	793	843	Valley.....	477	495	588	793	843
Wheatland.....	477	495	588	793	843	Wibaux.....	477	495	588	793	843

NEBRASKA

METROPOLITAN FMR AREAS

Lincoln, NE HMFA.....					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Omaha-Council Bluffs, NE-IA HMFA.....	456	512	652	915	1108	Lancaster			
Saunders County, NE HMFA.....	540	614	766	1023	1052	Cass, Douglas, Sarpy, Washington			
Seward County, NE HMFA.....	560	562	675	984	1014	Saunders			
Sioux City, IA-NE-SD MSA.....	357	441	551	732	929	Seward			
	429	504	661	832	857	Dakota, Dixon			

NONMETROPOLITAN COUNTIES

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Adams.....	383	448	589	745	767	Antelope.....	458	459	551	690	713
Arthur.....	416	480	551	727	750	Banner.....	412	418	551	715	857
Blaine.....	460	461	553	684	797	Boone.....	458	459	551	690	713
Box Butte.....	412	418	551	721	857	Boyd.....	412	418	551	715	857
Brown.....	412	418	551	715	857	Buffalo.....	414	485	638	868	1009
Burt.....	458	459	551	690	713	Butler.....	457	458	551	699	732
Cedar.....	458	459	551	690	713	Chase.....	416	480	551	727	750
Cherry.....	412	418	551	715	857	Cheyenne.....	412	418	551	715	857
Clay.....	387	454	597	764	887	Colfax.....	458	459	551	690	713
Cuming.....	458	459	551	690	713	Custer.....	460	461	553	684	797
Dawes.....	356	420	551	660	820	Dawson.....	475	515	574	699	720
Deuel.....	412	418	551	715	857	Dodge.....	437	512	673	804	981
Dundy.....	416	480	551	727	750	Fillmore.....	457	458	551	699	732
Franklin.....	387	454	597	764	887	Frontier.....	416	480	551	727	750
Furnas.....	416	480	551	727	750	Gage.....	458	459	551	672	693
Garden.....	412	418	551	715	857	Garfield.....	460	461	553	684	797
Gosper.....	416	480	551	727	750	Grant.....	416	480	551	727	750
Greeley.....	460	461	553	684	797	Hall.....	466	467	585	731	946
Hamilton.....	460	461	553	684	797	Harlan.....	387	454	597	764	887
Hayes.....	416	480	551	727	750	Hitchcock.....	416	480	551	727	750
Holt.....	412	418	551	715	857	Hooker.....	416	480	551	727	750
Howard.....	460	461	553	684	797	Jefferson.....	457	458	551	699	732
Johnson.....	457	458	551	699	732	Kearney.....	387	454	597	764	887
Keith.....	416	480	551	727	750	Keya Paha.....	412	418	551	715	857
Kimball.....	412	418	551	715	857	Knox.....	458	459	551	690	713

Lincoln.....	402	453	576	706	889	Logan.....	416	480	551	727	750
Loup.....	460	461	553	684	797	McPherson.....	416	480	551	727	750
Madison.....	407	430	565	770	794	Merrick.....	460	461	553	684	797
Morrill.....	412	418	551	715	857	Nance.....	458	459	551	690	713
Nemaha.....	457	458	551	699	732	Nuckolls.....	387	454	597	764	887

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NEBRASKA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0	BR	1	BR	2	BR	3	BR	4	BR
Otoe.....	457	460	551	551	683	716			
Perkins.....	416	480	551	551	727	750			
Pierce.....	458	459	551	551	690	713			
Polk.....	457	458	551	551	699	732			
Richardson.....	457	458	551	551	699	732			
Saline.....	486	513	586	513	716	740			
Sheridan.....	412	418	551	551	715	857			
Sioux.....	412	418	551	551	715	857			
Thayer.....	457	458	551	551	699	732			
Thurston.....	458	459	551	551	690	713			
Wayne.....	458	459	551	551	690	713			
Wheeler.....	460	461	553	553	684	797			

NEVADA

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Carson City, NV MSA.....	628	756	911	1327	1601	Carson
Las Vegas-Paradise, NV MSA.....	767	904	1063	1478	1778	Clark
Reno-Sparks, NV MSA.....	693	828	1024	1488	1798	Storey, Washoe

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR NONMETROPOLITAN COUNTIES

Churchill.....	677	679	853	1079	1268	Douglas.....	709	872	1060	1476	1636
Elko.....	610	664	861	1073	1381	Esmeralda.....	531	613	782	1038	1149
Eureka.....	531	613	782	1038	1149	Humboldt.....	536	628	824	986	1015
Lander.....	531	613	782	1038	1149	Lincoln.....	531	613	782	1038	1149
Lyon.....	561	631	830	1209	1246	Mineral.....	531	613	782	1038	1149
Nye.....	475	660	733	1068	1100	Pershing.....	531	613	782	1038	1149
White Pine.....	531	613	782	1038	1149						

NEW HAMPSHIRE

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Components of FMR AREA within STATE

Boston-Cambridge-Quincy, MA-NH HMA.....	1090	1156	1357	1623	1783	Rockingham County towns of Seabrook town, South Hampton town
Hillsborough County, NH (part) HMA.....	743	755	991	1444	1740	Hillsborough County towns of Antrim town, Bennington town,
						Deering town, Francestown town, Greenfield town, Hancock town, Hillsborough town, Lyndeborough town,

Temple town,									New Boston town, Peterborough town, Sharon town,
Lawrence, MA-NH HMFA.....	761	968	1171	1398	1442				Windsor town
town,									Rockingham County towns of Atkinson town, Chester
town,									Danville town, Derry town, Fremont town, Hampstead
town,									Kingston town, Newton town, Plaistow town, Raymond
Manchester, NH HMFA.....	716	879	1051	1256	1294				Salem town, Sandown town, Windham town
town,									Hillsborough County towns of Bedford town, Goffstown
									Manchester city, Weare town

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NEW HAMPSHIRE continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
Nashua, NH HMFA.....	792	932	1165	1558	1667	Hillsborough County towns of Amherst town, Brookline town,
Litchfield town,						Greenville town, Hollis town, Hudson town,
Vernon town,						Mason town, Merrimack town, Milford town, Mont
town						Nashua city, New Ipswich town, Pelham town, Wilton
Portsmouth-Rochester, NH HMFA.....	693	818	1020	1346	1519	Rockingham County towns of Brentwood town, East Kingston town, Epping town, Exeter town,
Greenland town,						Hampton town, Hampton Falls town, Kensington town, New Castle town, Newfields town, Newington town, Newmarket town, North Hampton town, Portsmouth city, Rye town, Stratham town
city,						Strafford County towns of Barrington town, Dover
town,						Durham town, Farmington town, Lee town, Madbury
Rochester city,						Middleton town, Milton town, New Durham town,
Western Rockingham County, NH HMFA.....	901	902	1085	1434	1479	Rollinsford town, Somersworth city, Strafford town
						Rockingham County towns of Auburn town, Candia town, Deerfield town, Londonderry town, Northwood town, Nottingham town

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	Towns within nonmetropolitan counties
Belknap County, NH.....	589	724	904	1193	1534	Alton town, Barnstead town, Belmont town, Center Harbor town,
town,						Gilford town, Gilmanton town, Laconia city, Meredith
Carroll County, NH.....	651	688	907	1234	1515	New Hampton town, Sanbornton town, Tilton town
town,						Albany town, Bartlett town, Brookfield town, Chatham
town,						Conway town, Eaton town, Effingham town, Freedom
Cheshire County, NH.....	722	771	966	1165	1418	Hale's location, Hart's location town, Jackson town, Madison town, Moultonborough town, Ossipee town, Sandwich town, Tamworth town, Tuftonboro town, Wakefield town, Wolfeboro town
						Alstead town, Chesterfield town, Dublin town, Fitzwilliam town, Gilsum town, Harrisville town,

town,						Hinsdale town, Jaffrey town, Keene city, Marlborough
town,						Marlow town, Nelson town, Richmond town, Rindge town, Roxbury town, Stoddard town, Sullivan town, Surry
town,						Swanzy town, Troy town, Walpole town, Westmoreland
Coos County, NH.....	423	553	650	912	1024	Winchester town Atkinson and Gilmanton Academy grant, Beans grant, Beans purchase, Berlin city, Cambridge township, Carroll town, Chandler's purchase, Clarksville town, Colebrook town, Columbia town, Crawford's purchase, Cutts grant, Dalton town, Dix's grant, Dixville
township,						Dummer town, Errol town, Ervings location, Gorham
town,						Greens grant, Hadleys purchase, Jefferson town, Kilkenny township, Lancaster town, Low and Burbanks
grant,						Martins location, Milan town, Millsfield township, Northumberland town, Odell township, Pinkhams grant, Pittsburg town, Randolph town, Sargent's purchase, Second College grant, Shelburne town, Stark town, Stewartstown town, Stratford town, Success township,

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NEW HAMPSHIRE continued

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR Towns within nonmetropolitan counties

Grafton County, NH.....	641	705	894	1202	1268	Thompson and Meserves purchase, Wentworth location, Whitefield town
town,						Alexandria town, Ashland town, Bath town, Benton
Campton town,						Bethlehem town, Bridgewater town, Bristol town,
town,						Canaan town, Dorchester town, Easton town, Ellsworth
town,						Enfield town, Franconia town, Grafton town, Groton
town,						Hanover town, Haverhill town, Hebron town, Holderness
town,						Landaff town, Lebanon city, Lincoln town, Lisbon
town,						Littleton town, Livermore town, Lyman town, Lyme
town,						Monroe town, Orange town, Orford town, Piermont town,
town,						Plymouth town, Rumney town, Sugar Hill town, Thornton
town,						Warren town, Waterville Valley town, Wentworth town,
Merrimack County, NH.....	643	761	993	1226	1572	Woodstock town
town,						Allenstown town, Andover town, Boscawen town, Bow
town,						Bradford town, Canterbury town, Chichester town,
town,						Concord city, Danbury town, Dunbarton town, Epsom
town,						Franklin city, Henniker town, Hill town, Hooksett
town,						Hopkinton town, Loudon town, Newbury town, New London
town,						Northfield town, Pembroke town, Pittsfield town,
Sullivan County, NH.....	544	659	840	1138	1230	Salisbury town, Sutton town, Warner town, Webster
Cornish town,						Wilnot town
town,						Acworth town, Charlestown town, Claremont city,
Washington town						Croydon town, Goshen town, Grantham town, Langdon
NEW JERSEY						Lempster town, Newport town, Plainfield town,
						Springfield town, Sunapee town, Unity town,

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Countries of FMR AREA within STATE
Atlantic City-Hamilton, NJ MSA.....	838	923	1101	1396	1566	Atlantic
Bergen-Passaic, NJ HMFA.....	1099	1230	1379	1703	1961	Bergen, Passaic
Jersey City, NJ HMFA.....	995	1052	1227	1487	1601	Hudson
Middlesex-Somerset-Hunterdon, NJ HMFA.....	1155	1198	1409	1768	2085	Hunterdon, Middlesex, Somerset
Monmouth-Ocean, NJ HMFA.....	901	1041	1271	1656	1797	Monmouth, Ocean
Newark, NJ HMFA.....	916	1119	1279	1531	1693	Essex, Morris, Sussex, Union
Ocean City, NJ MSA.....	741	756	951	1246	1283	Cape May
*Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA..	803	915	1095	1339	1615	Burlington, Camden, Gloucester, Salem
Trenton-Ewing, NJ MSA.....	873	1005	1208	1444	1620	Mercer
Vineland-Millville-Bridgeton, NJ MSA.....	802	805	1014	1232	1298	Cumberland
Warren County, NJ HMFA.....	796	891	1042	1247	1284	Warren

NEW MEXICO

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Countries of FMR AREA within STATE
*Albuquerque, NM MSA.....	526	619	782	1139	1365	Bernalillo, Sandoval, Torrance, Valencia
Farmington, NM MSA.....	496	525	632	836	942	San Juan
Las Cruces, NM MSA.....	479	517	576	795	882	Dona Ana

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NEW MEXICO continued

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS						Counties of FMR AREA within STATE								
Santa Fe, NM MSA.....						641	795	967	1266	1513	Santa Fe			
NONMETROPOLITAN COUNTIES						0 BR	1 BR	2 BR	3 BR	4 BR				
NONMETROPOLITAN COUNTIES						0 BR	1 BR	2 BR	3 BR	4 BR				
Catron.....	388	437	523	762	785				Chaves.....	418	420	536	701	723
Cibola.....	436	470	523	760	825				Colfax.....	463	494	556	702	730
Curry.....	435	451	523	708	920				De Baca.....	435	448	523	706	859
Eddy.....	349	445	523	702	852				Grant.....	419	486	552	778	800
Guadalupe.....	513	520	619	777	811				Harding.....	435	448	523	706	859
Hidalgo.....	388	437	523	762	785				Lea.....	433	471	523	688	724
Lincoln.....	409	515	627	789	1102				Los Alamos.....	651	759	996	1195	1231
Luna.....	434	471	523	667	801				Mckinley.....	413	485	638	762	988
Mora.....	513	520	619	777	811				Otero.....	400	473	523	765	920
Quay.....	435	448	523	706	859				Rio Arriba.....	467	475	562	727	807
Roosevelt.....	434	445	523	725	896				San Miguel.....	437	472	581	772	896
Sierra.....	339	422	523	764	919				Socorro.....	435	436	523	627	888
Taos.....	622	675	748	895	923				Union.....	435	448	523	706	859

NEW YORK

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS						Counties of FMR AREA within STATE					
0 BR	1 BR	2 BR	3 BR	4 BR							
					Albany-Schenectady-Troy, NY MSA.....	690	716	874	1046	1143	Albany, Rensselaer, Saratoga, Schenectady, Schoharie
					Binghamton, NY MSA.....	602	604	723	944	1107	Broome, Tioga
					Buffalo-Niagara Falls, NY MSA.....	605	606	728	901	994	Erie, Niagara
					Elmira, NY MSA.....	659	661	793	1019	1062	Chemung
					Glens Falls, NY MSA.....	626	662	833	1051	1184	Warren, Washington
					Ithaca, NY MSA.....	795	818	958	1159	1202	Tompkins
					Kingston, NY MSA.....	771	836	1001	1268	1576	Ulster
					Nassau-Suffolk, NY HMFA.....	1167	1348	1592	2113	2302	Nassau, Suffolk
					New York, NY HMFA.....	1129	1222	1359	1672	1880	Bronx, Kings, New York, Putnam, Queens, Richmond, Rockland
					Poughkeepsie-Newburgh-Middletown, NY MSA.....	784	922	1128	1383	1473	Dutchess, Orange
					Rochester, NY MSA.....	594	657	803	964	1021	Livingston, Monroe, Ontario, Orleans, Wayne
					Syracuse, NY MSA.....	628	630	759	972	1052	Madison, Onondaga, Oswego
					Utica-Rome, NY MSA.....	622	623	750	920	1044	Herkimer, Oneida
					Westchester County, NY Statutory Exception Area...	1169	1394	1621	1955	2410	Westchester

Chenango.....	586	590	707	891	1241	Clinton.....	662	665	797	1012	1316
Columbia.....	722	737	869	1050	1119	Cortland.....	630	631	771	980	1203
Delaware.....	593	596	715	884	1163	Essex.....	623	625	750	998	1085
Franklin.....	571	573	684	878	972	Fulton.....	489	597	755	904	960
Genesee.....	682	684	822	1019	1153	Greene.....	625	675	822	1069	1164
Hamilton.....	629	631	757	943	1093	Jefferson.....	650	651	783	1009	1060

NEW YORK continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Lewis.....	580	583	699	874	976	Montgomery.....				580	623	699	884	958
Otsego.....	614	629	739	982	1021	St. Lawrence.....				580	582	700	886	968
Schuyler.....	632	636	762	1016	1049	Seneca.....				670	671	805	1059	1340
Steuben.....	618	619	744	955	1054	Sullivan.....				638	707	907	1086	1272
Wyoming.....	599	616	723	1053	1149	Yates.....				616	624	741	960	988
NORTH CAROLINA														
METROPOLITAN FMR AREAS														
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE				
Anson County, NC HMFA.....			489	526	588	827	873	Anson						
Asheville, NC HMFA.....			521	608	694	930	1219	Buncombe, Henderson, Madison						
Burlington, NC MSA.....			635	657	766	1040	1072	Alamance						
Charlotte-Gastonia-Concord, NC-SC HMFA.....			670	726	806	1016	1182	Cabarrus, Gaston, Mecklenburg, Union						
Durham-Chapel Hill, NC HMFA.....			542	742	832	1087	1172	Chatham, Durham, Orange						
Fayetteville, NC HMFA.....			580	627	700	994	1176	Cumberland						
Goldsboro, NC MSA.....			448	531	622	779	1041	Wayne						
Greene County, NC HMFA.....			489	490	588	831	858	Greene						
Greensboro-High Point, NC HMFA.....			553	631	703	891	953	Gulford, Randolph						
Greenville, NC HMFA.....			517	536	661	916	946	Pitt						
Haywood County, NC HMFA.....			522	524	653	846	1094	Haywood						
Hickory-Lenoir-Morganton, NC MSA.....			524	551	633	812	946	Alexander, Burke, Caldwell, Catawba						
Hoke County, NC HMFA.....			537	583	646	884	1078	Hoke						
Jacksonville, NC MSA.....			530	568	638	896	1051	Onslow						
Pender County, NC HMFA.....			531	533	641	843	867	Pender						
Person County, NC HMFA.....			519	521	628	750	860	Person						
Raleigh-Cary, NC MSA.....			687	770	856	1076	1115	Franklin, Johnston, Wake						
Rockingham County, NC HMFA.....			481	509	603	749	772	Rockingham						
Rocky Mount, NC MSA.....			383	462	588	730	752	Edgecombe, Nash						
Virginia Beach-Norfolk-Newport News, VA-NC MSA.....			774	807	934	1277	1539	Currituck						
Wilmington, NC HMFA.....			610	673	813	1139	1172	Brunswick, New Hanover						
Winston-Salem, NC MSA.....			507	577	669	912	1072	Davie, Forsyth, Stokes, Yadkin						
NONMETROPOLITAN COUNTIES														
0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES									
Allegany.....	437	513	588	771	795	Ashe.....				487	489	588	777	919
Avery.....	458	565	668	799	943	Beaufort.....				383	499	588	708	728
Bertie.....	403	511	588	704	726	Bladen.....				382	464	588	857	916
Canden.....	440	573	677	914	937	Carteret.....				543	544	654	952	1147
Caswell.....	499	500	611	747	780	Cherokee.....				382	495	588	854	1030
Chowan.....	440	573	677	914	937	Clay.....				488	490	588	771	898
Cleveland.....	584	586	704	927	1041	Columbus.....				412	530	588	704	725

Craven.....	498	568	651	878	1096	Dare.....	673	827	1093	1125
Davidson.....	511	512	617	804	919	Duplin.....	488	588	744	767
Gates.....	440	573	677	914	937	Graham.....	488	490	588	898
Granville.....	549	550	661	825	981	Halifax.....	383	531	748	858
Harnett.....	507	551	611	825	1073	Hertford.....	383	527	771	793

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NORTH CAROLINA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Hyde.....	440	573	677	914	937	Iredell.....	599	604	722
Jackson.....	516	534	635	834	860	Jones.....	502	543	649
Lee.....	435	595	672	826	1179	Lenoir.....	447	449	590
Lincoln.....	415	574	638	771	792	McDowell.....	428	511	660
Macon.....	451	490	632	768	1109	Martin.....	489	518	588
Mitchell.....	458	565	668	799	943	Montgomery.....	487	529	588
Moore.....	547	548	690	992	1210	Northampton.....	384	518	588
Pamlico.....	393	500	588	740	761	Pasquotank.....	436	563	669
Perquimans.....	440	573	677	914	937	Polk.....	551	553	678
Richmond.....	423	530	588	739	762	Robeson.....	419	507	588
Rowan.....	565	612	679	969	1035	Rutherford.....	539	542	662
Sampson.....	489	499	588	817	1035	Scotland.....	492	493	625
Stanly.....	463	500	611	832	906	Surry.....	439	529	588
Swain.....	488	490	588	771	898	Transylvania.....	502	698	773
Tyrrell.....	440	573	677	914	937	Vance.....	492	493	593
Warren.....	505	506	607	742	763	Washington.....	415	560	638
Watauga.....	495	604	760	924	1193	Wilkes.....	430	493	588
Wilson.....	561	562	682	816	865	Yancey.....	487	489	588

NORTH DAKOTA

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Bismarck, ND MSA.....	434	454	565	818	841	Burleigh, Morton	429	432	518	725	910
Fargo, ND-MN MSA.....	416	494	628	906	1048	Cass	363	422	518	686	717
Grand Forks, ND-MN MSA.....	403	506	621	787	1069	Grand Forks	363	422	518	686	717
NONMETROPOLITAN COUNTIES											
Adams.....	363	422	518	686	717	Barnes.....	429	432	518	725	910
Benson.....	424	426	518	714	901	Billings.....	363	422	518	686	717
Bottineau.....	395	433	539	759	827	Bowman.....	363	422	518	686	717
Burke.....	395	433	539	759	827	Cavalier.....	424	426	518	714	901
Dickey.....	424	426	518	714	901	Divide.....	363	422	518	686	717
Dunn.....	363	422	518	686	717	Eddy.....	424	426	518	714	901
Emmons.....	395	433	539	759	827	Foster.....	424	426	518	714	901
Golden Valley.....	363	422	518	686	717	Grant.....	363	422	518	686	717
Griggs.....	424	426	518	714	901	Hettinger.....	363	422	518	686	717
Kidder.....	395	433	539	759	827	LaMoure.....	424	426	518	714	901

Logan.....	395	433	539	759	827	McHenry.....	395	433	539	759	827
McIntosh.....	395	433	539	759	827	McKenzie.....	363	422	518	686	717
McLean.....	395	433	539	759	827	Mercer.....	363	422	518	686	717
Mountrail.....	395	433	539	759	827	Nelson.....	401	498	594	804	892
Oliver.....	363	422	518	686	717	Pembina.....	401	498	594	804	892

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

NORTH DAKOTA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Pierce.....	395	433	539	759	827	Ramsey.....	384	394	519	647	818
Ransom.....	424	426	518	714	901	Renville.....	395	433	539	759	827
Richland.....	350	421	533	692	821	Rolette.....	395	433	539	759	827
Sargent.....	424	426	518	714	901	Sheridan.....	395	433	539	759	827
Sioux.....	363	422	518	686	717	Slope.....	363	422	518	686	717
Stark.....	368	448	518	754	911	Steele.....	401	498	594	804	892
Stutsman.....	431	433	518	717	910	Towner.....	424	426	518	714	901
Traill.....	401	498	594	804	892	Walsh.....	401	498	594	804	892
Ward.....	339	421	518	715	849	Wells.....	424	426	518	714	901
Williams.....	337	411	518	682	723						
OHIO											
METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Akron, OH MSA.....					595	762	969	999	Portage, Summit		
Brown County, OH HMFA.....					433	454	599	773	Brown		
Canton-Massillon, OH MSA.....					460	510	644	813	862	Carroll, Stark	
Cincinnati-Middleton, OH-KY-IN HMFA.....					473	560	726	972	1009	Butler, Clermont, Hamilton, Warren	
Cleveland-Elyria-Mentor, OH MSA.....					526	610	735	942	1001	Cuyahoga, Geauga, Lake, Lorain, Medina	
Columbus, OH HMFA.....					510	593	750	944	1025	Delaware, Fairfield, Franklin, Licking, Madison, Morrow,	
Dayton, OH HMFA.....					495	565	696	937	1118	Pickaway	
Huntington-Ashland, WV-KY-OH MSA.....					414	490	588	725	749	Greene, Miami, Montgomery	
Lima, OH MSA.....					480	486	602	742	762	Allen	
Mansfield, OH MSA.....					395	481	607	788	819	Richland	
Parkersburg-Marietta-Vienna, WV-OH MSA.....					429	459	588	781	843	Washington	
Preble County, OH HMFA.....					519	535	649	840	871	Preble	
Sandusky, OH MSA.....					433	521	666	869	914	Erie	
Springfield, OH MSA.....					484	538	648	838	1076	Clark	
Toledo, OH MSA.....					482	537	664	857	934	Fulton, Lucas, Ottawa, Wood	
Union County, OH HMFA.....					631	632	759	909	937	Union	
Weirton-Steubenville, WV-OH MSA.....					389	477	588	734	797	Jefferson	
Wheeling, WV-OH MSA.....					382	460	588	739	863	Belmont	
Youngstown-Warren-Boardman, OH HMFA.....					439	492	595	749	808	Mahoning, Trumbull	
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Adams.....	478	496	588	779	823	Ashland.....	415	494	640	826	849
Ashtabula.....	428	502	640	813	948	Athens.....	488	530	588	756	787
Auglaize.....	430	462	605	787	808	Champaign.....	409	500	630	777	835
Clinton.....	455	562	623	908	1066	Columbiana.....	469	495	598	740	899

Coshocton.....	409	493	588	760	867	Crawford.....	486	493	588	757	829
Darke.....	382	488	588	783	806	Defiance.....	443	508	616	777	946
Fayette.....	471	541	661	796	1062	Gallia.....	399	530	588	748	982
Guernsey.....	413	510	588	777	799	Hancock.....	439	513	665	904	960
Hardin.....	488	530	588	737	965	Harrison.....	392	468	588	753	774
Henry.....	400	491	594	764	788	Highland.....	488	489	588	792	818

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

OHIO continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR		0 BR	1 BR	2 BR	3 BR	4 BR	
Hocking.....	381	530	588	839	863	Holmes.....	489	490	588	776	823
Huron.....	430	520	636	882	971	Jackson.....	496	498	597	716	738
Knox.....	517	521	625	800	917	Logan.....	533	539	641	806	833
Marion.....	424	534	653	828	1008	Meigs.....	489	530	588	806	830
Mercer.....	384	498	588	792	816	Monroe.....	489	490	588	722	807
Morgan.....	489	490	588	722	807	Muskingum.....	476	489	588	753	950
Noble.....	489	490	588	722	807	Paulding.....	432	473	588	767	791
Perry.....	488	489	588	736	757	Pike.....	382	492	588	704	733
Putnam.....	411	455	599	743	775	Ross.....	445	504	588	727	834
Sandusky.....	521	533	627	779	851	Scioto.....	470	492	588	772	923
Seneca.....	434	455	588	739	761	Shelby.....	488	499	649	810	897
Tuscarawas.....	393	459	605	766	789	Van Wert.....	382	457	588	716	739
Vinton.....	429	530	588	805	1002	Wayne.....	436	542	668	798	873
Williams.....	485	492	610	808	892	Wyandot.....	489	490	588	806	830

OKLAHOMA

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Fort Smith, AR-OK HMFA.....	394	447	557	742	808	Sequoyah	464	480	557	756	780
Grady County, OK HMFA.....	402	448	557	754	866	Grady	464	480	557	756	780
Lawton, OK MSA.....	451	487	612	894	1075	Comanche	464	480	557	756	780
Le Flore County, OK HMFA.....	377	439	557	689	844	Le Flore	383	424	557	667	833
Lincoln County, OK HMFA.....	461	462	557	734	757	Lincoln	450	485	561	705	810
Oklahoma City, OK HMFA.....	499	545	662	894	958	Canadian, Cleveland, Logan, McClain, Oklahoma	464	480	557	756	780
Okmulgee County, OK HMFA.....	376	423	557	756	803	Okmulgee	423	458	577	835	977
Pawnee County, OK HMFA.....	465	479	557	722	743	Pawnee	430	431	557	797	820
Tulsa, OK HMFA.....	535	582	711	939	970	Creek, Osage, Rogers, Tulsa, Wagoner	464	480	557	756	780
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Adair.....	465	466	557	665	685	Alfalfa.....	464	480	557	756	780
Atoka.....	403	452	557	724	845	Beaver.....	464	480	557	756	780
Beckham.....	463	501	557	729	977	Blaine.....	464	480	557	756	780
Bryan.....	452	454	557	720	858	Caddo.....	383	424	557	667	833
Carter.....	492	524	593	738	790	Cherokee.....	450	485	561	705	810
Choctaw.....	461	499	557	790	813	Cimarron.....	464	480	557	756	780
Coal.....	403	452	557	724	845	Cotton.....	423	458	577	835	977
Craig.....	376	439	578	692	1016	Custer.....	430	431	557	797	820
Delaware.....	400	450	557	748	771	Dewey.....	464	480	557	756	780
Ellis.....	464	480	557	756	780	Garfield.....	457	482	579	802	825

Garvin.....	360	421	557	732	892	Grant.....	464	480	557	756	780
Greer.....	432	448	557	749	784	Harmon.....	432	448	557	749	784
Harper.....	464	480	557	756	780	Haskell.....	362	435	557	701	769
Hughes.....	450	513	612	780	802	Jackson.....	383	497	558	783	807
Jefferson.....	423	458	577	835	977	Johnston.....	403	452	557	724	845

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

OKLAHOMA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Kay.....	378	469	582	804	831	Kingfisher.....	464	480	557
Kiowa.....	432	448	557	749	784	Latimer.....	362	435	557
Love.....	403	452	557	724	845	McCurtain.....	361	422	557
McIntosh.....	412	466	558	698	792	Major.....	464	480	557
Marshall.....	403	452	557	724	845	Mayes.....	361	502	557
Murray.....	464	465	557	749	959	Muskogee.....	421	496	588
Noble.....	406	472	568	790	813	Nowata.....	424	449	557
Okfuskee.....	450	513	612	780	802	Ottawa.....	465	466	557
Payne.....	493	565	692	980	1009	Pittsburg.....	380	444	585
Pontotoc.....	392	437	557	759	783	Pottawatomie.....	484	550	612
Pushmataha.....	362	435	557	701	769	Roger Mills.....	432	448	557
Seminole.....	361	446	557	669	689	Stephens.....	365	423	557
Texas.....	433	519	585	740	885	Tillman.....	423	458	577
Washington.....	460	461	562	787	866	Washita.....	432	448	557
Woods.....	413	442	557	810	835	Woodward.....	387	452	557

OREGON

METROPOLITAN FMR AREAS

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Bend, OR MSA.....	554	644	768	1119	1154	Deschutes	554	644	768
Corvallis, OR MSA.....	520	631	786	1142	1313	Benton	520	631	786
Eugene-Springfield, OR MSA.....	499	605	766	1072	1193	Lane	499	605	766
Medford, OR MSA.....	513	610	766	1115	1147	Jackson	513	610	766
Portland-Vancouver-Beaverton, OR-WA MSA.....	626	726	839	1222	1467	Clackamas, Columbia, Multnomah, Washington, Yamhill	626	726	839
Salem, OR MSA.....	508	564	675	981	1183	Marion, Polk	508	564	675

NONMETROPOLITAN COUNTIES

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Baker.....	406	473	624	908	935	Clatsop.....	459	570	705
Coos.....	444	538	682	905	1042	Crook.....	437	562	672
Curry.....	501	576	680	993	1199	Douglas.....	433	516	666
Gilliam.....	470	551	665	901	1054	Grant.....	470	551	665
Harney.....	420	489	615	850	904	Hood River.....	472	584	727
Jefferson.....	522	556	630	916	1031	Josephine.....	505	579	700
Klamath.....	418	491	625	874	971	Lake.....	420	489	615
Lincoln.....	521	595	759	1052	1188	Linn.....	498	604	753
Malheur.....	445	507	618	894	920	Morrow.....	470	551	665
Sherman.....	470	551	665	901	1054	Tillamook.....	483	577	742

Umatilla.....	436	497	636	893	996	Union.....	417	485	640	934	961
Walla.....	413	481	635	909	977	Wasco.....	484	542	675	959	1187
Wheeler.....	470	551	665	901	1054						

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

PENNSYLVANIA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Allentown-Bethlehem-Easton, PA HMFA.....	596	726	859	1112	1176	Carbon, Lehigh, Northampton
Altoona, PA MSA.....	465	509	616	807	833	Blair
Armstrong County, PA HMFA.....	482	523	579	741	972	Armstrong
Erie, PA MSA.....	459	518	669	800	910	Erie
Harrisburg-Carlisle, PA MSA.....	570	651	820	1035	1073	Cumberland, Dauphin, Perry
Johnstown, PA MSA.....	463	471	579	729	835	Cambria
Lancaster, PA MSA.....	531	630	776	985	1034	Lancaster
Lebanon, PA MSA.....	443	529	682	925	954	Lebanon
*Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA..	803	915	1095	1339	1615	Bucks, Chester, Delaware, Montgomery, Philadelphia
Pike County, PA HMFA.....	812	844	978	1324	1622	Pike
Pittsburgh, PA HMFA.....	556	610	730	907	980	Allegheny, Beaver, Butler, Fayette, Washington,
Westmoreland						
Reading, PA MSA.....	550	614	757	1012	1044	Berks
Scranton--Wilkes-Barre, PA MSA.....	446	532	639	810	856	Lackawanna, Luzerne, Wyoming
Sharon, PA HMFA.....	466	488	595	729	801	Mercer
State College, PA MSA.....	637	710	836	999	1030	Centre
Williamsport, PA MSA.....	450	516	622	817	840	Lycoming
York-Hanover, PA MSA.....	506	581	737	890	923	York

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Adams.....	543	594	710	956	1060	Bedford.....	441	501	579	692	919
Bradford.....	377	505	579	724	887	Cameron.....	484	502	581	770	829
Clarion.....	481	523	579	739	772	Clearfield.....	441	487	579	830	979
Clinton.....	522	524	631	755	776	Columbia.....	467	512	624	798	946
Crawford.....	461	511	579	768	878	Elk.....	482	504	579	750	907
Forest.....	482	512	579	750	772	Franklin.....	450	512	646	850	1042
Fulton.....	386	492	579	714	835	Greene.....	481	512	579	692	712
Huntingdon.....	376	466	579	748	770	Indiana.....	515	536	620	740	810
Jefferson.....	394	487	579	767	790	Juniata.....	446	483	581	790	815
Lawrence.....	421	549	646	773	907	McKean.....	486	512	584	783	842
Mifflin.....	408	472	579	752	941	Monroe.....	593	730	913	1166	1305
Montour.....	518	594	684	818	844	Northumberland.....	398	519	579	717	743
Potter.....	481	522	579	767	789	Schuylkill.....	386	503	579	723	795
Snyder.....	402	528	621	777	838	Somerset.....	481	481	579	712	753
Sullivan.....	382	512	587	736	876	Susquehanna.....	470	512	600	721	795
Tioga.....	496	545	606	796	851	Union.....	556	579	669	879	946
Venango.....	445	486	579	731	830	Warren.....	376	483	579	752	796
Wayne.....	562	565	710	887	1000						

RHODE ISLAND

METROPOLITAN FMR AREAS	0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
Newport-Middleton-Portsmouth, RI HMFA.....	812	990	1224	1662	2148	Newport County towns of Middletown town, Newport city,
Providence-Fall River, RI-MA HMFA.....	751	836	963	1151	1419	Portsmouth town Bristol County towns of Barrington town, Bristol town,
						Warren town

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

RHODE ISLAND continued

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Components of FMR AREA within STATE

town,
 Kent County towns of Coventry town, East Greenwich
 Warwick city, West Greenwich town, West Warwick town
 Newport County towns of Jamestown town, Little

Compton town,

Tiverton town
 Providence County towns of Burrillville town,
 Central Falls city, Cranston city, Cumberland town,
 East Providence city, Foster town, Gloucester town,
 Johnston town, Lincoln town, North Providence town,
 North Smithfield town, Pawtucket city, Providence

city,

Scituate town, Smithfield town, Woonsocket city
 Washington County towns of Charlestown town, Exeter

town,

Narragansett town, North Kingstown town, Richmond

town,

South Kingstown town

Westerly-Hopkinton-New Shoreham, RI HMFA..... 688 865 1012 1209 1579 Washington County towns of Hopkinton town, New

Shoreham town,

Westerly town

SOUTH CAROLINA

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Anderson, SC MSA..... 417 541 615 779 801 Anderson
 Augusta-Richmond County, GA-SC MSA..... 533 578 649 869 914 Aiken, Edgefield
 Charleston-North Charleston-Summerville, SC MSA... 689 763 863 1124 1309 Berkeley, Charleston, Dorchester
 Charlotte-Gastonia-Concord, NC-SC HMFA..... 670 726 806 1016 1182 York
 Columbia, SC HMFA..... 632 688 767 947 977 Calhoun, Fairfield, Lexington, Richland, Saluda
 Darlington County, SC HMFA..... 360 461 554 665 717 Darlington
 Florence, SC HMFA..... 431 485 561 673 845 Florence
 Greenville-Mauldin-Easley, SC MSA..... 546 592 659 870 894 Greenville, Pickens
 Kershaw County, SC HMFA..... 405 510 627 788 915 Kershaw
 Laurens County, SC HMFA..... 493 535 593 750 875 Laurens
 Myrtle Beach-North Myrtle Beach-Conway, SC MSA... 616 677 791 945 1145 Horry
 Spartanburg, SC MSA..... 534 552 645 811 835 Spartanburg
 Sumter, SC MSA..... 478 519 575 739 782 Sumter

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR

NONMETROPOLITAN COUNTIES

Abbeville..... 359 499 554 673 693
 Bamberg..... 460 461 554 739 761
 Allendale..... 461 499 554 688 889
 Barnwell..... 459 483 554 667 863

[illegible]

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

SOUTH CAROLINA continued

NONMETROPOLITAN COUNTIES				NONMETROPOLITAN COUNTIES				0 BR 1 BR 2 BR 3 BR 4 BR				
Williamsburg.....				483	484	581	696	793				
SOUTH DAKOTA												
METROPOLITAN FMR AREAS												
				0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE			
Meade County, SD HMFA.....				353	422	546	794	886	Meade			
Rapid City, SD HMFA.....				498	581	732	969	996	Pennington			
Sioux City, IA-NE-SD MSA.....				429	504	661	832	857	Union			
Sioux Falls, SD MSA.....				508	534	682	891	985	Lincoln, McCook, Minnehaha, Turner			
NONMETROPOLITAN COUNTIES												
				0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES			
Aurora.....				350	407	536	687	733	Beadle.....	446	447	
Bennett.....				404	420	536	717	798	Bon Homme.....	350	407	
Brookings.....				349	437	538	759	945	Brown.....	392	420	
Brule.....				350	407	536	687	733	Buffalo.....	350	407	
Butte.....				404	420	536	717	798	Campbell.....	390	408	
Charles Mix.....				350	407	536	687	733	Clark.....	359	417	
Clay.....				408	434	570	786	1000	Codington.....	395	461	
Corson.....				404	420	536	717	798	Custer.....	404	420	
Davison.....				368	432	567	727	782	Day.....	390	408	
Deuel.....				359	417	536	725	855	Dewey.....	404	420	
Douglas.....				350	407	536	687	733	Edmunds.....	390	408	
Fall River.....				396	413	543	704	784	Faulk.....	390	408	
Grant.....				359	417	536	725	855	Gregory.....	350	407	
Haakon.....				404	420	536	717	798	Hamlin.....	359	417	
Hand.....				390	408	536	708	841	Hanson.....	350	407	
Harding.....				404	420	536	717	798	Hughes.....	357	447	
Hutchinson.....				350	407	536	687	733	Hyde.....	350	407	
Jackson.....				404	420	536	717	798	Jerauld.....	390	408	
Jones.....				404	420	536	717	798	Kingsbury.....	359	417	
Lake.....				359	417	536	725	855	Lawrence.....	379	460	
Lyman.....				350	407	536	687	733	McPherson.....	390	408	
Marshall.....				390	408	536	708	841	Mellette.....	404	420	
Miner.....				359	417	536	725	855	Moody.....	359	417	
Perkins.....				404	420	536	717	798	Potter.....	404	420	
Roberts.....				390	408	536	708	841	Sanborn.....	350	407	
Shannon.....				404	420	536	717	798	Spink.....	390	408	

Stanley.....	350	407	536	687	733
Todd.....	404	420	536	717	798
Walworth.....	390	408	536	708	841
Ziebach.....	404	420	536	717	798
Sully.....	350	407	536	687	733
Tripp.....	350	407	536	687	733
Yankton.....	376	446	579	759	780

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

TENNESSEE

METROPOLITAN FMR AREAS

0 BR 1 BR 2 BR 3 BR 4 BR Counties of FMR AREA within STATE

Chattanooga, TN-GA MSA..... 537 568 669 824 968 Hamilton, Marion, Sequatchie
 Clarksville, TN-KY HMFA..... 550 572 664 960 988 Montgomery
 Cleveland, TN MSA..... 471 481 620 778 989 Bradley, Polk
 Hickman County, TN HMFA..... 366 509 564 822 848 Hickman
 Jackson, TN MSA..... 508 554 700 937 963 Chester, Madison
 Johnson City, TN MSA..... 392 475 588 730 910 Carter, Unicoi, Washington
 Kingsport-Bristol-Bristol, TN-VA MSA..... 428 460 571 765 915 Hawkins, Sullivan
 Knoxville, TN MSA..... 529 608 732 981 1012 Anderson, Blount, Knox, Loudon, Union
 Macon County, TN HMFA..... 353 430 543 647 718 Macon
 Memphis, TN-MS-AR HMFA..... 648 705 783 1043 1076 Fayette, Shelby, Tipton
 Morristown, TN MSA..... 461 463 556 729 822 Grainger, Hamblen, Jefferson
 Nashville-Davidson--Murfreesboro--Franklin, TN MSA 615 702 807 1047 1077 Cannon, Cheatham, Davidson, Dickson, Robertson,
 Rutherford,

Sumner, Trousdale, Williamson, Wilson

Smith County, TN HMFA..... 470 471 564 752 777 Smith
 Stewart County, TN HMFA..... 360 469 554 756 779 Stewart

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR

0 BR 1 BR 2 BR 3 BR 4 BR

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR

Bedford..... 441 540 679 850 875 Benton..... 425 426 539 666 731
 Bledsoe..... 353 442 539 708 729 Campbell..... 447 449 539 694 826
 Carroll..... 446 447 539 665 743 Claiborne..... 350 447 539 721 809
 Clay..... 436 437 539 700 720 Cocke..... 351 434 539 646 880
 Coffee..... 484 485 582 789 862 Crockett..... 448 486 539 703 725
 Cumberland..... 446 447 539 764 945 Decatur..... 403 443 539 693 789
 DeKalb..... 447 449 539 778 804 Dyer..... 365 429 562 749 818
 Fentress..... 436 437 539 700 720 Franklin..... 371 445 572 832 1002
 Gibson..... 441 452 539 677 749 Giles..... 381 447 590 710 730
 Greene..... 350 441 539 730 750 Grundy..... 353 442 539 708 729
 Hancock..... 447 448 539 690 830 Hardeman..... 390 483 539 730 946
 Hardin..... 395 440 539 715 736 Haywood..... 454 470 615 735 807
 Henderson..... 378 501 585 697 719 Henry..... 353 413 544 651 792
 Houston..... 425 426 539 666 731 Humphreys..... 448 485 539 768 793
 Jackson..... 436 437 539 700 720 Johnson..... 349 434 539 723 758
 Lake..... 400 448 539 700 741 Lauderdale..... 474 475 572 695 718
 Lawrence..... 371 416 539 667 761 Lewis..... 362 421 543 692 712
 Lincoln..... 447 448 539 659 678 McMinn..... 476 478 574 687 915
 McNairy..... 350 412 539 778 801 Marshall..... 436 463 607 730 916
 Maury..... 465 581 716 911 939 Meigs..... 353 442 539 708 729
 Monroe..... 427 428 543 649 829 Moore..... 474 475 568 750 774

Morgan.....	445	446	539	674	786	Obion.....	370	446	539	711	749
Overton.....	351	442	539	659	678	Perry.....	362	421	543	692	712
Pickett.....	436	437	539	700	720	Putnam.....	450	451	562	809	868
Rhea.....	349	431	539	716	736	Roane.....	474	489	568	759	780
Scott.....	447	456	539	714	949	Sevier.....	541	586	661	795	1161
Van Buren.....	436	437	539	700	720	Warren.....	437	442	569	762	907

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

TENNESSEE continued

NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	0 BR	1 BR	2 BR	3 BR	4 BR
Wayne.....	362	421	543	692	712	Weakley.....	391	481	539	789	950					
White.....	404	410	539	762	783											

TEXAS

METROPOLITAN FMR AREAS

0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	0 BR	1 BR	2 BR	3 BR	4 BR
Abilene, TX MSA.....	486	511	645	840	1062	Callahan, Jones, Taylor				
Amarillo, TX MSA.....	496	537	671	925	1036	Armstrong, Carson, Potter, Randall				
Aransas County, TX HMFA.....	443	550	655	955	984	Aransas				
Atascosa County, TX HMFA.....	383	446	589	744	766	Atascosa				
Austin County, TX HMFA.....	571	573	689	914	943	Austin				
Austin-Round Rock, TX MSA.....	688	783	954	1284	1462	Bastrop, Caldwell, Hays, Travis, Williamson				
Beaumont-Port Arthur, TX MSA.....	516	579	692	858	889	Hardin, Jefferson, Orange				
Brazoria County, TX HMFA.....	561	625	718	990	1063	Brazoria				
Brownsville-Harlingen, TX MSA.....	454	524	600	742	838	Cameron				
Calhoun County, TX HMFA.....	420	497	637	803	1075	Calhoun				
College Station-Bryan, TX MSA.....	605	685	836	1059	1092	Burleson, Robertson				
Corpus Christi, TX HMFA.....	640	658	816	1120	1221	Nueces, San Patricio				
Dallas, TX HMFA.....	669	740	894	1164	1377	Collin, Dallas, Delta, Denton, Ellis, Hunt, Kaufman, Rockwall				
El Paso, TX MSA.....	468	502	598	858	1017	El Paso				
Fort Worth-Arlington, TX HMFA.....	666	708	861	1150	1274	Johnson, Parker, Tarrant				
*Houston-Baytown-Sugar Land, TX HMFA.....	661	735	892	1189	1495	Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery,				

Kendall County, TX HMFA.....	743	744	895	1303	1572	San Jacinto, Waller				
Killeen-Temple-Fort Hood, TX HMFA.....	529	585	743	1081	1302	Kendall				
Lampasas County, TX HMFA.....	382	487	588	858	1005	Bell, Coryell				
Laredo, TX MSA.....	510	558	668	873	1144	Lampasas				
Longview, TX HMFA.....	542	570	654	895	921	Webb				
Lubbock, TX MSA.....	469	572	722	1022	1055	Gregg, Upshur				
McAllen-Edinburg-Mission, TX MSA.....	505	555	655	785	903	Crosby, Lubbock				
Medina County, TX HMFA.....	522	580	682	816	992	Hidalgo				
Midland, TX MSA.....	583	632	831	1211	1434	Medina				
Odessa, TX MSA.....	530	562	736	1061	1232	Midland				
Rusk County, TX HMFA.....	505	506	607	727	748	Ector				
San Angelo, TX MSA.....	460	531	676	967	1057	Rusk				
San Antonio, TX HMFA.....	579	645	796	1027	1247	Irion, Tom Green				
Sherman-Denison, TX MSA.....	596	628	738	970	1122	Bandera, Bexar, Comal, Guadalupe, Wilson				
Texarkana, TX-Texarkana, AR MSA.....	501	506	623	760	827	Grayson				
Tyler, TX MSA.....	541	559	716	981	1072	Bowie				
Victoria, TX HMFA.....	485	559	716	891	1055	Smith				
Waco, TX MSA.....	591	592	736	921	952	Goliad, Victoria				
						McLennan				

Wichita Falls, TX MSA.....	533	560	667	936	964	Archer, Clay, Wichita
Wise County, TX HMFA.....	548	549	660	806	896	Wise
NONMETROPOLITAN COUNTIES						
Anderson.....	527	552	636	837	1098	Andrews.....
Angelina.....	504	574	642	831	857	Bailey.....
Baylor.....	399	473	588	749	889	Bea.....
NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR 1 BR 2 BR 3 BR 4 BR	
487	501	588	787	879		
453	505	588	765	970		
492	493	591	794	889		

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

TEXAS continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Blanco.....	469	504	637	836	958	Borden.....	486	487	588	759	783
Bosque.....	488	489	588	714	856	Brewster.....	428	447	588	703	762
Briscoe.....	479	482	588	783	808	Brooks.....	488	524	588	840	936
Brown.....	470	511	644	819	940	Burnet.....	480	562	738	928	955
Camp.....	494	495	608	830	856	Cass.....	383	529	588	807	951
Castro.....	479	482	588	783	808	Cherokee.....	478	524	588	786	818
Childress.....	479	482	588	783	808	Cochran.....	453	505	588	765	970
Coke.....	461	531	675	971	1058	Coleman.....	469	504	637	836	958
Collingsworth.....	479	482	588	783	808	Colorado.....	470	519	588	777	799
Comanche.....	478	513	607	773	843	Concho.....	486	487	588	759	783
Cooke.....	543	545	687	848	873	Cottle.....	399	473	588	749	889
Crane.....	487	516	588	763	906	Crockett.....	486	487	588	759	783
Culberson.....	487	516	588	763	906	Dallam.....	440	483	637	761	781
Dawson.....	486	487	588	759	783	Deaf Smith.....	382	487	588	854	973
DeWitt.....	435	451	588	768	831	Dickens.....	453	505	588	765	970
Dimmit.....	482	484	588	800	949	Donley.....	479	482	588	783	808
Duval.....	406	510	588	783	834	Eastland.....	478	513	607	773	843
Edwards.....	482	484	588	800	949	Erath.....	477	517	645	787	811
Falls.....	389	530	597	762	790	Fannin.....	512	516	615	767	790
Fayette.....	488	553	670	832	857	Fisher.....	454	455	588	841	913
Floyd.....	453	505	588	765	970	Foard.....	399	473	588	749	889
Franklin.....	443	508	614	752	904	Freestone.....	389	530	597	780	804
Frio.....	474	582	708	896	1066	Gaines.....	488	520	588	763	914
Garza.....	453	505	588	765	970	Gillespie.....	499	583	766	1061	1092
Glasscock.....	486	487	588	759	783	Gonzales.....	403	460	588	855	880
Gray.....	455	456	588	738	761	Grimes.....	524	575	640	833	858
Hale.....	395	500	588	720	804	Hall.....	479	482	588	783	808
Hamilton.....	469	504	637	836	958	Hansford.....	479	482	588	783	808
Hardeman.....	399	473	588	749	889	Harrison.....	473	477	627	810	834
Hartley.....	479	482	588	783	808	Haskell.....	454	455	588	841	913
Hemphill.....	479	482	588	783	808	Henderson.....	485	502	660	865	892
Hill.....	383	530	588	833	908	Hockley.....	458	487	588	816	841
Hood.....	588	637	709	937	1244	Hopkins.....	441	509	621	787	1090
Houston.....	568	610	684	819	886	Howard.....	487	492	588	826	848
Hudspeth.....	487	516	588	763	906	Hutchinson.....	493	495	593	710	882
Jack.....	399	473	588	749	889	Jackson.....	383	495	588	717	1034
Jasper.....	489	490	588	727	841	Jeff Davis.....	487	516	588	763	906

Jim Hogg.....	488	524	588	840	936	Jim Wells.....	393	529	588	781	806
Karnes.....	436	449	588	770	833	Kenedy.....	488	524	588	840	936
Kent.....	454	455	588	841	913	Kerr.....	593	642	722	931	960
Kimble.....	486	487	588	759	783	King.....	453	505	588	765	970
Kinney.....	482	484	588	800	949	Kleberg.....	505	540	607	886	1068

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

TEXAS continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Knox.....	399	473	588	749	889	Lamar.....	443	513	644	811	907
Lamb.....	453	505	588	765	970	La Salle.....	482	484	588	800	949
Lavaca.....	470	519	588	777	799	Lee.....	473	538	597	817	842
Leon.....	524	575	640	833	858	Limestone.....	383	532	588	753	779
Lipscomb.....	479	482	588	783	808	Live Oak.....	406	510	588	783	834
Llano.....	609	613	807	965	994	Loving.....	487	516	588	763	906
Lynn.....	453	505	588	765	970	McCulloch.....	488	490	588	856	883
McMullen.....	406	510	588	783	834	Madison.....	524	575	640	833	858
Marion.....	494	495	608	830	856	Martin.....	486	487	588	759	783
Mason.....	486	487	588	759	783	Matagorda.....	385	505	591	861	1038
Maverick.....	490	491	588	854	881	Menard.....	486	487	588	759	783
Milam.....	383	473	588	761	809	Mills.....	469	504	637	836	958
Mitchell.....	454	455	588	841	913	Montague.....	446	570	636	803	1115
Moore.....	415	510	588	856	881	Morris.....	443	508	614	752	904
Motley.....	453	505	588	765	970	Nacogdoches.....	478	599	706	843	1155
Navarro.....	552	562	679	825	851	Newton.....	487	488	588	764	1030
Nolan.....	456	457	588	758	1030	Ochiltree.....	479	482	588	821	846
Oldham.....	479	482	588	783	808	Palo Pinto.....	500	501	621	858	882
Panola.....	489	530	588	716	1033	Parmer.....	479	482	588	783	808
Pecos.....	485	530	588	713	863	Polk.....	489	495	588	704	724
Presidio.....	487	516	588	763	906	Rains.....	496	498	619	834	860
Reagan.....	486	487	588	759	783	Real.....	482	484	588	800	949
Red River.....	443	508	614	752	904	Reeves.....	488	520	588	754	914
Refugio.....	406	510	588	783	834	Roberts.....	479	482	588	783	808
Runnels.....	486	487	588	759	783	Sabine.....	487	488	588	764	1030
San Augustine.....	487	488	588	764	1030	San Saba.....	469	504	637	836	958
Schleicher.....	486	487	588	759	783	Scurry.....	388	459	588	856	940
Shackelford.....	454	455	588	841	913	Shelby.....	488	490	588	845	1030
Sherman.....	479	482	588	783	808	Somervell.....	478	513	607	775	843
Starr.....	488	532	588	857	1036	Stephens.....	437	447	588	810	880
Sterling.....	486	487	588	759	783	Stonewall.....	454	455	588	841	913
Sutton.....	486	487	588	759	783	Swisher.....	479	482	588	783	808
Terrell.....	487	516	588	763	906	Terry.....	452	504	588	773	967
Throckmorton.....	454	455	588	841	913	Titus.....	461	547	649	780	1140
Trinity.....	568	610	684	819	886	Tyler.....	488	489	588	757	981
Upton.....	486	487	588	759	783	Uvalde.....	383	522	588	766	1031
Val Verde.....	420	502	593	738	859	Van Zandt.....	521	524	640	895	921

Walker.....	584	624	755	972	1258	Ward.....	489	495	588	733	870
Washington.....	560	637	705	989	1021	Wharton.....	472	530	588	778	801
Wheeler.....	479	482	588	783	808	Wilbarger.....	382	455	588	755	842
Willacy.....	488	530	588	856	953	Winkler.....	487	516	588	763	906
Wood.....	442	446	588	857	1031	Yoakum.....	453	505	588	765	970

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

TEXAS continued

NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Young.....	384	447	589	747	869	Zapata.....	488	524	588	840	936
Zavala.....	482	484	588	800	949						

UTAH

METROPOLITAN FMR AREAS

Logan, UT-ID MSA.....	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	0 BR	1 BR	2 BR	3 BR	4 BR
Ogden-Clearfield, UT MSA.....	491	530	663	889	1098	Cache					
Provo-Orem, UT MSA.....	506	608	749	1030	1218	Davis, Morgan, Weber					
Salt Lake City, UT HMFA.....	544	598	699	1017	1225	Juab, Utah					
St. George, UT MSA.....	638	693	836	1176	1369	Salt Lake					
Summit County, UT HMFA.....	560	587	697	1013	1140	Washington					
Tooele County, UT HMFA.....	686	953	1059	1483	1857	Summit					
	532	595	708	895	1240	Tooele					

NONMETROPOLITAN COUNTIES

NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR
Beaver.....	535	537	656	929	989	Box Elder.....	417	511	643	850	989
Carbon.....	488	489	588	773	907	Daggett.....	495	538	596	773	1047
Duchesne.....	662	720	798	1030	1402	Emery.....	495	538	596	773	1047
Garfield.....	535	537	656	929	989	Grand.....	496	540	599	772	1051
Iron.....	491	518	596	868	1047	Kane.....	535	537	656	929	987
Millard.....	535	537	656	929	989	Piute.....	535	537	656	929	989
Rich.....	499	530	663	891	1081	San Juan.....	495	538	596	773	1047
Sanpete.....	535	537	656	929	989	Sevier.....	535	537	656	929	989
Uintah.....	571	621	688	903	1016	Wasatch.....	554	647	853	1019	1224
Wayne.....	535	537	656	929	989						

VERMONT

METROPOLITAN FMR AREAS

0 BR	1 BR	2 BR	3 BR	4 BR	Components of FMR AREA within STATE
804	889	1116	1428	1601	Chittenden County towns of Bolton town, Buels gore, Burlington city, Charlotte town, Colchester town,
					Hinesburg town, Huntington town, Jericho town,
					Richmond town, St. George town, Shelburne town,
					South Burlington city, Underhill town, Westford
					Williston town, Winoski city
					Franklin County towns of Bakersfield town, Berkshire

Fletcher town,
Montgomery town,

town,

Enosburg town, Fairfax town, Fairfield town,

Franklin town, Georgia town, Highgate town,

Richford town, St. Albans city, St. Albans town,

Sheldon town, Swanton town

Grand Isle County towns of Alburg town, Grand Isle

Isle La Motte town, North Hero town, South Hero town

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

VERMONT continued

NONMETROPOLITAN COUNTIES

0 BR 1 BR 2 BR 3 BR 4 BR Towns within nonmetropolitan counties

Addison County, VT.....	579	725	872	1147	1529	Addison town, Bridport town, Bristol town, Cornwall town,
town,						Ferrisburg town, Goshen town, Granville town, Hancock
town,						Leicester town, Lincoln town, Middlebury town,
Monkton town,						New Haven town, Orwell town, Pantton town, Ripton
town,						Salisbury town, Shoreham town, Starksboro town,
town						Vergennes city, Waltham town, Weybridge town, Whiting
Bennington County, VT.....	578	724	843	1098	1291	Arlington town, Bennington town, Dorset town,
Peru town,						Glastenbury town, Landgrove town, Manchester town,
town,						Pownal town, Readsboro town, Rupert town, Sandgate
						Searsburg town, Shaftsbury town, Stamford town,
Caledonia County, VT.....	545	567	711	900	932	Sunderland town, Winhall town, Woodford town
						Barnet town, Burke town, Danville town, Groton town,
town,						Hardwick town, Kirby town, Lyndon town, Newark town,
						Peacham town, Ryegate town, St. Johnsbury town,
						Sheffield town, Stannard town, Sutton town, Walden
Essex County, VT.....	564	633	769	980	1150	Waterford town, Wheelock town
town,						Averill town, Avery's gore, Bloomfield town, Brighton
town,						Brunswick town, Canaan town, Concord town, East Haven
						Ferdinand town, Granby town, Guildhall town,
Lemington town,						Lewis town, Lunenburg town, Maidstone town, Norton
town,						Victory town, Warner's grant, Warren's gore
Lamoille County, VT.....	570	685	797	1110	1400	Belvidere town, Cambridge town, Eden town, Elmore
town,						Hyde Park town, Johnson town, Morristown town, Stowe
town,						Waterville town, Wolcott town
Orange County, VT.....	608	687	800	1114	1148	Bradford town, Braintree town, Brookfield town,
Chelsea town,						Corinth town, Fairlee town, Newbury town, Orange
town,						

town,						Randolph town, Strafford town, Thetford town, Topsham
Orleans County, VT.....	411	568	635	802	1008	Tunbridge town, Vershire town, Washington town,
Charleston town,						West Fairlee town, Williamstown town
town,						Albany town, Barton town, Brownington town,
town,						Coventry town, Craftsbury town, Derby town, Glover
						Greensboro town, Holland town, Irasburg town, Jay
						Lowell town, Morgan town, Newport city, Newport town,
						Troy town, Westfield town, Westmore town
Rutland County, VT.....	522	683	794	1050	1343	Benson town, Brandon town, Castleton town, Chittenden
town,						Clarendon town, Danby town, Fair Haven town,
Hubbardton town,						Ira town, Killington town, Mendon town,
						Middletown Springs town, Mount Holly town, Mount
Tabor town,						Pawlet town, Pittsfield town, Pittsford town,
Poultney town,						Proctor town, Rutland city, Rutland town, Shrewsbury
town,						Sudbury town, Tinmouth town, Wallingford town, Wells
town,						West Haven town, West Rutland town
Washington County, VT.....	574	671	840	1135	1270	Barre city, Barre town, Berlin town, Cabot town,
Calais town,						Duxbury town, East Montpelier town, Fayston town,
						Marshfield town, Middlesex town, Montpelier city,
						Moretown town, Northfield town, Plainfield town,
						Roxbury town, Waitsfield town, Warren town, Waterbury
town,						Woodbury town, Worcester town
Windham County, VT.....	679	708	930	1123	1159	Athens town, Brattleboro town, Brookline town, Dover
town,						

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

VERMONT continued

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	
Towns within nonmetropolitan counties						

town,						Dummerston town, Grafton town, Guilford town, Halifax
Newfane town,						Jamaica town, Londonderry town, Marlboro town,
town,						Putney town, Rockingham town, Somersett town, Stratton
						Townshend town, Vernon town, Wardsboro town,
						Westminster town, Whitingham town, Wilmington town,
						Windham town
Windsor County, VT.....	640	717	843	1147	1365	Andover town, Baltimore town, Barnard town, Bethel
town,						Bridgewater town, Cavendish town, Chester town,
town,						Hartford town, Hartland town, Ludlow town, Norwich
town,						Plymouth town, Pomfret town, Reading town, Rochester
town,						Royalton town, Sharon town, Springfield town,
town,						Stockbridge town, Weathersfield town, Weston town,
town,						West Windsor town, Windsor town, Woodstock town

VIRGINIA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	
Counties of FMR AREA within STATE						

Blacksburg-Christiansburg-Radford, VA HMFA.....	556	608	681	934	1197	Montgomery, Radford city
Charlottesville, VA MSA.....	635	763	903	1170	1295	Albemarle, Fluvanna, Greene, Nelson, Charlottesville
city						
Danville, VA MSA.....	404	463	598	746	861	Pittsylvania, Danville city
Franklin County, VA HMFA.....	371	444	571	683	727	Franklin
Giles County, VA HMFA.....	372	482	571	728	1004	Giles
Harrisonburg, VA MSA.....	512	569	692	969	996	Rockingham, Harrisonburg city
Kingsport-Bristol-Bristol, TN-VA MSA.....	428	460	571	765	915	Scott, Washington, Bristol city
Louisa County, VA HMFA.....	621	704	802	959	987	Louisa
Lynchburg, VA MSA.....	513	526	634	782	872	Amherst, Appomattox, Bedford, Campbell, Bedford city,
						Lynchburg city
Pulaski County, VA HMFA.....	433	458	571	818	879	Pulaski
*Richmond, VA HMFA.....	768	832	930	1241	1481	Amelia, Caroline, Charles, Chesterfield, Cumberland,
Queen,						Dinwiddie, Goochland, Hanover, Henrico, King and
Sussex,						King William, New Kent, Powhatan, Prince George,
city,						Colonial Heights city, Hopewell city, Petersburg

Roanoke, VA HMFA.....	509	542	700	888	970	Richmond city
Virginia Beach-Norfolk-Newport News, VA-NC MSA....	774	807	934	1277	1539	Botetourt, Craig, Roanoke, Roanoke city, Salem city Gloucester, Isle of Wight, James, Mathews, Surry, York,
						Chesapeake city, Hampton city, Newport News city, Norfolk city, Poquoson city, Portsmouth city, Suffolk city,
Warren County, VA HMFA.....	562	654	814	1144	1179	Virginia Beach city, Williamsburg city Warren
Washington-Arlington-Alexandria, DC-VA-MD HMFA....	1061	1198	1364	1745	2285	Arlington, Clarke, Fairfax, Fauquier, Loudoun, Prince William, Spotsylvania, Stafford, Alexandria city,
Winchester, VA-WV MSA.....	558	579	764	1054	1085	Fairfax city, Falls Church city, Fredericksburg city, Manassas city, Manassas Park city Frederick, Winchester city

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

VIRGINIA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Accomack.....	390	533	729	898	Alleghany.....	371	476	571	694
Augusta.....	498	512	668	955	Bath.....	489	509	632	872
Bland.....	476	492	571	728	Brunswick.....	491	507	591	737
Buchanan.....	476	492	571	728	Buckingham.....	475	513	571	734
Carroll.....	475	515	571	685	Charlotte.....	475	513	571	734
Culpeper.....	640	651	771	997	Dickenson.....	476	509	571	745
Essex.....	459	566	697	949	Floyd.....	525	571	633	881
Grayson.....	476	492	571	728	Greensville.....	492	533	592	715
Halifax.....	371	516	571	767	Henry.....	440	458	571	732
Highland.....	489	509	632	872	King George.....	647	648	779	1133
Lancaster.....	458	564	687	845	Lee.....	370	447	571	734
Lunenburg.....	491	507	591	737	Madison.....	505	563	680	941
Mecklenburg.....	374	466	575	706	Middlesex.....	458	564	687	837
Northampton.....	458	564	687	837	Northumberland.....	458	564	687	837
Nottoway.....	475	513	571	811	Orange.....	457	629	700	1019
Page.....	389	453	595	768	Patrick.....	473	516	571	707
Prince Edward.....	554	555	667	798	Rappahannock.....	505	563	680	941
Richmond.....	458	564	687	837	Rockbridge.....	456	513	571	831
Russell.....	372	493	571	699	Shenandoah.....	469	503	615	820
Smyth.....	472	513	571	725	Southampton.....	413	572	634	784
Tazewell.....	476	477	571	733	Westmoreland.....	464	565	714	980
Wise.....	475	484	571	743	Wythe.....	371	470	571	749
Buena Vista city.....	456	513	571	831	Clifton Forge city.....	371	476	571	694
Covington city.....	371	476	571	694	Emporia city.....	492	533	592	715
Franklin city.....	413	572	634	784	Galax city.....	475	515	571	685
Lexington city.....	456	513	571	831	Martinsville city.....	440	458	571	732
Norton city.....	475	484	571	743	Staunton city.....	498	512	668	955
Waynesboro city.....	498	512	668	955					
WASHINGTON					Counties of FMR AREA within STATE				
METROPOLITAN FMR AREAS					0 BR	1 BR	2 BR	3 BR	4 BR
Bellingham, WA MSA.....			588	649	814	1188	1338	Whatcom	
Bremerton-Silverdale, WA MSA.....			647	726	894	1279	1397	Kitsap	
Kennewick-Pasco-Richland, WA MSA.....			518	565	709	959	1136	Benton, Franklin	
Lewiston, ID-WA MSA.....			494	513	642	912	1111	Asotin	
Longview, WA MSA.....			460	579	672	979	1116	Cowlitz	
Mount Vernon-Anacortes, WA MSA.....			590	730	906	1239	1547	Skagit	

Olympia, WA MSA.....	609	684	874	1269	1535	Thurston
Portland-Vancouver-Beaverton, OR-WA MSA.....	626	726	839	1222	1467	Clark, Skamania
Seattle-Bellevue, WA HMFA.....	770	878	1056	1492	1823	King, Snohomish
Spokane, WA MSA.....	449	526	693	951	1079	Spokane
*Tacoma, WA HMFA.....	665	776	968	1410	1587	Pierce
Wenatchee-East Wenatchee, WA MSA.....	536	567	717	967	1114	Chelan, Douglas

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

WASHINGTON continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	0 BR	1 BR	2 BR	3 BR	4 BR
Yakima, WA MSA.....	494	580	750	988	1042	Yakima					
NONMETROPOLITAN COUNTIES											
Adams.....	417	497	637	855	882	Clallam.....	526	582	757	1106	1140
Columbia.....	430	502	662	894	1067	Perry.....	417	493	637	855	882
Garfield.....	430	502	662	894	1067	Grant.....	425	506	654	884	907
Grays Harbor.....	432	507	666	938	964	Island.....	779	781	942	1371	1654
Jefferson.....	539	661	808	1175	1209	Kittitas.....	482	562	741	993	1031
Klickitat.....	558	566	672	943	972	Lewis.....	465	595	715	955	999
Lincoln.....	417	493	637	855	882	Mason.....	524	616	739	1009	1196
Okanogan.....	466	562	660	903	994	Pacific.....	457	492	645	915	951
Pend Oreille.....	417	493	637	855	882	San Juan.....	659	709	876	1259	1537
Stevens.....	414	499	637	873	953	Wahkiakum.....	464	576	673	980	1124
Walla Walla.....	430	502	662	952	981	Whitman.....	466	513	666	940	1152

WEST VIRGINIA

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE	0 BR	1 BR	2 BR	3 BR	4 BR
Boone County, WV HMFA.....	353	458	543	672	744	Boone					
Charleston, WV HMFA.....	468	511	639	814	838	Clay, Kanawha, Lincoln, Putnam					
Cumberland, MD-WV MSA.....	414	501	588	793	926	Mineral					
Huntington-Ashland, WV-KY-OH MSA.....	414	490	588	725	749	Cabell, Wayne					
Jefferson County, WV HMFA.....	504	680	774	1130	1361	Jefferson					
Martinsburg, WV HMFA.....	541	610	733	981	1176	Berkeley, Morgan					
Morgantown, WV MSA.....	492	511	605	785	930	Monongalia, Preston					
Parkersburg-Marietta-Vienna, WV-OH MSA.....	429	459	588	781	843	Pleasants, Wirt, Wood					
Weirton-Steubenville, WV-OH MSA.....	389	477	588	734	797	Brooke, Hancock					
Wheeling, WV-OH MSA.....	382	460	588	739	863	Marshall, Ohio					
Winchester, VA-WV MSA.....	558	579	764	1054	1085	Hampshire					
NONMETROPOLITAN COUNTIES											
Barbour.....	418	436	543	711	749	Braxton.....	418	436	543	711	749
Calhoun.....	396	471	572	743	854	Doddridge.....	374	477	563	678	802
Fayette.....	452	453	543	672	722	Gilmer.....	418	436	543	711	749
Grant.....	473	546	614	804	998	Greenbrier.....	431	491	543	653	858
Hardy.....	473	546	614	804	998	Harrison.....	466	467	561	703	785
Jackson.....	396	471	572	743	854	Lewis.....	428	464	543	681	700
Logan.....	379	460	543	667	686	McDowell.....	453	469	543	741	941

Marion.....	387	495	594	710	865	Mason.....	451	460	543	688	735
Mercer.....	451	468	543	734	930	Mingo.....	353	476	543	684	888
Monroe.....	451	490	543	677	700	Nicholas.....	451	489	543	691	756
Pendleton.....	472	545	615	803	996	Pocahontas.....	451	469	543	665	788
Raleigh.....	457	486	548	700	721	Randolph.....	427	428	552	712	733

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

WEST VIRGINIA continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Ritchie.....	396	471	572	743	854	Roane.....	396	471	572
Summers.....	451	490	543	677	700	Taylor.....	374	477	563
Tucker.....	418	436	543	711	749	Tyler.....	396	471	572
Upshur.....	353	441	543	729	753	Webster.....	451	469	543
Wetzel.....	355	483	543	691	786	Wyoming.....	453	469	543

WISCONSIN

METROPOLITAN FMR AREAS

Counties of FMR AREA within STATE

0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Appleton, WI MSA.....	527	542	672	969	997	Calumet, Outagamie	527	542	672
Columbia County, WI HMFA.....	500	584	769	1038	1071	Columbia	500	584	769
Duluth, MN-WI MSA.....	409	499	629	790	1006	Douglas	409	499	629
Eau Claire, WI MSA.....	416	497	621	841	876	Chippewa, Eau Claire	416	497	621
Fond du Lac, WI MSA.....	502	538	648	851	923	Fond du Lac	502	538	648
Green Bay, WI HMFA.....	543	556	700	984	1014	Brown, Kewaunee	543	556	700
Iowa County, WI HMFA.....	482	562	740	884	909	Iowa	482	562	740
Janesville, WI MSA.....	494	577	719	941	968	Rock	494	577	719
Kenosha County, WI HMFA.....	652	679	843	1159	1334	Kenosha	652	679	843
La Crosse, WI-MN MSA.....	412	483	635	843	1035	La Crosse	412	483	635
Madison, WI HMFA.....	610	761	899	1206	1494	Dane	610	761	899
*Milwaukee-Waukesha-West Allis, WI MSA.....	602	718	858	1081	1114	Milwaukee, Ozaukee, Washington, Waukesha	602	718	858
Minneapolis-St. Paul-Bloomington, MN-WI MSA.....	628	741	899	1177	1322	Pierce, St. Croix	628	741	899
Oconto County, WI HMFA.....	437	530	588	761	793	Oconto	437	530	588
Oshkosh-Neenah, WI MSA.....	466	548	649	851	1103	Winnebago	466	548	649
Racine, WI MSA.....	506	591	742	923	1013	Racine	506	591	742
Sheboygan, WI MSA.....	418	538	635	785	963	Sheboygan	418	538	635
Wausau, WI MSA.....	415	518	639	853	943	Marathon	415	518	639

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Adams.....	442	485	600	781	805	Ashland.....	454	456	588
Barron.....	391	493	588	750	772	Bayfield.....	402	469	588
Buffalo.....	409	464	593	752	785	Burnett.....	402	469	588
Clark.....	380	449	588	804	828	Crawford.....	489	523	588
Dodge.....	585	587	707	895	966	Door.....	432	552	664
Dunn.....	447	482	605	882	906	Florence.....	393	475	588
Forest.....	442	485	600	781	805	Grant.....	488	489	588
Green.....	431	464	609	773	903	Green Lake.....	442	507	588
Iron.....	402	469	588	753	781	Jackson.....	409	464	593
Jefferson.....	503	589	776	930	1172	Juneau.....	388	478	596

Lafayette.....	434	457	588	753	844	Langlade.....	488	489	588	776	846
Lincoln.....	490	491	588	856	883	Manitowoc.....	391	458	603	721	897
Marquette.....	490	529	588	770	794	Marquette.....	452	507	617	795	882
Menominee.....	452	507	617	795	882	Monroe.....	404	471	521	788	861
Oneida.....	438	479	628	803	1105	Pepin.....	409	464	593	752	785

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

WISCONSIN continued

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Polk.....	447	522	686	844	871	Portage.....	514	520	621	822	846
Price.....	402	469	588	753	781	Richland.....	413	462	588	754	778
Rusk.....	402	469	588	753	781	Sauk.....	444	590	677	910	939
Sawyer.....	402	473	588	753	781	Shawano.....	405	477	588	734	843
Taylor.....	402	469	588	753	781	Trempealeau.....	462	464	588	803	827
Vernon.....	467	469	588	743	810	Vilas.....	442	485	600	817	842
Walworth.....	518	610	795	992	1024	Washburn.....	402	469	588	753	781
Waupaca.....	397	499	606	791	815	Waushara.....	452	507	617	795	882
Wood.....	390	479	593	722	790						

WYOMING

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Casper, WY MSA.....	479	524	662	662	963	1160	Natrona				
Cheyenne, WY MSA.....	571	603	764	764	1040	1339	Laramie				
NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES						
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR		
Albany.....	520	596	756	1038	1099	Big Horn.....	516	539	645	842	1007
Campbell.....	579	623	698	945	1030	Carbon.....	402	481	618	774	941
Converse.....	383	473	588	802	1034	Crook.....	516	539	645	842	1007
Fremont.....	510	512	651	816	1040	Goshen.....	496	497	599	739	1017
Hot Springs.....	516	539	645	842	1007	Johnson.....	517	539	664	843	1008
Lincoln.....	569	603	686	916	1084	Niobrara.....	516	539	645	842	1007
Park.....	483	555	653	820	1081	Platte.....	516	539	645	842	1007
Sheridan.....	519	559	687	879	1072	Sublette.....	573	603	700	916	1085
Sweetwater.....	478	580	728	1018	1056	Teton.....	887	989	1244	1640	1688
Uinta.....	496	625	712	973	1154	Washakie.....	516	539	645	842	1007
Weston.....	516	539	645	842	1007						

GUAM

NONMETROPOLITAN COUNTIES					NONMETROPOLITAN COUNTIES				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR
Pacific Islands.....	786	844	1030	1501	1794				

PUERTO RICO

METROPOLITAN FMR AREAS					Counties of FMR AREA within STATE				
0 BR	1 BR	2 BR	3 BR	4 BR	0 BR	1 BR	2 BR	3 BR	4 BR

Aguadilla-Isabela-San Sebastián, PR MSA.....	339	369	409	526	589	Aguada, Aguadilla, Añasco, Isabela, Lares, Moca, Rincón,
Arecibo, PR HMFA.....	358	389	432	589	690	San Sebastián
Barranquitas-Aibonito-Quebradillas, PR HMFA.....	353	381	424	540	620	Arecibo, Camuy, Hatillo
Caguas, PR HMFA.....	393	426	474	657	792	Aibonito, Barranquitas, Ciales, Maunabo, Orocovich, Quebradillas
						Caguas, Cayey, Cidra, Gurabo, San Lorenzo

SCHEDULE B - FY 2010 PROPOSED FAIR MARKET RENTS FOR EXISTING HOUSING

PUERTO RICO continued

METROPOLITAN FMR AREAS

	0 BR	1 BR	2 BR	3 BR	4 BR	Counties of FMR AREA within STATE
Fajardo, PR MSA.....	408	444	493	717	864	Ceiba, Fajardo, Luquillo
Guayama, PR MSA.....	359	387	431	612	758	Arroyo, Guayama, Patillas
Mayagüez, PR MSA.....	386	419	465	556	767	Hormigueros, Mayagüez
Ponce, PR MSA.....	416	452	500	695	792	Juana Díaz, Ponce, Villalba
San Germán-Cabo Rojo, PR MSA.....	336	349	404	528	570	Cabo Rojo, Lajas, Sabana Grande, San Germán
San Juan-Guaynabo, PR HMFA.....	478	518	576	763	902	Aguas Buenas, Barceloneta, Bayamón, Canóvanas, Carolina,
Humacao,						Cataño, Comerío, Corozal, Dorado, Florida, Guaynabo,
						Juncos, Las Piedras, Loíza, Manatí, Morovis, Naguabo,
						Naranjito, Río Grande, San Juan, Toa Alta, Toa Baja,
						Trujillo Alto, Vega Alta, Vega Baja, Yabucoa
Yauco, PR MSA.....	332	351	399	503	640	Guánica, Guayanilla, Peñuelas, Yauco
NONMETROPOLITAN COUNTIES	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES
Adjuntas.....	331	358	399	547	593	Coamo.....
Culebra.....	331	358	399	547	593	Jayuya.....
Las Marías.....	331	358	399	547	593	Maricao.....
Salinas.....	331	358	399	547	593	Santa Isabel.....
Utua.....	331	358	399	547	593	Vieques.....

VIRGIN ISLANDS

NONMETROPOLITAN COUNTIES

	0 BR	1 BR	2 BR	3 BR	4 BR	NONMETROPOLITAN COUNTIES
St. Croix.....	577	601	729	911	1042	St. John.....
St. Thomas.....	657	785	1010	1251	1308	

Note1: The FMRs for unit sizes larger than 4 BRs are calculated by adding 15% to the 4 BR FMR for each extra bedroom.

Note2: 50th percentile FMRs are indicated by an * before the FMR Area name.

07/27/2009

SCHEDULE D - FY 2010 FAIR MARKET RENTS FOR MANUFACTURED HOME
SPACES IN THE SECTION 8 HOUSING CHOICE VOUCHER PROGRAM

Space State Rent	Area Name
California	Los Angeles-Long Beach, CA HUD Metro FMR A
\$640	
\$777	Orange County, CA HUD Metro FMR Area
\$504	Riverside-San Bernardino-Ontario, CA MSA
\$770	San Diego-Carlsbad-San Marcos, CA MSA
\$669	Santa Rosa-Petaluma, CA MSA
\$538	Vallejo-Fairfield, CA MSA
Colorado	Boulder, CO MSA
\$439	
Maryland	St. Mary's County
\$474	
Oregon	Bend, OR MSA
\$343	
\$459	Salem, OR MSA
Pennsylvania	Adams County
\$532	
Washington	Olympia, WA MSA
\$564	
\$622	Seattle-Bellevue, WA HUD Metro FMR Area
West Virginia	Logan County
\$430	
\$430	McDowell County
\$430	Mercer County
\$430	Mingo County
\$430	Wyoming County



Federal Register

**Tuesday,
August 4, 2009**

Part IV

Department of the Treasury

Internal Revenue Service

**26 CFR Parts 1 and 31, and 602
Treatment of Services Under Section 482;
Allocation of Income and Deductions
From Intangible Property; Stewardship
Expense; Final Rule**

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 1 and 31, and 602**

[TD 9456]

RIN 1545-B178, 1545-B179, 1545-B180

Treatment of Services Under Section 482; Allocation of Income and Deductions From Intangible Property; Stewardship Expense**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that provide guidance regarding the treatment of controlled services transactions under section 482 and the allocation of income from intangible property, in particular with respect to contributions by a controlled party to the value of intangible property owned by another controlled party. This document also contains final regulations that modify the regulations under section 861 concerning stewardship expenses to be consistent with the changes made to the regulations under section 482. These final regulations potentially affect controlled taxpayers within the meaning of section 482. They provide updated guidance necessary to reflect economic and legal developments since the issuance of the current guidance.

DATES: *Effective Date:* These regulations are effective on July 31, 2009.*Applicability Dates:* These regulations apply to taxable years beginning after July 31, 2009.**FOR FURTHER INFORMATION CONTACT:**

Carol B. Tan or Gregory A. Spring, (202) 435-5265 for matters relating to section 482, or Richard L. Chewning (202) 622-3850 for matters relating to stewardship expenses (not toll-free numbers).

SUPPLEMENTARY INFORMATION:**Paperwork Reduction Act**

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-2149. The collection of information in these final regulations is in § 1.482-9. This information is required to enable the IRS to verify that a taxpayer is reporting the correct amount of taxable income. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless it displays a valid control number.

Books and records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 482 of the Internal Revenue Code generally provides that the Secretary may allocate gross income, deductions, and credits between or among two or more organizations, trades or businesses owned or controlled by the same interests in order to prevent evasion of taxes or clearly to reflect income of a controlled taxpayer.

Regulations under section 482 published in the **Federal Register** (33 FR 5849) on April 16, 1968, provided guidance with respect to a wide range of controlled transactions, including transfers of tangible and intangible property and the provision of services. Revised and updated transfer pricing regulations were published in the **Federal Register** (59 FR 34971, 60 FR 65553, 61 FR 21955, and 68 FR 51171) on July 8, 1994, December 20, 1995, May 13, 1996, and August 26, 2003. While comprehensive in other respects, these regulations did not modify substantively the rules dealing with controlled services transactions. On September 10, 2003, proposed regulations relating to the treatment of controlled services transactions and the allocation of income from intangible property, in particular with respect to contributions by a controlled party to the value of intangible property owned by another controlled party (the 2003 proposed regulations), were published in the **Federal Register** (68 FR 53448, REG-146893-02 and REG-115037-00).

On August 4, 2006, temporary regulations relating to the treatment of controlled services transactions, the allocation of income from intangible property, and stewardship expenses (the 2006 temporary regulations) were published in the **Federal Register** (71 FR 44466, TD 9278, REG-146893-02, REG-115037-00, and REG-138603-03). A notice of proposed rulemaking cross-referencing the temporary regulations was published in the **Federal Register** on the same day (71 FR 44247, REG-146893-02, REG-115037-00, and REG-138603-03). Written comments responding to the notice of proposed rulemaking were received, and a public hearing was held on October 27, 2006.

The 2006 temporary regulations are generally effective with respect to

taxable years beginning after December 31, 2006, and Notice 2007-5, 2007-1 C.B. 269, published on January 16, 2007, partially modified the effective date of the 2006 temporary regulations as it pertained to the identification of controlled services transactions eligible to be priced at cost. Accordingly, the 2006 temporary regulations related to the new services cost method in § 1.482-9T(b) (described in Section A.1 in this preamble) apply to taxable years after December 31, 2007, with the exception of the business judgment rule described in § 1.482-9T(b)(2), which had the same effective date (taxable years after December 31, 2006) as the other provisions of the temporary regulations.

By issuing the 2006 temporary regulations in temporary and proposed form, the Treasury Department and the IRS provided taxpayers an opportunity to submit additional comments prior to the time these regulations became effective. See § 601.601(d)(2)(ii)(b). After consideration of all the comments, the proposed regulations under section 482 are adopted as revised by this Treasury decision, and the corresponding temporary regulations are removed.

Explanation of Revisions and Summary of Comments*Introduction*

The Treasury Department and the IRS received a number of comments on the 2006 temporary regulations from taxpayers, their representatives, as well as industry and professional groups. Commentators generally approved of the 2006 temporary regulations and found the changes from the 2003 proposed regulations to be useful. Specifically, commentators approved of the replacement of the simplified cost-based method with the services cost method (SCM) and the inclusion of the shared services arrangement provision in the SCM rules. Commentators also generally approved of changes made to the profit split method. However, commentators did express concerns with some aspects of the 2006 temporary regulations.

While these final regulations reflect some modifications in response to comments received on the 2006 temporary regulations, both the format and the substance of the final regulations are generally consistent with the 2006 temporary regulations. The changes adopted are intended to make certain clarifications and improvements without fundamentally altering the policies reflected in the 2006 temporary regulations.

Explanation of Provisions

A. Controlled Services

1. Services Cost Method—Treas. Reg. § 1.482–9(b)

a. Applicability of the Services Cost Method

Most comments focused on the SCM. Several commentators requested confirmation that application of the SCM is a matter within the control of the taxpayer, provided that the underlying services otherwise qualify for the SCM. Some commentators stated that the 2006 temporary regulations could be interpreted as requiring a taxpayer to apply the SCM if all the conditions for that method were satisfied.

Notice 2007–5 confirmed that taxpayers control whether the SCM applies. The final regulations make this clear. Section 1.482–9(b)(1) provides that, if a taxpayer applies the SCM in accordance with the rules of § 1.482–9(b), which requires that a statement evidencing the taxpayer's intent to apply the SCM be contained in the taxpayer's books and records, then the SCM will be considered the best method for purposes of § 1.482–1(c).

b. Specified Covered Services

Several commentators contended that the proposed list of specified covered services in Announcement 2006–50, 2006–2 C.B. 321, is too narrow. One commentator listed tax planning and public relations activities as examples of activities not on the list that illustrated the narrowness of the list. Some commentators suggested that the list should refer to departments, cost centers, or accounting classifications, rather than to specific activities or groups of activities. One commentator suggested that all activities in particular departments should be identified as eligible for the SCM. Commentators also stated that a comprehensive analysis would be required and that it would be too burdensome to track employee time for activities that are specified covered services vs. non-specified covered services. See § 601.601(d)(2)(ii)(b). The Treasury Department and the IRS also received suggestions to broaden the general administrative provision and add additional specific activities to the list of specified covered services, including warehousing and distribution, quality control and quality assurance relating to manufacturing and construction, and environmental remediation.

The SCM is intended to provide a practical and administrable means of identifying low-margin services that

may be evaluated by reference to total services cost without a markup. The list of services eligible to be priced at cost in the specified covered services portion of the SCM was added specifically in response to requests from commentators that the former simplified cost-based method be eliminated and replaced with just such a list of eligible services. In response to public comments, the Treasury Department and the IRS published Rev. Proc. 2007–13, 2007–1 C.B. 295, which added several categories as well as activities within existing categories. In particular, public relations and tax planning services were added to the list, and the individual categories of specified covered services were expanded to include “other similar activities.”

After careful consideration, the Treasury Department and the IRS believe that Rev. Proc. 2007–13 strikes the appropriate balance between broadening the list to include services similar to the specific services described and expanding the categories of services. The Treasury Department and the IRS do not believe that other additional services suggested by commentators were appropriate, but will continue to consider other recommendations for additional services to be added to the list in the future.

One commentator expressed concern that a review of services to determine if they qualify as specified covered services may require a more extensive analysis than under previous regulations, including interviews of individual employees or of small groups of employees. Although the covered services list is not applied on a departmental basis, a reasonable aggregation of similar services may be appropriate for performing the specified covered services analysis in some cases. To determine if the services cost method should apply to a particular service (or group of services) performed by a group of employees, the aggregation principle of Treas. Reg. § 1.482–1(f)(2)(i)(A) should be followed as appropriate. In certain cases, aggregation may assure a more accurate result, especially if it recognizes synergies that an individual employee analysis might ignore. An aggregation of employee services may, thus, efficiently evaluate the work of employees engaged in a common function, as well as recognize the added value that their collaborative effort might produce. Conversely, analysis on an aggregate basis does not permit characterization of an individual service as a specified covered service if it, in fact, is not a specified covered service.

c. Low Margin Covered Services

Commentators provided comments on low margin covered services described in § 1.482–9T(b)(4)(ii) of the 2006 temporary regulations. One commentator believed that the 7 percent limit is too high for the SCM. In the commentator's view, the limit should be lower because the 7 percent figure will cover activities that are risky. Most of the commentators, however, believed that the 7 percent limit is an appropriate measure. The Treasury Department and the IRS continue to believe that the 7 percent limit is appropriate in light of its purpose. That is, it minimizes the compliance burden on taxpayers and the IRS for relatively low-margin services.

Several commentators requested more guidance on low margin covered services. One commentator suggested that the Treasury Department and the IRS develop an analysis to determine if certain services have a markup of 7 percent or less and publish the results. For example, the IRS could develop a set of comparables for various groups of low margin services, such as human resources, accounting and finance, information services, and training. Some commentators requested guidance on when and how often a transfer pricing study is needed to support a determination that services are low margin covered services. In this regard, some commentators requested that the regulations specify a period of years (such as three years) for which a transfer pricing study may be valid for purposes of determining if a service is a low margin covered service. In support of this request, one commentator stated that the regulations could provide, for example, that the reliance period could apply to taxpayers whose facts and circumstances have not changed materially from the time the service was most recently established as a covered service.

The Treasury Department and IRS did not adopt this proposal. Because there may be significant differences among services across different businesses, a standardized, IRS-developed comparables set would not be feasible and would conflict with the fact intensive nature of an appropriately robust transfer pricing analysis. For similar reasons, the Treasury Department and the IRS did not adopt the proposal to specify the frequency or timing of transfer pricing analyses to support taxpayer positions. To do so would be inconsistent with a proper comparability analysis, including consideration of the time at which

transactions were undertaken, as well as other relevant economic circumstances.

One other commentator requested that the midpoint should be used in measuring a comparable markup on total services costs for purposes of low margin covered services. While it may be true that, in some cases, the midpoint could be used depending on the statistical method used, the interquartile range ordinarily provides an acceptable measure of an arm's length range. See § 1.482-1(e)(2)(iii)(B). Therefore, the Treasury Department and the IRS believe that the interquartile range of the comparable median markup is an appropriate measure.

d. Excluded Activities

One commentator requested that engineering be removed from the list of services that are ineligible for the SCM in § 1.482-9T(b)(3) of the 2006 temporary regulations. This comment was not adopted, since, in the view of the Treasury Department and the IRS, intragroup engineering services generally should be subject to a robust transfer pricing analysis.

e. Business Judgment Rule

Several commentators expressed concern over how the business judgment rule would be administered. Some commentators requested that statements in the preamble about the business judgment rule in the 2006 temporary regulations be incorporated in final regulations. Other commentators suggested that the business judgment rule should be applied by reference to one or more trades or business of the controlled group rather than of the renderer, recipient, or both. These commentators claimed that the business judgment rule may yield incorrect results in some cases, for example, where a headquarters services company or other legal entity is established solely to provide centralized support services. The activities performed by such an entity would potentially be ineligible for the SCM under the business judgment rule because they would constitute the entity's core capability.

The Treasury Department and the IRS agree that the business judgment rule should be determined on a controlled group basis and expressed this view in Notice 2007-5. The final regulations clarify that the business judgment rule is determined by reference to a trade or business of the controlled group.

Section 3.04 of Notice 2007-5 clarified that the business judgment rule "is satisfied by a reasonable exercise of the taxpayer's business judgment, not a reasonable exercise of the IRS's judgment in examining the taxpayer."

The Treasury Department and the IRS reiterate that the final regulations incorporate a high threshold for application of the business judgment rule to exclude services otherwise eligible for the SCM. Section 1.482-9(b)(5) provides that the rule is based on a taxpayer's reasonable conclusion in its business judgment that the rule is satisfied. It has come to the attention of the Treasury Department and the IRS that the clarification in the notice of the business judgment rule has been misconstrued as creating a non-rebuttable presumption that a taxpayer's determination under the business judgment rule is always correct. This construction of the clarification was not intended and is not supported by the plain language of the business judgment rule. The business judgment rule requires a reasonable conclusion by the taxpayer. Thus, the taxpayer's business judgment is only the starting point of the analysis, and the taxpayer must make a reasonable conclusion in that regard. Whether the taxpayer's conclusion is reasonable may be subject to examination by the IRS in the course of an audit.

One commentator suggested that the regulations adopt a "principal activity" test similar to the test described in the *Organisation for Economic Cooperation and Development Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations (OECD Guidelines)* in place of the business judgment rule. The Treasury Department and the IRS decline to adopt this suggestion. Another commentator pointed out that the examples illustrating the business judgment rule more accurately describe a high value service or intangible property, rather than a covered service. The Treasury Department and the IRS agree that some of the examples in the temporary regulations could be read as describing transfers of intangible property rather than provisions of services involving the intangible property. Some examples have been edited to improve clarity, including to ensure that they cannot be read as describing transfers of intangible property.

Commentators also raised questions concerning how to evidence the necessary business judgment; for example, whether an executive's representation must be preferred to the tax director's. The business judgment rule is applied on a case-by-case basis and takes into account the taxpayer's facts and circumstances.

One other commentator requested that the business judgment rule take into account whether a particular activity,

such as that of a corporate tax department, contributes to the operating profit (as defined in § 1.482-5(d)(3)) of one or more controlled parties. Notice 2007-5 provided several clarifications to the business judgment rule, including a clarification that the business judgment rule should take into account whether a particular activity contributes to the operating profit of one or more controlled parties. After further consideration, the Treasury Department and the IRS decided not to add an operating profit consideration to the business judgment rule because the operating profit concept is broader than the intended rule and because it would implicitly require taxpayers to do the type of economic analysis (and create the attendant administrative burden for taxpayers) that the business judgment rule is intended to eliminate.

The Treasury Department and the IRS continue to believe, however, that the conclusion in Notice 2007-5 is correct—that activities such as back office tax services should not fail the business judgment rule because they may affect net income by reducing domestic or foreign income taxes. Depending on the facts and circumstances, tax services may or may not satisfy the business judgment rule.

f. Reorganization of the SCM

Section 1.482-9T(b) of the 2006 temporary regulations contains several requirements, all of which have to be satisfied in order for the SCM to be applicable. In other words, the requirements under § 1.482-9T(b) are conjunctive; failure to satisfy one of the requirements renders a service ineligible for SCM treatment regardless of whether any of the other requirements is satisfied. The Treasury Department and the IRS are aware that the rules under § 1.482-9T(b) have been misinterpreted as disjunctive such that satisfaction of only one of the requirements renders a service eligible for the SCM. This view is unsupported by the plain language of § 1.482-9T(b). To improve clarity, the requirements for the SCM are reorganized in the final regulations. Section 1.482-9(b)(2) lists the conditions necessary for a service to be eligible for the SCM and provides a cross-reference to the paragraph in § 1.482-9(b) that corresponds to each condition. In summary, to be eligible for the SCM, a service must be a covered service, the service cannot be an excluded activity, the service cannot be precluded from constituting a covered service by reason of the business judgment rule, and adequate books and records must be maintained with respect to the service. The

reorganization does not substantively change the SCM rules.

Modifications have also been made to the list of excluded activities to harmonize it with Rev. Proc. 2007-13. In particular, instead of referring to "excluded transactions," the regulations now refer to "excluded activities."

g. Shared Services Arrangements

In general, commentators supported the shared services arrangement (SSA) provision in the 2006 temporary regulations as a useful mechanism for allocation of costs from shared or centralized services. Commentators called into question, however, the restriction of SSAs to covered services priced under the SCM. In response, Notice 2007-5 provided that a SSA may be used for controlled services transactions outside of the SCM context. Specifically, Notice 2007-5 states: "This Notice confirms that taxpayers may also make allocations of arm's length charges for services ineligible for the SCM that yield a benefit to multiple members of a controlled group. In such a case, however, the flexible rules under the SCM for establishing the joint benefits and selecting the allocation key are inapplicable. Instead, the more robust analysis under the general transfer pricing rules applies for purposes of determining the appropriate arm's length charges, benefits, allocation keys, *etc.*" The Treasury Department and the IRS considered providing additional SSA rules to services priced under methods other than the SCM, but concluded that such rules would be unnecessary. In any event, as stated in Notice 2007-5, the flexible SSA rules for establishing the joint benefits and selecting the allocation key are inapplicable in the non-SCM context.

Other commentators requested that a SSA should be respected even if a party that reasonably anticipates a benefit makes a payment equivalent to its share under an SSA to the service provider pursuant to a different arrangement. For example, assume that a controlled service provider performs services to ten taxpayers that are members of its controlled group. Assume further that nine of the service recipients agree in a single written contract to allocate the arm's length charge based on a reasonable allocation basis, but the tenth service recipient pays for its share of the services pursuant to a separate agreement. These comments were not adopted because whether an agreement constitutes a SSA requires a case-by-case determination based on the facts and circumstances.

Some commentators observed that the SSA rules require the allocation of costs

on the basis that "most reliably reflects" the participants' respective shares of reasonably anticipated benefits, but some of the examples use the phrase "precisely known." This led the commentators to question whether the SSA rules create an unattainable standard or, at least, a higher standard than the reasonable standard for allocation of costs described in Treas. Reg. § 1.482-9T(k) and to suggest a change to the examples. The examples do not create a standard based on precisely known shares of reasonably anticipated benefits. Rather, the examples use hypothetical, precisely known reasonably anticipated benefits as a measuring stick to provide an easily understood comparative analysis of potential allocation keys for illustrative purposes. The suggested changes are not adopted.

2. Comparable Uncontrolled Services Price Method—Treas. Reg. § 1.482-9(c)

The comparable uncontrolled services price (CUSP) method evaluates whether the consideration in a controlled services transaction is arm's length by comparison to the price charged in a comparable uncontrolled services transaction. This method is closely analogous to the comparable uncontrolled price (CUP) method in § 1.482-3(b).

One commentator objected to the statement in the second sentence of § 1.482-9T(c)(1) of the 2006 temporary regulations that, to be evaluated under the CUSP method, a controlled service ordinarily must be "identical to or have a high degree of similarity" to the uncontrolled comparable transactions. The commentator claimed that such language creates a higher standard for determining the best method than in the rest of the section 482 regulations. For example, both § 1.482-1(c)(1) and § 1.482-9T(c)(2)(i) refer to the "most reliable measure of an arm's length result" standard. The sentence in question was intended merely as a guide to when the CUSP method is applicable. It was not intended to change the standard under the best method rule. To avoid further confusion, the sentence is removed, but without effecting a substantive change.

The CUSP method in these final regulations is substantially similar to the corresponding method in the 2006 temporary regulations.

3. Cost of Services Plus Method—Treas. Reg. § 1.482-9(e)

The cost of services plus method is generally analogous to the cost plus method for transfers of tangible property in existing § 1.482-3(d). The cost of

services plus method evaluates whether the amount charged in a controlled services transaction is arm's length by reference to the gross services profit markup realized in comparable uncontrolled transactions. Section 1.482-9T(e)(3)(ii)(A) provides that, if the appropriate gross services profit markup is derived from comparable uncontrolled services transactions of other service providers, then, in evaluating comparability, the controlled taxpayer must consider the results under this method expressed as a markup on total services costs of the controlled taxpayer because functional differences may be reflected in differences in service costs other than those included in comparable transactional costs.

One commentator objected to the required consideration of the results of the cost of services plus method expressed as a markup on total services costs of the controlled taxpayer when external comparables are utilized. In the commentator's view, this rule requires a confirming analysis under a comparable profits method (CPM) and, therefore, places an undue burden on the taxpayer. The same commentator also expressed the concern that the rule would create an even greater burden by requiring two sets of external comparables for application of the two methods.

These comments are not adopted for several reasons. First, the restatement of the price does not require researching two sets of external comparables under two different methods. The sole purpose of the calculation is to determine whether it is necessary to perform additional evaluation of functional comparability under the cost of services plus method. That is, if the price indicates a markup on the renderer's total services cost that is either low or negative when restated, this may indicate differences in functions that have not been accounted for under the traditional comparability factors under the cost of services plus method. Thus, a low or negative markup merely suggests the need for additional inquiry, which may lead to a determination that the cost of services plus method is not the most reliable measure of an arm's length result under the best method rule.

The cost of services plus method is adopted in the final regulations without change.

4. Profit Split Method—Treas. Reg. §§ 1.482-9(g) and 1.482-6(c)(3)(i)(B)

The final regulations provide additional guidance concerning application of the comparable profit

split and the residual profit split methods to controlled services transactions in § 1.482–9(g) and § 1.482–6(c)(3)(i)(B). Generally, the comparable profit split and the residual profit split methods evaluate whether the allocation of the combined operating profit or loss attributable to one or more controlled transactions is arm's length by reference to the relative value of each controlled taxpayer's contributions to the combined operating profit or loss.

The Treasury Department and the IRS received several comments on the profit split method. One commentator requested that § 1.482–8T(b), *Example 12* of the 2006 temporary regulations explain why the profit split method is preferable to using the financial results of a set of publicly-traded companies engaged in selling merchandise and related promotion and marketing activities. *Example 12* is revised in the final regulations to address this comment.

Another commentator argued that the profit split method should not apply to a party that does not own valuable intangible property or does not use any such property in the related party transaction being evaluated. The commentator noted that other parts of the regulations, such as the CPM, CUSP method, and costs of services plus method reference valuable intangible property in the examples. The same commentator asserted that the profit split method should be limited to parties that bear substantial risk in their intercompany transactions. The Treasury Department and the IRS believe that limiting application of the profit split method to contributions of valuable intangible property or the bearing of risks would be inappropriate. The changes in the 2006 temporary regulations to routine and non-routine contributions is an appropriate standard and conformed to the changes to § 1.482–6T(c)(3)(i)(B)(1), which defines a nonroutine contribution as “a contribution that is not accounted for as a routine contribution.” In other words, a nonroutine contribution is one for which the return cannot be determined by reference to market benchmarks.

The 2006 temporary regulations provide that the residual profit split method ordinarily is used where multiple controlled taxpayers make significant nonroutine contributions. A commentator requested that this provision be removed because it suggests that the method always applies where there are no market benchmarks. The provision regarding the residual profit split method that the commentator requested be removed has been changed to conform to language in

the cost sharing regulations. Accordingly, § 1.482–9(g)(1) provides that the residual profit split method may not be used where only one controlled taxpayer makes significant nonroutine contributions. The commentator also claimed that the residual profit split method contains an inconsistency because, although the method applies when there are no market benchmarks, the method includes a market benchmark analysis for comparability purposes. Compare §§ 1.482–9(g)(1) and 1.482–6(c)(3)(i)(B)(2). The Treasury Department and the IRS do not consider that there is an inconsistency. The method contemplates the use of market benchmarks, if available, to determine the profit split that will be applied to the return to nonroutine contributions already determined under the method. The same commentator requested that the sentence in § 1.482–6T(c)(2)(ii)(B) of the 2006 temporary regulations relating to the comparable profit split method that states that “the comparable profit split method may not be used if the combined operating profit (as a percentage of the combined assets) of the uncontrolled comparables varies significantly from that earned by the controlled taxpayers” should be deleted. These comments are not adopted, since the stated condition is fundamental to comparability under the method.

5. Contingent Payments—Treas. Reg. § 1.482–9(i)

The 2006 temporary regulations provide detailed guidance concerning contingent-payment contractual terms. The rules built on the principle that, in structuring controlled transactions, taxpayers are free to choose from among a wide range of risk allocations. The provision acknowledged that contingent-payment terms—terms requiring compensation to be paid only if specified results are obtained—may be particularly relevant in the context of controlled services transactions.

Commentators raised several concerns about the substance and scope of this provision. One commentator said that the regulations do not address whether a taxpayer may, in the absence of a written agreement, present facts to demonstrate that a contingent payment arrangement best reflects the economic substance of the underlying transactions. The Treasury Department and the IRS do not agree that an arrangement may be treated as a contingent payment arrangement under § 1.482–9(i)(2) if the arrangement does not satisfy the requirements of the contingent payment arrangement provision, including the written contract requirement. However, where

the Commissioner exercises its authority pursuant to § 1.482–1(d)(3)(ii)(B) to impute contractual terms, the taxpayer may present additional facts to indicate if an alternative agreement best reflects the economic substance of the underlying transaction, consistent with the parties' course of conduct in a particular case. See § 1.482–1(d)(3)(ii)(C), *Examples 4 and 6*.

The same commentator also pointed out that the requirement to evaluate whether a specified contingency bears a direct relationship to the controlled services transaction based on all of the facts and circumstances should be combined with the specified contingency requirement. The Treasury Department and the IRS agree that the language in § 1.482–9(i)(2) should be clarified. Accordingly, the regulations remove the last sentence in § 1.482–9T(i)(2)(i)(C) of the 2006 temporary regulations relating to a specified contingency and combine it with the requirement under § 1.482–9T(i)(2)(i)(B). Thus, § 1.482–9(i)(2)(i)(B) now requires that the contract state that payment for a controlled services transaction is contingent (in whole or in part) upon the happening of a future benefit (within the meaning of § 1.482–9(l)(3)) for the recipient directly related to the activity or group of activities. For this purpose, whether the future benefit is directly related to the activity or group of activities is evaluated based on all the facts and circumstances.

6. Total Services Costs—Treas. Reg. § 1.482–9(j)

In the 2006 temporary regulations, total services costs include all costs directly identified with provision of the controlled services, as well as all other costs reasonably allocable to such services under § 1.482–9(k). “Costs” must reflect all resources expended, used, or made available to render the service. Generally accepted accounting principles (GAAP) or Federal income tax accounting rules may provide an appropriate starting point, but neither would necessarily be conclusive in evaluating whether an item must be included in total services costs.

Another commentator requested that value added costs (that is, labor costs and depreciation) should be distinguished from total services costs. The commentator stated that a markup on value added costs may be more reliable than a markup on total costs in certain instances and that this could be a useful measure for any of the transfer pricing methods, including the cost of services plus method. The regulations already provide flexibility in the context of the cost of services plus method,

which is determined by reference to comparable transactional costs, the comparable profits method, and unspecified methods. Consequently, the comment is not adopted. The definition of total services costs in these regulations is, thus, similar to the provisions in the 2006 temporary regulations.

Section 1.482–9T(j) of the 2006 temporary regulations explicitly states that total services costs include stock-based compensation, and *Examples 3* through *6* of § 1.482–9T(f)(3) illustrate when stock-based compensation constitutes a material difference requiring adjustments for comparability and reliability purposes. Commentators requested further guidance regarding the valuation, comparability, and reliability considerations for stock-based compensation. Other commentators objected to the explicit statement that stock-based compensation can be a total services cost. These final regulations do not provide further guidance regarding stock-based compensation. The Treasury Department and the IRS continue to consider technical issues involving stock-based compensation in the services and other contexts and intend to address those issues in a subsequent guidance project.

7. Controlled Services Transactions and Shareholder Activities—Treas. Reg. § 1.482–9(l)

Section 1.482–9(l) sets forth a threshold test for determining whether an activity constitutes a controlled services transaction subject to the general framework of § 1.482–9. Section 1.482–9(l)(3) provides rules for determining whether an activity provides a benefit. Paragraphs (l)(3)(ii) through (v) provide guidelines that indicate the presence or absence of a benefit. Section 1.482–9T(l)(3)(iv) of the 2006 temporary regulations provides that an activity is a shareholder activity if the sole effect of that activity is either to protect the renderer's capital investment in the recipient or in other members of the controlled group, or to facilitate compliance by the renderer with reporting, legal, or regulatory requirements applicable specifically to the renderer, or both.

The Treasury Department and the IRS received comments on shareholder activities. Some commentators asserted that the “sole effect” language is too restrictive and that the language should be replaced by a “primary effect” standard. Other commentators argued that the language appropriately encompasses shareholder activities. Another commentator requested a change to the regulations such that a

shareholder activity should be considered to have a sole effect only if the benefits provided to the other controlled group members are either (i) indirect or remote or (ii) duplicative.

The Treasury Department and the IRS believe that the “sole effect” language is appropriate. The “primary effect” language in the 2003 proposed regulations could inappropriately include activities that are not true shareholder activities and may even consist of substantial activities that are non-shareholder activities. An activity that is described in § 1.482–9(l)(3)(ii) through (iv) does not produce a benefit, but the mere fact that an activity is not described in § 1.482–9(l)(3)(ii) through (iv) does not mean that the activity necessarily provides a benefit. An activity not described in § 1.482–9(l)(3)(ii) through (iv) provides a benefit only if it satisfies the incremental value standard of § 1.482–9(l)(3)(i). Furthermore, for that purpose, it may be more reliable, depending on the facts and circumstances, to measure incremental value on a functional aggregate activity, rather than a component activity-by-activity basis.

8. Third Party Costs—Treas. Reg. § 1.482–9(l)(4)

Under § 1.482–9T(l)(4) of the 2006 temporary regulations, a controlled services transaction may be analyzed as a single transaction or as two separate transactions depending on which approach provides the most reliable measure of the arm's length result under the best method rule in existing § 1.482–1(c). Two examples are provided illustrating different alternatives when a controlled services transaction included expenses related to a third-party contract (third party costs) with a controlled taxpayer. In both examples, third party costs that could be reliably disaggregated could be charged at cost. Commentators requested that all third party costs be treated as “pass through” items that are not subject to a markup applicable to costs incurred by the renderer in its capacity as service provider.

The Treasury Department and the IRS continue to maintain the view that whether to consider “pass through” items as disaggregated from, or aggregated with, other functions and costs, depends on which analysis most reliably reflects an arm's length result. Therefore, the rules of § 1.482–9(l)(4) are adopted without change.

9. Coordination With Other Transfer Pricing Rules—Treas. Reg. § 1.482–9(m) and Guarantees

Section 1.482–9(m) provides coordination rules applicable to a controlled services transaction that is combined with, or includes elements of, a non-services transaction. These coordination rules rely on the best method rule in existing § 1.482–1(c)(1) to determine which method or methods would provide the most reliable measure of an arm's length result for a particular controlled transaction.

a. Services Subject to a Qualified Cost Sharing Arrangement—Treas. Reg. § 1.482–9(m)(3)

Section 1.482–9T(m)(3) of the 2006 temporary regulations states that services provided by a controlled participant under a qualified cost sharing arrangement are subject to existing § 1.482–7. As part of the temporary cost sharing regulations (TD 9441, 2009–7 I.R.B. 460, 74 FR 340) published on January 5, 2009, the Treasury Department and the IRS replaced the coordination rules with new § 1.482–9T(m)(3). Section 1.482–9(m)(3) is reserved pending finalization of the cost sharing regulations.

b. Global Dealing Operations

The Treasury Department and the IRS are working on new global dealing regulations. The intent of the Treasury Department and the IRS is that, when final global dealing regulations are issued, those regulations will govern the evaluation of the activities performed by a global dealing operation. Pending the issuance of new global dealing regulations, taxpayers may rely on the proposed global dealing regulations to govern financial transactions entered into in connection with a global dealing operation as defined in proposed § 1.482–8. Thus, the cross-reference under proposed § 1.482–9(m)(6) (71 FR 44247), which provides that a controlled services transaction does not include a financial transaction entered into in connection with a global dealing operation as defined in proposed § 1.482–8, remains in proposed form. Section 1.482–9(m)(6) in these final regulations is reserved pending issuance of global dealing regulations.

c. Guarantees, Including Financial Guarantees

Financial transactions, including guarantees, are explicitly excluded from eligibility for the SCM by § 1.482–9(b)(4)(viii). However, no inference is intended that financial transactions (including guarantees) would otherwise be considered the provision of services

for transfer pricing purposes. The Treasury Department and the IRS intend to issue future guidance regarding financial guarantees.

B. Income Attributable to Intangible Property—Treas. Reg. § 1.482–4(f)(3) and (4)

Paragraphs (3) and (4) of § 1.482–4(f) provide rules for determining the owner of intangible property for purposes of section 482 and also provide rules for determining the arm's length compensation in situations where a controlled party other than the owner makes contributions to the value of intangible property. Section 1.482–4(f)(3)(i)(A) provides that the legal owner of intangible property pursuant to the intellectual property law of the relevant jurisdiction, or the holder of rights constituting intangible property pursuant to contractual terms (such as the terms of a license) or other legal provision, will be considered the sole owner of intangible property for purposes of this section unless such ownership is inconsistent with the economic substance of the underlying transactions. Some commentators believe that the rules should specify that a holder of bare legal title to intangible property should not be presumed to be the owner when other parties have all of the other benefits and burdens of ownership. After considering the public comments, the Treasury Department and the IRS continue to believe that the legal ownership standard as set forth in § 1.482–4(f)(3)(i)(A) is the appropriate framework for determining ownership of intangible property under section 482.

The provisions of § 1.482–4(f)(3) and (4) are adopted without change.

C. Economic Substance

A number of commentators expressed similar and sometimes interrelated concerns regarding economic substance considerations, imputation of contractual terms, the realistic alternatives principle, and the rules for income attributable to intangible property. The common thread running through these comments is a concern that the IRS will inappropriately treat taxpayers as having engaged in transactions different from those in which they actually engaged.

Section 1.482–4(f)(3)(i)(A) provides that, if no owner of intangible property is identified under the intellectual property law of the relevant jurisdiction, or pursuant to contractual terms (including terms imputed pursuant to § 1.482–1(d)(3)(ii)(B)) or other legal provision, then the controlled taxpayer that has control of intangible property,

based on all the facts and circumstances, will be considered the sole owner of intangible property for purposes of this section. One commentator believes that the control rule for determining ownership of non-legally protected intangibles allows the IRS to attribute ownership of intangible property in a manner that is inconsistent with economic substance. Accordingly, the comment suggests that such control determinations must be consistent with economic substance in all cases. In the context of the control rule in § 1.482–4(f)(3)(i)(A), this is already reflected in the language “including terms imputed pursuant to § 1.482–1(d)(3)(ii)(B).”

Section 1.482–9T(h) of the 2006 temporary regulations provides that, consistent with the specified methods, an unspecified method should take into account the general principle that uncontrolled taxpayers compare the terms of a particular transaction to the realistic alternatives to that transaction, including economically similar transactions structured as other than services transactions, and only enter into a transaction if none of the alternatives is preferable to it. The realistic alternatives concept was imported from § 1.482–1(f)(2)(ii) to be consistent with the general aim to coordinate the analyses under the various sections of the regulations under section 482. This provision allows flexibility to consider non-services alternatives to a services transaction, for example, a transfer or license of intangible property, if such an approach provides the most reliable measure of an arm's length result.

Commentators suggested that the realistic alternative principle be clarified so that only transactions actually engaged in by the controlled taxpayer can constitute realistic alternatives or that the principle be removed altogether on the grounds that it inappropriately treats taxpayers as engaging in transactions other than those they chose. The Treasury Department and the IRS do not agree with the assertion that consideration of realistic alternatives improperly disregards a taxpayer's chosen arrangement and that the realistic alternative principle is limited to internal comparables. It is a longstanding principle under § 1.482–1(f)(2)(ii)(A) and in the valuation field, generally, that, although the Commissioner will evaluate the results of a transaction as actually structured by the taxpayer unless it lacks economic substance, the Commissioner may consider alternatives available in determining the arm's length valuation

of the controlled transaction. The realistic alternatives principle does not recast the transaction. Rather, it assumes that taxpayers are rational and will not choose to price an arrangement in a manner that makes them worse off economically than another available alternative. Thus, if the price associated with a realistic alternative appears preferable in comparison with the price associated with the chosen arrangement, the logical implication is that the actual arrangement has been priced incorrectly through a flawed application of the best method rule. This is further reflected in the example in § 1.482–9T(h), which illustrates when realistic alternatives may be considered to evaluate the arm's length consideration, and explicitly states that the best method rule of § 1.482–1(c) governs the analysis.

The unspecified method provisions in these final regulations are adopted without change.

Section 1.482–9(i)(3) provides that, consistent with the authority in § 1.482–1(d)(3)(ii)(B), the Commissioner may impute contingent-payment contractual terms in a controlled services transaction if the economic substance of the transaction is consistent with the existence of such terms. When the 2003 proposed regulations were issued, commentators expressed concerns with the rule for imputing contingent payment terms to the extent that it permits the IRS to recast arrangements if there is a disagreement about the pricing of a service. The temporary regulations responded to this concern by providing a new *Example 5* in § 1.482–1T(d)(3)(ii)(C) to illustrate that if a taxpayer's pricing is outside of the arm's length range, that fact alone would not support imputation of additional contractual terms based on economic substance grounds. Commentators responded, however, that the last sentence of *Example 5* perpetuated the same problem of allowing the IRS to recast arrangements if there were pricing disputes between a taxpayer and the IRS.

The Treasury Department and the IRS agree that the last sentence of *Example 5* in § 1.482–1T(d)(3)(ii)(C) did not clearly convey its intended meaning, which is that a transfer pricing method and the price derived from the application of that method do not inform the terms of the transaction or the risks borne by the entities. Rather, the selection and application of a transfer pricing method should be based on a comparability analysis of the transaction, which must consider the risks borne by each entity in the transaction. Thus, the last sentence in § 1.482–1T(d)(3)(ii)(C) *Example 5*,

paragraph (iv), was intended to explain that the IRS is not required to accept the transfer pricing method and form of payment terms of a transaction as represented by a taxpayer if they are inconsistent with the conduct of the entities and the economic substance of the transaction. Because this sentence caused confusion, it has been removed. However, the Treasury Department and the IRS affirm that the IRS may impute contingent-payment terms where the economic substance of the transaction is consistent with the existence of such terms.

D. Stewardship Expenses—§ 1.861–8

The regulations under § 1.861–8(e)(4) conform to, and are consistent with, the language relating to controlled services transactions as set forth in § 1.482–9(l). The regulations under § 1.861–8(e)(4) are applicable for taxable years beginning after December 31, 2006.

E. Effective/Applicability Date—§ 1.482–9(n)

These regulations are applicable for taxable years beginning after July 31, 2009. Controlled taxpayers may elect to apply retroactively all of the provisions of these regulations to any taxable year beginning after September 10, 2003. Such election will be effective for the year of the election and all subsequent taxable years.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. It is hereby certified that the collections of information in this regulation will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the collections of information are related to elective provisions for determining taxable income that simplify and reduce compliance burdens in connection with controlled services transactions. When collection of information is required, it is expected to take taxpayers approximately 2 hours to comply, and the administrative and economic costs will be nominal in comparison with the resulting simplification and reduction of compliance burdens. Thus, the economic impact of the collections of information will not be significant. Similarly, while some small entities may be subject to the collections of

information if they elect one of the provisions, the collections of information are not expected to affect a substantial number of small entities. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Carol B. Tan and Gregory A. Spring, Office of Associate Chief Counsel (International) for matters relating to section 482, and Richard L. Chewning, Office of Associate Chief Counsel (International) for matters relating to stewardship expenses.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social Security and Unemployment compensation.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR parts 1, 31, and 602 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

Section 1.482–9 also issued under 26 U.S.C. 482. * * *

■ **Par. 2.** Section 1.482–0 is amended as follows:

■ 1. The introductory text is revised.

■ 2. The entries for § 1.482–1(a)(1), (d)(3)(ii)(C), (d)(3)(v), (f)(2)(ii)(A), (f)(2)(iii)(B), (g)(4)(iii), (i) and (j) are revised.

■ 3. The entries for § 1.482–2(b), (e) and (f) are revised.

■ 4. The entries for § 1.482–4(f)(3), (f)(4), (g), and (h) are revised.

■ 5. The entry for § 1.482–4(f)(7) is removed.

■ 6. The entries for § 1.482–6(c)(2)(ii)(B)(1), (c)(2)(ii)(D), (c)(3)(i)(A),

(c)(3)(i)(B), (c)(3)(ii)(D), and (d) are revised.

■ 7. The entry for § 1.482–8(c) is added.

■ 8. The entries for § 1.482–9 are revised.

The addition and revisions read as follows:

§ 1.482–0 Outline of regulations under section 482.

This section contains major captions for §§ 1.482–1 through 1.482–9.

§ 1.482–1 Allocation of income and deductions among taxpayers.

- (a) * * *
- (1) Purpose and scope.
- * * * * *
- (d) * * *
- (3) * * *
- (ii) * * *
- (C) Examples.
- * * * * *
- (v) Property or services.
- * * * * *
- (f) * * *
- (2) * * *
- (ii) * * *
- (A) In general.
- * * * * *
- (iii) * * *
- (A) * * *
- (B) Circumstances warranting consideration of multiple year data.
- * * * * *
- (g) * * *
- (4) * * *
- (iii) Examples.
- * * * * *
- (i) Definitions.
- (j) Effective/applicability date.

§ 1.482–2 Determination of taxable income in specific situations.

- * * * * *
- (b) Rendering of services.
- * * * * *
- (e) [Reserved]. For further guidance, see § 1.482–0T, the entry for § 1.482–2T(e).
- (f) Effective/applicability date.
- * * * * *

§ 1.482–4 Methods to determine taxable income in connection with a transfer of intangible property.

- * * * * *
- (f) * * *
- (3) Ownership of intangible property.
- (i) Identification of owner.
- (A) In general.
- (B) [Reserved]. For further guidance, see § 1.482–0T, the entry for § 1.482–4T(f)(3)(i)(B).
- (ii) Examples.
- (4) Contribution to the value of intangible property owned by another.
- (i) In general.

(ii) Examples.

* * * * *

(g) [Reserved]. For further guidance, see § 1.482-0T, the entry for § 1.482-4T(g).

(h) Effective/applicability date.

* * * * *

§ 1.482-6 Profit split method.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) * * *.

(1) In general.

* * * * *

(D) Other factors affecting reliability.

* * * * *

(3) * * *

(i) * * *

(A) Allocate income to routine contributions.

(B) Allocate residual profit.

(1) Nonroutine contributions generally.

(2) Nonroutine contributions of intangible property.

(ii) * * *

(D) Other factors affecting reliability.

* * * * *

(d) Effective/applicability date.

§ 1.482-8 Examples of the best method rule.

* * * * *

(c) Effective/applicability date.

§ 1.482-9 Methods to determine taxable income in connection with a controlled services transaction.

(a) In general.

(b) Services cost method.

(1) In general.

(2) Eligibility for the services cost method.

(3) Covered services.

(i) Specified covered services.

(ii) Low margin covered services.

(4) Excluded activities.

(5) Not services that contribute significantly to fundamental risks of business success or failure.

(6) Adequate books and records.

(7) Shared services arrangement.

(i) In general.

(ii) Requirements for shared services arrangement.

(A) Eligibility.

(B) Allocation.

(C) Documentation.

(iii) Definitions and special rules.

(A) Participant.

(B) Aggregation.

(C) Coordination with cost sharing arrangements.

(8) Examples.

(c) Comparable uncontrolled services price method.

(1) In general.

(2) Comparability and reliability considerations.

(i) In general.

(ii) Comparability.

(A) In general.

(B) Adjustments for differences between controlled and uncontrolled transactions.

(iii) Data and assumptions.

(3) Arm's length range.

(4) Examples.

(5) Indirect evidence of the price of a comparable uncontrolled services transaction.

(i) In general.

(ii) Example.

(d) Gross services margin method.

(1) In general.

(2) Determination of arm's length price.

(i) In general.

(ii) Relevant uncontrolled transaction.

(iii) Applicable uncontrolled price.

(iv) Appropriate gross services profit.

(v) Arm's length range.

(3) Comparability and reliability considerations.

(i) In general.

(ii) Comparability.

(A) Functional comparability.

(B) Other comparability factors.

(C) Adjustments for differences between controlled and uncontrolled transactions.

(D) Buy-sell distributor.

(iii) Data and assumptions.

(A) In general.

(B) Consistency in accounting.

(4) Examples.

(e) Cost of services plus method.

(1) In general.

(2) Determination of arm's length price.

(i) In general.

(ii) Appropriate gross services profit.

(iii) Comparable transactional costs.

(iv) Arm's length range.

(3) Comparability and reliability considerations.

(i) In general.

(ii) Comparability.

(A) Functional comparability.

(B) Other comparability factors.

(C) Adjustments for differences between the controlled and uncontrolled transactions.

(iii) Data and assumptions.

(A) In general.

(B) Consistency in accounting.

(4) Examples.

(f) Comparable profits method.

(1) In general.

(2) Determination of arm's length result.

(i) Tested party.

(ii) Profit level indicators.

(iii) Comparability and reliability considerations—Data and assumptions—Consistency

in accounting.

(3) Examples.

(g) Profit split method.

(1) In general.

(2) Examples.

(h) Unspecified methods.

(i) Contingent-payment contractual terms for services.

(1) Contingent-payment contractual terms recognized in general.

(2) Contingent-payment arrangement.

(i) General requirements.

(A) Written contract.

(B) Specified contingency.

(C) Basis for payment.

(ii) Economic substance and conduct.

(3) Commissioner's authority to

impute contingent-payment terms.

(4) Evaluation of arm's length charge.

(5) Examples.

(j) Total services costs.

(k) Allocation of costs.

(1) In general.

(2) Appropriate method of allocation and apportionment.

(i) Reasonable method standard.

(ii) Use of general practices.

(3) Examples.

(l) Controlled services transaction.

(1) In general.

(2) Activity.

(3) Benefit.

(i) In general.

(ii) Indirect or remote benefit.

(iii) Duplicative activities.

(iv) Shareholder activities.

(v) Passive association.

(4) Disaggregation of transactions.

(5) Examples.

(m) Coordination with transfer pricing rules for other transactions.

(1) Services transactions that include other types of transactions.

(2) Services transactions that effect a transfer of intangible property.

(3) [Reserved]. For further guidance, see § 1.482-0T, the entry for § 1.482-9T(m)(3).

(4) Other types of transactions that include controlled services transactions.

(5) Examples.

(n) Effective/applicability date.

(1) In general.

(2) Election to apply regulations to earlier taxable years.

■ **Par. 3.** Section 1.482-0T is amended as follows:

■ 1. Revise the section heading and introductory text.

■ 2. Revise the section headings for §§ 1.482-1T, 1.482-4T and 1.482.9T and the entries for §§ 1.482-1T, 1.482-2T, 1.482-4T and 1.482.9T.

■ 3. Remove the entries for § 1.482-6T.

The revisions read as follows:

§ 1.482-0T Outline of regulations under section 482 (temporary).

This section contains major captions for §§ 1.482-1T, 1.482-2T, 1.482-4T, 1.482-7T, 1.482-8T, and 1.482-9T.

§ 1.482–1T Allocation of income and deductions among taxpayers (temporary).

(a) through (b)(2) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–1(a) through (b)(2).

(i) Methods.

(ii) [Reserved]. For further guidance, see § 1.482–0, the entry for § 1.482–1(b)(2)(ii).

(iii) Coordination of methods applicable to certain intangible development arrangements.

(c) through (i) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–1(c) through (i).

(j) Effective/applicability date.

(k) Expiration date.

§ 1.482–2T Determination of taxable income in specific situations (temporary).

(a) through (d) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–2(a) through (d).

(e) Cost sharing arrangement.

(f) Effective/applicability date.

(1) In general.

(2) Election to apply regulation to earlier taxable years.

(3) Expiration date.

§ 1.482–4T Methods to determine taxable income in connection with a transfer of intangible property (temporary).

(a) through (f)(3)(i)(A) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–4(a) through (f)(3)(i)(A).

(B) Cost sharing arrangements.

(f)(3)(ii) through (f)(6) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–4(f)(3)(ii) through (f)(6).

(g) Coordination with rules governing cost sharing arrangements.

(h) Effective/applicability date.

(i) Expiration date.

* * * * *

§ 1.482–9T Methods to determine taxable income in connection with a controlled services transaction (temporary).

(a) through (m)(2) [Reserved]. For further guidance, see § 1.482–0, the entries for § 1.482–9(a) through (m)(2).

(3) Coordination with rules governing cost sharing arrangements.

(n) Effective/applicability dates.

(o) Expiration date.

■ **Par. 4.** Section 1.482–1 is amended by revising paragraphs (a)(1), (d)(3)(ii)(C) *Examples 3, 4, 5, and 6*, (d)(3)(v), (f)(2)(ii)(A), (f)(2)(iii)(B), (g)(4)(i), (g)(4)(iii) *Example 1*, (i), and (j)(6) to read as follows:

§ 1.482–1 Allocation of income and deductions among taxpayers.

(a) *In general*—(1) *Purpose and scope.* The purpose of section 482 is to ensure that taxpayers clearly reflect income

attributable to controlled transactions and to prevent the avoidance of taxes with respect to such transactions. Section 482 places a controlled taxpayer on a tax parity with an uncontrolled taxpayer by determining the true taxable income of the controlled taxpayer. This section sets forth general principles and guidelines to be followed under section 482. Section 1.482–2 provides rules for the determination of the true taxable income of controlled taxpayers in specific situations, including controlled transactions involving loans or advances or the use of tangible property. Sections 1.482–3 through 1.482–6 provide rules for the determination of the true taxable income of controlled taxpayers in cases involving the transfer of property. Section 1.482–7T sets forth the cost sharing provisions applicable to taxable years beginning on or after January 5, 2009. Section 1.482–8 provides examples illustrating the application of the best method rule. Finally, § 1.482–9 provides rules for the determination of the true taxable income of controlled taxpayers in cases involving the performance of services.

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(C) * * *

Example 3. Contractual terms imputed from economic substance. (i) FP, a foreign producer of wristwatches, is the registered holder of the YY trademark in the United States and in other countries worldwide. In year 1, FP enters the United States market by selling YY wristwatches to its newly organized United States subsidiary, USSub, for distribution in the United States market. USSub pays FP a fixed price per wristwatch. USSub and FP undertake, without separate compensation, marketing activities to establish the YY trademark in the United States market. Unrelated foreign producers of trademarked wristwatches and their authorized United States distributors respectively undertake similar marketing activities in independent arrangements involving distribution of trademarked wristwatches in the United States market. In years 1 through 6, USSub markets and sells YY wristwatches in the United States. Further, in years 1 through 6, USSub undertakes incremental marketing activities in addition to the activities similar to those observed in the independent distribution transactions in the United States market. FP does not directly or indirectly compensate USSub for performing these incremental activities during years 1 through 6. Assume that, aside from these incremental activities, and after any adjustments are made to improve the reliability of the comparison, the price paid per wristwatch by the independent, authorized distributors of wristwatches would provide the most reliable measure of the arm's length price paid per YY wristwatch by USSub.

(ii) By year 7, the wristwatches with the YY trademark generate a premium return in the United States market, as compared to wristwatches marketed by the independent distributors. In year 7, substantially all the premium return from the YY trademark in the United States market is attributed to FP, for example through an increase in the price paid per watch by USSub, or by some other means.

(iii) In determining whether an allocation of income is appropriate in year 7, the Commissioner may consider the economic substance of the arrangements between USSub and FP, and the parties' course of conduct throughout their relationship. Based on this analysis, the Commissioner determines that it is unlikely that, *ex ante*, an uncontrolled taxpayer operating at arm's length would engage in the incremental marketing activities to develop or enhance intangible property owned by another party unless it received contemporaneous compensation or otherwise had a reasonable anticipation of receiving a future benefit from those activities. In this case, USSub's undertaking the incremental marketing activities in years 1 through 6 is a course of conduct that is inconsistent with the parties' attribution to FP in year 7 of substantially all the premium return from the enhanced YY trademark in the United States market. Therefore, the Commissioner may impute one or more agreements between USSub and FP, consistent with the economic substance of their course of conduct, which would afford USSub an appropriate portion of the premium return from the YY trademark wristwatches. For example, the Commissioner may impute a separate services agreement that affords USSub contingent-payment compensation for its incremental marketing activities in years 1 through 6, which benefited FP by contributing to the value of the trademark owned by FP. In the alternative, the Commissioner may impute a long-term, exclusive agreement to exploit the YY trademark in the United States that allows USSub to benefit from the incremental marketing activities it performed. As another alternative, the Commissioner may require FP to compensate USSub for terminating USSub's imputed long-term, exclusive agreement to exploit the YY trademark in the United States, an agreement that USSub made more valuable at its own expense and risk. The taxpayer may present additional facts that could indicate which of these or other alternative agreements best reflects the economic substance of the underlying transactions, consistent with the parties' course of conduct in the particular case.

Example 4. Contractual terms imputed from economic substance. (i) FP, a foreign producer of athletic gear, is the registered holder of the AA trademark in the United States and in other countries worldwide. In year 1, FP enters into a licensing agreement that affords its newly organized United States subsidiary, USSub, exclusive rights to certain manufacturing and marketing intangible property (including the AA trademark) for purposes of manufacturing and marketing athletic gear in the United States under the AA trademark. The contractual terms of this

agreement obligate USSub to pay FP a royalty based on sales, and also obligate both FP and USSub to undertake without separate compensation specified types and levels of marketing activities. Unrelated foreign businesses license independent United States businesses to manufacture and market athletic gear in the United States, using trademarks owned by the unrelated foreign businesses. The contractual terms of these uncontrolled transactions require the licensees to pay royalties based on sales of the merchandise, and obligate the licensors and licensees to undertake without separate compensation specified types and levels of marketing activities. In years 1 through 6, USSub manufactures and sells athletic gear under the AA trademark in the United States. Assume that, after adjustments are made to improve the reliability of the comparison for any material differences relating to marketing activities, manufacturing or marketing intangible property, and other comparability factors, the royalties paid by independent licensees would provide the most reliable measure of the arm's length royalty owed by USSub to FP, apart from the additional facts in paragraph (ii) of this *Example 4*.

(ii) In years 1 through 6, USSub performs incremental marketing activities with respect to the AA trademark athletic gear, in addition to the activities required under the terms of the license agreement with FP, that are also incremental as compared to those observed in the comparables. FP does not directly or indirectly compensate USSub for performing these incremental activities during years 1 through 6. By year 7, AA trademark athletic gear generates a premium return in the United States, as compared to similar athletic gear marketed by independent licensees. In year 7, USSub and FP enter into a separate services agreement under which FP agrees to compensate USSub on a cost basis for the incremental marketing activities that USSub performed during years 1 through 6, and to compensate USSub on a cost basis for any incremental marketing activities it may perform in year 7 and subsequent years. In addition, the parties revise the license agreement executed in year 1, and increase the royalty to a level that attributes to FP substantially all the premium return from sales of the AA trademark athletic gear in the United States.

(iii) In determining whether an allocation of income is appropriate in year 7, the Commissioner may consider the economic substance of the arrangements between USSub and FP and the parties' course of conduct throughout their relationship. Based on this analysis, the Commissioner determines that it is unlikely that, ex ante, an uncontrolled taxpayer operating at arm's length would engage in the incremental marketing activities to develop or enhance intangible property owned by another party unless it received contemporaneous compensation or otherwise had a reasonable anticipation of a future benefit. In this case, USSub's undertaking the incremental marketing activities in years 1 through 6 is a course of conduct that is inconsistent with the parties' adoption in year 7 of contractual terms by which FP compensates USSub on a cost basis for the incremental marketing

activities that it performed. Therefore, the Commissioner may impute one or more agreements between USSub and FP, consistent with the economic substance of their course of conduct, which would afford USSub an appropriate portion of the premium return from the AA trademark athletic gear. For example, the Commissioner may impute a separate services agreement that affords USSub contingent-payment compensation for the incremental activities it performed during years 1 through 6, which benefited FP by contributing to the value of the trademark owned by FP. In the alternative, the Commissioner may impute a long-term, exclusive United States license agreement that allows USSub to benefit from the incremental activities. As another alternative, the Commissioner may require FP to compensate USSub for terminating USSub's imputed long-term United States license agreement, a license that USSub made more valuable at its own expense and risk. The taxpayer may present additional facts that could indicate which of these or other alternative agreements best reflects the economic substance of the underlying transactions, consistent with the parties' course of conduct in this particular case.

Example 5. Non-arm's length compensation. (i) The facts are the same as in paragraph (i) of *Example 4*. As in *Example 4*, assume that, after adjustments are made to improve the reliability of the comparison for any material differences relating to marketing activities, manufacturing or marketing intangible property, and other comparability factors, the royalties paid by independent licensees would provide the most reliable measure of the arm's length royalty owed by USSub to FP, apart from the additional facts described in paragraph (ii) of this *Example 5*.

(ii) In years 1 through 4, USSub performs certain incremental marketing activities with respect to the AA trademark athletic gear, in addition to the activities required under the terms of the basic license agreement, that are also incremental as compared with those activities observed in the comparables. At the start of year 1, FP enters into a separate services agreement with USSub, which states that FP will compensate USSub quarterly, in an amount equal to specified costs plus X%, for these incremental marketing functions. Further, these written agreements reflect the intent of the parties that USSub receive such compensation from FP throughout the term of the agreement, without regard to the success or failure of the promotional activities. During years 1 through 4, USSub performs marketing activities pursuant to the separate services agreement and in each year USSub receives the specified compensation from FP on a cost of services plus basis.

(iii) In evaluating year 4, the Commissioner performs an analysis of independent parties that perform promotional activities comparable to those performed by USSub and that receive separately-stated compensation on a current basis without contingency. The Commissioner determines that the magnitude of the specified cost plus X% is outside the arm's length range in each of years 1 through 4. Based on an evaluation of all the facts and circumstances, the Commissioner makes an allocation to require

payment of compensation to USSub for the promotional activities performed in year 4, based on the median of the interquartile range of the arm's length markups charged by the uncontrolled comparables described in paragraph (e)(3) of this section.

(iv) Given that based on facts and circumstances, the terms agreed by the controlled parties were that FP would bear all risks associated with the promotional activities performed by USSub to promote the AA trademark product in the United States market, and given that the parties' conduct during the years examined was consistent with this allocation of risk, the fact that the cost of services plus markup on USSub's services was outside the arm's length range does not, without more, support imputation of additional contractual terms based on alternative views of the economic substance of the transaction, such as terms indicating that USSub, rather than FP, bore the risk associated with these activities.

Example 6. Contractual terms imputed from economic substance. (i) Company X is a member of a controlled group that has been in operation in the pharmaceutical sector for many years. In years 1 through 4, Company X undertakes research and development activities. As a result of those activities, Company X developed a compound that may be more effective than existing medications in the treatment of certain conditions.

(ii) Company Y is acquired in year 4 by the controlled group that includes Company X. Once Company Y is acquired, Company X makes available to Company Y a large amount of technical data concerning the new compound, which Company Y uses to register patent rights with respect to the compound in several jurisdictions, making Company Y the legal owner of such patents. Company Y then enters into licensing agreements with group members that afford Company Y 100% of the premium return attributable to use of the intangible property by its subsidiaries.

(iii) In determining whether an allocation is appropriate in year 4, the Commissioner may consider the economic substance of the arrangements between Company X and Company Y, and the parties' course of conduct throughout their relationship. Based on this analysis, the Commissioner determines that it is unlikely that an uncontrolled taxpayer operating at arm's length would make available the results of its research and development or perform services that resulted in transfer of valuable know-how to another party unless it received contemporaneous compensation or otherwise had a reasonable anticipation of receiving a future benefit from those activities. In this case, Company X's undertaking the research and development activities and then providing technical data and know-how to Company Y in year 4 is inconsistent with the registration and subsequent exploitation of the patent by Company Y. Therefore, the Commissioner may impute one or more agreements between Company X and Company Y consistent with the economic substance of their course of conduct, which would afford Company X an appropriate portion of the premium return from the patent rights. For example, the Commissioner

may impute a separate services agreement that affords Company X contingent-payment compensation for its services in year 4 for the benefit of Company Y, consisting of making available to Company Y technical data, know-how, and other fruits of research and development conducted in previous years. These services benefited Company Y by giving rise to and contributing to the value of the patent rights that were ultimately registered by Company Y. In the alternative, the Commissioner may impute a transfer of patentable intangible property rights from Company X to Company Y immediately preceding the registration of patent rights by Company Y. The taxpayer may present additional facts that could indicate which of these or other alternative agreements best reflects the economic substance of the underlying transactions, consistent with the parties' course of conduct in the particular case.

* * * * *

(v) *Property or services.* Evaluating the degree of comparability between controlled and uncontrolled transactions requires a comparison of the property or services transferred in the transactions. This comparison may include any intangible property that is embedded in tangible property or services being transferred (embedded intangibles). The comparability of the embedded intangibles will be analyzed using the factors listed in § 1.482-4(c)(2)(iii)(B)(1) (comparable intangible property). The relevance of product comparability in evaluating the relative reliability of the results will depend on the method applied. For guidance concerning the specific comparability considerations applicable to transfers of tangible and intangible property and performance of services, see §§ 1.482-3 through 1.482-6 and § 1.482-9; see also §§ 1.482-3(f), 1.482-4(f)(4), and 1.482-9(m), dealing with the coordination of the intangible and tangible property and performance of services rules.

* * * * *

(f) * * *

(2) * * *

(ii) *Allocation based on taxpayer's actual transactions—(A) In general.* The Commissioner will evaluate the results of a transaction as actually structured by the taxpayer unless its structure lacks economic substance. However, the Commissioner may consider the alternatives available to the taxpayer in determining whether the terms of the controlled transaction would be acceptable to an uncontrolled taxpayer faced with the same alternatives and operating under comparable circumstances. In such cases the Commissioner may adjust the consideration charged in the controlled transaction based on the cost or profit of an alternative as adjusted to account for

material differences between the alternative and the controlled transaction, but will not restructure the transaction as if the alternative had been adopted by the taxpayer. See paragraph (d)(3) of this section (factors for determining comparability; contractual terms and risk); §§ 1.482-3(e), 1.482-4(d), and 1.482-9(h) (unspecified methods).

* * * * *

(iii) * * *

(B) *Circumstances warranting consideration of multiple year data.* The extent to which it is appropriate to consider multiple year data depends on the method being applied and the issue being addressed. Circumstances that may warrant consideration of data from multiple years include the extent to which complete and accurate data are available for the taxable year under review, the effect of business cycles in the controlled taxpayer's industry, or the effects of life cycles of the product or intangible property being examined. Data from one or more years before or after the taxable year under review must ordinarily be considered for purposes of applying the provisions of paragraph (d)(3)(iii) of this section (risk), paragraph (d)(4)(i) of this section (market share strategy), § 1.482-4(f)(2) (periodic adjustments), § 1.482-5 (comparable profits method), § 1.482-9(f) (comparable profits method for services), and § 1.482-9(i) (contingent-payment contractual terms for services). On the other hand, multiple year data ordinarily will not be considered for purposes of applying the comparable uncontrolled price method of § 1.482-3(b) or the comparable uncontrolled services price method of § 1.482-9(c) (except to the extent that risk or market share strategy issues are present).

* * * * *

(g) * * *

(4) *Setoffs—(i) In general.* If an allocation is made under section 482 with respect to a transaction between controlled taxpayers, the Commissioner will take into account the effect of any other non-arm's length transaction between the same controlled taxpayers in the same taxable year which will result in a setoff against the original section 482 allocation. Such setoff, however, will be taken into account only if the requirements of paragraph (g)(4)(ii) of this section are satisfied. If the effect of the setoff is to change the characterization or source of the income or deductions, or otherwise distort taxable income, in such a manner as to affect the U.S. tax liability of any member, adjustments will be made to reflect the correct amount of each

category of income or deductions. For purposes of this setoff provision, the term arm's length refers to the amount defined in paragraph (b) of this section (arm's length standard), without regard to the rules in § 1.482-2(a) that treat certain interest rates as arm's length rates of interest.

* * * * *

(iii) * * *

Example 1. P, a U.S. corporation, renders construction services to S, its foreign subsidiary in Country Y, in connection with the construction of S's factory. An arm's length charge for such services determined under § 1.482-9 would be \$100,000. During the same taxable year P makes available to S the use of a machine to be used in the construction of the factory, and the arm's length rental value of the machine is \$25,000. P bills S \$125,000 for the services, but does not charge S for the use of the machine. No allocation will be made with respect to the undercharge for the machine if P notifies the district director of the basis of the claimed setoff within 30 days after the date of the letter from the district director transmitting the examination report notifying P of the proposed adjustment, establishes that the excess amount charged for services was equal to an arm's length charge for the use of the machine and that the taxable income and income tax liabilities of P are not distorted, and documents the correlative allocations resulting from the proposed setoff.

* * * * *

(i) *Definitions.* The definitions set forth in paragraphs (i)(1) through (i)(10) of this section apply to this section and §§ 1.482-2 through 1.482-9.

* * * * *

(j) * * *

(6)(i) The provisions of paragraphs (a)(1), (d)(3)(ii)(C) *Example 3*, *Example 4*, *Example 5*, and *Example 6*, (d)(3)(v), (f)(2)(ii)(A), (f)(2)(iii)(B), (g)(4)(i), (g)(4)(iii), and (i) of this section are generally applicable for taxable years beginning after July 31, 2009.

(ii) A person may elect to apply the provisions of paragraphs (a)(1), (b)(2)(i), (d)(3)(ii)(C) *Example 3*, *Example 4*, *Example 5*, and *Example 6*, (d)(3)(v), (f)(2)(ii)(A), (f)(2)(iii)(B), (g)(4)(i), (g)(4)(iii), and (i) of this section to earlier taxable years in accordance with the rules set forth in § 1.482-9(n)(2).

■ **Par. 5.** Section 1.482-1T is amended by revising paragraphs (a), (b)(1), the first sentence in paragraph (b)(2)(i), (b)(2)(ii), the second sentence in paragraph (b)(2)(iii), (c), (d), (e), (f), (g), (h), (i), and (j) to read as follows:

§ 1.482-1T Allocation of income and deductions among taxpayers (temporary).

(a) through (b)(1) [Reserved]. For further guidance, see § 1.482-1(a) through (b)(1).

(b)(2) * * * (i) * * * Sections 1.482-2 through 1.482-6, 1.482-7T and 1.482-

9 provide specific methods to be used to evaluate whether transactions between or among members of the controlled group satisfy the arm's length standard, and if they do not, to determine the arm's length result. * * *

(ii) [Reserved]. For further guidance, see § 1.482-1(b)(2)(ii).

(iii) * * * Sections 1.482-4 and 1.482-9, as appropriate, provide the specific methods to be used to determine arm's length results of arrangements, including partnerships, for sharing the costs and risks of developing intangible property, other than a cost sharing arrangement covered by § 1.482-7T. * * *

(c) through (j)(5) [Reserved]. For further guidance, see § 1.482-1(c) through (j)(5).

(j)(6)(i) The provisions of paragraphs (b)(2)(i) and (b)(2)(iii) of this section are generally applicable on January 5, 2009.

(ii) [Reserved]. For further guidance, see § 1.482-1(j)(6)(ii).

(iii) The applicability of paragraphs (b)(2)(i) and (b)(2)(iii) of this section expires on or before December 30, 2011.

■ **Par. 6.** Section 1.482-2 is amended by revising paragraph (b), (e), and adding paragraph (f) to read as follows:

§ 1.482-2 Determination of taxable income in specific situations.

* * * * *

(b) *Rendering of services.* For rules governing allocations under section 482 to reflect an arm's length charge for controlled transactions involving the rendering of services, see § 1.482-9.

* * * * *

(e) [Reserved]. For further guidance, see § 1.482-2T(e).

(f) *Effective/applicability date*—(1) *In general.* The provision of paragraph (b) of this section is generally applicable for taxable years beginning after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the provisions of paragraph (b) of this section to earlier taxable years in accordance with the rules set forth in § 1.482-9(n)(2).

■ **Par. 7.** Section 1.482-2T is amended as follows:

■ 1. Revise paragraphs (a), (b), (c), (d), and (f)(2).

■ 2. Remove the first sentence in both paragraphs (f)(1) and (f)(3).

The revisions read as follows:

§ 1.482-2T Determination of taxable income in specific situations (temporary).

(a) through (d) [Reserved]. For further guidance, see § 1.482-2(a) through (d).

* * * * *

(f) * * *

(2) [Reserved]. For further guidance, see § 1.482-2(f)(2).

* * * * *

■ **Par. 8.** Section 1.482-4 is amended as follows:

■ 1. Revise paragraphs (f)(3) and (f)(4).

■ 2. Add paragraphs (g) and (h).

The revisions and addition read as follows:

§ 1.482-4 Methods to determine taxable income in connection with a transfer of intangible property.

* * * * *

(f) * * *

(3) *Ownership of intangible property*—(i) *Identification of owner*—(A) *In general.* The legal owner of intangible property pursuant to the intellectual property law of the relevant jurisdiction, or the holder of rights constituting an intangible property pursuant to contractual terms (such as the terms of a license) or other legal provision, will be considered the sole owner of the respective intangible property for purposes of this section unless such ownership is inconsistent with the economic substance of the underlying transactions. See § 1.482-1(d)(3)(ii)(B) (identifying contractual terms). If no owner of the respective intangible property is identified under the intellectual property law of the relevant jurisdiction, or pursuant to contractual terms (including terms imputed pursuant to § 1.482-1(d)(3)(ii)(B)) or other legal provision, then the controlled taxpayer who has control of the intangible property, based on all the facts and circumstances, will be considered the sole owner of the intangible property for purposes of this section.

(B) [Reserved]. For further guidance, see § 1.482-4T(f)(3)(i)(B).

(ii) *Examples.* The principles of this paragraph (f)(3) are illustrated by the following examples:

Example 1. FP, a foreign corporation, is the registered holder of the AA trademark in the United States. FP licenses to its U.S. subsidiary, USSub, the exclusive rights to manufacture and market products in the United States under the AA trademark. FP is the owner of the trademark pursuant to intellectual property law. USSub is the owner of the license pursuant to the terms of the license, but is not the owner of the trademark. See paragraphs (b)(3) and (4) of this section (defining an intangible as, among other things, a trademark or a license).

Example 2. The facts are the same as in *Example 1.* As a result of its sales and marketing activities, USSub develops a list of several hundred creditworthy customers that regularly purchase AA trademarked products. Neither the terms of the contract between FP and USSub nor the relevant intellectual property law specify which party

owns the customer list. Because USSub has knowledge of the contents of the list, and has practical control over its use and dissemination, USSub is considered the sole owner of the customer list for purposes of this paragraph (f)(3).

(4) *Contribution to the value of intangible property owned by another*—(i) *In general.* The arm's length consideration for a contribution by one controlled taxpayer that develops or enhances the value, or may be reasonably anticipated to develop or enhance the value, of intangible property owned by another controlled taxpayer will be determined in accordance with the applicable rules under section 482. If the consideration for such a contribution is embedded within the contractual terms for a controlled transaction that involves such intangible property, then ordinarily no separate allocation will be made with respect to such contribution. In such cases, pursuant to § 1.482-1(d)(3), the contribution must be accounted for in evaluating the comparability of the controlled transaction to uncontrolled comparables, and accordingly in determining the arm's length consideration in the controlled transaction.

(ii) *Examples.* The principles of this paragraph (f)(4) are illustrated by the following examples:

Example 1. A, a member of a controlled group, allows B, another member of the controlled group, to use tangible property, such as laboratory equipment, in connection with B's development of an intangible that B owns. By furnishing tangible property, A makes a contribution to the development of intangible property owned by another controlled taxpayer, B. Pursuant to paragraph (f)(4)(i) of this section, the arm's length charge for A's furnishing of tangible property will be determined under the rules for use of tangible property in § 1.482-2(c).

Example 2. (i) *Facts.* FP, a foreign producer of wristwatches, is the registered holder of the YY trademark in the United States and in other countries worldwide. FP enters into an exclusive, five-year, renewable agreement with its newly organized U.S. subsidiary, USSub. The contractual terms of the agreement grant USSub the exclusive right to re-sell YY trademark wristwatches in the United States, obligate USSub to pay a fixed price per wristwatch throughout the entire term of the contract, and obligate both FP and USSub to undertake without separate compensation specified types and levels of marketing activities.

(ii) The consideration for FP's and USSub's marketing activities, as well as the consideration for the exclusive right to re-sell YY trademarked merchandise in the United States, are embedded in the transfer price paid for the wristwatches. Accordingly, pursuant to paragraph (f)(4)(i) of this section, ordinarily no separate allocation would be

appropriate with respect to these embedded contributions.

(iii) Whether an allocation is warranted with respect to the transfer price for the wristwatches is determined under §§ 1.482–1, 1.482–3, and this section through § 1.482–6. The comparability analysis would include consideration of all relevant factors, including the nature of the intangible property embedded in the wristwatches and the nature of the marketing activities required under the agreement. This analysis would also take into account that the compensation for the activities performed by USSub and FP, as well as the consideration for USSub's use of the YY trademark, is embedded in the transfer price for the wristwatches, rather than provided for in separate agreements. See §§ 1.482–3(f) and 1.482–9(m)(4).

Example 3. (i) *Facts.* FP, a foreign producer of athletic gear, is the registered holder of the AA trademark in the United States and in other countries. In year 1, FP licenses to a newly organized U.S. subsidiary, USSub, the exclusive rights to use certain manufacturing and marketing intangible property to manufacture and market athletic gear in the United States under the AA trademark. The license agreement obligates USSub to pay a royalty based on sales of trademarked merchandise. The license agreement also obligates FP and USSub to perform without separate compensation specified types and levels of marketing activities. In year 1, USSub manufactures and sells athletic gear under the AA trademark in the United States.

(ii) The consideration for FP's and USSub's respective marketing activities is embedded in the contractual terms of the license for the AA trademark. Accordingly, pursuant to paragraph (f)(4)(i) of this section, ordinarily no separate allocation would be appropriate with respect to the embedded contributions in year 1. See § 1.482–9(m)(4).

(iii) Whether an allocation is warranted with respect to the royalty under the license agreement would be analyzed under § 1.482–1, and this section through § 1.482–6. The comparability analysis would include consideration of all relevant factors, such as the term and geographical exclusivity of the license, the nature of the intangible property subject to the license, and the nature of the marketing activities required to be undertaken pursuant to the license. Pursuant to paragraph (f)(4)(i) of this section, the analysis would also take into account the fact that the compensation for the marketing services is embedded in the royalty paid for use of the AA trademark, rather than provided for in a separate services agreement. For illustrations of application of the best method rule, see § 1.482–8 *Examples 10, 11, and 12.*

Example 4. (i) *Facts.* The year 1 facts are the same as in *Example 3*, with the following exceptions. In year 2, USSub undertakes certain incremental marketing activities in addition to those required by the contractual terms of the license for the AA trademark executed in year 1. The parties do not execute a separate agreement with respect to these incremental marketing activities performed by USSub. The license agreement executed in year 1 is of sufficient duration

that it is reasonable to anticipate that USSub will obtain the benefit of its incremental activities, in the form of increased sales or revenues of trademarked products in the U.S. market.

(ii) To the extent that it was reasonable to anticipate that USSub's incremental marketing activities would increase the value only of USSub's intangible property (that is, USSub's license to use the AA trademark for a specified term), and not the value of the AA trademark owned by FP, USSub's incremental activities do not constitute a contribution for which an allocation is warranted under paragraph (f)(4)(i) of this section.

Example 5. (i) *Facts.* The year 1 facts are the same as in *Example 3*. In year 2, FP and USSub enter into a separate services agreement that obligates USSub to perform certain incremental marketing activities to promote AA trademark athletic gear in the United States, above and beyond the activities specified in the license agreement executed in year 1. In year 2, USSub begins to perform these incremental activities, pursuant to the separate services agreement with FP.

(ii) Whether an allocation is warranted with respect to USSub's incremental marketing activities covered by the separate services agreement would be evaluated under §§ 1.482–1 and 1.482–9, including a comparison of the compensation provided for the services with the results obtained under a method pursuant to § 1.482–9, selected and applied in accordance with the best method rule of § 1.482–1(c).

(iii) Whether an allocation is warranted with respect to the royalty under the license agreement is determined under § 1.482–1, and this section through § 1.482–6. The comparability analysis would include consideration of all relevant factors, such as the term and geographical exclusivity of the license, the nature of the intangible property subject to the license, and the nature of the marketing activities required to be undertaken pursuant to the license. The comparability analysis would take into account that the compensation for the incremental activities by USSub is provided for in the separate services agreement, rather than embedded in the royalty paid for use of the AA trademark. For illustrations of application of the best method rule, see § 1.482–8 *Examples 10, 11, and 12.*

Example 6. (i) *Facts.* The year 1 facts are the same as in *Example 3*. In year 2, FP and USSub enter into a separate services agreement that obligates FP to perform incremental marketing activities, not specified in the year 1 license, by advertising AA trademarked athletic gear in selected international sporting events, such as the Olympics and the soccer World Cup. FP's corporate advertising department develops and coordinates these special promotions. The separate services agreement obligates USSub to pay an amount to FP for the benefit to USSub that may reasonably be anticipated as the result of FP's incremental activities. The separate services agreement is not a qualified cost sharing arrangement under § 1.482–7T. FP begins to perform the incremental activities in year 2 pursuant to the separate services agreement.

(ii) Whether an allocation is warranted with respect to the incremental marketing activities performed by FP under the separate services agreement would be evaluated under § 1.482–9. Under the circumstances, it is reasonable to anticipate that FP's activities would increase the value of USSub's license as well as the value of FP's trademark. Accordingly, the incremental activities by FP may constitute in part a controlled services transaction for which USSub must compensate FP. The analysis of whether an allocation is warranted would include a comparison of the compensation provided for the services with the results obtained under a method pursuant to § 1.482–9, selected and applied in accordance with the best method rule of § 1.482–1(c).

(iii) Whether an allocation is appropriate with respect to the royalty under the license agreement would be evaluated under §§ 1.482–1 through 1.482–3, this section, and §§ 1.482–5 and 1.482–6. The comparability analysis would include consideration of all relevant factors, such as the term and geographical exclusivity of USSub's license, the nature of the intangible property subject to the license, and the marketing activities required to be undertaken by both FP and USSub pursuant to the license. This comparability analysis would take into account that the compensation for the incremental activities performed by FP was provided for in the separate services agreement, rather than embedded in the royalty paid for use of the AA trademark. For illustrations of application of the best method rule, see § 1.482–8, *Example 10, Example 11, and Example 12.*

* * * * *

(g) [Reserved]. For further guidance, see § 1.482–4T(g).

(h) *Effective/applicability date*—(1) *In general.* The provisions of paragraphs (f)(3)(i)(A), (f)(3)(ii), and (f)(4) of this section are generally applicable for taxable years beginning after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the provisions of paragraphs (f)(3)(i)(A), (f)(3)(ii), and (f)(4) of this section to earlier taxable years in accordance with the rules set forth in § 1.482–9(n)(2).

■ **Par. 9.** Section 1.482–4T is amended as follows:

■ 1. Revise paragraphs (a), (b), (c), (d), (e), (f)(1), (f)(2), (f)(3)(i)(A), (f)(3)(ii), (f)(4), (f)(5), (f)(6), and (h)(3).

■ 2. Redesignate paragraph (h)(1) as paragraph (h), revise the heading and remove the first sentence in newly-designated paragraph (h).

■ 3. Remove paragraph (h)(2).

■ 4. Redesignate paragraph (h)(3) as paragraph (i).

The revisions read as follows:

§ 1.482-4T Methods to determine taxable income in connection with a transfer of intangible property (temporary).

(a) through (f)(3)(i)(A) [Reserved]. For further guidance, see § 1.482-4(a) through (f)(3)(i)(A).

(B) * * *

(f)(3)(ii) through (f)(6) [Reserved]. For further guidance, see § 1.482-4(f)(3)(ii) through (f)(6)

(g) * * *

(h) *Effective/applicability date.* * * *

* * * * *

■ **Par. 10.** Section 1.482-6 is amended by revising paragraphs (c)(2)(ii)(B)(1), (c)(2)(ii)(D), (c)(3)(i)(A), (c)(3)(i)(B), (c)(3)(ii)(D), and adding paragraph (d) to read as follows:

§ 1.482-6 Profit split method.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) *Comparability—(1) In general.* The degree of comparability between the controlled and uncontrolled taxpayers is determined by applying the comparability provisions of § 1.482-1(d). The comparable profit split compares the division of operating profits among the controlled taxpayers to the division of operating profits among uncontrolled taxpayers engaged in similar activities under similar circumstances. Although all of the factors described in § 1.482-1(d)(3) must be considered, comparability under this method is particularly dependent on the considerations described under the comparable profits method in § 1.482-5(c)(2) or § 1.482-9(f)(2)(iii) because this method is based on a comparison of the operating profit of the controlled and uncontrolled taxpayers. In addition, because the contractual terms of the relationship among the participants in the relevant business activity will be a principal determinant of the allocation of functions and risks among them, comparability under this method also depends particularly on the degree of similarity of the contractual terms of the controlled and uncontrolled taxpayers. Finally, the comparable profit split may not be used if the combined operating profit (as a percentage of the combined assets) of the uncontrolled comparables varies significantly from that earned by the controlled taxpayers.

* * * * *

(D) *Other factors affecting reliability.* Like the methods described in §§ 1.482-3, 1.482-4, 1.482-5, and 1.482-9, the comparable profit split relies exclusively on external market benchmarks. As indicated in § 1.482-1(c)(2)(i), as the degree of comparability between the controlled and

uncontrolled transactions increases, the relative weight accorded the analysis under this method will increase. In addition, the reliability of the analysis under this method may be enhanced by the fact that all parties to the controlled transaction are evaluated under the comparable profit split. However, the reliability of the results of an analysis based on information from all parties to a transaction is affected by the reliability of the data and the assumptions pertaining to each party to the controlled transaction. Thus, if the data and assumptions are significantly more reliable with respect to one of the parties than with respect to the others, a different method, focusing solely on the results of that party, may yield more reliable results.

* * * * *

(3) * * *

(i) * * *

(A) *Allocate income to routine contributions.* The first step allocates operating income to each party to the controlled transactions to provide a market return for its routine contributions to the relevant business activity. Routine contributions are contributions of the same or a similar kind to those made by uncontrolled taxpayers involved in similar business activities for which it is possible to identify market returns. Routine contributions ordinarily include contributions of tangible property, services and intangible property that are generally owned by uncontrolled taxpayers engaged in similar activities. A functional analysis is required to identify these contributions according to the functions performed, risks assumed, and resources employed by each of the controlled taxpayers. Market returns for the routine contributions should be determined by reference to the returns achieved by uncontrolled taxpayers engaged in similar activities, consistent with the methods described in §§ 1.482-3, 1.482-4, 1.482-5 and 1.482-9.

(B) *Allocate residual profit—(1) Nonroutine contributions generally.* The allocation of income to the controlled taxpayer's routine contributions will not reflect profits attributable to each controlled taxpayer's contributions to the relevant business activity that are not routine (nonroutine contributions). A nonroutine contribution is a contribution that is not accounted for as a routine contribution. Thus, in cases where such nonroutine contributions are present there normally will be an unallocated residual profit after the allocation of income described in paragraph (c)(3)(i)(A) of this section. Under this second step, the residual

profit generally should be divided among the controlled taxpayers based upon the relative value of their nonroutine contributions to the relevant business activity. The relative value of the nonroutine contributions of each taxpayer should be measured in a manner that most reliably reflects each nonroutine contribution made to the controlled transaction and each controlled taxpayer's role in the nonroutine contributions. If the nonroutine contribution by one of the controlled taxpayers is also used in other business activities (such as transactions with other controlled taxpayers), an appropriate allocation of the value of the nonroutine contribution must be made among all the business activities in which it is used.

(2) *Nonroutine contributions of intangible property.* In many cases, nonroutine contributions of a taxpayer to the relevant business activity may be contributions of intangible property. For purposes of paragraph (c)(3)(i)(B)(1) of this section, the relative value of nonroutine intangible property contributed by taxpayers may be measured by external market benchmarks that reflect the fair market value of such intangible property. Alternatively, the relative value of nonroutine intangible property contributions may be estimated by the capitalized cost of developing the intangible property and all related improvements and updates, less an appropriate amount of amortization based on the useful life of each intangible property. Finally, if the intangible property development expenditures of the parties are relatively constant over time and the useful life of the intangible property contributed by all parties is approximately the same, the amount of actual expenditures in recent years may be used to estimate the relative value of nonroutine intangible property contributions.

* * * * *

(ii) * * *

(D) *Other factors affecting reliability.* Like the methods described in §§ 1.482-3, 1.482-4, 1.482-5, and 1.482-9, the first step of the residual profit split relies exclusively on external market benchmarks. As indicated in § 1.482-1(c)(2)(i), as the degree of comparability between the controlled and uncontrolled transactions increases, the relative weight accorded the analysis under this method will increase. In addition, to the extent the allocation of profits in the second step is not based on external market benchmarks, the reliability of the analysis will be decreased in relation to an analysis

under a method that relies on market benchmarks. Finally, the reliability of the analysis under this method may be enhanced by the fact that all parties to the controlled transaction are evaluated under the residual profit split. However, the reliability of the results of an analysis based on information from all parties to a transaction is affected by the reliability of the data and the assumptions pertaining to each party to the controlled transaction. Thus, if the data and assumptions are significantly more reliable with respect to one of the parties than with respect to the others, a different method, focusing solely on the results of that party, may yield more reliable results.

* * * * *

(d) *Effective/applicability date*—(1) *In general.* The provisions of paragraphs (c)(2)(ii)(B)(1) and (D), (c)(3)(i)(A) and (B), and (c)(3)(ii)(D) of this section are generally applicable for taxable years beginning after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the provisions of paragraphs (c)(2)(ii)(B)(1) and (D), (c)(3)(i)(A) and (B), and (c)(3)(ii)(D) of this section to earlier taxable years in accordance with the rules set forth in § 1.482–9(n)(2).

§ 1.482–6T [Removed]

■ **Par. 11.** Section 1.482–6T is removed.

■ **Par. 12.** Section 1.482–8 is amended by revising paragraph (b) *Examples 10, 11, 12, 13, 14, 15, 16, 17 and 18*, and adding paragraph (c) to read as follows:

§ 1.482–8 Examples of the best method rule.

* * * * *

(b) * * *

Example 10. Cost of services plus method preferred to other methods. (i) FP designs and manufactures consumer electronic devices that incorporate advanced technology. In year 1, FP introduces Product X, an entertainment device targeted primarily at the youth market. FP's wholly-owned, exclusive U.S. distributor, USSub, sells Product X in the U.S. market. USSub hires an independent marketing firm, Agency A, to promote Product X in the U.S. market. Agency A has successfully promoted other electronic products on behalf of other uncontrolled parties. USSub executes a one-year, renewable contract with Agency A that requires it to develop the market for Product X, within an annual budget set by USSub. In years 1 through 3, Agency A develops advertising, buys media, and sponsors events featuring Product X. Agency A receives a markup of 25% on all expenses of promoting Product X, with the exception of media buys, which are reimbursed at cost. During year 3, sales of Product X decrease sharply, as Product X is displaced by competitors' products. At the end of year 3, sales of Product X are discontinued.

(ii) Prior to the start of year 4, FP develops a new entertainment device, Product Y. Like Product X, Product Y is intended for sale to the youth market, but it is marketed under a new trademark distinct from that used for Product X. USSub decides to perform all U.S. market promotion for Product Y. USSub hires key Agency A staff members who handled the successful Product X campaign. To promote Product Y, USSub intends to use methods similar to those used successfully by Agency A to promote Product X (print advertising, media, event sponsorship, etc.). FP and USSub enter into a one-year, renewable agreement concerning promotion of Product Y in the U.S. market. Under the agreement, FP compensates USSub for promoting Product Y, based on a cost of services plus markup of A%. Third-party media buys by USSub in connection with Product Y are reimbursed at cost.

(iii) Assume that under the contractual arrangements between FP and USSub, the arm's length consideration for Product Y and the trademark or other intangible property may be determined reliably under one or more transfer pricing methods. At issue in this example is the separate evaluation of the arm's length compensation for the year 4 promotional activities performed by USSub pursuant to its contract with FP.

(iv) USSub's accounting records contain reliable data that separately state the costs incurred to promote Product Y. A functional analysis indicates that USSub's activities to promote Product Y in year 4 are similar to activities performed by Agency A during years 1 through 3 under the contract with FP. In other respects, no material differences exist in the market conditions or the promotional activities performed in year 4, as compared to those in years 1 through 3.

(v) It is possible to identify uncontrolled distributors or licensees of electronic products that perform, as one component of their business activities, promotional activities similar to those performed by USSub. However, it is unlikely that publicly available accounting data from these companies would allow computation of the comparable transactional costs or total services costs associated with the marketing or promotional activities that these entities perform, as one component of business activities. If that were possible, the comparable profits method for services might provide a reliable measure of an arm's length result. The functional analysis of the marketing activities performed by USSub in year 4 indicates that they are similar to the activities performed by Agency A in years 1 through 3 for Product X. Because reliable information is available concerning the markup on costs charged in a comparable uncontrolled transaction, the most reliable measure of an arm's length price is the cost of services plus method in § 1.482–9(e).

Example 11. CPM for services preferred to other methods. (i) FP manufactures furniture and accessories for residential use. FP sells its products to retailers in Europe under the trademark, "Moda." FP holds all worldwide rights to the trademark, including in the United States. USSub is FP's wholly-owned subsidiary in the U.S. market and the exclusive U.S. distributor of FP's

merchandise. Historically, USSub dealt only with specialized designers in the U.S. market and advertised in trade publications targeted to this market. Although items sold in the U.S. and Europe are physically identical, USSub's U.S. customers generally resell the merchandise as non-branded merchandise.

(ii) FP retains an independent firm to evaluate the feasibility of selling FP's trademarked merchandise in the general wholesale and retail market in the United States. The study concludes that this segment of the U.S. market, which is not exploited by USSub, may generate substantial profits. Based on this study, FP enters into a separate agreement with USSub, which provides that USSub will develop this market in the United States for the benefit of FP. USSub separately accounts for personnel expenses, overhead, and out-of-pocket costs attributable to the initial stage of the marketing campaign (Phase I). USSub receives as compensation its costs, plus a markup of X%, for activities in Phase I. At the end of Phase I, FP will evaluate the program. If success appears likely, USSub will begin full-scale distribution of trademarked merchandise in the new market segment, pursuant to agreements negotiated with FP at that time.

(iii) Assume that under the contractual arrangements in effect between FP and USSub, the arm's length consideration for the merchandise and the trademark or other intangible property may be determined reliably under one or more transfer pricing methods. At issue in this example is the separate evaluation of the arm's length compensation for the marketing activities conducted by USSub in years 1 and following.

(iv) A functional analysis reveals that USSub's activities consist primarily of modifying the promotional materials created by FP, negotiating media buys, and arranging promotional events. FP separately compensates USSub for all Phase I activities, and detailed accounting information is available regarding the costs of these activities. The Phase I activities of USSub are similar to those of uncontrolled companies that perform, as their primary business activity, a range of advertising and media relations activities on a contract basis for uncontrolled parties.

(v) No information is available concerning the comparable uncontrolled prices for services in transactions similar to those engaged in by FP and USSub. Nor is any information available concerning uncontrolled transactions that would allow application of the cost of services plus method. It is possible to identify uncontrolled distributors or licensees of home furnishings that perform, as one component of their business activities, promotional activities similar to those performed by USSub. However, it is unlikely that publicly available accounting data from these companies would allow computation of the comparable transactional costs or total services costs associated with the marketing or promotional activities that these entities performed, as one component of their business activities. On the other hand, it is possible to identify uncontrolled advertising and media relations companies, the principal

business activities of which are similar to the Phase I activities of USSub. Under these circumstances, the most reliable measure of an arm's length price is the comparable profits method of § 1.482-9(f). The uncontrolled advertising comparables' treatment of material items, such as classification of items as cost of goods sold or selling, general, and administrative expenses, may differ from that of USSub. Such inconsistencies in accounting treatment between the uncontrolled comparables and the tested party, or among the comparables, are less important when using the ratio of operating profit to total services costs under the comparable profits method for services in § 1.482-9(f). Under this method, the operating profit of USSub from the Phase I activities is compared to the operating profit of uncontrolled parties that perform general advertising and media relations as their primary business activity.

Example 12. Residual profit split preferred to other methods. (i) USP is a manufacturer of athletic apparel sold under the AA trademark, to which FP owns the worldwide rights. USP sells AA trademark apparel in countries throughout the world, but prior to year 1, USP did not sell its merchandise in Country X. In year 1, USP acquires an uncontrolled Country X company which becomes its wholly-owned subsidiary, XSub. USP enters into an exclusive distribution arrangement with XSub in Country X. Before being acquired by USP in year 1, XSub distributed athletic apparel purchased from uncontrolled suppliers and resold that merchandise to retailers. After being acquired by USP in year 1, XSub continues to distribute merchandise from uncontrolled suppliers and also begins to distribute AA trademark apparel. Under a separate agreement with USP, XSub uses its best efforts to promote the AA trademark in Country X, with the goal of maximizing sales volume and revenues from AA merchandise.

(ii) Prior to year 1, USP executed long-term endorsement contracts with several prominent professional athletes. These contracts give USP the right to use the names and likenesses of the athletes in any country in which AA merchandise is sold during the term of the contract. These contracts remain in effect for five years, starting in year 1. Before being acquired by USP, XSub renewed a long-term agreement with SportMart, an uncontrolled company that owns a nationwide chain of sporting goods retailers in Country X. XSub has been SportMart's primary supplier from the time that SportMart began operations. Under the agreement, SportMart will provide AA merchandise preferred shelf-space and will feature AA merchandise at no charge in its print ads and seasonal promotions. In consideration for these commitments, USP and XSub grant SportMart advance access to new products and the right to use the professional athletes under contract with USP in SportMart advertisements featuring AA merchandise (subject to approval of content by USP).

(iii) Assume that it is possible to segregate all transactions by XSub that involve distribution of merchandise acquired from uncontrolled distributors (non-controlled

transactions). In addition, assume that, apart from the activities undertaken by USP and XSub to promote AA apparel in Country X, the arm's length compensation for other functions performed by USP and XSub in the Country X market in years 1 and following can be reliably determined. At issue in this *Example 12* is the application of the residual profit split analysis to determine the appropriate division between USP and XSub of the balance of the operating profits from the Country X market, that is the portion attributable to nonroutine contributions to the marketing and promotional activities.

(iv) A functional analysis of the marketing and promotional activities conducted in the Country X market, as described in this example, indicates that both USP and XSub made nonroutine contributions to the business activity. USP contributed the long-term endorsement contracts with professional athletes. XSub contributed its long-term contractual rights with SportMart, which were made more valuable by its successful, long-term relationship with SportMart.

(v) Based on the facts and circumstances, including the fact that both USP and XSub made valuable nonroutine contributions to the marketing and promotional activities and an analysis of the availability (or lack thereof) of comparable and reliable market benchmarks, the Commissioner determines that the most reliable measure of an arm's length result is the residual profit split method in § 1.482-9(g). The residual profit split analysis would take into account both routine and nonroutine contributions by USP and XSub, in order to determine an appropriate allocation of the combined operating profits in the Country X market from the sale of AA merchandise and from related promotional and marketing activities.

Examples 13 through 18. [Reserved]. For further guidance, see § 1.482-8T(b) *Examples 13 through 18*.

(c) *Effective/applicability date*—(1) *In general.* The provisions of paragraph (b) *Examples 10, 11, and 12* of this section are generally applicable for taxable years beginning after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the provisions of paragraph (b) *Examples 10, 11, and 12* of this section to earlier taxable years in accordance with the rules set forth in § 1.482-9(n)(2).

■ **Par. 13.** Section 1.482-8T is amended as follows:

■ 1. Revise paragraph (b) *Examples 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12*.

■ 2. Redesignate paragraph (c)(1) as paragraph (c), revise the heading and remove the first sentence in newly-designated paragraph (c).

■ 3. Remove paragraph (c)(2).

■ 4. Redesignate paragraph (c)(3) as paragraph (d) and remove the first sentence.

The revisions read as follows:

§ 1.482-8T Examples of the best method rule (temporary).

* * * * *

(b) *Examples 1 through 12.* [Reserved]. For further guidance, see § 1.482-8(b) *Examples 1 through 12*.

* * * * *

(c) *Effective/applicability date.* * * *

* * * * *

■ **Par. 14.** Section 1.482-9 is added to read as follows:

§ 1.482-9 Methods to determine taxable income in connection with a controlled services transaction.

(a) *In general.* The arm's length amount charged in a controlled services transaction must be determined under one of the methods provided for in this section. Each method must be applied in accordance with the provisions of § 1.482-1, including the best method rule of § 1.482-1(c), the comparability analysis of § 1.482-1(d), and the arm's length range of § 1.482-1(e), except as those provisions are modified in this section. The methods are—

(1) The services cost method, described in paragraph (b) of this section;

(2) The comparable uncontrolled services price method, described in paragraph (c) of this section;

(3) The gross services margin method, described in paragraph (d) of this section;

(4) The cost of services plus method, described in paragraph (e) of this section;

(5) The comparable profits method, described in § 1.482-5 and in paragraph (f) of this section;

(6) The profit split method, described in § 1.482-6 and in paragraph (g) of this section; and

(7) Unspecified methods, described in paragraph (h) of this section.

(b) *Services cost method*—(1) *In general.* The services cost method evaluates whether the amount charged for certain services is arm's length by reference to the total services costs (as defined in paragraph (j) of this section) with no markup. If a taxpayer applies the services cost method in accordance with the rules of this paragraph (b), then it will be considered the best method for purposes of § 1.482-1(c), and the Commissioner's allocations will be limited to adjusting the amount charged for such services to the properly determined amount of such total services costs.

(2) *Eligibility for the services cost method.* To apply the services cost method to a service in accordance with the rules of this paragraph (b), all of the following requirements must be satisfied with respect to the service—

(i) The service is a covered service as defined in paragraph (b)(3) of this section;

(ii) The service is not an excluded activity as defined in paragraph (b)(4) of this section;

(iii) The service is not precluded from constituting a covered service by the business judgment rule described in paragraph (b)(5) of this section; and

(iv) Adequate books and records are maintained as described in paragraph (b)(6) of this section.

(3) *Covered services.* For purposes of this paragraph (b), covered services consist of a controlled service transaction or a group of controlled service transactions (*see* § 1.482–1(f)(2)(i) (aggregation of transactions)) that meet the definition of specified covered services or low margin covered services.

(i) *Specified covered services.* Specified covered services are controlled services transactions that the Commissioner specifies by revenue procedure. Services will be included in such revenue procedure based upon the Commissioner's determination that the specified covered services are support services common among taxpayers across industry sectors and generally do not involve a significant median comparable markup on total services costs. For the definition of the median comparable markup on total services costs, *see* paragraph (b)(3)(ii) of this section. The Commissioner may add to, subtract from, or otherwise revise the specified covered services described in the revenue procedure by subsequent revenue procedure, which amendments will ordinarily be prospective only in effect.

(ii) *Low margin covered services.* Low margin covered services are controlled services transactions for which the median comparable markup on total services costs is less than or equal to seven percent. For purposes of this paragraph (b), the median comparable markup on total services costs means the excess of the arm's length price of the controlled services transaction determined under the general section 482 regulations without regard to this paragraph (b), using the interquartile range described in § 1.482–1(e)(2)(iii)(C) and as necessary adjusting to the median of such interquartile range, over total services costs, expressed as a percentage of total services costs.

(4) *Excluded activity.* The following types of activities are excluded activities:

(i) Manufacturing.

(ii) Production.

(iii) Extraction, exploration, or processing of natural resources.

(iv) Construction.

(v) Reselling, distribution, acting as a sales or purchasing agent, or acting under a commission or other similar arrangement.

(vi) Research, development, or experimentation.

(vii) Engineering or scientific.

(viii) Financial transactions, including guarantees.

(ix) Insurance or reinsurance.

(5) *Not services that contribute significantly to fundamental risks of business success or failure.* A service cannot constitute a covered service unless the taxpayer reasonably concludes in its business judgment that the service does not contribute significantly to key competitive advantages, core capabilities, or fundamental risks of success or failure in one or more trades or businesses of the controlled group, as defined in § 1.482–1(i)(6). In evaluating the reasonableness of the conclusion required by this paragraph (b)(5), consideration will be given to all the facts and circumstances.

(6) *Adequate books and records.* Permanent books of account and records are maintained for as long as the costs with respect to the covered services are incurred by the renderer. Such books and records must include a statement evidencing the taxpayer's intention to apply the services cost method to evaluate the arm's length charge for such services. Such books and records must be adequate to permit verification by the Commissioner of the total services costs incurred by the renderer, including a description of the services in question, identification of the renderer and the recipient of such services, and sufficient documentation to allow verification of the methods used to allocate and apportion such costs to the services in question in accordance with paragraph (k) of this section.

(7) *Shared services arrangement—(i) In general.* If the services cost method is used to evaluate the amount charged for covered services, and such services are the subject of a shared services arrangement, then the arm's length charge to each participant for such services will be the portion of the total costs of the services otherwise determined under the services cost method of this paragraph (b) that is properly allocated to such participant pursuant to the arrangement.

(ii) *Requirements for shared services arrangement.* A shared services arrangement must meet the requirements described in this paragraph (b)(7).

(A) *Eligibility.* To be eligible for treatment under this paragraph (b)(7), a shared services arrangement must—

(1) Include two or more participants;

(2) Include as participants all controlled taxpayers that reasonably anticipate a benefit (as defined under paragraph (l)(3)(i) of this section) from one or more covered services specified in the shared services arrangement; and

(3) Be structured such that each covered service (or each reasonable aggregation of services within the meaning of paragraph (b)(7)(iii)(B) of this section) confers a benefit on at least one participant in the shared services arrangement.

(B) *Allocation.* The costs for covered services must be allocated among the participants based on their respective shares of the reasonably anticipated benefits from those services, without regard to whether the anticipated benefits are in fact realized. Reasonably anticipated benefits are benefits as defined in paragraph (l)(3)(i) of this section. The allocation of costs must provide the most reliable measure of the participants' respective shares of the reasonably anticipated benefits under the principles of the best method rule. *See* § 1.482–1(c). The allocation must be applied on a consistent basis for all participants and services. The allocation to each participant in each taxable year must reasonably reflect that participant's respective share of reasonably anticipated benefits for such taxable year. If the taxpayer reasonably concluded that the shared services arrangement (including any aggregation pursuant to paragraph (b)(7)(iii)(B) of this section) allocated costs for covered services on a basis that most reliably reflects the participants' respective shares of the reasonably anticipated benefits attributable to such services, as provided for in this paragraph (b)(7), then the Commissioner may not adjust such allocation basis.

(C) *Documentation.* The taxpayer must maintain sufficient documentation to establish that the requirements of this paragraph (b)(7) are satisfied, and include—

(1) A statement evidencing the taxpayer's intention to apply the services cost method to evaluate the arm's length charge for covered services pursuant to a shared services arrangement;

(2) A list of the participants and the renderer or renderers of covered services under the shared services arrangement;

(3) A description of the basis of allocation to all participants, consistent with the participants' respective shares of reasonably anticipated benefits; and

(4) A description of any aggregation of covered services for purposes of the shared services arrangement, and an indication whether this aggregation (if any) differs from the aggregation used to evaluate the median comparable markup for any low margin covered services described in paragraph (b)(3)(ii) of this section.

(iii) *Definitions and special rules—(A) Participant.* A participant is a controlled taxpayer that reasonably anticipates benefits from covered services subject to a shared services arrangement that substantially complies with the requirements described in this paragraph (b)(7).

(B) *Aggregation.* Two or more covered services may be aggregated in a reasonable manner taking into account all the facts and circumstances, including whether the relative magnitude of reasonably anticipated benefits of the participants sharing the costs of such aggregated services may be reasonably reflected by the allocation basis employed pursuant to paragraph (b)(7)(ii)(B) of this section. The aggregation of services under a shared services arrangement may differ from the aggregation used to evaluate the median comparable markup for any low margin covered services described in paragraph (b)(3)(ii) of this section, provided that such alternative aggregation can be implemented on a reasonable basis, including appropriately identifying and isolating relevant costs, as necessary.

(C) *Coordination with cost sharing arrangements.* To the extent that an allocation is made to a participant in a shared services arrangement that is also a participant in a cost sharing arrangement subject to § 1.482-7T, such amount with respect to covered services is first allocated pursuant to the shared services arrangement under this paragraph (b)(7). Costs allocated pursuant to a shared services arrangement may (if applicable) be further allocated between the intangible property development activity under § 1.482-7T and other activities of the participant.

(8) *Examples.* The application of this section is illustrated by the following examples. No inference is intended whether the presence or absence of one or more facts is determinative of the conclusion in any example. For purposes of *Examples 1* through *14*, assume that Company P and its subsidiaries, Company Q and Company R, are corporations and members of the same group of controlled entities (PQR Controlled Group). For purposes of *Example 15*, assume that Company P and its subsidiary, Company S, are

corporations and members of the same group of controlled entities (PS Controlled Group). For purposes of *Examples 16* through *24*, assume that Company P and its subsidiaries, Company X, Company Y, and Company Z, are corporations and members of the same group of controlled entities (PXYZ Group) and that Company P and its subsidiaries satisfy all of the requirements for a shared services arrangement specified in paragraphs (b)(7)(ii) and (iii) of this section.

Example 1. Data entry services. (i) Company P, Company Q, and Company R own and operate hospitals. Each owns an electronic database of medical information gathered by doctors and nurses during interviews and treatment of its patients. All three databases are maintained and updated by Company P's administrative support employees who perform data entry activities by entering medical information from the paper records of Company P, Company Q, and Company R into their respective databases.

(ii) Assume that these services relating to data entry are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 2. Data entry services. (i) Company P, Company Q, and Company R specialize in data entry, data processing, and data conversion. Company Q and Company R's data entry activities involve converting medical information data contained in paper records to a digital format. Company P specializes in data entry activities. This specialization reflects, in part, proprietary quality control systems and specially trained data entry experts used to ensure the highest degree of accuracy of data entry services. Company P is engaged by Company Q and Company R to perform these data entry activities for them. Company Q and Company R then charge their customers for the data entry activities performed by Company P.

(ii) Assume that these services performed by Company P relating to data entry are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 3. Recruiting services. (i) Company P, Company Q, and Company R are

manufacturing companies that sell their products to unrelated retail establishments. Company P's human resources department recruits mid-level managers and engineers for itself as well as for Company Q and Company R by attending job fairs and other recruitment events. For recruiting higher-level managers and engineers, each of these companies uses recruiters from unrelated executive search firms.

(ii) Assume that these services relating to recruiting are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 4. Recruiting services. (i) Company Q and Company R are executive recruiting service companies that are hired by other companies to recruit professionals. Company P is a recruiting agency that is engaged by Company Q and Company R to perform recruiting activities on their behalf in certain geographic areas.

(ii) Assume that the services performed by Company P are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 5. Credit analysis services. (i) Company P is a manufacturer and distributor of clothing for retail stores. Company Q and Company R are distributors of clothing for retail stores. As part of its operations, personnel in Company P perform credit analysis on its customers. Most of the customers have a history of purchases from Company P, and the credit analysis involves a review of the recent payment history of the customer's account. For new customers, the personnel in Company P perform a basic credit check of the customer using reports from a credit reporting agency. On behalf of Company Q and Company R, Company P performs credit analysis on customers who order clothing from Company Q and Company R using the same method as Company P uses for itself.

(ii) Assume that these services relating to credit analysis are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success

or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 6. Credit analysis services. (i) Company P, Company Q, and Company R lease furniture to retail customers who present a significant credit risk and are generally unable to lease furniture from other providers. As part of its leasing operations, personnel in Company P perform credit analysis on each of the potential lessees. The personnel have developed special expertise in determining whether a particular customer who presents a significant credit risk (as indicated by credit reporting agencies) will be likely to make the requisite lease payments on a timely basis. Also, as part of its operations, Company P performs similar credit analysis services for Company Q and Company R, which charge correspondingly high monthly lease payments.

(ii) Assume that these services relating to credit analysis are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 7. Credit analysis services. (i) Company P is a large full-service bank, which provides products and services to corporate and consumer markets, including unsecured loans, secured loans, lines of credit, letters of credit, conversion of foreign currency, consumer loans, trust services, and sales of certificates of deposit. Company Q makes routine consumer loans to individuals, such as auto loans and home equity loans. Company R makes only business loans to small businesses.

(ii) Company P performs credit analysis and prepares credit reports for itself, as well as for Company Q and Company R. Company P, Company Q and Company R regularly employ these credit reports in the ordinary course of business in making decisions regarding extensions of credit to potential customers (including whether to lend, rate of interest, and loan terms).

(iii) Assume that these services relating to credit analysis are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the credit analysis services constitute part of a "financial transaction" described in paragraph (b)(4)(viii) of this section. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 8. Data verification services. (i) Company P, Company Q and Company R are manufacturers of industrial supplies. Company P's accounting department performs periodic reviews of the accounts payable information of Company P, Company Q and Company R, and identifies any

inaccuracies in the records, such as double-payments and double-charges.

(ii) Assume that these services relating to verification of data are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 9. Data verification services. (i) Company P gathers and inputs information regarding accounts payable and accounts receivable from unrelated parties and utilizes its own computer system to analyze that information for purposes of identifying errors in payment and receipts (data mining). Company P is compensated for these services based on a fee that reflects a percentage of amounts collected by customers as a result of the data mining services. These activities constitute a significant portion of Company P's business. Company P performs similar activities for Company Q and Company R by analyzing their accounts payable and accounts receivable records.

(ii) Assume that these services relating to data mining are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 10. Legal services. (i) Company P is a domestic corporation with two wholly-owned foreign subsidiaries, Company Q and Company R. Company P and its subsidiaries manufacture and distribute equipment used by industrial customers. Company P maintains an in-house legal department consisting of attorneys experienced in a wide range of business and commercial matters. Company Q and Company R maintain small legal departments, consisting of attorneys experienced in matters that most frequently arise in the normal course of business of Company Q and Company R in their respective jurisdictions.

(ii) Company P seeks to maintain in-house legal staff with the ability to address the majority of legal matters that arise in the United States with respect to the operations of Company P, as well as any U.S. reporting or compliance obligations of Company Q or Company R. These include the preparation and review of corporate contracts relating to, for example, product sales, equipment purchases and leases, business liability insurance, real estate, employee salaries and benefits. Company P relies on outside attorneys for major business transactions and highly technical matters such as patent

licenses. The in-house legal staffs of Company Q and Company R are much more limited. It is necessary for Company P to retain several local law firms to handle litigation and business disputes arising from the activities of Company Q and Company R. Although Company Q and Company R pay the fees of these law firms, the hiring authority and general oversight of the firms' representation is in the legal department of Company P.

(iii) In determining what portion of the legal expenses of Company P may be allocated to Company Q and Company R, Company P first excludes any expenses relating to legal services that constitute shareholder activities and other items that are not properly analyzed as controlled services. Assume that the remaining services relating to general legal functions performed by in-house legal counsel are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these latter services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 11. Legal services. (i) Company P is a domestic holding company whose operating companies, Company Q and Company R, generate electric power for consumers by operating nuclear plants. Assume that, although Company P owns 100% of the stock of Companies Q and R, the companies do not elect to file a consolidated Federal income tax return with Company P.

(ii) Company P maintains an in-house legal department that includes attorneys who are experts in the areas of Federal utilities regulation, Federal labor and environmental law, and securities law. Companies Q and R maintain their own, smaller in-house legal staffs comprising experienced attorneys in the areas of state and local utilities regulation, state labor and employment law, and general commercial law. The legal department of Company P performs general oversight of the legal affairs of the company and determines whether a particular matter would be more efficiently handled by the Company P legal department, by the legal staffs in the operating companies, or in rare cases, by retained outside counsel. In general, Company P has succeeded in minimizing duplication and overlap of functions between the legal staffs of the various companies or by retained outside counsel.

(iii) The domestic nuclear power plant operations of Companies Q and R are subject to extensive regulation by the U.S. Nuclear Regulatory Commission (NRC). Operators are required to obtain pre-construction approval, operating licenses, and, at the end of the operational life of the nuclear reactor, nuclear decommissioning certificates. Company P files consolidated financial statements on behalf of itself, as well as Companies Q and R, with the United States

Securities and Exchange Commission (SEC). In these SEC filings, Company P discloses that failure to obtain any of these licenses (and the related periodic renewals) or agreeing to licenses on terms less favorable than those granted to competitors would have a material adverse impact on the operations of Company Q or Company R. Company Q and Company R do not have in-house legal staff with experience in the NRC area. Company P maintains a group of in-house attorneys with specialized expertise in the NRC area that exclusively represents Company Q and Company R before the NRC. Although Company P occasionally hires an outside law firm or industry expert to assist on particular NRC matters, the majority of the work is performed by the specialized legal staff of Company P.

(iv) Certain of the legal services performed by Company P constitute duplicative or shareholder activities that do not confer a benefit on the other companies and therefore do not need to be allocated to the other companies, while certain other legal services are eligible to be charged to Company Q and Company R in accordance with the services cost method.

(v) Assume that the specialized legal services relating to nuclear licenses performed by in-house legal counsel of Company P are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 12. Group of services. (i) Company P, Company Q, and Company R are manufacturing companies that sell their products to unrelated retail establishments. Company P has an enterprise resource planning (ERP) system that maintains data relating to accounts payable and accounts receivable information for all three companies. Company P's personnel perform the daily operations on this ERP system such as inputting data relating to accounts payable and accounts receivable into the system and extracting data relating to accounts receivable and accounts payable in the form of reports or electronic media and providing those data to all three companies. Periodically, Company P's computer specialists also modify the ERP system to adapt to changing business functions in all three companies. Company P's computer specialists make these changes by either modifying the underlying software program or by purchasing additional software or hardware from unrelated third party vendors.

(ii) Assume that the services relating to accounts payable and accounts receivable are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive

advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

(iii) Assume that the services performed by Company P's computer specialists that relate to modifying the ERP system are specifically excluded from the services described in a revenue procedure referenced in paragraph (b)(3) of this section as developing hardware or software solutions (such as systems integration, Web site design, writing computer programs, modifying general applications software, or recommending the purchase of commercially available hardware or software). If these services do not constitute low margin covered services within the meaning of paragraph (b)(3)(ii) of this section, then Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 13. Group of services. (i) Company P manufactures and sells widgets under an exclusive contract to Customer 1. Company Q and Company R sell widgets under exclusive contracts to Customer 2 and Customer 3, respectively. At least one year in advance, each of these customers can accurately forecast its need for widgets. Using these forecasts, each customer over the course of the year places orders for widgets with the appropriate company, Company P, Company Q, or Company R. A customer's actual need for widgets seldom deviates from that customer's forecasted need.

(ii) It is most efficient for the PQR Controlled Group companies to manufacture and store an inventory of widgets in advance of delivery. Although all three companies sell widgets, only Company P maintains a centralized warehouse for widgets. Pursuant to a contract, Company P provides storage of these widgets to Company Q and Company R at an arm's length price.

(iii) Company P's personnel also obtain orders from all three companies' customers to draw up purchase orders for widgets as well as make payment to suppliers for widget replacement parts. In addition, Company P's personnel use data entry to input information regarding orders and sales of widgets and replacement parts for all three companies into a centralized computer system. Company P's personnel also maintain the centralized computer system and extract data for all three companies when necessary.

(iv) Assume that these services relating to tracking purchases and sales of inventory are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances of the business of the PQR Controlled Group, the taxpayer could reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. If these services meet the other requirements of this paragraph (b), Company P will be eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 14. Group of services. (i) Company P, Company Q, and Company R assemble and sell gadgets to unrelated customers. Each of these companies purchases the components necessary for assembly of the gadgets from unrelated suppliers. As a service to its subsidiaries, Company P's personnel obtain orders for components from all three companies, prepare purchase orders, and make payment to unrelated suppliers for the components. In addition, Company P's personnel use data entry to input information regarding orders and sales of gadgets for all three companies into a centralized computer. Company P's personnel also maintain the centralized computer system and extract data for all three companies on an as-needed basis. The services provided by Company P personnel, in conjunction with the centralized computer system, constitute a state-of-the-art inventory management system that allows Company P to order components necessary for assembly of the gadgets on a "just-in-time" basis.

(ii) Unrelated suppliers deliver the components directly to Company P, Company Q and Company R. Each company stores the components in its own facilities for use in filling specific customer orders. The companies do not maintain any inventory that is not identified in specific customer orders. Because of the efficiencies associated with services provided by personnel of Company P, all three companies are able to significantly reduce their inventory-related costs. Company P's Chief Executive Officer makes a statement in one of its press conferences with industry analysts that its inventory management system is critical to the company's success.

(iii) Assume that these services relating to tracking purchases and sales of inventory are specified covered services within the meaning of paragraph (b)(3)(i) of this section. Under the facts and circumstances, the taxpayer is unable to reasonably conclude that these services do not contribute significantly to the controlled group's key competitive advantages, core capabilities, or fundamental risks of success or failure in the group's business. Company P is not eligible to charge these services to Company Q and Company R in accordance with the services cost method.

Example 15. Low margin covered services. Company P renders certain accounting services to Company S. Company P uses the services cost method for the accounting services, and determines the amount charged as its total cost of rendering the services, with no markup. Based on an application of the section 482 regulations without regard to this paragraph (b), the interquartile range of arm's length markups on total services costs for these accounting services is between 3% and 9%, and the median is 6%. Because the median comparable markup on total services costs is 6%, which is less than 7%, the accounting services constitute low margin covered services within the meaning of paragraph (b)(3)(ii) of this section.

Example 16. Shared services arrangement and reliable measure of reasonably anticipated benefit (allocation key). (i) Company P operates a centralized data processing facility that performs automated

invoice processing and order generation for all of its subsidiaries, Companies X, Y, Z, pursuant to a shared services arrangement.

(ii) In evaluating the shares of reasonably anticipated benefits from the centralized data processing services, the total value of the merchandise on the invoices and orders may not provide the most reliable measure of reasonably anticipated benefits shares, because value of merchandise sold does not bear a relationship to the anticipated benefits from the underlying covered services.

(iii) The total volume of orders and invoices processed may provide a more reliable basis for evaluating the shares of reasonably anticipated benefits from the data processing services. Alternatively, depending on the facts and circumstances, total central processing unit time attributable to the transactions of each subsidiary may provide a more reliable basis on which to evaluate the shares of reasonably anticipated benefits.

Example 17. Shared services arrangement and reliable measure of reasonably anticipated benefit (allocation key). (i) Company P operates a centralized center that performs human resources functions, such as administration of pension, retirement, and health insurance plans that are made available to employees of its subsidiaries, Companies X, Y, Z, pursuant to a shared services arrangement.

(ii) In evaluating the shares of reasonably anticipated benefits from these centralized services, the total revenues of each subsidiary may not provide the most reliable measure of reasonably anticipated benefit shares, because total revenues do not bear a relationship to the shares of reasonably anticipated benefits from the underlying services.

(iii) Employee headcount or total compensation paid to employees may provide a more reliable basis for evaluating the shares of reasonably anticipated benefits from the covered services.

Example 18. Shared services arrangement and reliable measure of reasonably anticipated benefit (allocation key). (i) Company P performs human resource services (service A) on behalf of the PXYZ Group that qualify for the services cost method. Under that method, Company P determines the amount charged for these services pursuant to a shared services arrangement based on an application of paragraph (b)(7) of this section. Service A constitutes a specified covered service described in a revenue procedure pursuant to paragraph (b)(3)(i) of this section. The total services costs for service A otherwise determined under the services cost method is 300.

(ii) Companies X, Y and Z reasonably anticipate benefits from service A. Company P does not reasonably anticipate benefits from service A. Assume that if relative reasonably anticipated benefits were precisely known, the appropriate allocation of charges pursuant to paragraph (k) of this section to Company X, Y and Z for service A is as follows:

SERVICE A
[Total cost 300]

Company	
X	150
Y	75
Z	75

(iii) The total number of employees (employee headcount) in each company is as follows:

Company X—600 employees.
Company Y—250 employees.
Company Z—250 employees.

(iv) Company P allocates the 300 total services costs of service A based on employee headcount as follows:

SERVICE A
[Total cost 300]

Allocation key	Company	
	Headcount	Amount
X	600	164
Y	250	68
Z	250	68

(v) Based on these facts, Company P may reasonably conclude that the employee headcount allocation basis most reliably reflects the participants' respective shares of the reasonably anticipated benefits attributable to service A.

Example 19. Shared services arrangement and reliable measure of reasonably anticipated benefit (allocation key). (i) Company P performs accounts payable services (service B) on behalf of the PXYZ Group and determines the amount charged for the services under such method pursuant to a shared services arrangement based on an application of paragraph (b)(7) of this section. Service B is a specified covered service described in a revenue procedure pursuant to paragraph (b)(3)(i) of this section. The total services costs for service B otherwise determined under the services cost method is 500.

(ii) Companies X, Y and Z reasonably anticipate benefits from service B. Company P does not reasonably anticipate benefits from service B. Assume that if relative reasonably anticipated benefits were precisely known, the appropriate allocation of charges pursuant to paragraph (k) of this section to Companies X, Y and Z for service B is as follows:

SERVICE B
[Total cost 500]

Company	
X	125
Y	205
Z	170

(iii) The total number of employees (employee headcount) in each company is as follows:

Company X—600.
Company Y—200.
Company Z—200.

(iv) The total number of transactions (transaction volume) with uncontrolled customers by each company is as follows:

Company X—2,000.
Company Y—4,000.
Company Z—3,500.

(v) If Company P allocated the 500 total services costs of service B based on employee headcount, the resulting allocation would be as follows:

SERVICE B
[Total cost 500]

Allocation key	Company	
	Headcount	Amount
X	600	300
Y	200	100
Z	200	100

(vi) In contrast, if Company P used volume of transactions with uncontrolled customers as the allocation basis under the shared services arrangement, the allocation would be as follows:

SERVICE B
[Total cost 500]

Allocation key	Company	
	Transaction Volume	Amount
X	2,000	105
Y	4,000	211
Z	3,500	184

(vii) Based on these facts, Company P may reasonably conclude that the transaction volume, but not the employee headcount, allocation basis most reliably reflects the participants' respective shares of the reasonably anticipated benefits attributable to service B.

Example 20. Shared services arrangement and aggregation. (i) Company P performs human resource services (service A) and accounts payable services (service B) on behalf of the PXYZ Group that qualify for the services cost method. Company P determines the amount charged for these services under such method pursuant to a shared services arrangement based on an application of paragraph (b)(7) of this section. Service A and service B are specified covered services described in a revenue procedure pursuant to paragraph (b)(3)(i) of this section. The total services costs otherwise determined under the services cost method for service A is 300 and for service B is 500; total services costs

for services A and B are 800. Company P determines that aggregation of services A and B for purposes of the arrangement is appropriate.

(ii) Companies X, Y and Z reasonably anticipate benefits from services A and B. Company P does not reasonably anticipate benefits from services A and B. Assume that if relative reasonably anticipated benefits were precisely known, the appropriate allocation of total charges pursuant to paragraph (k) of this section to Companies X, Y and Z for services A and B is as follows:

SERVICES A AND B

[Total cost 800]

Company	
X	350
Y	100
Z	350

(iii) The total volume of transactions with uncontrolled customers in each company is as follows:

Company X—2,000.

Company Y—4,000.

Company Z—4,000.

(iv) The total number of employees in each company is as follows:

Company X—600.

Company Y—200.

Company Z—200.

(v) If Company P allocated the 800 total services costs of services A and B based on transaction volume or employee headcount, the resulting allocation would be as follows:

AGGREGATED SERVICES AB

[Total cost 800]

Company	Allocation key		Allocation key	
	Transaction volume	Amount	Headcount	Amount
X	2,000	160	600	480
Y	4,000	320	200	160
Z	4,000	320	200	160

(vi) In contrast, if aggregated services AB were allocated by reference to the total U.S. dollar value of sales to uncontrolled parties (trade sales) by each company, the following results would obtain:

AGGREGATED SERVICES AB

[Total costs 800]

Company	Allocation key	
	Trade sales (millions)	Amount
X	\$400	314
Y	120	94
Z	500	392

(vii) Based on these facts, Company P may reasonably conclude that the trade sales, but not the transaction volume or the employee headcount, allocation basis most reliably reflects the participants' respective shares of the reasonably anticipated benefits attributable to services AB.

Example 21. Shared services arrangement and aggregation. (i) Company P performs services A through P on behalf of the PXYZ Group that qualify for the services cost method. Company P determines the amount charged for these services under such method pursuant to a shared services arrangement based on an application of paragraph (b)(7) of this section. All of these services A through P constitute either specified covered services or low margin covered services described in paragraph (b)(3) of this section.

The total services costs for services A through P otherwise determined under the services cost method is 500. Company P determines that aggregation of services A through P for purposes of the arrangement is appropriate.

(ii) Companies X and Y reasonably anticipate benefits from services A through P and Company Z reasonably anticipates benefits from services A through M but not from services N through P (Company Z performs services similar to services N through P on its own behalf). Company P does not reasonably anticipate benefits from services A through P. Assume that if relative reasonably anticipated benefits were precisely known, the appropriate allocation of total charges pursuant to paragraph (k) of this section to Company X, Y, and Z for services A through P is as follows:

Company	Services A–M (cost 490)	Services N–P (cost 10)	Services A–P (total cost 500)
X	90	5	95
Y	240	5	245
Z	160	160

(iii) The total volume of transactions with uncontrolled customers in each company is as follows:

Company X—2,000.

Company Y—4,500.

Company Z—3,500.

(iv) Company P allocates the 500 total services costs of services A through P based on transaction volume as follows:

AGGREGATED SERVICES A–Z

[Total costs 500]

Company	Allocation key	
	Transaction volume	Amount
X	2,000	100
Y	4,500	225
Z	3,500	175

(v) Based on these facts, Company P may reasonably conclude that the transaction volume allocation basis most reliably reflects

the participants' respective shares of the reasonably anticipated benefits attributable to services A through P.

Example 22. Renderer reasonably anticipates benefits. (i) Company P renders services on behalf of the PXYZ Group that qualify for the services cost method. Company P determines the amount charged for these services under such method. Company P's share of reasonably anticipated benefits from services A, B, C, and D is 20% of the total reasonably anticipated benefits of all participants. Company P's total services cost for services A, B, C, and D charged within the Group is 100.

(ii) Based on an application of paragraph (b)(7) of this section, Company P charges 80 which is allocated among Companies X, Y, and Z. No charge is made to Company P under the shared services arrangement for activities that it performs on its own behalf.

Example 23. Coordination with cost sharing arrangement. (i) Company P performs human resource services (service A) on behalf of the PXYZ Group that qualify for the services cost method. Company P determines the amount charged for these services under such method pursuant to a shared services arrangement based on an application of paragraph (b)(7) of this section. Service A constitutes a specified covered service described in a revenue procedure pursuant to paragraph (b)(3)(i) of this section. The total services costs for service A otherwise determined under the services cost method is 300.

(ii) Company X, Y, Z, and P reasonably anticipate benefits from service A. Using a basis of allocation that is consistent with the controlled participants' respective shares of the reasonably anticipated benefits from the shared services, the total charge of 300 is allocated as follows:

X—100.

Y—50.

Z—25.

P—125.

(iii) In addition to performing services, P undertakes 500 of R&D and incurs manufacturing and other costs of 1,000.

(iii) Companies P and X enter into a cost sharing arrangement in accordance with § 1.482–7T. Under the arrangement, Company P will undertake all intangible property development activities. All of Company P's research and development (R&D) activity is devoted to the intangible property development activity under the cost sharing arrangement. Company P will manufacture, market, and otherwise exploit the product in its defined territory. Companies P and X will share intangible property development costs in accordance with their reasonably anticipated benefits from the intangible property, and Company X will make payments to Company P as required under § 1.482–7T. Company X will manufacture, market, and otherwise exploit the product in the rest of the world.

(iv) A portion of the charge under the shared services arrangement is in turn allocable to the intangible property development activity undertaken by Company P. The most reliable estimate of the proportion allocable to the intangible property development activity is determined to be 500 (Company P's R&D expenses) divided by 1,500 (Company P's total non-covered services costs), or one-third. Accordingly, one-third of Company P's charge of 125, or 42, is allocated to the intangible property development activity. Companies P and X must share the intangible property development costs of the cost shared intangible property (including the charge of 42 that is allocated under the shared services arrangement) in proportion to their respective shares of reasonably anticipated benefits under the cost sharing arrangement. That is, the reasonably anticipated benefit shares under the cost

sharing arrangement are determined separately from reasonably anticipated benefit shares under the shared services arrangement.

Example 24. Coordination with cost sharing arrangement. (i) The facts and analysis are the same as in *Example 25*, except that Company X also performs intangible property development activities related to the cost sharing arrangement. Using a basis of allocation that is consistent with the controlled participants' respective shares of the reasonably anticipated benefits from the shared services, the 300 of service costs is allocated as follows:

X—100.

Y—50.

Z—25.

P—125.

(ii) In addition to performing services, Company P undertakes 500 of R&D and incurs manufacturing and other costs of 1,000. Company X undertakes 400 of R&D and incurs manufacturing and other costs of 600.

(iii) Companies P and X enter into a cost sharing arrangement in accordance with § 1.482–7T. Under the arrangement, both Companies P and X will undertake intangible property development activities. All of the research and development activity conducted by Companies P and X is devoted to the intangible property development activity under the cost sharing arrangement. Both Companies P and X will manufacture, market, and otherwise exploit the product in their respective territories and will share intangible property development costs in accordance with their reasonably anticipated benefits from the intangible property, and both will make payments as required under § 1.482–7T.

(iv) A portion of the charge under the shared services arrangement is in turn allocable to the intangible property development activities undertaken by Companies P and X. The most reliable estimate of the portion allocable to Company P's intangible property development activity is determined to be 500 (Company P's R&D expenses) divided by 1,500 (P's total non-covered services costs), or one-third. Accordingly, one-third of Company P's allocated services cost method charge of 125, or 42, is allocated to its intangible property development activity.

(v) In addition, it is necessary to determine the portion of the charge under the shared services arrangement to Company X that should be further allocated to Company X's intangible property development activities under the cost sharing arrangement. The most reliable estimate of the portion allocable to Company X's intangible property development activity is 400 (Company X's R&D expenses) divided by 1,000 (Company X's costs), or 40%. Accordingly, 40% of the 100 that was allocated to Company X, or 40, is allocated in turn to Company X's intangible property development activities. Company X makes a payment to Company P of 100 under the shared services arrangement and includes 40 of services cost method charges in the pool of intangible property development costs.

(vi) The parties' respective contributions to intangible property development costs under the cost sharing arrangement are as follows:
P: $500 + (0.333 \times 125) = 542$
X: $400 + (0.40 \times 100) = 440$

(c) **Comparable uncontrolled services price method—(1) In general.** The comparable uncontrolled services price method evaluates whether the amount charged in a controlled services transaction is arm's length by reference to the amount charged in a comparable uncontrolled services transaction.

(2) **Comparability and reliability considerations—(i) In general.** Whether results derived from application of this method are the most reliable measure of the arm's length result must be determined using the factors described under the best method rule in § 1.482–1(c). The application of these factors under the comparable uncontrolled services price method is discussed in paragraphs (c)(2)(ii) and (iii) of this section.

(ii) **Comparability—(A) In general.** The degree of comparability between controlled and uncontrolled transactions is determined by applying the provisions of § 1.482–1(d). Although all of the factors described in § 1.482–1(d)(3) must be considered, similarity of the services rendered, and of the intangible property (if any) used in performing the services, generally will have the greatest effects on comparability under this method. In addition, because even minor differences in contractual terms or economic conditions could materially affect the amount charged in an uncontrolled transaction, comparability under this method depends on close similarity with respect to these factors, or adjustments to account for any differences. The results derived from applying the comparable uncontrolled services price method generally will be the most direct and reliable measure of an arm's length price for the controlled transaction if an uncontrolled transaction has no differences from the controlled transaction that would affect the price, or if there are only minor differences that have a definite and reasonably ascertainable effect on price and for which appropriate adjustments are made. If such adjustments cannot be made, or if there are more than minor differences between the controlled and uncontrolled transactions, the comparable uncontrolled services price method may be used, but the reliability of the results as a measure of the arm's length price will be reduced. Further, if there are material differences for which reliable adjustments cannot be made, this method ordinarily will not provide

a reliable measure of an arm's length result.

(B) *Adjustments for differences between controlled and uncontrolled transactions.* If there are differences between the controlled and uncontrolled transactions that would affect price, adjustments should be made to the price of the uncontrolled transaction according to the comparability provisions of § 1.482-1(d)(2). Specific examples of factors that may be particularly relevant to application of this method include—

- (1) Quality of the services rendered;
- (2) Contractual terms (for example, scope and terms of warranties or guarantees regarding the services, volume, credit and payment terms, allocation of risks, including any contingent-payment terms and whether costs were incurred without a provision for current reimbursement);
- (3) Intangible property (if any) used in rendering the services;
- (4) Geographic market in which the services are rendered or received;
- (5) Risks borne (for example, costs incurred to render the services, without provision for current reimbursement);
- (6) Duration or quantitative measure of services rendered;
- (7) Collateral transactions or ongoing business relationships between the renderer and the recipient, including arrangement for the provision of tangible property in connection with the services; and
- (8) Alternatives realistically available to the renderer and the recipient.

(iii) *Data and assumptions.* The reliability of the results derived from the comparable uncontrolled services price method is affected by the completeness and accuracy of the data used and the reliability of the assumptions made to apply the method. See § 1.482-1(c) (best method rule).

(3) *Arm's length range.* See § 1.482-1(e)(2) for the determination of an arm's length range.

(4) *Examples.* The principles of this paragraph (c) are illustrated by the following examples:

Example 1. Internal comparable uncontrolled services price. Company A, a United States corporation, performs shipping, stevedoring, and related services for controlled and uncontrolled parties on a short-term or as-needed basis. Company A charges uncontrolled parties in Country X a uniform fee of \$60 per container to place loaded cargo containers in Country X on oceangoing vessels for marine transportation. Company A also performs identical services in Country X for its wholly-owned subsidiary, Company B, and there are no substantial differences between the controlled and uncontrolled transactions. In evaluating the appropriate measure of the

arm's length price for the container-loading services performed for Company B, because Company A renders substantially identical services in Country X to both controlled and uncontrolled parties, it is determined that the comparable uncontrolled services price constitutes the best method for determining the arm's length price for the controlled services transaction. Based on the reliable data provided by Company A concerning the price charged for services in comparable uncontrolled transactions, a loading charge of \$60 per cargo container will be considered the most reliable measure of the arm's length price for the services rendered to Company B. See paragraph (c)(2)(ii)(A) of this section.

Example 2. External comparable uncontrolled services price. (i) The facts are the same as in *Example 1*, except that Company A performs services for Company B, but not for uncontrolled parties. Based on information obtained from unrelated parties (which is determined to be reliable under the comparability standards set forth in paragraph (c)(2) of this section), it is determined that uncontrolled parties in Country X perform services comparable to those rendered by Company A to Company B, and that such parties charge \$60 per cargo container.

(ii) In evaluating the appropriate measure of an arm's length price for the loading services that Company A renders to Company B, the \$60 per cargo container charge is considered evidence of a comparable uncontrolled services price. See paragraph (c)(2)(ii)(A) of this section.

Example 3. External comparable uncontrolled services price. The facts are the same as in *Example 2*, except that uncontrolled parties in Country X render similar loading and stevedoring services, but only under contracts that have a minimum term of one year. If the difference in the duration of the services has a material effect on prices, adjustments to account for these differences must be made to the results of the uncontrolled transactions according to the provisions of § 1.482-1(d)(2), and such adjusted results may be used as a measure of the arm's length result.

Example 4. Use of valuable intangible property. (i) Company A, a United States corporation in the biotechnology sector, renders research and development services exclusively to its affiliates. Company B is Company A's wholly-owned subsidiary in Country X. Company A renders research and development services to Company B.

(ii) In performing its research and development services function, Company A uses proprietary software that it developed internally. Company A uses the software to evaluate certain genetically engineered compounds developed by Company B. Company A owns the copyright on this software and does not license it to uncontrolled parties.

(iii) No uncontrolled parties can be identified that perform services identical or with a high degree of similarity to those performed by Company A. Because there are material differences for which reliable adjustments cannot be made, the comparable uncontrolled services price method is unlikely to provide a reliable measure of the

arm's length price. See paragraph (c)(2)(ii)(A) of this section.

Example 5. Internal comparable. (i) Company A, a United States corporation, and its subsidiaries render computer consulting services relating to systems integration and networking to business clients in various countries. Company A and its subsidiaries render only consulting services, and do not manufacture computer hardware or software nor distribute such products. The controlled group is organized according to industry specialization, with key industry specialists working for Company A. These personnel typically form the core consulting group that teams with consultants from the local-country subsidiaries to serve clients in the subsidiaries' respective countries.

(ii) Company A and its subsidiaries sometimes undertake engagements directly for clients, and sometimes work as subcontractors to unrelated parties on more extensive supply-chain consulting engagements for clients. In undertaking the latter engagements with third party consultants, Company A typically prices its services based on consulting hours worked multiplied by a rate determined for each category of employee. The company also charges, at no markup, for out-of-pocket expenses such as travel, lodging, and data acquisition charges. The Company has established the following schedule of hourly rates:

Category	Rate
Project managers	\$400 per hour.
Technical staff	\$300 per hour.

(iii) Thus, for example, a project involving 100 hours of the time of project managers and 400 hours of technical staff time would result in the following project fees (without regard to any out-of-pocket expenses): $([100 \text{ hrs.} \times \$400/\text{hr.}] + [400 \text{ hrs.} \times \$300/\text{hr.}]) = \$40,000 + \$120,000 = \$160,000$.

(iv) Company B, a Country X subsidiary of Company A, contracts to perform consulting services for a Country X client in the banking industry. In undertaking this engagement, Company B uses its own consultants and also uses Company A project managers and technical staff that specialize in the banking industry for 75 hours and 380 hours, respectively. In determining an arm's length charge, the price that Company A charges for consulting services as a subcontractor in comparable uncontrolled transactions will be considered evidence of a comparable uncontrolled services price. Thus, in this case, a payment of \$144,000, (or $[75 \text{ hrs.} \times \$400/\text{hr.}] + [380 \text{ hrs.} \times \$300/\text{hr.}] = \$30,000 + \$114,000$) may be used as a measure of the arm's length price for the work performed by Company A project managers and technical staff. In addition, if the comparable uncontrolled services price method is used, then, consistent with the practices employed by the comparables with respect to similar types of expenses, Company B must reimburse Company A for appropriate out-of-pocket expenses. See paragraph (c)(2)(ii)(A) of this section.

Example 6. Adjustments for differences. (i) The facts are the same as in *Example 5*,

except that the engagement is undertaken with the client on a fixed fee basis. That is, prior to undertaking the engagement Company B and Company A estimate the resources required to undertake the engagement, and, based on hourly fee rates, charge the client a single fee for completion of the project. Company A's portion of the engagement results in fees of \$144,000.

(ii) The engagement, once undertaken, requires 20% more hours by each of Companies A and B than originally estimated. Nevertheless, the unrelated client pays the fixed fee that was agreed upon at the start of the engagement. Company B pays Company A \$144,000, in accordance with the fixed fee arrangement.

(iii) Company A often enters into similar fixed fee engagements with clients. In addition, Company A's records for similar engagements show that when it experiences cost overruns, it does not collect additional fees from the client for the difference between projected and actual hours. Accordingly, in evaluating whether the fees paid by Company B to Company A are arm's length, it is determined that no adjustments to the intercompany service charge are warranted. See § 1.482-1(d)(3)(ii) and paragraph (c)(2)(ii)(A) of this section.

(5) *Indirect evidence of the price of a comparable uncontrolled services transaction*—(i) *In general.* The price of a comparable uncontrolled services transaction may be derived based on indirect measures of the price charged in comparable uncontrolled services transactions, but only if—

(A) The data are widely and routinely used in the ordinary course of business in the particular industry or market segment for purposes of determining prices actually charged in comparable uncontrolled services transactions;

(B) The data are used to set prices in the controlled services transaction in the same way they are used to set prices in uncontrolled services transactions of the controlled taxpayer, or in the same way they are used by uncontrolled taxpayers to set prices in uncontrolled services transactions; and

(C) The amount charged in the controlled services transaction may be reliably adjusted to reflect differences in quality of the services, contractual terms, market conditions, risks borne (including contingent-payment terms), duration or quantitative measure of services rendered, and other factors that may affect the price to which uncontrolled taxpayers would agree.

(ii) *Example.* The following example illustrates this paragraph (c)(5):

Example. Indirect evidence of comparable uncontrolled services price.

(i) Company A is a United States insurance company. Company A's wholly-owned Country X subsidiary, Company B, performs specialized risk analysis for Company A as well as for uncontrolled parties. In determining the price actually charged to

uncontrolled entities for performing such risk analysis, Company B uses a proprietary, multi-factor computer program, which relies on the gross value of the policies in the customer's portfolio, the relative composition of those policies, their location, and the estimated number of personnel hours necessary to complete the project. Uncontrolled companies that perform comparable risk analysis in the same industry or market-segment use similar proprietary computer programs to price transactions with uncontrolled customers (the competitors' programs may incorporate different inputs, or may assign different weights or values to individual inputs, in arriving at the price).

(ii) During the taxable year subject to audit, Company B performed risk analysis for uncontrolled parties as well as for Company A. Because prices charged to uncontrolled customers reflected the composition of each customer's portfolio together with other factors, the prices charged in Company B's uncontrolled transactions do not provide a reliable basis for determining the comparable uncontrolled services price for the similar services rendered to Company A. However, in evaluating an arm's length price for the studies performed by Company B for Company A, Company B's proprietary computer program may be considered as indirect evidence of the comparable uncontrolled services price that would be charged to perform the services for Company A. The reliability of the results obtained by application of this internal computer program as a measure of an arm's length price for the services will be increased to the extent that Company A used the internal computer program to generate actual transaction prices for risk-analysis studies performed for uncontrolled parties during the same taxable year under audit; Company A used data that are widely and routinely used in the ordinary course of business in the insurance industry to determine the price charged; and Company A reliably adjusted the price charged in the controlled services transaction to reflect differences that may affect the price to which uncontrolled taxpayers would agree.

(d) *Gross services margin method*—(1) *In general.* The gross services margin method evaluates whether the amount charged in a controlled services transaction is arm's length by reference to the gross profit margin realized in comparable uncontrolled transactions. This method ordinarily is used in cases where a controlled taxpayer performs services or functions in connection with an uncontrolled transaction between a member of the controlled group and an uncontrolled taxpayer. This method may be used where a controlled taxpayer renders services (agent services) to another member of the controlled group in connection with a transaction between that other member and an uncontrolled taxpayer. This method also may be used in cases where a controlled taxpayer contracts to

provide services to an uncontrolled taxpayer (intermediary function) and another member of the controlled group actually performs a portion of the services provided.

(2) *Determination of arm's length price*—(i) *In general.* The gross services margin method evaluates whether the price charged or amount retained by a controlled taxpayer in the controlled services transaction in connection with the relevant uncontrolled transaction is arm's length by determining the appropriate gross profit of the controlled taxpayer.

(ii) *Relevant uncontrolled transaction.* The relevant uncontrolled transaction is a transaction between a member of the controlled group and an uncontrolled taxpayer as to which the controlled taxpayer performs agent services or an intermediary function.

(iii) *Applicable uncontrolled price.* The applicable uncontrolled price is the price paid or received by the uncontrolled taxpayer in the relevant uncontrolled transaction.

(iv) *Appropriate gross services profit.* The appropriate gross services profit is computed by multiplying the applicable uncontrolled price by the gross services profit margin in comparable uncontrolled transactions. The determination of the appropriate gross services profit will take into account any functions performed by other members of the controlled group, as well as any other relevant factors described in § 1.482-1(d)(3). The comparable gross services profit margin may be determined by reference to the commission in an uncontrolled transaction, where that commission is stated as a percentage of the price charged in the uncontrolled transaction.

(v) *Arm's length range.* See § 1.482-1(e)(2) for determination of the arm's length range.

(3) *Comparability and reliability considerations*—(i) *In general.* Whether results derived from application of this method are the most reliable measure of the arm's length result must be determined using the factors described under the best method rule in § 1.482-1(c). The application of these factors under the gross services margin method is discussed in paragraphs (d)(3)(ii) and (iii) of this section.

(ii) *Comparability*—(A) *Functional comparability.* The degree of comparability between an uncontrolled transaction and a controlled transaction is determined by applying the comparability provisions of § 1.482-1(d). A gross services profit provides compensation for services or functions that bear a relationship to the relevant uncontrolled transaction, including an

operating profit in return for the investment of capital and the assumption of risks by the controlled taxpayer performing the services or functions under review. Therefore, although all of the factors described in § 1.482-1(d)(3) must be considered, comparability under this method is particularly dependent on similarity of services or functions performed, risks borne, intangible property (if any) used in providing the services or functions, and contractual terms, or adjustments to account for the effects of any such differences. If possible, the appropriate gross services profit margin should be derived from comparable uncontrolled transactions by the controlled taxpayer under review, because similar characteristics are more likely found among different transactions by the same controlled taxpayer than among transactions by other parties. In the absence of comparable uncontrolled transactions involving the same controlled taxpayer, an appropriate gross services profit margin may be derived from transactions of uncontrolled taxpayers involving comparable services or functions with respect to similarly related transactions.

(B) *Other comparability factors.* Comparability under this method is not dependent on close similarity of the relevant uncontrolled transaction to the related transactions involved in the uncontrolled comparables. However, substantial differences in the nature of the relevant uncontrolled transaction and the relevant transactions involved in the uncontrolled comparables, such as differences in the type of property transferred or service provided in the relevant uncontrolled transaction, may indicate significant differences in the services or functions performed by the controlled and uncontrolled taxpayers with respect to their respective relevant transactions. Thus, it ordinarily would be expected that the services or functions performed in the controlled and uncontrolled transactions would be with respect to relevant transactions involving the transfer of property within the same product categories or the provision of services of the same general type (for example, information-technology systems design). Furthermore, significant differences in the intangible property (if any) used by the controlled taxpayer in the controlled services transaction as distinct from the uncontrolled comparables may also affect the reliability of the comparison. Finally, the reliability of profit measures based on gross services profit may be adversely affected by factors that have less effect on prices. For example, gross

services profit may be affected by a variety of other factors, including cost structures or efficiency (for example, differences in the level of experience of the employees performing the service in the controlled and uncontrolled transactions). Accordingly, if material differences in these factors are identified based on objective evidence, the reliability of the analysis may be affected.

(C) *Adjustments for differences between controlled and uncontrolled transactions.* If there are material differences between the controlled and uncontrolled transactions that would affect the gross services profit margin, adjustments should be made to the gross services profit margin, according to the comparability provisions of § 1.482-1(d)(2). For this purpose, consideration of the total services costs associated with functions performed and risks assumed may be necessary because differences in functions performed are often reflected in these costs. If there are differences in functions performed, however, the effect on gross services profit of such differences is not necessarily equal to the differences in the amount of related costs. Specific examples of factors that may be particularly relevant to this method include—

(1) Contractual terms (for example, scope and terms of warranties or guarantees regarding the services or function, volume, credit and payment terms, and allocation of risks, including any contingent-payment terms);

(2) Intangible property (if any) used in performing the services or function;

(3) Geographic market in which the services or function are performed or in which the relevant uncontrolled transaction takes place; and

(4) Risks borne, including, if applicable, inventory-type risk.

(D) *Buy-sell distributor.* If a controlled taxpayer that performs an agent service or intermediary function is comparable to a distributor that takes title to goods and resells them, the gross profit margin earned by such distributor on uncontrolled sales, stated as a percentage of the price for the goods, may be used as the comparable gross services profit margin.

(iii) *Data and assumptions—(A) In general.* The reliability of the results derived from the gross services margin method is affected by the completeness and accuracy of the data used and the reliability of the assumptions made to apply this method. See § 1.482-1(c) (best method rule).

(B) *Consistency in accounting.* The degree of consistency in accounting practices between the controlled

transaction and the uncontrolled comparables that materially affect the gross services profit margin affects the reliability of the results under this method.

(4) *Examples.* The principles of this paragraph (d) are illustrated by the following examples:

Example 1. Agent services. Company A and Company B are members of a controlled group. Company A is a foreign manufacturer of industrial equipment. Company B is a U.S. company that acts as a commission agent for Company A by arranging for Company A to make direct sales of the equipment it manufactures to unrelated purchasers in the U.S. market. Company B does not take title to the equipment but instead receives from Company A commissions that are determined as a specified percentage of the sales price for the equipment that is charged by Company A to the unrelated purchaser. Company B also arranges for direct sales of similar equipment by unrelated foreign manufacturers to unrelated purchasers in the U.S. market. Company B charges these unrelated foreign manufacturers a commission fee of 5% of the sales price charged by the unrelated foreign manufacturers to the unrelated U.S. purchasers for the equipment. Information regarding the comparable agent services provided by Company B to unrelated foreign manufacturers is sufficiently complete to conclude that it is likely that all material differences between the controlled and uncontrolled transactions have been identified and adjustments for such differences have been made. If the comparable gross services profit margin is 5% of the price charged in the relevant transactions involved in the uncontrolled comparables, then the appropriate gross services profit that Company B may earn and the arm's length price that it may charge Company A for its agent services is equal to 5% of the applicable uncontrolled price charged by Company A in sales of equipment in the relevant uncontrolled transactions.

Example 2. Agent services. The facts are the same as in *Example 1*, except that Company B does not act as a commission agent for unrelated parties and it is not possible to obtain reliable information concerning commission rates charged by uncontrolled commission agents that engage in comparable transactions with respect to relevant sales of property. It is possible, however, to obtain reliable information regarding the gross profit margins earned by unrelated parties that briefly take title to and then resell similar property in uncontrolled transactions, in which they purchase the property from foreign manufacturers and resell the property to purchasers in the U.S. market. Analysis of the facts and circumstances indicates that, aside from certain minor differences for which adjustments can be made, the uncontrolled parties that resell property perform similar functions and assume similar risks as Company B performs and assumes when it acts as a commission agent for Company A's sales of property. Under these circumstances, the gross profit margin earned by the

unrelated distributors on the purchase and resale of property may be used, subject to any adjustments for any material differences between the controlled and uncontrolled transactions, as a comparable gross services profit margin. The appropriate gross services profit that Company B may earn and the arm's length price that it may charge Company A for its agent services is therefore equal to this comparable gross services margin, multiplied by the applicable uncontrolled price charged by Company A in its sales of equipment in the relevant uncontrolled transactions.

Example 3. Agent services. (i) Company A and Company B are members of a controlled group. Company A is a U.S. corporation that renders computer consulting services, including systems integration and networking, to business clients.

(ii) In undertaking engagements with clients, Company A in some cases pays a commission of 3% of its total fees to unrelated parties that assist Company A in obtaining consulting engagements. Typically, such fees are paid to non-computer consulting firms that provide strategic management services for their clients. When Company A obtains a consulting engagement with a client of a non-computer consulting firm, Company A does not subcontract with the other consulting firm, nor does the other consulting firm play any role in Company A's consulting engagement.

(iii) Company B, a Country X subsidiary of Company A, assists Company A in obtaining an engagement to perform computer consulting services for a Company B banking industry client in Country X. Although Company B has an established relationship with its Country X client and was instrumental in arranging for Company A's engagement with the client, Company A's particular expertise was the primary consideration in motivating the client to engage Company A. Based on the relative contributions of Companies A and B in obtaining and undertaking the engagement, Company B's role was primarily to facilitate the consulting engagement between Company A and the Country X client. Information regarding the commissions paid by Company A to unrelated parties for providing similar services to facilitate Company A's consulting engagements is sufficiently complete to conclude that it is likely that all material differences between these uncontrolled transactions and the controlled transaction between Company B and Company A have been identified and that appropriate adjustments have been made for any such differences. If the comparable gross services margin earned by unrelated parties in providing such agent services is 3% of total fees charged in the relevant transactions involved in the uncontrolled comparables, then the appropriate gross services profit that Company B may earn and the arm's length price that it may charge Company A for its agent services is equal to this comparable gross services margin (3%), multiplied by the applicable uncontrolled price charged by Company A in its relevant uncontrolled consulting engagement with Company B's client.

Example 4. Intermediary function. (i) The facts are the same as in *Example 3*, except

that Company B contracts directly with its Country X client to provide computer consulting services and Company A performs the consulting services on behalf of Company B. Company A does not enter into a consulting engagement with Company B's Country X client. Instead, Company B charges its Country X client an uncontrolled price for the consulting services, and Company B pays a portion of the uncontrolled price to Company A for performing the consulting services on behalf of Company B.

(ii) Analysis of the relative contributions of Companies A and B in obtaining and undertaking the consulting contract indicates that Company B functioned primarily as an intermediary contracting party, and the gross services margin method is the most reliable method for determining the amount that Company B may retain as compensation for its intermediary function with respect to Company A's consulting services. In this case, therefore, because Company B entered into the relevant uncontrolled transaction to provide services, Company B receives the applicable uncontrolled price that is paid by the Country X client for the consulting services. Company A technically performs services for Company B when it performs, on behalf of Company B, the consulting services Company B contracted to provide to the Country X client. The arm's length amount that Company A may charge Company B for performing the consulting services on Company B's behalf is equal to the applicable uncontrolled price received by Company B in the relevant uncontrolled transaction, less Company B's appropriate gross services profit, which is the amount that Company B may retain as compensation for performing the intermediary function.

(iii) Reliable data concerning the commissions that Company A paid to uncontrolled parties for assisting it in obtaining engagements to provide consulting services similar to those it has provided on behalf of Company B provide useful information in applying the gross services margin method. However, consideration should be given to whether the third party commission data may need to be adjusted to account for any additional risk that Company B may have assumed as a result of its function as an intermediary contracting party, compared with the risk it would have assumed if it had provided agent services to assist Company A in entering into an engagement to provide its consulting service directly. In this case, the information regarding the commissions paid by Company A to unrelated parties for providing agent services to facilitate its performance of consulting services for unrelated parties is sufficiently complete to conclude that all material differences between these uncontrolled transactions and the controlled performance of an intermediary function, including possible differences in the amount of risk assumed in connection with performing that function, have been identified and that appropriate adjustments have been made. If the comparable gross services margin earned by unrelated parties in providing such agent services is 3% of total fees charged in Company B's relevant

uncontrolled transactions, then the appropriate gross services profit that Company B may retain as compensation for performing an intermediary function (and the amount, therefore, that is deducted from the applicable uncontrolled price to arrive at the arm's length price that Company A may charge Company B for performing consulting services on Company B's behalf) is equal to this comparable gross services margin (3%), multiplied by the applicable uncontrolled price charged by Company B in its contract to provide services to the uncontrolled party.

Example 5. External comparable. (i) The facts are the same as in *Example 4*, except that neither Company A nor Company B engages in transactions with third parties that facilitate similar consulting engagements.

(ii) Analysis of the relative contributions of Companies A and B in obtaining and undertaking the contract indicates that Company B's role was primarily to facilitate the consulting arrangement between Company A and the Country X client. Although no reliable internal data are available regarding comparable transactions with uncontrolled entities, reliable data exist regarding commission rates for similar facilitating services between uncontrolled parties. These data indicate that a 3% commission (3% of total engagement fee) is charged in such transactions. Information regarding the uncontrolled comparables is sufficiently complete to conclude that it is likely that all material differences between the controlled and uncontrolled transactions have been identified and adjusted for. If the appropriate gross services profit margin is 3% of total fees, then an arm's length result of the controlled services transaction is for Company B to retain an amount equal to 3% of total fees paid to it.

(e) *Cost of services plus method*—(1) *In general.* The cost of services plus method evaluates whether the amount charged in a controlled services transaction is arm's length by reference to the gross services profit markup realized in comparable uncontrolled transactions. The cost of services plus method is ordinarily used in cases where the controlled service renderer provides the same or similar services to both controlled and uncontrolled parties. This method is ordinarily not used in cases where the controlled services transaction involves a contingent-payment arrangement, as described in paragraph (i)(2) of this section.

(2) *Determination of arm's length price*—(i) *In general.* The cost of services plus method measures an arm's length price by adding the appropriate gross services profit to the controlled taxpayer's comparable transactional costs.

(ii) *Appropriate gross services profit.* The appropriate gross services profit is computed by multiplying the controlled taxpayer's comparable transactional costs by the gross services profit

markup, expressed as a percentage of the comparable transactional costs earned in comparable uncontrolled transactions.

(iii) *Comparable transactional costs.* Comparable transactional costs consist of the costs of providing the services under review that are taken into account as the basis for determining the gross services profit markup in comparable uncontrolled transactions. Depending on the facts and circumstances, such costs typically include all compensation attributable to employees directly involved in the performance of such services, materials and supplies consumed or made available in rendering such services, and may include as well other costs of rendering the services. Comparable transactional costs must be determined on a basis that will facilitate comparison with the comparable uncontrolled transactions. For that reason, comparable transactional costs may not necessarily equal total services costs, as defined in paragraph (j) of this section, and in appropriate cases may be a subset of total services costs. Generally accepted accounting principles or Federal income tax accounting rules (where Federal income tax data for comparable transactions or business activities are available) may provide useful guidance but will not conclusively establish the appropriate comparable transactional costs for purposes of this method.

(iv) *Arm's length range.* See § 1.482-1(e)(2) for determination of an arm's length range.

(3) *Comparability and reliability considerations*—(i) *In general.* Whether results derived from the application of this method are the most reliable measure of the arm's length result must be determined using the factors described under the best method rule in § 1.482-1(c).

(ii) *Comparability*—(A) *Functional comparability.* The degree of comparability between controlled and uncontrolled transactions is determined by applying the comparability provisions of § 1.482-1(d). A service renderer's gross services profit provides compensation for performing services related to the controlled services transaction under review, including an operating profit for the service renderer's investment of capital and assumptions of risks. Therefore, although all of the factors described in § 1.482-1(d)(3) must be considered, comparability under this method is particularly dependent on similarity of services or functions performed, risks borne, intangible property (if any) used in providing the services or functions, and contractual terms, or adjustments to

account for the effects of any such differences. If possible, the appropriate gross services profit markup should be derived from comparable uncontrolled transactions of the same taxpayer participating in the controlled services transaction because similar characteristics are more likely to be found among services provided by the same service provider than among services provided by other service providers. In the absence of such services transactions, an appropriate gross services profit markup may be derived from comparable uncontrolled services transactions of other service providers. If the appropriate gross services profit markup is derived from comparable uncontrolled services transactions of other service providers, in evaluating comparability the controlled taxpayer must consider the results under this method expressed as a markup on total services costs of the controlled taxpayer, because differences in functions performed may be reflected in differences in service costs other than those included in comparable transactional costs.

(B) *Other comparability factors.* Comparability under this method is less dependent on close similarity between the services provided than under the comparable uncontrolled services price method. Substantial differences in the services may, however, indicate significant functional differences between the controlled and uncontrolled taxpayers. Thus, it ordinarily would be expected that the controlled and uncontrolled transactions would involve services of the same general type (for example, information-technology systems design). Furthermore, if a significant amount of the controlled taxpayer's comparable transactional costs consists of service costs incurred in a tax accounting period other than the tax accounting period under review, the reliability of the analysis would be reduced. In addition, significant differences in the value of the services rendered, due for example to the use of valuable intangible property, may also affect the reliability of the comparison. Finally, the reliability of profit measures based on gross services profit may be adversely affected by factors that have less effect on prices. For example, gross services profit may be affected by a variety of other factors, including cost structures or efficiency-related factors (for example, differences in the level of experience of the employees performing the service in the controlled and uncontrolled transactions). Accordingly, if material differences in these factors

are identified based on objective evidence, the reliability of the analysis may be affected.

(C) *Adjustments for differences between the controlled and uncontrolled transactions.* If there are material differences between the controlled and uncontrolled transactions that would affect the gross services profit markup, adjustments should be made to the gross services profit markup earned in the comparable uncontrolled transaction according to the provisions of § 1.482-1(d)(2). For this purpose, consideration of the comparable transactional costs associated with the functions performed and risks assumed may be necessary, because differences in the functions performed are often reflected in these costs. If there are differences in functions performed, however, the effect on gross services profit of such differences is not necessarily equal to the differences in the amount of related comparable transactional costs. Specific examples of the factors that may be particularly relevant to this method include—

- (1) The complexity of the services;
- (2) The duration or quantitative measure of services;
- (3) Contractual terms (for example, scope and terms of warranties or guarantees provided, volume, credit and payment terms, allocation of risks, including any contingent-payment terms);
- (4) Economic circumstances; and
- (5) Risks borne.

(iii) *Data and assumptions*—(A) *In general.* The reliability of the results derived from the cost of services plus method is affected by the completeness and accuracy of the data used and the reliability of the assumptions made to apply this method. See § 1.482-1(c) (Best method rule).

(B) *Consistency in accounting.* The degree of consistency in accounting practices between the controlled transaction and the uncontrolled comparables that materially affect the gross services profit markup affects the reliability of the results under this method. Thus, for example, if differences in cost accounting practices would materially affect the gross services profit markup, the ability to make reliable adjustments for such differences would affect the reliability of the results obtained under this method. Further, reliability under this method depends on the extent to which the controlled and uncontrolled transactions reflect consistent reporting of comparable transactional costs. For purposes of this paragraph (e)(3)(iii)(B), the term *comparable transactional costs* includes the cost of acquiring tangible

property that is transferred (or used) with the services, to the extent that the arm's length price of the tangible property is not separately evaluated as a controlled transaction under another provision.

(4) *Examples.* The principles of this paragraph (e) are illustrated by the following examples:

Example 1. Internal comparable. (i) Company A designs and assembles information-technology networks and systems. When Company A renders services for uncontrolled parties, it receives compensation based on time and materials as well as certain other related costs necessary to complete the project. This fee includes the cost of hardware and software purchased from uncontrolled vendors and incorporated in the final network or system, plus a reasonable allocation of certain specified overhead costs incurred by Company A in providing these services. Reliable accounting records maintained by Company A indicate that Company A earned a gross services profit markup of 10% on its time, materials and specified overhead in providing design services during the year under examination on information technology projects for uncontrolled entities.

(ii) Company A designed an information-technology network for its Country X subsidiary, Company B. The services rendered to Company B are similar in scope and complexity to services that Company A rendered to uncontrolled parties during the year under examination. Using Company A's accounting records (which are determined to be reliable under paragraph (e)(3) of this section), it is possible to identify the comparable transactional costs involved in the controlled services transaction with reference to the costs incurred by Company A in rendering similar design services to uncontrolled parties. Company A's records indicate that it does not incur any additional types of costs in rendering similar services to uncontrolled customers. The data available are sufficiently complete to conclude that it is likely that all material differences between the controlled and uncontrolled transactions have been identified and adjusted for. Based on the gross services profit markup data derived from Company A's uncontrolled transactions involving similar design services, an arm's length result for the controlled services transaction is equal to the price that will allow Company A to earn a 10% gross services profit markup on its comparable transactional costs.

Example 2. Inability to adjust for differences in comparable transactional costs. The facts are the same as in *Example 1*, except that Company A's staff that rendered the services to Company B consisted primarily of engineers in training status or on temporary rotation from other Company A subsidiaries. In addition, the Company B network incorporated innovative features, including specially designed software suited to Company B's requirements. The use of less-experienced personnel and staff on temporary rotation, together with the special features of the Company B network, significantly increased

the time and costs associated with the project as compared to time and costs associated with similar projects completed for uncontrolled customers. These factors constitute material differences between the controlled and the uncontrolled transactions that affect the determination of Company A's comparable transactional costs associated with the controlled services transaction, as well as the gross services profit markup. Moreover, it is not possible to perform reliable adjustments for these differences on the basis of the available accounting data. Under these circumstances, the reliability of the cost of services plus method as a measure of an arm's length price is substantially reduced.

Example 3. Operating loss by reference to total services costs. The facts and analysis are the same as in *Example 1*, except that an unrelated Company C, instead of Company A, renders similar services to uncontrolled parties and publicly available information indicates that Company C earned a gross services profit markup of 10% on its time, materials and certain specified overhead in providing those services. As in *Example 1*, Company A still provides services for its Country X subsidiary, Company B. In accordance with the requirements in paragraph (e)(3)(ii) of this section, the taxpayer performs additional analysis and restates the results of Company A's controlled services transaction with its Country X subsidiary, Company B, in the form of a markup on Company A's total services costs. This analysis by reference to total services costs shows that Company A generated an operating loss on the controlled services transaction, which indicates that functional differences likely exist between the controlled services transaction performed by Company A and uncontrolled services transactions performed by Company C, and that these differences may not be reflected in the comparable transactional costs. Upon further scrutiny, the presence of such functional differences between the controlled and uncontrolled transactions may indicate that the cost of services plus method does not provide the most reliable measure of an arm's length result under the facts and circumstances.

Example 4. Internal comparable. (i) Company A, a U.S. corporation, and its subsidiaries perform computer consulting services relating to systems integration and networking for business clients in various countries. Company A and its subsidiaries render only consulting services and do not manufacture or distribute computer hardware or software to clients. The controlled group is organized according to industry specialization, with key industry specialists working for Company A. These personnel typically form the core consulting group that teams with consultants from the local-country subsidiaries to serve clients in the subsidiaries' respective countries.

(ii) On some occasions, Company A and its subsidiaries undertake engagements directly for clients. On other occasions, they work as subcontractors for uncontrolled parties on more extensive consulting engagements for clients. In undertaking the latter engagements with third-party consultants, Company A

typically prices its services at four times the compensation costs of its consultants, defined as the consultants' base salary plus estimated fringe benefits, as defined in this table:

Category	Rate
Project managers	\$100 per hour.
Technical staff	75 per hour.

(iii) In uncontrolled transactions, Company A also charges the customer, at no markup, for out-of-pocket expenses such as travel, lodging, and data acquisition charges. Thus, for example, a project involving 100 hours of time from project managers, and 400 hours of technical staff time would result in total compensation costs to Company A of $(100 \text{ hrs.} \times \$100/\text{hr.}) + (400 \text{ hrs.} \times \$75/\text{hr.}) = \$10,000 + \$30,000 = \$40,000$. Applying the markup of 300%, the total fee charged would thus be $(4 \times \$40,000)$, or \$160,000, plus out-of-pocket expenses.

(iv) Company B, a Country X subsidiary of Company A, contracts to render consulting services to a Country X client in the banking industry. In undertaking this engagement, Company B uses its own consultants and also uses the services of Company A project managers and technical staff that specialize in the banking industry for 75 hours and 380 hours, respectively. The data available are sufficiently complete to conclude that it is likely that all material differences between the controlled and uncontrolled transactions have been identified and adjusted for. Based on reliable data concerning the compensation costs to Company A, an arm's length result for the controlled services transaction is equal to \$144,000. This is calculated as follows: $[4 \times (75 \text{ hrs.} \times \$100/\text{hr.})] + [4 \times (380 \text{ hrs.} \times \$75/\text{hr.})] = \$30,000 + \$114,000 = \$144,000$, reflecting a 300% markup on the total compensation costs for Company A project managers and technical staff. In addition, consistent with Company A's pricing of uncontrolled transactions, Company B must reimburse Company A for appropriate out-of-pocket expenses incurred in performing the services.

(f) *Comparable profits method*—(1) *In general.* The comparable profits method evaluates whether the amount charged in a controlled transaction is arm's length, based on objective measures of profitability (profit level indicators) derived from uncontrolled taxpayers that engage in similar business activities under similar circumstances. The rules in § 1.482–5 relating to the comparable profits method apply to controlled services transactions, except as modified in this paragraph (f).

(2) *Determination of arm's length result*—(i) *Tested party.* This paragraph (f) applies where the relevant business activity of the tested party as determined under § 1.482–5(b)(2) is the rendering of services in a controlled services transaction. Where the tested party determined under § 1.482–5(b)(2) is instead the recipient of the controlled

services, the rules under this paragraph (f) are not applicable to determine the arm's length result.

(ii) *Profit level indicators.* In addition to the profit level indicators provided in § 1.482-5(b)(4), a profit level indicator that may provide a reliable basis for comparing operating profits of the tested party involved in a controlled services transaction and uncontrolled comparables is the ratio of operating profit to total services costs (as defined in paragraph (j) of this section).

(iii) *Comparability and reliability considerations—Data and assumptions—Consistency in accounting.* Consistency in accounting practices between the relevant business activity of the tested party and the uncontrolled service providers is particularly important in determining the reliability of the results under this method, but less than in applying the cost of services plus method.

Adjustments may be appropriate if materially different treatment is applied to particular cost items related to the relevant business activity of the tested party and the uncontrolled service providers. For example, adjustments may be appropriate where the tested party and the uncontrolled comparables use inconsistent approaches to classify similar expenses as “cost of goods sold” and “selling, general, and administrative expenses.” Although distinguishing between these two categories may be difficult, the distinction is less important to the extent that the ratio of operating profit to total services costs is used as the appropriate profit level indicator. Determining whether adjustments are necessary under these or similar circumstances requires thorough analysis of the functions performed and consideration of the cost accounting practices of the tested party and the uncontrolled comparables. Other adjustments as provided in § 1.482-

5(c)(2)(iv) may also be necessary to increase the reliability of the results under this method.

(3) *Examples.* The principles of this paragraph (f) are illustrated by the following examples:

Example 1. Ratio of operating profit to total services costs as the appropriate profit level indicator. (i) A Country T parent firm, Company A, and its Country Y subsidiary, Company B, both engage in manufacturing as their principal business activity. Company A also performs certain advertising services for itself and its affiliates. In year 1, Company A renders advertising services to Company B.

(ii) Based on the facts and circumstances, it is determined that the comparable profits method will provide the most reliable measure of an arm's length result. Company A is selected as the tested party. No data are available for comparable independent manufacturing firms that render advertising services to third parties. Financial data are available, however, for ten independent firms that render similar advertising services as their principal business activity in Country X. The ten firms are determined to be comparable under § 1.482-5(c). Neither Company A nor the comparable companies use valuable intangible property in rendering the services.

(iii) Based on the available financial data of the comparable companies, it cannot be determined whether these comparable companies report costs for financial accounting purposes in the same manner as the tested party. The publicly available financial data of the comparable companies segregate total services costs into cost of goods sold and sales, general and administrative costs, with no further segmentation of costs provided. Due to the limited information available regarding the cost accounting practices used by the comparable companies, the ratio of operating profits to total services costs is determined to be the most appropriate profit level indicator. This ratio includes total services costs to minimize the effect of any inconsistency in accounting practices between Company A and the comparable companies.

Example 2. Application of the operating profit to total services costs profit level indicator. (i) Company A is a foreign subsidiary of Company B, a U.S. corporation.

Company B is under examination for its year 1 taxable year. Company B renders management consulting services to Company A. Company B's consulting function includes analyzing Company A's operations, benchmarking Company A's financial performance against companies in the same industry, and to the extent necessary, developing a strategy to improve Company A's operational performance. The accounting records of Company B allow reliable identification of the total services costs of the consulting staff associated with the management consulting services rendered to Company A. Company A reimburses Company B for its costs associated with rendering the consulting services, with no markup.

(ii) Based on all the facts and circumstances, it is determined that the comparable profits method will provide the most reliable measure of an arm's length result. Company B is selected as the tested party, and its rendering of management consulting services is identified as the relevant business activity. Data are available from ten domestic companies that operate in the industry segment involving management consulting and that perform activities comparable to the relevant business activity of Company B. These comparables include entities that primarily perform management consulting services for uncontrolled parties. The comparables incur similar risks as Company B incurs in performing the consulting services and do not make use of valuable intangible property or special processes.

(iii) Based on the available financial data of the comparables, it cannot be determined whether the comparables report their costs for financial accounting purposes in the same manner as Company B reports its costs in the relevant business activity. The available financial data for the comparables report only an aggregate figure for costs of goods sold and operating expenses, and do not segment the underlying services costs. Due to this limitation, the ratio of operating profits to total services costs is determined to be the most appropriate profit level indicator.

(iv) For the taxable years 1 through 3, Company B shows the following results for the services performed for Company A:

	Year 1	Year 2	Year 3	Average
Revenues	1,200,000	1,100,000	1,300,000	1,200,000
Cost of Goods Sold	100,000	100,000	N/A	66,667
Operating Expenses	1,100,000	1,000,000	1,300,000	1,133,333
Operating Profit	0	0	0	0

(v) After adjustments have been made to account for identified material differences between the relevant business activity of Company B and the comparables, the average ratio for the taxable years 1 through 3 of operating profit to total services costs is calculated for each of the uncontrolled service providers. Applying each ratio to Company B's average total services costs from the relevant business activity for the taxable years 1 through 3 would lead to the

following comparable operating profit (COP) for the services rendered by Company B:

Uncontrolled service provider	OP/Total service costs (percent)	Company B COP
Company 1 ...	15.75	\$189,000
Company 2 ...	15.00	180,000
Company 3 ...	14.00	168,000
Company 4 ...	13.30	159,600

Uncontrolled service provider	OP/Total service costs (percent)	Company B COP
Company 5 ...	12.00	144,000
Company 6 ...	11.30	135,600
Company 7 ...	11.25	135,000
Company 8 ...	11.18	134,160
Company 9 ...	11.11	133,320
Company 10	10.75	129,000

(vi) The available data are not sufficiently complete to conclude that it is likely that all material differences between the relevant business activity of Company B and the comparables have been identified. Therefore, an arm's length range can be established only pursuant to § 1.482-1(e)(2)(iii)(B). The arm's length range is established by reference to the interquartile range of the results as calculated under § 1.482-1(e)(2)(iii)(C), which consists of the results ranging from \$168,000 to \$134,160. Company B's reported average operating profit of zero (\$0) falls outside this range. Therefore, an allocation may be appropriate.

(vii) Because Company B reported income of zero, to determine the amount, if any, of the allocation, Company B's reported operating profit for year 3 is compared to the comparable operating profits derived from the comparables' results for year 3. The ratio of operating profit to total services costs in year 3 is calculated for each of the comparables and applied to Company B's year 3 total services costs to derive the following results:

Uncontrolled service provider	OP/Total service costs (for year 3) (percent)	Company B COP
Company 1 ...	15.00	\$195,000
Company 2 ...	14.75	191,750
Company 3 ...	14.00	182,000
Company 4 ...	13.50	175,500
Company 5 ...	12.30	159,900
Company 6 ...	11.05	143,650
Company 7 ...	11.03	143,390

Uncontrolled service provider	OP/Total service costs (for year 3) (percent)	Company B COP
Company 8 ...	11.00	143,000
Company 9 ...	10.50	136,500
Company 10	10.25	133,250

(viii) Based on these results, the median of the comparable operating profits for year 3 is \$151,775. Therefore, Company B's income for year 3 is increased by \$151,775, the difference between Company B's reported operating profit for year 3 of zero and the median of the comparable operating profits for year 3.

Example 3. Material difference in accounting for stock-based compensation. (i) Taxpayer, a U.S. corporation the stock of which is publicly traded, performs controlled services for its wholly-owned subsidiaries. The arm's length price of these controlled services is evaluated under the comparable profits method for services in paragraph (f) of this section by reference to the net cost plus profit level indicator (PLI). Taxpayer is the tested party under paragraph (f)(2)(i) of this section. The Commissioner identifies the most narrowly identifiable business activity of the tested party for which data are available that incorporate the controlled transaction (the relevant business activity). The Commissioner also identifies four uncontrolled domestic service providers, Companies A, B, C, and D, each of which performs exclusively activities similar to the relevant business activity of Taxpayer that is

subject to analysis under paragraph (f) of this section. The stock of Companies A, B, C, and D is publicly traded on a U.S. stock exchange. Assume that Taxpayer makes an election to apply these regulations to earlier taxable years.

(ii) Stock options are granted to the employees of Taxpayer that engage in the relevant business activity. Assume that, as determined under a method in accordance with U.S. generally accepted accounting principles, the fair value of such stock options attributable to the employees' performance of the relevant business activity is 500 for the taxable year in question. In evaluating the controlled services, Taxpayer includes salaries, fringe benefits, and related compensation of these employees in "total services costs," as defined in paragraph (j) of this section. Taxpayer does not include any amount attributable to stock options in total services costs, nor does it deduct that amount in determining "reported operating profit" within the meaning of § 1.482-5(d)(5), for the year under examination.

(iii) Stock options are granted to the employees of Companies A, B, C, and D. Under a fair value method in accordance with U.S. generally accepted accounting principles, the comparables include in total compensation the value of the stock options attributable to the employees' performance of the relevant business activity for the annual financial reporting period, and treat this amount as an expense in determining operating profit for financial accounting purposes. The treatment of employee stock options is summarized in the following table:

	Salaries and other non-option compensation	Stock options fair value	Stock options expensed
Taxpayer	1,000	500	0
Company A	7,000	2,000	2,000
Company B	4,300	250	250
Company C	12,000	4,500	4,500
Company D	15,000	2,000	2,000

(iv) A material difference in accounting for stock-based compensation (within the meaning of § 1.482-7T(d)(3)(i)) exists. Analysis indicates that this difference would materially affect the measure of an arm's length result under this paragraph (f). In making an adjustment to improve comparability under §§ 1.482-1(d)(2) and 1.482-5(c)(2)(iv), the Commissioner includes in total services costs of the tested party the total compensation costs of 1,500 (including stock option fair value). In addition, the Commissioner calculates the net cost plus

PLI by reference to the financial-accounting data of Companies A, B, C, and D, which take into account compensatory stock options.

Example 4. Material difference in utilization of stock-based compensation.

(i) The facts are the same as in paragraph (i) of *Example 3*.

(ii) No stock options are granted to the employees of Taxpayer that engage in the relevant business activity. Thus, no deduction for stock options is made in determining "reported operating profit"

(within the meaning of § 1.482-5(d)(5)) for the taxable year under examination.

(iii) Stock options are granted to the employees of Companies A, B, C, and D, but none of these companies expense stock options for financial accounting purposes. Under a method in accordance with U.S. generally accepted accounting principles, however, Companies A, B, C, and D disclose the fair value of the stock options for financial accounting purposes. The utilization and treatment of employee stock options is summarized in the following table:

	Salaries and other non-option compensation	Stock options fair value	Stock options expensed
Taxpayer	1,000	0	N/A
Company A	7,000	2,000	0
Company B	4,300	250	0
Company C	12,000	4,500	0
Company D	15,000	2,000	0

(iv) A material difference in the utilization of stock-based compensation (within the meaning of § 1.482-7T(d)(3)(i)) exists. Analysis indicates that these differences would materially affect the measure of an arm's length result under this paragraph (f). In evaluating the comparable operating profits of the tested party, the Commissioner uses Taxpayer's total services costs, which include total compensation costs of 1,000. In considering whether an adjustment is

necessary to improve comparability under §§ 1.482-1(d)(2) and 1.482-5(c)(2)(iv), the Commissioner recognizes that the total compensation provided to employees of Taxpayer is comparable to the total compensation provided to employees of Companies A, B, C, and D. Because Companies A, B, C, and D do not expense stock-based compensation for financial accounting purposes, their reported operating profits must be adjusted in order to improve

comparability with the tested party. The Commissioner increases each comparable's total services costs, and also reduces its reported operating profit, by the fair value of the stock-based compensation incurred by the comparable company.

(v) The adjustments to the data of Companies A, B, C, and D described in paragraph (iv) of this *Example 4* are summarized in the following table:

	Salaries and other non-option compensation	Stock options fair value	Total services costs (A)	Operating profit (B)	Net cost plus PLI (B/A) (Percent)
Per financial statements:					
Company A	7,000	2,000	25,000	6,000	24.00
Company B	4,300	250	12,500	2,500	20.00
Company C	12,000	4,500	36,000	11,000	30.56
Company D	15,000	2,000	27,000	7,000	25.93
As adjusted:					
Company A	7,000	2,000	27,000	4,000	14.81
Company B	4,300	250	12,750	2,250	17.65
Company C	12,000	4,500	40,500	6,500	16.05
Company D	15,000	2,000	29,000	5,000	17.24

Example 5. Non-material difference in utilization of stock-based compensation.

(i) The facts are the same as in paragraph (i) of *Example 3*.

(ii) Stock options are granted to the employees of Taxpayer that engage in the relevant business activity. Assume that, as determined under a method in accordance with U.S. generally accepted accounting principles, the fair value of such stock options attributable to the employees'

performance of the relevant business activity is 50 for the taxable year. Taxpayer includes salaries, fringe benefits, and all other compensation of these employees (including the stock option fair value) in "total services costs," as defined in paragraph (j) of this section, and deducts these amounts in determining "reported operating profit" within the meaning of § 1.482-5(d)(5), for the taxable year under examination.

(iii) Stock options are granted to the employees of Companies A, B, C, and D, but none of these companies expense stock options for financial accounting purposes. Under a method in accordance with U.S. generally accepted accounting principles, however, Companies A, B, C, and D disclose the fair value of the stock options for financial accounting purposes. The utilization and treatment of employee stock options is summarized in the following table:

	Salaries and other non-option compensation	Stock options fair value	Stock options expensed
Taxpayer	1,000	50	50
Company A	7,000	100	0
Company B	4,300	40	0
Company C	12,000	130	0
Company D	15,000	75	0

(iv) Analysis of the data reported by Companies A, B, C, and D indicates that an

adjustment for differences in utilization of stock-based compensation would not have a

material effect on the determination of an arm's length result.

	Salaries and other non-option compensation	Stock options fair value	Total services costs (A)	Operating profit (B)	Net cost plus PLI (B/A) (percent)
Per financial statements:					
Company A	7,000	100	25,000	6,000	24.00
Company B	4,300	40	12,500	2,500	20.00
Company C	12,000	130	36,000	11,000	30.56
Company D	15,000	75	27,000	7,000	25.93
As adjusted:					
Company A	7,000	100	25,100	5,900	23.51
Company B	4,300	40	12,540	2,460	19.62
Company C	12,000	130	36,130	10,870	30.09
Company D	15,000	75	27,075	6,925	25.58

(v) Under the circumstances, the difference in utilization of stock-based compensation

would not materially affect the determination of the arm's length result under this

paragraph (f). Accordingly, in calculating the net cost plus PLI, no comparability

adjustment is made to the data of Companies A, B, C, or D pursuant to §§ 1.482–1(d)(2) and 1.482–5(c)(2)(iv).

Example 6. Material difference in comparables' accounting for stock-based compensation. (i) The facts are the same as in paragraph (i) of *Example 3*.

(ii) Stock options are granted to the employees of Taxpayer that engage in the relevant business activity. Assume that, as determined under a method in accordance with U.S. generally accepted accounting principles, the fair value of such stock

options attributable to employees' performance of the relevant business activity is 500 for the taxable year. Taxpayer includes salaries, fringe benefits, and all other compensation of these employees (including the stock option fair value) in "total services costs," as defined in paragraph (j) of this section, and deducts these amounts in determining "reported operating profit" (within the meaning of § 1.482–5(d)(5)) for the taxable year under examination.

(iii) Stock options are granted to the employees of Companies A, B, C, and D.

Companies A and B expense the stock options for financial accounting purposes in accordance with U.S. generally accepted accounting principles. Companies C and D do not expense the stock options for financial accounting purposes. Under a method in accordance with U.S. generally accepted accounting principles, however, Companies C and D disclose the fair value of these options in their financial statements. The utilization and accounting treatment of options are depicted in the following table:

	Salary and other non-option compensation	Stock options fair value	Stock options expensed
Taxpayer	1,000	500	500
Company A	7,000	2,000	2,000
Company B	4,300	250	250
Company C	12,000	4,500	0
Company D	15,000	2,000	0

(iv) A material difference in accounting for stock-based compensation (within the meaning of § 1.482–7T(d)(3)(i)) exists. Analysis indicates that this difference would materially affect the measure of the arm's length result under paragraph (f) of this section. In evaluating the comparable operating profits of the tested party, the Commissioner includes in total services costs Taxpayer's total compensation costs of 1,500 (including stock option fair value of 500). In considering whether an adjustment is necessary to improve comparability under

§§ 1.482–1(d)(2) and 1.482–5(c)(2)(iv), the Commissioner recognizes that the total employee compensation (including stock options provided by Taxpayer and Companies A, B, C, and D) provides a reliable basis for comparison. Because Companies A and B expense stock-based compensation for financial accounting purposes, whereas Companies C and D do not, an adjustment to the comparables' operating profit is necessary. In computing the net cost plus PLI, the Commissioner uses the financial-accounting data of Companies A and B, as

reported. The Commissioner increases the total services costs of Companies C and D by amounts equal to the fair value of their respective stock options, and reduces the operating profits of Companies C and D accordingly.

(v) The adjustments described in paragraph (iv) of this *Example 6* are depicted in the following table. For purposes of illustration, the unadjusted data of Companies A and B are also included.

	Salaries and other non-option compensation	Stock options fair value	Total services costs (A)	Operating profit (B)	Net cost plus PLI (B/A) (percent)
Per financial statements:					
Company A	7,000	2,000	27,000	4,000	14.80
Company B	4,300	250	12,750	2,250	17.65
As adjusted:					
Company C	12,000	4,500	40,500	6,500	16.05
Company D	15,000	2,000	29,000	5,000	17.24

(g) *Profit split method*—(1) *In general.* The profit split method evaluates whether the allocation of the combined operating profit or loss attributable to one or more controlled transactions is arm's length by reference to the relative value of each controlled taxpayer's contribution to that combined operating profit or loss. The relative value of each controlled taxpayer's contribution is determined in a manner that reflects the functions performed, risks assumed and resources employed by such controlled taxpayer in the relevant business activity. For application of the profit split method (both the comparable profit split and the residual profit split), see § 1.482–6. The residual profit split method may not be used where only one

controlled taxpayer makes significant nonroutine contributions.

(2) *Examples.* The principles of this paragraph (g) are illustrated by the following examples:

Example 1. Residual profit split. (i) Company A, a corporation resident in Country X, auctions spare parts by means of an interactive database. Company A maintains a database that lists all spare parts available for auction. Company A developed the software used to run the database. Company A's database is managed by Company A employees in a data center located in Country X, where storage and manipulation of data also take place. Company A has a wholly-owned subsidiary, Company B, located in Country Y. Company B performs marketing and advertising activities to promote Company A's interactive database. Company B solicits unrelated companies to auction spare parts

on Company A's database, and solicits customers interested in purchasing spare parts online. Company B owns and maintains a computer server in Country Y, where it receives information on spare parts available for auction. Company B has also designed a specialized communications network that connects its data center to Company A's data center in Country X. The communications network allows Company B to enter data from uncontrolled companies on Company A's database located in Country X. Company B's communications network also allows uncontrolled companies to access Company A's interactive database and purchase spare parts. Company B bore the risks and cost of developing this specialized communications network. Company B enters into contracts with uncontrolled companies and provides the companies access to Company A's database through the Company B network.

(ii) Analysis of the facts and circumstances indicates that both Company A and Company

B possess valuable intangible property that they use to conduct the spare parts auction business. Company A bore the economic risks of developing and maintaining software and the interactive database. Company B bore the economic risks of developing the necessary technology to transmit information from its server to Company A's data center, and to allow uncontrolled companies to access Company A's database. Company B helped to enhance the value of Company A's trademark and to establish a network of customers in Country Y. In addition, there are no market comparables for the transactions between Company A and Company B to reliably evaluate them separately. Given the facts and circumstances, the Commissioner determines that a residual profit split method will provide the most reliable measure of an arm's length result.

(iii) Under the residual profit split method, profits are first allocated based on the routine contributions of each taxpayer. Routine contributions include general sales, marketing or administrative functions performed by Company B for Company A for which it is possible to identify market returns. Any residual profits will be allocated based on the nonroutine contributions of each taxpayer. Since both Company A and Company B provided nonroutine contributions, the residual profits are allocated based on these contributions.

Example 2. Residual profit split. (i) Company A, a Country 1 corporation, provides specialized services pertaining to the processing and storage of Level 1 hazardous waste (for purposes of this example, the most dangerous type of waste). Under long-term contracts with private companies and governmental entities in Country 1, Company A performs multiple services, including transportation of Level 1 waste, development of handling and storage protocols, recordkeeping, and supervision of waste-storage facilities owned and maintained by the contracting parties. Company A's research and development unit has also developed new and unique processes for transport and storage of Level 1 waste that minimize environmental and occupational effects. In addition to this novel technology, Company A has substantial know-how and a long-term record of safe operations in Country 1.

(ii) Company A's subsidiary, Company B, has been in operation continuously for a number of years in Country 2. Company B has successfully completed several projects in Country 2 involving Level 2 and Level 3 waste, including projects with government-owned entities. Company B has a license in Country 2 to handle Level 2 waste (Level 3 does not require a license). Company B has established a reputation for completing these projects in a responsible manner. Company B has cultivated contacts with procurement officers, regulatory and licensing officials, and other government personnel in Country 2.

(iii) Country 2 government publishes invitations to bid on a project to handle the country's burgeoning volume of Level 1 waste, all of which is generated in government-owned facilities. Bidding is

limited to companies that are domiciled in Country 2 and that possess a license from the government to handle Level 1 or Level 2 waste. In an effort to submit a winning bid to secure the contract, Company B points to its Level 2 license and its record of successful completion of projects, and also demonstrates to these officials that it has access to substantial technical expertise pertaining to processing of Level 1 waste.

(iv) Company A enters into a long-term technical services agreement with Company B. Under this agreement, Company A agrees to supply to Company B project managers and other technical staff who have detailed knowledge of Company A's proprietary Level 1 remediation techniques. Company A commits to perform under any long-term contracts entered into by Company B. Company B agrees to compensate Company A based on a markup on Company A's marginal costs (pro rata compensation and current expenses of Company A personnel). In the bid on the Country 2 contract for Level 1 waste remediation, Company B proposes to use a multi-disciplinary team of specialists from Company A and Company B. Project managers from Company A will direct the team, which will also include employees of Company B and will make use of physical assets and facilities owned by Company B. Only Company A and Company B personnel will perform services under the contract. Country 2 grants Company B a license to handle Level 1 waste.

(v) Country 2 grants Company B a five-year, exclusive contract to provide processing services for all Level 1 hazardous waste generated in Country 2. Under the contract, Company B is to be paid a fixed price per ton of Level 1 waste that it processes each year. Company B undertakes that all services provided will meet international standards applicable to processing of Level 1 waste. Company B begins performance under the contract.

(vi) Analysis of the facts and circumstances indicates that both Company A and Company B make nonroutine contributions to the Level 1 waste processing activity in Country 2. In addition, it is determined that reliable comparables are not available for the services that Company A provides under the long-term contract, in part because those services incorporate specialized knowledge and process intangible property developed by Company A. It is also determined that reliable comparables are not available for the Level 2 license in Country 2, the successful track record, the government contacts with Country 2 officials, and other intangible property that Company B provided. In view of these facts, the Commissioner determines that the residual profit split method for services in paragraph (g) of this section provides the most reliable means of evaluating the arm's length results for the transaction. In evaluating the appropriate returns to Company A and Company B for their respective contributions, the Commissioner takes into account that the controlled parties incur different risks, because the contract between the controlled parties provides that Company A will be compensated on the basis of marginal costs incurred, plus a markup, whereas the

contract between Company B and the government of Country 2 provides that Company B will be compensated on a fixed-price basis per ton of Level 1 waste processed.

(vii) In the first stage of the residual profit split, an arm's length return is determined for routine activities performed by Company B in Country 2, such as transportation, recordkeeping, and administration. In addition, an arm's length return is determined for routine activities performed by Company A (administrative, human resources, etc.) in connection with providing personnel to Company B. After the arm's length return for these functions is determined, residual profits may be present. In the second stage of the residual profit split, any residual profit is allocated by reference to the relative value of the nonroutine contributions made by each taxpayer. Company A's nonroutine contributions include its commitment to perform under the contract and the specialized technical knowledge made available through the project managers under the services agreement with Company B. Company B's nonroutine contributions include its licenses to handle Level 1 and Level 2 waste in Country 2, its knowledge of and contacts with procurement, regulatory and licensing officials in the government of Country 2, and its record in Country 2 of successfully handling non-Level 1 waste.

(h) *Unspecified methods.* Methods not specified in paragraphs (b) through (g) of this section may be used to evaluate whether the amount charged in a controlled services transaction is arm's length. Any method used under this paragraph (h) must be applied in accordance with the provisions of § 1.482-1. Consistent with the specified methods, an unspecified method should take into account the general principle that uncontrolled taxpayers evaluate the terms of a transaction by considering the realistic alternatives to that transaction, including economically similar transactions structured as other than services transactions, and only enter into a particular transaction if none of the alternatives is preferable to it. For example, the comparable uncontrolled services price method compares a controlled services transaction to similar uncontrolled transactions to provide a direct estimate of the price to which the parties would have agreed had they resorted directly to a market alternative to the controlled services transaction. Therefore, in establishing whether a controlled services transaction achieved an arm's length result, an unspecified method should provide information on the prices or profits that the controlled taxpayer could have realized by choosing a realistic alternative to the controlled services transaction (for example, outsourcing a particular service function, rather than performing the

function itself). As with any method, an unspecified method will not be applied unless it provides the most reliable measure of an arm's length result under the principles of the best method rule. See § 1.482-1(c). Therefore, in accordance with § 1.482-1(d) (comparability), to the extent that an unspecified method relies on internal data rather than uncontrolled comparables, its reliability will be reduced. Similarly, the reliability of a method will be affected by the reliability of the data and assumptions used to apply the method, including any projections used.

Example. (i) Company T, a U.S. corporation, develops computer software programs including a real estate investment program that performs financial analysis of commercial real properties. Companies U, V, and W are owned by Company T. The primary business activity of Companies U, V, and W is commercial real estate development. For business reasons, Company T does not sell the computer program to its customers (on a compact disk or via download from Company T's server through the Internet). Instead, Company T maintains the software program on its own server and allows customers to access the program through the Internet by using a password. The transactions between Company T and Companies U, V, and W are structured as controlled services transactions whereby Companies U, V, and W obtain access via the Internet to Company T's software program for financial analysis. Each year, Company T provides a revised version of the computer program including the most recent data on the commercial real estate market, rendering the old version obsolete.

(ii) In evaluating whether the consideration paid by Companies U, V, and W to Company T was arm's length, the Commissioner may consider, subject to the best method rule of § 1.482-1(c), Company T's alternative of selling the computer program to Companies U, V, and W on a compact disk or via download through the Internet. The Commissioner determines that the controlled services transactions between Company T and Companies U, V, and W are comparable to the transfer of a similar software program on a compact disk or via download through the Internet between uncontrolled parties. Subject to adjustments being made for material differences between the controlled services transactions and the comparable uncontrolled transactions, the uncontrolled transfers of tangible property may be used to evaluate the arm's length results for the controlled services transactions between Company T and Companies U, V, and W.

(i) *Contingent-payment contractual terms for services—(1) Contingent-payment contractual terms recognized in general.* In the case of a contingent-payment arrangement, the arm's length result for the controlled services transaction generally would not require payment by the recipient to the renderer in the tax accounting period in which

the service is rendered if the specified contingency does not occur in that period. If the specified contingency occurs in a tax accounting period subsequent to the period in which the service is rendered, the arm's length result for the controlled services transaction generally would require payment by the recipient to the renderer on a basis that reflects the recipient's benefit from the services rendered and the risks borne by the renderer in performing the activities in the absence of a provision that unconditionally obligates the recipient to pay for the activities performed in the tax accounting period in which the service is rendered.

(2) *Contingent-payment arrangement.* For purposes of this paragraph (i), an arrangement will be treated as a contingent-payment arrangement if it meets all of the requirements in paragraph (i)(2)(i) of this section and is consistent with the economic substance and conduct requirement in paragraph (i)(2)(ii) of this section.

(i) *General requirements—(A) Written contract.* The arrangement is set forth in a written contract entered into prior to, or contemporaneous with, the start of the activity or group of activities constituting the controlled services transaction.

(B) *Specified contingency.* The contract states that payment for a controlled services transaction is contingent (in whole or in part) upon the happening of a future benefit (within the meaning of § 1.482-9(l)(3)) for the recipient directly related to the activity or group of activities. For purposes of the preceding sentence, whether the future benefit is directly related to the activity or group of activities is evaluated based on all the facts and circumstances.

(C) *Basis for payment.* The contract provides for payment on a basis that reflects the recipient's benefit from the services rendered and the risks borne by the renderer.

(ii) *Economic substance and conduct.* The arrangement, including the contingency and the basis for payment, is consistent with the economic substance of the controlled transaction and the conduct of the controlled parties. See § 1.482-1(d)(3)(ii)(B).

(3) *Commissioner's authority to impute contingent-payment terms.* Consistent with the authority in § 1.482-1(d)(3)(ii)(B), the Commissioner may impute contingent-payment contractual terms in a controlled services transaction if the economic substance of the transaction is consistent with the existence of such terms.

(4) *Evaluation of arm's length charge.* Whether the amount charged in a contingent-payment arrangement is arm's length will be evaluated in accordance with this section and other applicable regulations under section 482. In evaluating whether the amount charged in a contingent-payment arrangement for the manufacture, construction, or development of tangible or intangible property owned by the recipient is arm's length, the charge determined under the rules of §§ 1.482-3 and 1.482-4 for the transfer of similar property may be considered. See § 1.482-1(f)(2)(ii).

(5) *Examples.* The principles of this paragraph (i) are illustrated by the following examples:

Example 1. (i) Company X is a member of a controlled group that has operated in the pharmaceutical sector for many years. In year 1, Company X enters into a written services agreement with Company Y, another member of the controlled group, whereby Company X will perform certain research and development activities for Company Y. The parties enter into the agreement before Company X undertakes any of the research and development activities covered by the agreement. At the time the agreement is entered into, the possibility that any new products will be developed is highly uncertain and the possible market or markets for any products that may be developed are not known and cannot be estimated with any reliability. Under the agreement, Company Y will own any patent or other rights that result from the activities of Company X under the agreement and Company Y will make payments to Company X only if such activities result in commercial sales of one or more derivative products. In that event, Company Y will pay Company X, for a specified period, x% of Company Y's gross sales of each of such products. Payments are required with respect to each jurisdiction in which Company Y has sales of such a derivative product, beginning with the first year in which the sale of a product occurs in the jurisdiction and continuing for six additional years with respect to sales of that product in that jurisdiction.

(ii) As a result of research and development activities performed by Company X for Company Y in years 1 through 4, a compound is developed that may be more effective than existing medications in the treatment of certain conditions. Company Y registers the patent rights with respect to the compound in several jurisdictions in year 4. In year 6, Company Y begins commercial sales of the product in Jurisdiction A and, in that year, Company Y makes the payment to Company X that is required under the agreement. Sales of the product continue in Jurisdiction A in years 7 through 9 and Company Y makes the payments to Company X in years 7 through 9 that are required under the agreement.

(iii) The years under examination are years 6 through 9. In evaluating whether the contingent-payment terms will be recognized, the Commissioner considers

whether the conditions of paragraph (i)(2) of this section are met and whether the arrangement, including the specified contingency and basis of payment, is consistent with the economic substance of the controlled services transaction and with the conduct of the controlled parties. The Commissioner determines that the contingent-payment arrangement is reflected in the written agreement between Company X and Company Y; that commercial sales of products developed under the arrangement represent future benefits for Company Y directly related to the controlled services transaction; and that the basis for the payment provided for in the event such sales occur reflects the recipient's benefit and the renderer's risk. Consistent with § 1.482-1(d)(3)(ii)(B) and (iii)(B), the Commissioner determines that the parties' conduct over the term of the agreement has been consistent with their contractual allocation of risk; that Company X has the financial capacity to bear the risk that its research and development services may be unsuccessful and that it may not receive compensation for such services; and that Company X exercises managerial and operational control over the research and development, such that it is reasonable for Company X to assume the risk of those activities. Based on all these facts, the Commissioner determines that the contingent-payment arrangement is consistent with economic substance.

(iv) In determining whether the amount charged under the contingent-payment arrangement in each of years 6 through 9 is arm's length, the Commissioner evaluates under this section and other applicable rules under section 482 the compensation paid in each year for the research and development services. This analysis takes into account that under the contingent-payment terms Company X bears the risk that it might not receive payment for its services in the event that those services do not result in marketable products and the risk that the magnitude of its payment depends on the magnitude of product sales, if any. The Commissioner also considers the alternatives reasonably available to the parties in connection with the controlled services transaction. One such alternative, in view of Company X's willingness and ability to bear the risk and expenses of research and development activities, would be for Company X to undertake such activities on its own behalf and to license the rights to products successfully developed as a result of such activities. Accordingly, in evaluating whether the compensation of x% of gross sales that is paid to Company X during the first four years of commercial sales of derivative products is arm's length, the Commissioner may consider the royalties (or other consideration) charged for intangible property that are comparable to those incorporated in the derivative products and that resulted from Company X's research and development activities under the contingent-payment arrangement.

Example 2. (i) The facts are the same as in *Example 1*, except that no commercial sales ever materialize with regard to the patented compound so that, consistent with the agreement, Company Y makes no payments to Company X in years 6 through 9.

(ii) Based on all the facts and circumstances, the Commissioner determines that the contingent-payment arrangement is consistent with economic substance, and the result (no payments in years 6 through 9) is consistent with an arm's length result.

Example 3. (i) The facts are the same as in *Example 1*, except that, in the event that Company X's activities result in commercial sales of one or more derivative products by Company Y, Company Y will pay Company X a fee equal to the research and development costs borne by Company X plus an amount equal to x% of such costs, with the payment to be made in the first year in which any such sales occur. The x% markup on costs is within the range, ascertainable in year 1, of markups on costs of independent contract researchers that are compensated under terms that unconditionally obligate the recipient to pay for the activities performed in the tax accounting period in which the service is rendered. In year 6, Company Y makes the single payment to Company X that is required under the arrangement.

(ii) The years under examination are years 6 through 9. In evaluating whether the contingent-payment terms will be recognized, the Commissioner considers whether the requirements of paragraph (i)(2) of this section were met at the time the written agreement was entered into and whether the arrangement, including the specified contingency and basis for payment, is consistent with the economic substance of the controlled services transaction and with the conduct of the controlled parties. The Commissioner determines that the contingent-payment terms are reflected in the written agreement between Company X and Company Y and that commercial sales of products developed under the arrangement represent future benefits for Company Y directly related to the controlled services transaction. However, in this case, the Commissioner determines that the basis for payment provided for in the event such sales occur (costs of the services plus x%, representing the markup for contract research in the absence of any nonpayment risk) does not reflect the recipient's benefit and the renderer's risks in the controlled services transaction. Based on all the facts and circumstances, the Commissioner determines that the contingent-payment arrangement is not consistent with economic substance.

(iii) Accordingly, the Commissioner determines to exercise its authority to impute contingent-payment contractual terms that accord with economic substance, pursuant to paragraph (i)(3) of this section and § 1.482-1(d)(3)(ii)(B). In this regard, the Commissioner takes into account that at the time the arrangement was entered into, the possibility that any new products would be developed was highly uncertain and the possible market or markets for any products that may be developed were not known and could not be estimated with any reliability. In such circumstances, it is reasonable to conclude that one possible basis of payment, in order to reflect the recipient's benefit and the renderer's risks, would be a charge equal to a percentage of commercial sales of one or more derivative products that result from the research and development activities. The

Commissioner in this case may impute terms that require Company Y to pay Company X a percentage of sales of the products developed under the agreement in each of years 6 through 9.

(iv) In determining an appropriate arm's length charge under such imputed contractual terms, the Commissioner conducts an analysis under this section and other applicable rules under section 482, and considers the alternatives reasonably available to the parties in connection with the controlled services transaction. One such alternative, in view of Company X's willingness and ability to bear the risks and expenses of research and development activities, would be for Company X to undertake such activities on its own behalf and to license the rights to products successfully developed as a result of such activities. Accordingly, for purposes of its determination, the Commissioner may consider the royalties (or other consideration) charged for intangible property that are comparable to those incorporated in the derivative products that resulted from Company X's research and development activities under the contingent-payment arrangement.

(j) *Total services costs.* For purposes of this section, total services costs means all costs of rendering those services for which total services costs are being determined. Total services costs include all costs in cash or in kind (including stock-based compensation) that, based on analysis of the facts and circumstances, are directly identified with, or reasonably allocated in accordance with the principles of paragraph (k)(2) of this section to, the services. In general, costs for this purpose should comprise provision for all resources expended, used, or made available to achieve the specific objective for which the service is rendered. Reference to generally accepted accounting principles or Federal income tax accounting rules may provide a useful starting point but will not necessarily be conclusive regarding inclusion of costs in total services costs. Total services costs do not include interest expense, foreign income taxes (as defined in § 1.901-2(a)), or domestic income taxes.

(k) *Allocation of costs—(1) In general.* In any case where the renderer's activity that results in a benefit (within the meaning of paragraph (l)(3) of this section) for one recipient in a controlled services transaction also generates a benefit for one or more other members of a controlled group (including the benefit, if any, to the renderer), and the amount charged under this section in the controlled services transaction is determined under a method that makes reference to costs, costs must be allocated among the portions of the activity performed for the benefit of the

first mentioned recipient and such other members of the controlled group under this paragraph (k). The principles of this paragraph (k) must also be used whenever it is appropriate to allocate and apportion any class of costs (for example, overhead costs) in order to determine the total services costs of rendering the services. In no event will an allocation of costs based on a generalized or non-specific benefit be appropriate.

(2) *Appropriate method of allocation and apportionment*—(i) *Reasonable method standard.* Any reasonable method may be used to allocate and apportion costs under this section. In establishing the appropriate method of allocation and apportionment, consideration should be given to all bases and factors, including, for example, total services costs, total costs for a relevant activity, assets, sales, compensation, space utilized, and time spent. The costs incurred by supporting departments may be apportioned to other departments on the basis of reasonable overall estimates, or such costs may be reflected in the other departments' costs by applying reasonable departmental overhead rates. Allocations and apportionments of costs must be made on the basis of the full cost, as opposed to the incremental cost.

(ii) *Use of general practices.* The practices used by the taxpayer to apportion costs in connection with

preparation of statements and analyses for the use of management, creditors, minority shareholders, joint venturers, clients, customers, potential investors, or other parties or agencies in interest will be considered as potential indicators of reliable allocation methods, but need not be accorded conclusive weight by the Commissioner. In determining the extent to which allocations are to be made to or from foreign members of a controlled group, practices employed by the domestic members in apportioning costs among themselves will also be considered if the relationships with the foreign members are comparable to the relationships among the domestic members of the controlled group. For example, if for purposes of reporting to public stockholders or to a governmental agency, a corporation apportions the costs attributable to its executive officers among the domestic members of a controlled group on a reasonable and consistent basis, and such officers exercise comparable control over foreign members of the controlled group, such domestic apportionment practice will be considered in determining the allocations to be made to the foreign members.

(3) *Examples.* The principles of this paragraph (k) are illustrated by the following examples:

Example 1. Company A pays an annual license fee of 500x to an uncontrolled

taxpayer for unlimited use of a database within the corporate group. Under the terms of the license with the uncontrolled taxpayer, Company A is permitted to use the database for its own use and in rendering research services to its subsidiary, Company B. Company B obtains benefits from the database that are similar to those that it would obtain if it had independently licensed the database from the uncontrolled taxpayer. Evaluation of the arm's length charge (under a method in which costs are relevant) to Company B for the controlled services that incorporate use of the database must take into account the full amount of the license fee of 500x paid by Company A, as reasonably allocated and apportioned to the relevant benefits, although the incremental use of the database for the benefit of Company B did not result in an increase in the license fee paid by Company A.

Example 2. (i) Company A is a consumer products company located in the United States. Companies B and C are wholly-owned subsidiaries of Company A and are located in Countries B and C, respectively. Company A and its subsidiaries manufacture products for sale in their respective markets. Company A hires a consultant who has expertise regarding a manufacturing process used by Company A and its subsidiary, Company B. Company C, the Country C subsidiary, uses a different manufacturing process, and accordingly will not receive any benefit from the outside consultant hired by Company A. In allocating and apportioning the cost of hiring the outside consultant (100), Company A determines that sales constitute the most appropriate allocation key.

(ii) Company A and its subsidiaries have the following sales:

Company	A	B	C	Total
Sales	400	100	200	700

(iii) Because Company C does not obtain any benefit from the consultant, none of the costs are allocated to it. Rather, the costs of

100 are allocated and apportioned ratably to Company A and Company B as the entities that obtain a benefit from the campaign,

based on the total sales of those entities (500). An appropriate allocation of the costs of the consultant is as follows:

Company	A	B	Total
Allocation	400/500	100/500	
Amount	80	20	100

(1) *Controlled services transaction*—(1) *In general.* A controlled services transaction includes any activity (as defined in paragraph (1)(2) of this section) by one member of a group of controlled taxpayers (the renderer) that results in a benefit (as defined in paragraph (1)(3) of this section) to one or more other members of the controlled group (the recipient(s)).

(2) *Activity.* An activity includes the performance of functions, assumptions of risks, or use by a renderer of tangible or intangible property or other

resources, capabilities, or knowledge, such as knowledge of and ability to take advantage of particularly advantageous situations or circumstances. An activity also includes making available to the recipient any property or other resources of the renderer.

(3) *Benefit*—(i) *In general.* An activity is considered to provide a benefit to the recipient if the activity directly results in a reasonably identifiable increment of economic or commercial value that enhances the recipient's commercial position, or that may reasonably be

anticipated to do so. An activity is generally considered to confer a benefit if, taking into account the facts and circumstances, an uncontrolled taxpayer in circumstances comparable to those of the recipient would be willing to pay an uncontrolled party to perform the same or similar activity on either a fixed or contingent-payment basis, or if the recipient otherwise would have performed for itself the same activity or a similar activity. A benefit may result to the owner of intangible property if the renderer engages in an activity that

is reasonably anticipated to result in an increase in the value of that intangible property. Paragraphs (l)(3)(ii) through (v) of this section provide guidelines that indicate the presence or absence of a benefit for the activities in the controlled services transaction.

(ii) *Indirect or remote benefit.* An activity is not considered to provide a benefit to the recipient if, at the time the activity is performed, the present or reasonably anticipated benefit from that activity is so indirect or remote that the recipient would not be willing to pay, on either a fixed or contingent-payment basis, an uncontrolled party to perform a similar activity, and would not be willing to perform such activity for itself for this purpose. The determination whether the benefit from an activity is indirect or remote is based on the nature of the activity and the situation of the recipient, taking into consideration all facts and circumstances.

(iii) *Duplicative activities.* If an activity performed by a controlled taxpayer duplicates an activity that is performed, or that reasonably may be anticipated to be performed, by another controlled taxpayer on or for its own account, the activity is generally not considered to provide a benefit to the recipient, unless the duplicative activity itself provides an additional benefit to the recipient.

(iv) *Shareholder activities.* An activity is not considered to provide a benefit if the sole effect of that activity is either to protect the renderer's capital investment in the recipient or in other members of the controlled group, or to facilitate compliance by the renderer with reporting, legal, or regulatory requirements applicable specifically to the renderer, or both. Activities in the nature of day-to-day management generally do not relate to protection of the renderer's capital investment. Based on analysis of the facts and circumstances, activities in connection with a corporate reorganization may be considered to provide a benefit to one or more controlled taxpayers.

(v) *Passive association.* A controlled taxpayer generally will not be considered to obtain a benefit where that benefit results from the controlled taxpayer's status as a member of a controlled group. A controlled taxpayer's status as a member of a controlled group may, however, be taken into account for purposes of evaluating comparability between controlled and uncontrolled transactions.

(4) *Disaggregation of transactions.* A controlled services transaction may be analyzed as two separate transactions for purposes of determining the arm's

length consideration, if that analysis is the most reliable means of determining the arm's length consideration for the controlled services transaction. See the best method rule under § 1.482-1(c).

(5) *Examples.* The principles of this paragraph (l) are illustrated by the following examples. In each example, assume that Company X is a U.S. corporation and Company Y is a wholly-owned subsidiary of Company X in Country B.

Example 1. In general. In developing a worldwide advertising and promotional campaign for a consumer product, Company X pays for and obtains designation as an official sponsor of the Olympics. This designation allows Company X and all its subsidiaries, including Company Y, to identify themselves as sponsors and to use the Olympic logo in advertising and promotional campaigns. The Olympic sponsorship campaign generates benefits to Company X, Company Y, and other subsidiaries of Company X.

Example 2. Indirect or remote benefit. Based on recommendations contained in a study performed by its internal staff, Company X implements certain changes in its management structure and the compensation of managers of divisions located in the United States. No changes were recommended or considered for Company Y in Country B. The internal study and the resultant changes in its management may increase the competitiveness and overall efficiency of Company X. Any benefits to Company Y as a result of the study are, however, indirect or remote. Consequently, Company Y is not considered to obtain a benefit from the study.

Example 3. Indirect or remote benefit. Based on recommendations contained in a study performed by its internal staff, Company X decides to make changes to the management structure and management compensation of its subsidiaries, in order to increase their profitability. As a result of the recommendations in the study, Company X implements substantial changes in the management structure and management compensation scheme of Company Y. The study and the changes implemented as a result of the recommendations are anticipated to increase the profitability of Company X and its subsidiaries. The increased management efficiency of Company Y that results from these changes is considered to be a specific and identifiable benefit, rather than remote or speculative.

Example 4. Duplicative activities. At its corporate headquarters in the United States, Company X performs certain treasury functions for Company X and for its subsidiaries, including Company Y. These treasury functions include raising capital, arranging medium and long-term financing for general corporate needs, including cash management. Under these circumstances, the treasury functions performed by Company X do not duplicate the functions performed by Company Y's staff. Accordingly, Company Y is considered to obtain a benefit from the functions performed by Company X.

Example 5. Duplicative activities. The facts are the same as in *Example 4*, except that Company Y's functions include ensuring that the financing requirements of its own operations are met. Analysis of the facts and circumstances indicates that Company Y independently administers all financing and cash-management functions necessary to support its operations, and does not utilize financing obtained by Company X. Under the circumstances, the treasury functions performed by Company X are duplicative of similar functions performed by Company Y's staff, and the duplicative functions do not enhance Company Y's position. Accordingly, Company Y is not considered to obtain a benefit from the duplicative activities performed by Company X.

Example 6. Duplicative activities. Company X's in-house legal staff has specialized expertise in several areas, including intellectual property. The intellectual property legal staff specializes in technology licensing, patents, copyrights, and negotiating and drafting intellectual property agreements. Company Y is involved in negotiations with an unrelated party to enter into a complex joint venture that includes multiple licenses and cross-licenses of patents and copyrights. Company Y retains outside counsel that specializes in intellectual property law to review the transaction documents. Company Y does not have in-house counsel of its own to review intellectual property transaction documents. Outside counsel advises that the terms for the proposed transaction are advantageous to Company Y and that the contracts are valid and fully enforceable. Company X's intellectual property legal staff possess valuable knowledge of Company Y's patents and technological achievements. They are capable of identifying particular scientific attributes protected under patent that strengthen Company Y's negotiating position, and of discovering flaws in the patents offered by the unrelated party. To reduce risk associated with the transaction, Company X's intellectual property legal staff reviews the transaction documents before Company Y executes the contracts. Company X's intellectual property legal staff also separately evaluates the patents and copyrights with respect to the licensing arrangements and concurs in the opinion provided by outside counsel. The activities performed by Company X substantially duplicate the legal services obtained by Company Y, but they also reduce risk associated with the transaction in a way that confers an additional benefit on Company Y.

Example 7. Shareholder activities. Company X is a publicly held corporation. U.S. laws and regulations applicable to publicly held corporations such as Company X require the preparation and filing of periodic reports that show, among other things, profit and loss statements, balance sheets, and other material financial information concerning the company's operations. Company X, Company Y and each of the other subsidiaries maintain their own separate accounting departments that record individual transactions and prepare financial statements in accordance with their local accounting practices. Company Y, and

the other subsidiaries, forward the results of their financial performance to Company X, which analyzes and compiles these data into periodic reports in accordance with U.S. laws and regulations. Because Company X's preparation and filing of the reports relate solely to its role as an investor of capital or shareholder in Company Y or to its compliance with reporting, legal, or regulatory requirements, or both, these activities constitute shareholder activities and therefore Company Y is not considered to obtain a benefit from the preparation and filing of the reports.

Example 8. Shareholder activities. The facts are the same as in *Example 7*, except that Company Y's accounting department maintains a general ledger recording individual transactions, but does not prepare any financial statements (such as profit and loss statements and balance sheets). Instead, Company Y forwards the general ledger data to Company X, and Company X analyzes and compiles financial statements for Company Y, as well as for Company X's overall operations, for purposes of complying with U.S. reporting requirements. Company Y is subject to reporting requirements in Country B similar to those applicable to Company X in the United States. Much of the data that Company X analyzes and compiles regarding Company Y's operations for purposes of complying with the U.S. reporting requirements are made available to Company Y for its use in preparing reports that must be filed in Country B. Company Y incorporates these data, after minor adjustments for differences in local accounting practices, into the reports that it files in Country B. Under these circumstances, because Company X's analysis and compilation of Company Y's financial data does not relate solely to its role as an investor of capital or shareholder in Company Y, or to its compliance with reporting, legal, or regulatory requirements, or both, these activities do not constitute shareholder activities.

Example 9. Shareholder activities. Members of Company X's internal audit staff visit Company Y on a semiannual basis in order to review the subsidiary's adherence to internal operating procedures issued by Company X and its compliance with U.S. anti-bribery laws, which apply to Company Y on account of its ownership by a U.S. corporation. Because the sole effect of the reviews by Company X's audit staff is to protect Company X's investment in Company Y, or to facilitate Company X's compliance with U.S. anti-bribery laws, or both, the visits are shareholder activities and therefore Company Y is not considered to obtain a benefit from the visits.

Example 10. Shareholder activities. Country B recently enacted legislation that changed the foreign currency exchange controls applicable to foreign shareholders of Country B corporations. Company X concludes that it may benefit from changing the capital structure of Company Y, thus taking advantage of the new foreign currency exchange control laws in Country B. Company X engages an investment banking firm and a law firm to review the Country B legislation and to propose possible changes

to the capital structure of Company Y. Because Company X's retention of the firms facilitates Company Y's ability to pay dividends and other amounts and has the sole effect of protecting Company X's investment in Company Y, these activities constitute shareholder activities and Company Y is not considered to obtain a benefit from the activities.

Example 11. Shareholder activities. The facts are the same as in *Example 10*, except that Company Y bears the full cost of retaining the firms to evaluate the new foreign currency control laws in Country B and to make appropriate changes to its stock ownership by Company X. Company X is considered to obtain a benefit from the rendering by Company Y of these activities, which would be shareholder activities if conducted by Company X (see *Example 10*).

Example 12. Shareholder activities. The facts are the same as in *Example 10*, except that the new laws relate solely to corporate governance in Country B, and Company X retains the law firm and investment banking firm in order to evaluate whether restructuring would increase Company Y's profitability, reduce the number of legal entities in Country B, and increase Company Y's ability to introduce new products more quickly in Country B. Because Company X retained the law firm and the investment banking firm primarily to enhance Company Y's profitability and the efficiency of its operations, and not solely to protect Company X's investment in Company Y or to facilitate Company X's compliance with Country B's corporate laws, or to both, these activities do not constitute shareholder activities.

Example 13. Shareholder activities. Company X establishes detailed personnel policies for its subsidiaries, including Company Y. Company X also reviews and approves the performance appraisals of Company Y's executives, monitors levels of compensation paid to all Company Y personnel, and is involved in hiring and firing decisions regarding the senior executives of Company Y. Because this personnel-related activity by Company X involves day-to-day management of Company Y, this activity does not relate solely to Company X's role as an investor of capital or a shareholder of Company Y, and therefore does not constitute a shareholder activity.

Example 14. Shareholder activities. Each year, Company X conducts a two-day retreat for its senior executives. The purpose of the retreat is to refine the long-term business strategy of Company X and its subsidiaries, including Company Y, and to produce a confidential strategy statement. The strategy statement identifies several potential growth initiatives for Company X and its subsidiaries and lists general means of increasing the profitability of the company as a whole. The strategy statement is made available without charge to Company Y and the other subsidiaries of Company X. Company Y independently evaluates whether to implement some, all, or none of the initiatives contained in the strategy statement. Because the preparation of the strategy statement does not relate solely to Company X's role as an investor of capital or

a shareholder of Company Y, the expense of preparing the document is not a shareholder expense.

Example 15. Passive association/benefit. Company X is the parent corporation of a large controlled group that has been in operation in the information-technology sector for ten years. Company Y is a small corporation that was recently acquired by the Company X controlled group from local Country B owners. Several months after the acquisition of Company Y, Company Y obtained a contract to redesign and assemble the information-technology networks and systems of a large financial institution in Country B. The project was significantly larger and more complex than any other project undertaken to date by Company Y. Company Y did not use Company X's marketing intangible property to solicit the contract, and Company X had no involvement in the solicitation, negotiation, or anticipated execution of the contract. For purposes of this section, Company Y is not considered to obtain a benefit from Company X or any other member of the controlled group because the ability of Company Y to obtain the contract, or to obtain the contract on more favorable terms than would have been possible prior to its acquisition by the Company X controlled group, was due to Company Y's status as a member of the Company X controlled group and not to any specific activity by Company X or any other member of the controlled group.

Example 16. Passive association/benefit. The facts are the same as in *Example 15*, except that Company X executes a performance guarantee with respect to the contract, agreeing to assist in the project if Company Y fails to meet certain milestones. This performance guarantee allowed Company Y to obtain the contract on materially more favorable terms than otherwise would have been possible. Company Y is considered to obtain a benefit from Company X's execution of the performance guarantee.

Example 17. Passive association/benefit. The facts are the same as in *Example 15*, except that Company X began the process of negotiating the contract with the financial institution in Country B before acquiring Company Y. Once Company Y was acquired by Company X, the contract with the financial institution was entered into by Company Y. Company Y is considered to obtain a benefit from Company X's negotiation of the contract.

Example 18. Passive association/benefit. The facts are the same as in *Example 15*, except that Company X sent a letter to the financial institution in Country B, which represented that Company X had a certain percentage ownership in Company Y and that Company X would maintain that same percentage ownership interest in Company Y until the contract was completed. This letter allowed Company Y to obtain the contract on more favorable terms than otherwise would have been possible. Since this letter from Company X to the financial institution simply affirmed Company Y's status as a member of the controlled group and represented that this status would be maintained until the contract was completed,

Company Y is not considered to obtain a benefit from Company X's furnishing of the letter.

Example 19. Passive association/benefit. (i) S is a company that supplies plastic containers to companies in various industries. S establishes the prices for its containers through a price list that offers customers discounts based solely on the volume of containers purchased.

(ii) Company X is the parent corporation of a large controlled group in the information technology sector. Company Y is a wholly-owned subsidiary of Company X located in Country B. Company X and Company Y both purchase plastic containers from unrelated supplier S. In year 1, Company X purchases 1 million units and Company Y purchases 100,000 units. S, basing its prices on purchases by the entire group, completes the order for 1.1 million units at a price of \$0.95 per unit, and separately bills and ships the orders to each company. Companies X and Y undertake no bargaining with supplier S with respect to the price charged, and purchase no other products from supplier S.

(iii) R1 and its wholly-owned subsidiary R2 are a controlled group of taxpayers (unrelated to Company X or Company Y) each of which carries out functions comparable to those of Companies X and Y and undertakes purchases of plastic containers from supplier S, identical to those purchased from S by Company X and Company Y, respectively. S, basing its prices on purchases by the entire group, charges R1 and R2 \$0.95 per unit for the 1.1 million units ordered. R1 and R2 undertake no bargaining with supplier S with respect to the price charged, and purchase no other products from supplier S.

(iv) U is an uncontrolled taxpayer that carries out comparable functions and undertakes purchases of plastic containers from supplier S identical to Company Y. U is not a member of a controlled group, undertakes no bargaining with supplier S with respect to the price charged, and purchases no other products from supplier S. U purchases 100,000 plastic containers from S at the price of \$1.00 per unit.

(v) Company X charges Company Y a fee of \$5,000, or \$0.05 per unit of plastic containers purchased by Company Y, reflecting the fact that Company Y receives the volume discount from supplier S.

(vi) In evaluating the fee charged by Company X to Company Y, the Commissioner considers whether the transactions between R1, R2, and S or the transactions between U and S provide a more reliable measure of the transactions between Company X, Company Y and S. The Commissioner determines that Company Y's status as a member of a controlled group should be taken into account for purposes of evaluating comparability of the transactions, and concludes that the transactions between R1, R2, and S are more reliably comparable to the transactions between Company X, Company Y, and S. The comparable charge for the purchase was \$0.95 per unit. Therefore, obtaining the plastic containers at a favorable rate (and the resulting \$5,000 savings) is entirely due to Company Y's status as a member of the Company X

controlled group and not to any specific activity by Company X or any other member of the controlled group. Consequently, Company Y is not considered to obtain a benefit from Company X or any other member of the controlled group.

Example 20. Disaggregation of transactions. (i) X, a domestic corporation, is a pharmaceutical company that develops and manufactures ethical pharmaceutical products. Y, a Country B corporation, is a distribution and marketing company that also performs clinical trials for X in Country B. Because Y does not possess the capability to conduct the trials, it contracts with a third party to undertake the trials at a cost of \$100. Y also incurs \$25 in expenses related to the third-party contract (for example, in hiring and working with the third party).

(ii) Based on a detailed functional analysis, the Commissioner determines that Y performed functions beyond merely facilitating the clinical trials for X, such as audit controls of the third party performing those trials. In determining the arm's length price, the Commissioner may consider a number of alternatives. For example, for purposes of determining the arm's length price, the Commissioner may determine that the intercompany service is most reliably analyzed on a disaggregated basis as two separate transactions: in this case, the contract between Y and the third party could constitute an internal CUSP with a price of \$100. Y would be further entitled to an arm's length remuneration for its facilitating services. If the most reliable method is one that provides a markup on Y's costs, then "total services cost" in this context would be \$25. Alternatively, the Commissioner may determine that the intercompany service is most reliably analyzed as a single transaction, based on comparable uncontrolled transactions involving the facilitation of similar clinical trial services performed by third parties. If the most reliable method is one that provides a markup on all of Y's costs, and the base of the markup determined by the comparable companies includes the third-party clinical trial costs, then such a markup would be applied to Y's total services cost of \$125.

Example 21. Disaggregation of transactions. (i) X performs a number of administrative functions for its subsidiaries, including Y, a distributor of widgets in Country B. These services include those relating to working capital (inventory and accounts receivable/payable) management. To facilitate provision of these services, X purchases an ERP system specifically dedicated to optimizing working capital management. The system, which entails significant third-party costs and which includes substantial intellectual property relating to its software, costs \$1,000.

(ii) Based on a detailed functional analysis, the Commissioner determines that in providing administrative services for Y, X performed functions beyond merely operating the ERP system itself, since X was effectively using the ERP as an input to the administrative services it was providing to Y. In determining arm's length price for the services, the Commissioner may consider a number of alternatives. For example, if the

most reliable uncontrolled data is derived from companies that use similar ERP systems purchased from third parties to perform similar administrative functions for uncontrolled parties, the Commissioner may determine that a CPM is the best method for measuring the functions performed by X, and, in addition, that a markup on total services costs, based on the markup from the comparable companies, is the most reliable PLI. In this case, total services cost, and the basis for the markup, would include appropriate reflection of the ERP costs of \$1,000. Alternatively, X's functions may be most reliably measured based on comparable uncontrolled companies that perform similar administrative functions using their customers' own ERP systems. Under these circumstances, the total services cost would equal X's costs of providing the administrative services excluding the ERP cost of \$1,000.

(m) *Coordination with transfer pricing rules for other transactions—(1) Services transactions that include other types of transactions.* A transaction structured as a controlled services transaction may include other elements for which a separate category or categories of methods are provided, such as a loan or advance, a rental, or a transfer of tangible or intangible property. See §§ 1.482-1(b)(2) and 1.482-2(a), (c), and (d). Whether such an integrated transaction is evaluated as a controlled services transaction under this section or whether one or more elements should be evaluated separately under other sections of the section 482 regulations depends on which approach will provide the most reliable measure of an arm's length result. Ordinarily, an integrated transaction of this type may be evaluated under this section and its separate elements need not be evaluated separately, provided that each component of the transaction may be adequately accounted for in evaluating the comparability of the controlled transaction to the uncontrolled comparables and, accordingly, in determining the arm's length result in the controlled transaction. See § 1.482-1(d)(3).

(2) *Services transactions that effect a transfer of intangible property.* A transaction structured as a controlled services transaction may in certain cases include an element that constitutes the transfer of intangible property or may result in a transfer, in whole or in part, of intangible property. Notwithstanding paragraph (m)(1) of this section, if such element relating to intangible property is material to the evaluation, the arm's length result for the element of the transaction that involves intangible property must be corroborated or determined by an analysis under § 1.482-4.

(3) [Reserved]. For further guidance, see § 1.482–9T(m)(3).

(4) *Other types of transactions that include controlled services transactions.* A transaction structured other than as a controlled services transaction may include one or more elements for which separate pricing methods are provided in this section. Whether such an integrated transaction is evaluated under another section of the section 482 regulations or whether one or more elements should be evaluated separately under this section depends on which approach will provide the most reliable measure of an arm's length result. Ordinarily, a single method may be applied to such an integrated transaction, and the separate services component of the transaction need not be separately analyzed under this section, provided that the controlled services may be adequately accounted for in evaluating the comparability of the controlled transaction to the uncontrolled comparables and, accordingly, in determining the arm's length results in the controlled transaction. See § 1.482–1(d)(3).

(5) *Examples.* The principles of this paragraph (m) are illustrated by the following examples:

Example 1. (i) U.S. parent corporation Company X enters into an agreement to maintain equipment of Company Y, a foreign subsidiary. The maintenance of the equipment requires the use of spare parts. The cost of the spare parts necessary to maintain the equipment amounts to approximately 25 percent of the total costs of maintaining the equipment. Company Y pays a fee that includes a charge for labor and parts.

(ii) Whether this integrated transaction is evaluated as a controlled services transaction or is evaluated as a controlled services transaction and the transfer of tangible property depends on which approach will provide the most reliable measure of an arm's length result. If it is not possible to find comparable uncontrolled services transactions that involve similar services and tangible property transfers as the controlled transaction between Company X and Company Y, it will be necessary to determine the arm's length charge for the controlled services, and then to evaluate separately the arm's length charge for the tangible property transfers under § 1.482–1 and §§ 1.482–3 through 1.482–6. Alternatively, it may be possible to apply the comparable profits method of § 1.482–5 to evaluate the arm's length profit of Company X or Company Y from the integrated controlled transaction. The comparable profits method may provide the most reliable measure of an arm's length result if uncontrolled parties are identified that perform similar, combined functions of maintaining and providing spare parts for similar equipment.

Example 2. (i) U.S. parent corporation Company X sells industrial equipment to its

foreign subsidiary, Company Y. In connection with this sale, Company X renders to Company Y services that consist of demonstrating the use of the equipment and assisting in the effective start-up of the equipment. Company X structures the integrated transaction as a sale of tangible property and determines the transfer price under the comparable uncontrolled price method of § 1.482–3(b).

(ii) Whether this integrated transaction is evaluated as a transfer of tangible property or is evaluated as a controlled services transaction and a transfer of tangible property depends on which approach will provide the most reliable measure of an arm's length result. In this case, the controlled services may be similar to services rendered in the transactions used to determine the comparable uncontrolled price, or they may appropriately be considered a difference between the controlled transaction and comparable transactions with a definite and reasonably ascertainable effect on price for which appropriate adjustments can be made. See § 1.482–1(d)(3)(ii)(A)(6). In either case, application of the comparable uncontrolled price method to evaluate the integrated transaction may provide a reliable measure of an arm's length result, and application of a separate transfer pricing method for the controlled services element of the transaction is not necessary.

Example 3. (i) The facts are the same as in *Example 2* except that, after assisting Company Y in start-up, Company X also renders ongoing services, including instruction and supervision regarding Company Y's ongoing use of the equipment. Company X structures the entire transaction, including the incremental ongoing services, as a sale of tangible property, and determines the transfer price under the comparable uncontrolled price method of § 1.482–3(b).

(ii) Whether this integrated transaction is evaluated as a transfer of tangible property or is evaluated as a controlled services transaction and a transfer of tangible property depends on which approach will provide the most reliable measure of an arm's length result. It may not be possible to identify comparable uncontrolled transactions in which a seller of merchandise renders services similar to the ongoing services rendered by Company X to Company Y. In such a case, the incremental services in connection with ongoing use of the equipment could not be taken into account as a comparability factor because they are not similar to the services rendered in connection with sales of similar tangible property. Accordingly, it may be necessary to evaluate separately the transfer price for such services under this section in order to produce the most reliable measure of an arm's length result. Alternatively, it may be possible to apply the comparable profits method of § 1.482–5 to evaluate the arm's length profit of Company X or Company Y from the integrated controlled transaction. The comparable profits method may provide the most reliable measure of an arm's length result if uncontrolled parties are identified that perform the combined functions of selling equipment and rendering ongoing after-sale services associated with such

equipment. In that case, it would not be necessary to separately evaluate the transfer price for the controlled services under this section.

Example 4. (i) Company X, a U.S. corporation, and Company Y, a foreign corporation, are members of a controlled group. Both companies perform research and development activities relating to integrated circuits. In addition, Company Y manufactures integrated circuits. In years 1 through 3, Company X engages in substantial research and development activities, gains significant know-how regarding the development of a particular high-temperature resistant integrated circuit, and memorializes that research in a written report. In years 1 through 3, Company X generates overall net operating losses as a result of the expenditures associated with this research and development effort. At the beginning of year 4, Company X enters into a technical assistance agreement with Company Y. As part of this agreement, the researchers from Company X responsible for this project meet with the researchers from Company Y and provide them with a copy of the written report. Three months later, the researchers from Company Y apply for a patent for a high-temperature resistant integrated circuit based in large part upon the know-how obtained from the researchers from Company X.

(ii) The controlled services transaction between Company X and Company Y includes an element that constitutes the transfer of intangible property (such as, know-how). Because the element relating to the intangible property is material to the arm's length evaluation, the arm's length result for that element must be corroborated or determined by an analysis under § 1.482–4.

(6) *Global dealing operations.* [Reserved].

(n) *Effective/applicability date—(1) In general.* This section is generally applicable for taxable years beginning after July 31, 2009. In addition, a person may elect to apply the provisions of this section to earlier taxable years. See paragraph (n)(2) of this section.

(2) *Election to apply regulations to earlier taxable years—(i) Scope of election.* A taxpayer may elect to apply § 1.482–1(a)(1), (b)(2)(i), (d)(3)(ii)(C) *Examples 3 through 6*, (d)(3)(v), (f)(2)(ii)(A), (f)(2)(iii)(B), (g)(4)(i), (g)(4)(iii) *Example 1*, (i), (j)(6)(i) and (j)(6)(ii), § 1.482–2(b), (f)(1) and (2), § 1.482–4(f)(3)(i)(A), (f)(3)(ii) *Examples 1 and 2*, (f)(4), (h)(1) and (2), § 1.482–6(c)(2)(ii)(B)(1), (c)(2)(ii)(D), (c)(3)(i)(A), (c)(3)(i)(B), (c)(3)(ii)(D), and (d), § 1.482–8(b) *Examples 10 through 12*, (c)(1) and (c)(2), § 1.482–9(a) through (m)(2), and (m)(4) through (n)(2), § 1.861–8(a)(5)(ii), (b)(3), (e)(4), (f)(4)(i), (g) *Examples 17, 18, and 30*, § 1.6038A–3(a)(3) *Example 4* and (i), § 1.6662–6(d)(2)(ii)(B), (d)(2)(iii)(B)(4), (d)(2)(iii)(B)(6), and (g), and § 31.3121(s)–1(c)(2)(iii) and (d) of this chapter to any taxable year

beginning after September 10, 2003. Such election requires that all of the provisions of such sections be applied to such taxable year and all subsequent taxable years (earlier taxable years) of the taxpayer making the election.

(ii) *Effect of election.* An election to apply the regulations to earlier taxable years has no effect on the limitations on assessment and collection or on the limitations on credit or refund (see Chapter 66 of the Internal Revenue Code).

(iii) *Time and manner of making election.* An election to apply the regulations to earlier taxable years must be made by attaching a statement to the taxpayer's timely filed U.S. tax return (including extensions) for its first taxable year beginning after July 31, 2009.

(iv) *Revocation of election.* An election to apply the regulations to earlier taxable years may not be revoked without the consent of the Commissioner.

■ **Par. 15.** Section 1.482–9T is amended by revising paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m)(1), (m)(2), (m)(4), (m)(5), and (n), and adding paragraph (o) to read as follows:

§ 1.482–9T Methods to determine taxable income in connection with a controlled services transaction (temporary).

(a) through (m)(2) [Reserved]. For further guidance, see § 1.482–9(a) through (m)(2).

(3) * * *

(4) and (m)(5) [Reserved]. For further guidance, see § 1.482–9(m)(4) and (m)(5).

(n) *Effective/applicability date.* Paragraph (m)(3) of this section is generally applicable on January 5, 2009.

(o) *Expiration date.* The applicability of paragraph (m)(3) of this section expires on December 30, 2011.

■ **Par. 16.** Section 1.861–8 is amended by revising paragraphs (a)(5)(ii), (b)(3), (e)(4), (f)(4), (g) *Examples 17, 18 and 30*, and (h) to read as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

* * * * *

(a) * * *

(5) * * *

(ii) Paragraph (e)(4), the last sentence of paragraph (f)(4)(i), and paragraph (g), *Examples 17, 18, and 30* of this section are generally applicable for taxable years beginning after July 31, 2009. In addition, a person may elect to apply the provisions of paragraph (e)(4) of this section to earlier years. Such election shall be made in accordance with the rules set forth in § 1.482–9(n)(2).

* * * * *

(b) * * *

(3) *Supportive functions.* Deductions which are supportive in nature (such as overhead, general and administrative, and supervisory expenses) may relate to other deductions which can more readily be allocated to gross income. In such instance, such supportive deductions may be allocated and apportioned along with the deductions to which they relate. On the other hand, it would be equally acceptable to attribute supportive deductions on some reasonable basis directly to activities or property which generate, have generated or could reasonably be expected to generate gross income. This would ordinarily be accomplished by allocating the supportive expenses to all gross income or to another broad class of gross income and apportioning the expenses in accordance with paragraph (c)(1) of this section. For this purpose, reasonable departmental overhead rates may be utilized. For examples of the application of the principles of this paragraph (b)(3) to expenses other than expenses attributable to stewardship activities, see *Examples 19* through *21* of paragraph (g) of this section. See paragraph (e)(4)(ii) of this section for the allocation and apportionment of deductions attributable to stewardship expenses. However, supportive deductions that are described in § 1.861–14T(e)(3) shall be allocated and apportioned in accordance with the rules of § 1.861–14T and shall not be allocated and apportioned by reference only to the gross income of a single member of an affiliated group of corporations as defined in § 1.861–14T(d).

* * * * *

(e) * * *

(4) *Stewardship and controlled services*—(i) *Expenses attributable to controlled services.* If a corporation performs a controlled services transaction (as defined in § 1.482–9(l)(3)), which includes any activity by one member of a group of controlled taxpayers that results in a benefit to a related corporation, and the rendering corporation charges the related corporation for such services, section 482 and these regulations provide for an allocation where the charge is not consistent with an arm's length result as determined. The deductions for expenses of the corporation attributable to the controlled services transaction are considered definitely related to the amounts so charged and are to be allocated to such amounts.

(ii) *Stewardship expenses attributable to dividends received.* Stewardship expenses, which result from

“overseeing” functions undertaken for a corporation's own benefit as an investor in a related corporation, shall be considered definitely related and allocable to dividends received, or to be received, from the related corporation. For purposes of this section, stewardship expenses of a corporation are those expenses resulting from “duplicative activities” (as defined in § 1.482–9(l)(3)(iii)) or “shareholder activities” (as defined in § 1.482–9(l)(3)(iv)) of the corporation with respect to the related corporation. Thus, for example, stewardship expenses include expenses of an activity the sole effect of which is either to protect the corporation's capital investment in the related corporation or to facilitate compliance by the corporation with reporting, legal, or regulatory requirements applicable specifically to the corporation, or both. If a corporation has a foreign or international department which exercises overseeing functions with respect to related foreign corporations and, in addition, the department performs other functions that generate other foreign-source income (such as fees for services rendered outside of the United States for the benefit of foreign related corporations, foreign-source royalties, and gross income of foreign branches), some part of the deductions with respect to that department are considered definitely related to the other foreign-source income. In some instances, the operations of a foreign or international department will also generate United States source income (such as fees for services performed in the United States). Permissible methods of apportionment with respect to stewardship expenses include comparisons of time spent by employees weighted to take into account differences in compensation, or comparisons of each related corporation's gross receipts, gross income, or unit sales volume, assuming that stewardship activities are not substantially disproportionate to such factors. See paragraph (f)(5) of this section for the type of verification that may be required in this respect. See § 1.482–9(l)(5) for examples that illustrate the principles of § 1.482–9(l)(3). See *Example 17* and *Example 18* of paragraph (g) of this section for the allocation and apportionment of stewardship expenses. See paragraph (b)(3) of this section for the allocation and apportionment of deductions attributable to supportive functions other than stewardship expenses, such as expenses in the nature of day-to-day management, and paragraph (e)(5) of

this section generally for the allocation and apportionment of deductions attributable to legal and accounting fees and expenses.

* * * * *

(f) * * *

(4) *Adjustments made under other provisions of the Code*—(i) *In general.* If an adjustment which affects the taxpayer is made under section 482 or any other provision of the Code, it may be necessary to recompute the allocations and apportionments required by this section in order to reflect changes resulting from the adjustment. The recomputation made by the Commissioner shall be made using the same method of allocation and apportionment as was originally used by the taxpayer, provided such method as originally used conformed with paragraph (a)(2) of this section and, in light of the adjustment, such method does not result in a material distortion. In addition to adjustments which would be made aside from this section, adjustments to the taxpayer's income and deductions which would not otherwise be made may be required before applying this section in order to prevent a distortion in determining taxable income from a particular source of activity. For example, if an item included as a part of the cost of goods sold has been improperly attributed to specific sales, and, as a result, gross income under one of the operative sections referred to in paragraph (f)(1) of this section is improperly determined, it may be necessary for the Commissioner to make an adjustment to the cost of goods sold, consistent with the principles of this section, before applying this section. Similarly, if a domestic corporation transfers the stock in its foreign subsidiaries to a domestic subsidiary and the parent corporation continues to incur expenses in connection with protecting its capital investment in the foreign subsidiaries (see paragraph (e)(4) of this section), it may be necessary for the Commissioner to make an allocation under section 482 with respect to such expenses before making allocations and apportionments required by this section, even though the section 482 allocation might not otherwise be made.

* * * * *

(g) * * *

Example 17. Stewardship expenses (consolidation). (i) (A) *Facts.* X, a domestic corporation, wholly owns M, N, and O, also domestic corporations. X, M, N, and O file a consolidated income tax return. All the income of X and O is from sources within the United States, all of M's income is general category income from sources within South America, and all of N's income is general

category income from sources within Africa. X receives no dividends from M, N, or O. During the taxable year, the consolidated group of corporations earned consolidated gross income of \$550,000 and incurred total deductions of \$370,000 as follows:

	Gross income	Deductions
Corporations:		
X	\$100,000	\$50,000
M	250,000	100,000
N	150,000	200,000
O	50,000	20,000
Total ...	550,000	370,000

(B) Of the \$50,000 of deductions incurred by X, \$15,000 relates to X's ownership of M; \$10,000 relates to X's ownership of N; \$5,000 relates to X's ownership of O; and the sole effect of the entire \$30,000 of deductions is to protect X's capital investment in M, N, and O. X properly categorizes the \$30,000 of deductions as stewardship expenses. The remainder of X's deductions (\$20,000) relates to production of United States source income from its plant in the United States.

(ii) (A) *Allocation.* X's deductions of \$50,000 are definitely related and thus allocable to the types of gross income to which they give rise, namely \$25,000 wholly to general category income from sources outside the United States (\$15,000 for stewardship of M and \$10,000 for stewardship of N) and the remainder (\$25,000) wholly to gross income from sources within the United States. Expenses incurred by M and N are entirely related and thus wholly allocable to general category income earned from sources without the United States, and expenses incurred by O are entirely related and thus wholly allocable to income earned within the United States. Hence, no apportionment of expenses of X, M, N, or O is necessary. For purposes of applying the foreign tax credit limitation; the statutory grouping is general category gross income from sources without the United States and the residual grouping is gross income from sources within the United States. As a result of the allocation of deductions, the X consolidated group has taxable income from sources without the United States in the amount of \$75,000, computed as follows:

Foreign source general category gross income (\$250,000 from M + \$150,000 from N)	\$400,000
Less: Deductions allocable to foreign source general category gross income (\$25,000 from X, \$100,000 from M, and \$200,000 from N)	(325,000)
Total foreign-source taxable income	75,000

(B) Thus, in the combined computation of the general category limitation, the numerator of the limiting fraction (taxable income from sources outside the United States) is \$75,000.

Example 18. Stewardship and supportive expenses. (i) (A) *Facts.* X, a domestic corporation, manufactures and sells pharmaceuticals in the United States. X's domestic subsidiary S, and X's foreign subsidiaries T, U, and V perform similar functions in the United States and foreign countries T, U, and V, respectively. Each corporation derives substantial net income during the taxable year that is general category income described in section 904(d)(1). X's gross income for the taxable year consists of:

Domestic sales income	\$32,000,000
Dividends from S (before dividends received deduction)	3,000,000
Dividends from T	2,000,000
Dividends from U	1,000,000
Dividends from V	0
Royalties from T and U	1,000,000
Fees from U for services performed by X	1,000,000
Total gross income	40,000,000

(B) In addition, X incurs expenses of its supervision department of \$1,500,000.

(C) X's supervision department (the Department) is responsible for the supervision of its four subsidiaries and for rendering certain services to the subsidiaries, and this Department provides all the supportive functions necessary for X's foreign activities. The Department performs three principal types of activities. The first type consists of services for the direct benefit of U for which a fee is paid by U to X. The cost of the services for U is \$900,000 (which results in a total charge to U of \$1,000,000). The second type consists of activities described in § 1.482-9(l)(3)(iii) that are in the nature of shareholder oversight that duplicate functions performed by the subsidiaries' own employees and that do not provide an additional benefit to the subsidiaries. For example, a team of auditors from X's accounting department periodically audits the subsidiaries' books and prepares internal reports for use by X's management. Similarly, X's treasurer periodically reviews for the board of directors of X the subsidiaries' financial policies. These activities do not provide an additional benefit to the related corporations. The cost of the duplicative services and related supportive expenses is \$540,000. The third type of activity consists of providing services which are ancillary to the license agreements which X maintains with subsidiaries T and U. The cost of the ancillary services is \$60,000.

(ii) *Allocation.* The Department's outlay of \$900,000 for services rendered for the benefit of U is allocated to the \$1,000,000 in fees paid by U. The remaining \$600,000 in the Department's deductions are definitely related to the types of gross income to which they give rise, namely dividends from subsidiaries S, T, U, and V and royalties from T and U. However, \$60,000 of the \$600,000 in deductions are found to be attributable to the ancillary services and are definitely related (and therefore allocable) solely to royalties received from T and U, while the remaining \$540,000 in deductions are

definitely related (and therefore allocable) to dividends received from all the subsidiaries.

(iii) (A) *Apportionment.* For purposes of applying the foreign tax credit limitation, the statutory grouping is general category gross income from sources outside the United States and the residual grouping is gross income from sources within the United States. X's deduction of \$540,000 for the Department's expenses and related supportive expenses which are allocable to dividends received from the subsidiaries must be apportioned between the statutory and residual groupings before the foreign tax

credit limitation may be applied. In determining an appropriate method for apportioning the \$540,000, a basis other than X's gross income must be used since the dividend payment policies of the subsidiaries bear no relationship either to the activities of the Department or to the amount of income earned by each subsidiary. This is evidenced by the fact that V paid no dividends during the year, whereas S, T, and U paid dividends of \$1 million or more each. In the absence of facts that would indicate a material distortion resulting from the use of such method, the stewardship expenses (\$540,000)

may be apportioned on the basis of the gross receipts of each subsidiary.

(B) The gross receipts of the subsidiaries were as follows:

S	\$4,000,000
T	3,000,000
U	500,000
V	1,500,000
Total	9,000,000

(C) Thus, the expenses of the Department are apportioned for purposes of the foreign tax credit limitation as follows:

Apportionment of stewardship expenses to the statutory grouping of gross income: $\$540,000 \times [(\$3,000,000 + \$500,000 + \$1,500,000)/\$9,000,000]$	\$300,000
Apportionment of supervisory expenses to the residual grouping of gross income: $\$540,000 \times [\$4,000,000/\$9,000,000]$	240,000
Total: Apportioned stewardship expense	540,000

* * * * *

Example 30. Income taxes. (i)(A) *Facts.* As in *Example 17* of this paragraph (g), X is a domestic corporation that wholly owns M, N, and O, also domestic corporations. X, M, N, and O file a consolidated income tax return. All the income of X and O is from sources within the United States, all of M's income is general category income from sources within South America, and all of N's income is general category income from sources within Africa. X receives no dividends from M, N, or O. During the taxable year, the consolidated group of corporations earned consolidated gross income of \$550,000 and incurred total deductions of \$370,000. X has gross income of \$100,000 and deductions of \$50,000, without regard to its deduction for state income tax. Of the \$50,000 of deductions incurred by X, \$15,000 relates to X's ownership of M; \$10,000 relates to X's ownership of N; \$5,000 relates to X's ownership of O; and the entire \$30,000 constitutes stewardship expenses. The remainder of X's \$20,000 of deductions (which is assumed not to include state income tax) relates to production of U.S. source income from its plant in the United States. M has gross income of \$250,000 and deductions of \$100,000, which yield foreign-source general category taxable income of \$150,000. N has gross income of \$150,000 and deductions of \$200,000, which yield a foreign-source general category loss of \$50,000. O has gross income of \$50,000 and deductions of \$20,000, which yield U.S. source taxable income of \$30,000.

(B) Unlike *Example 17* of this paragraph (g), however, X also has a deduction of \$1,800 for state A income taxes. X's state A taxable income is computed by first making adjustments to the Federal taxable income of X to derive apportionable taxable income for state A tax purposes. An analysis of state A law indicates that state A law also includes in its definition of the taxable business income of X which is apportionable to X's state A activities, the taxable income of M, N, and O, which is related to X's business. As in *Example 25* of this paragraph (g), the amount of apportionable taxable income attributable to business activities conducted in state A is determined by multiplying apportionable taxable income by a fraction

(the "state apportionment fraction") that compares the relative amounts of payroll, property, and sales within state A with worldwide payroll, property, and sales. Assuming that X's apportionable taxable income equals \$180,000, \$100,000 of which is from sources without the United States, and \$80,000 is from sources within the United States, and that the state apportionment fraction is equal to 10 percent, X has state A taxable income of \$18,000. The state A income tax of \$1,800 is then derived by applying the state A income tax rate of 10 percent to the \$18,000 of state A taxable income.

(ii) *Allocation and apportionment.* Assume that under *Example 29* of this paragraph (g), it is determined that X's deduction for state A income tax is definitely related to a class of gross income consisting of income from sources both within and without the United States, and that the state A tax is apportioned \$1,000 to sources without the United States, and \$800 to sources within the United States. Under *Example 17* of this paragraph (g), without regard to the deduction for X's state A income tax, X has a separate loss of (\$25,000) from sources without the United States. After taking into account the deduction for state A income tax, X's separate loss from sources without the United States is increased by the \$1,000 state A tax apportioned to sources without the United States, and equals a loss of (\$26,000), for purposes of computing the numerator of the consolidated general category foreign tax credit limitation.

■ **Par. 17.** Section 1.861-8T is amended by revising paragraphs (a)(3), (a)(4), (a)(5), (b), (e)(3), (e)(4), (e)(5), (e)(6), (e)(7), (e)(8), (e)(9), (e)(10), (e)(11), (f)(1)(i), (f)(1)(iii), (f)(2), (f)(3), (f)(4), (f)(5), (g) *Examples 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 30*, and (h) to read as follows:

§ 1.861-8T Computation of taxable income from sources within the United States and from other sources and activities (temporary).

* * * * *

(a)(3) through (b) [Reserved]. For further guidance, see § 1.861-8(a)(3) through (b).

* * * * *

(e) * * *

(3) through (f)(1)(i) [Reserved]. For further guidance, see § 1.861-8(e)(3) through (f)(1)(i).

* * * * *

(f)(1)(iii) through (g) *Examples 1 through 23* [Reserved]. For further guidance, see § 1.861-8(f)(1)(iii) through (g) *Examples 1 through 23*.

* * * * *

Example 30. [Reserved]. For further guidance, see § 1.861-8(g) *Example 30*.

(h) *Effective/applicability date.* (1) Paragraphs (f)(1)(vi)(E), (f)(1)(vi)(F), and (f)(1)(vi)(G) of this section apply to taxable years ending after April 9, 2008.

(2) Paragraph (e)(4), the last sentence of paragraph (f)(4)(i), and paragraph (g), *Examples 17, 18, and 30* of this section apply to taxable years beginning after July 31, 2009.

(3) Also, see paragraph (e)(12)(iv) of this section and 1.861-14(e)(6) for rules concerning the allocation and apportionment of deductions for charitable contributions.

■ **Par. 18.** Section 1.861-9T(k) is amended by adding new first and second sentences to read as follows:

§ 1.861-9T Allocation and apportionment of interest expense (temporary).

* * * * *

(k) * * * In general, the rules of this section apply for taxable years beginning after December 31, 1986. Paragraphs (b)(2) (concerning the treatment of certain foreign currency) and (d)(2) (concerning the treatment of interest incurred by nonresident aliens) of this section are applicable for taxable years commencing after December 31, 1988. * * *

■ **Par. 19.** Section 1.861–10T is amended by revising the section heading and adding new paragraph (f) to read as follows:

§ 1.861–10T Special allocations of interest expense (temporary).

* * * * *

(f) *Effective/applicability date.* (1) In general, the rules of this section apply for taxable years beginning after December 31, 1986.

(2) Paragraphs (b)(3)(ii) (providing an operating costs test for purposes of the nonrecourse indebtedness exception) and (b)(6) (concerning excess collateralization of nonrecourse borrowings) of this section are applicable for taxable years commencing after December 31, 1988.

(3) Paragraph (e) (concerning the treatment of related controlled foreign corporation indebtedness) of this section is applicable for taxable years commencing after December 31, 1987. For rules for taxable years beginning before January 1, 1987, and for later years to the extent permitted by § 1.861–13T, see § 1.861–8 (revised as of April 1, 1986).

■ **Par. 20.** Section 1.861–11T is amended by revising the section heading and adding new paragraph (h) to read as follows:

§ 1.861–11T Special rules for allocating and apportioning interest expense of an affiliated group of corporations (temporary).

* * * * *

(h) *Effective/applicability date.* The rules of this section apply for taxable years beginning after December 31, 1986.

■ **Par. 21.** Section 1.861–12T is amended by revising the section heading and adding new paragraph (k) to read as follows:

§ 1.861–12T Characterization rules and adjustments for certain assets (temporary).

* * * * *

(k) *Effective/applicability date.* The rules of this section apply for taxable years beginning after December 31, 1986.

■ **Par. 22.** Section 1.861–14T is amended by adding new paragraph (k) to read as follows:

§ 1.861–14T Special rules for allocating and apportioning certain expenses (other than interest expense) of an affiliated group of corporations (temporary).

* * * * *

(k) *Effective/applicability date.* The rules of this section apply for taxable years beginning after December 31, 1986.

§ 1.6038A–1 [Amended]

■ **Par. 23.** Section 1.6038A–1 is amended by removing paragraph (n)(3) and redesignating paragraphs (n)(4), (n)(5), (n)(6) and (n)(7) as paragraphs (n)(3), (n)(4), (n)(5) and (n)(6), respectively.

■ **Par. 24.** Section 1.6038A–3 is amended by revising paragraphs (a)(3) *Example 4*, and (i) to read as follows:

§ 1.6038A–3 Record maintenance.

(a) * * *
(3) * * *

Example 4. S, a U.S. reporting corporation, provides computer consulting services for its foreign parent, X. Based on the application of section 482 and the regulations, it is determined that the cost of services plus method, as described in § 1.482–9(e), will provide the most reliable measure of an arm's length result, based on the facts and circumstances of the controlled transaction between S and X. S is required to maintain records to permit verification upon audit of the comparable transactional costs (as described in § 1.482–9(e)(2)(iii)) used to calculate the arm's length price. Based on the facts and circumstances, if it is determined that X's records are relevant to determine the correct U.S. tax treatment of the controlled transaction between S and X, the record maintenance requirements under section 6038A(a) and this section will be applicable to the records of X.

* * * * *

(i) *Effective/applicability date—(1) In general.* This section is generally applicable on December 10, 1990. However, records described in this section in existence on or after March 20, 1990, must be maintained, without regard to when the taxable year to which the records relate began. Paragraph (a)(3) *Example 4* of this section is generally applicable for taxable years beginning after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the provisions of paragraph (a)(3) *Example 4* of this section to earlier taxable years in accordance with the rules set forth in § 1.482–9(n)(2).

§ 1.6038A–3T [Removed]

■ **Par. 25.** Section 1.6038A–3T is removed.

■ **Par. 26.** Section 1.6662–6 is amended by revising paragraphs (d)(2)(ii)(B), (d)(2)(iii)(B)(4), (d)(2)(iii)(B)(6), and (g) to read as follows:

§ 1.6662–6 Transactions between persons described in section 482 and net section 482 transfer price adjustments.

* * * * *

(d) * * *
(2) * * *
(ii) * * *

(B) *Services cost method.* A taxpayer's selection of the services cost method for certain services, described in § 1.482–9(b), and its application of that method to a controlled services transaction will be considered reasonable for purposes of the specified method requirement only if the taxpayer reasonably allocated and apportioned costs in accordance with § 1.482–9(k), and reasonably concluded that the controlled services transaction satisfies the requirements described in § 1.482–9(b)(2). Whether the taxpayer's conclusion was reasonable must be determined from all the facts and circumstances. The factors relevant to this determination include those described in paragraph (d)(2)(ii)(A) of this section, to the extent applicable.

* * * * *

(iii) * * *
(B) * * *

(4) A description of the method selected and an explanation of why that method was selected, including an evaluation of whether the regulatory conditions and requirements for application of that method, if any, were met;

* * * * *

(6) A description of the controlled transactions (including the terms of sale) and any internal data used to analyze those transactions. For example, if a profit split method is applied, the documentation must include a schedule providing the total income, costs, and assets (with adjustments for different accounting practices and currencies) for each controlled taxpayer participating in the relevant business activity and detailing the allocations of such items to that activity. Similarly, if a cost-based method (such as the cost plus method, the services cost method for certain services, or a comparable profits method with a cost-based profit level indicator) is applied, the documentation must include a description of the manner in which relevant costs are determined and are allocated and apportioned to the relevant controlled transaction.

* * * * *

(g) *Effective/applicability date—(1) In general.* This section is generally applicable on February 9, 1996. However, taxpayers may elect to apply this section to all open taxable years beginning after December 31, 1993.

(2) *Special rules.* The provisions of paragraphs (d)(2)(ii)(B), (d)(2)(iii)(B)(4) and (d)(2)(iii)(B)(6) of this section are applicable for taxable years beginning after July 31, 2009. However, taxpayers may elect to apply the provisions of paragraphs (d)(2)(ii)(B), (d)(2)(iii)(B)(4) and (d)(2)(iii)(B)(6) of this section to

earlier taxable years in accordance with the rules set forth in § 1.482–9(n)(2).

§ 1.6662–6T [Removed]

■ Par. 27. Section 1.6662–6T is removed.

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

■ Par. 28. The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ Par. 29. Section 31.3121(s)–1 is amended by revising paragraphs (c)(2)(iii) and (d) to read as follows:

§ 31.3121(s)–1 Concurrent employment by related corporations with common paymaster.

* * * * *

(c) * * *

(2) * * *

(iii) *Group-wide allocation rules.*

Under the group-wide method of allocation, the Commissioner may allocate the taxes imposed by sections 3102 and 3111 in an appropriate manner to a related corporation that remunerates an employee through a common paymaster if the common paymaster fails to remit the taxes to the Internal Revenue Service. Allocation in an appropriate manner varies according to the circumstances. It may be based on sales, property, corporate payroll, or any

other basis that reflects the distribution of the services performed by the employee, or a combination of the foregoing bases. To the extent practicable, the Commissioner may use the principles of § 1.482–2(b) of this chapter in making the allocations with respect to wages paid after December 31, 1978, and on or before July 31, 2009. To the extent practicable, the Commissioner may use the principles of § 1.482–9 of this chapter in making the allocations with respect to wages paid after July 31, 2009.

(d) *Effective/applicability date—(1) In general.* This section is applicable with respect to wages paid after December 31, 1978. The fourth sentence of paragraph (c)(2)(iii) of this section is applicable with respect to wages paid after December 31, 1978, and on or before July 31, 2009. The fifth sentence of paragraph (c)(2)(iii) of this section is applicable with respect to wages paid after July 31, 2009.

(2) *Election to apply regulation to earlier taxable years.* A person may elect to apply the fifth sentence of paragraph (c)(2)(iii) of this section to earlier taxable years in accordance with the rules set forth in § 1.482–9(n)(2) of this chapter.

§ 31.3121(s)–1T [Removed]

■ Par. 30. Section 31.3121(s)–1T is removed.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ Par. 31. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ Par. 32. In § 602.101, paragraph (b) is amended by adding an entry for “§ 1.482–9(b)” to the table to read follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control number
* * * * *	*
1.482–9(b)	1545–2149
* * * * *	*

Approved: July 25, 2009.

Linda E. Stiff,
Deputy Commissioner for Services and Enforcement.
Michael Mundaca,
Acting Assistant Secretary of the Treasury (Tax Policy).
[FR Doc. E9–18326 Filed 7–31–09; 8:45 am]
BILLING CODE 4830–01–P



Federal Register

**Tuesday,
August 4, 2009**

Part V

Environmental Protection Agency

**Sixty-Fourth Report of the TSCA
Interagency Testing Committee to the
Administrator of the Environmental
Protection Agency; Receipt of Report and
Request for Comments; Notice**

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2009-0206; FRL-8425-6]

Sixty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its 64th report to the Administrator of EPA on June 25, 2009. In the 64th ITC report, which is included with this notice, the ITC has no revisions to the TSCA section 4(e) *Priority Testing List* at this time.

DATES: Comments must be received on or before September 3, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0206, by one of the following methods:

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

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2009-0206. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2009-0206. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which

means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT:

Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

This notice is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process TSCA-covered chemicals and you may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this notice is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

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

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

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

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

- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations under TSCA section 4(a) requiring testing of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the ITC to recommend chemicals and chemical groups to the Administrator of EPA for

priority testing consideration. Section 4(e) of TSCA directs the ITC to revise the TSCA section 4(e) *Priority Testing List* at least every 6 months.

You may access additional information about the ITC at <http://www.epa.gov/opptintr/itc>.

A. The 64th ITC Report

The ITC has no revisions to the TSCA section 4(e) *Priority Testing List* at this time.

B. Status of the Priority Testing List

The *Priority Testing List* includes 2 alkylphenols, 12 lead compounds, 16 chemicals with insufficient dermal absorption rate data, and 207 HPV Challenge Program orphan chemicals.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: July 27, 2009.

Wendy C. Hamnett,

Acting Director, Office of Pollution Prevention and Toxics.

Sixty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency

Table of Contents

Summary

I. Background

II. ITC's Activities During this Reporting Period (November 2008 to May 2009)

III. The TSCA Interagency Testing Committee

Summary

The ITC has no revisions to the Toxic Substances Control Act (TSCA) section 4(e) *Priority Testing List* at this time.

The TSCA section 4(e) *Priority Testing List* is Table 1 of this unit.

TABLE 1.—TSCA SECTION 4(E) PRIORITY TESTING LIST (MAY 2009)

ITC Report	Date	Chemical Name/Group	Action
31	January 1993	2 Chemicals with insufficient dermal absorption rate data	Designated
32	May 1993	10 Chemicals with insufficient dermal absorption rate data	Designated
35	November 1994	4 Chemicals with insufficient dermal absorption rate data	Designated
37	November 1995	Branched 4-nonylphenol (mixed isomers)	Recommended
41	November 1997	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	Recommended
55	December 2004	203 High Production Volume (HPV) Challenge Program orphan chemicals	Recommended
56	August 2005	4 HPV Challenge Program orphan chemicals	Recommended
60	May 2007	12 Lead and lead compounds	Recommended

I. Background

The ITC was established by section 4(e) of TSCA “to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of rules for testing under section 4(a).... At least every six months ..., the Committee shall make such revisions to the *Priority Testing List* as it determines to be necessary and transmit them to the Administrator together with the Committee's reasons for the revisions” (Public Law 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*). ITC reports are available from the ITC's website (<http://www.epa.gov/opptintr/itc>) within a few days of submission to the EPA Administrator and from the EPA's website (<http://www.epa.gov/fedrgstr>) after publication in the **Federal Register**. The ITC produces its revisions to the *Priority Testing List* with administrative and technical support from the ITC staff, ITC members, and their U.S. Government organizations, and contract support provided by EPA. ITC

members and staff are listed at the end of this report.

II. ITC's Activities During this Reporting Period (November 2008 to May 2009)

During this reporting period, the ITC continued to discuss nanoscale materials and EPA's Nanoscale Materials Stewardship Program (NMSP) (For details on the NMSP, see the **Federal Register** issue of January 28, 2008 (73 FR 4861) (FRL–8344–5), available on-line at <http://www.epa.gov/fedrgstr>.) The ITC's initial discussions of nanoscale materials occurred in 2004 with briefings by scientists from EPA, National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH), and National Institute of Standards and Technology (NIST) and a review of the National Toxicology Program (NTP) Toxicological Evaluation of Nanoscale Materials. At that time, several ITC members were participating on an informal interagency nanoscale materials workgroup and were aware of the need to understand the health and environmental effects of nanoscale materials.

The EPA briefing discussed the potential regulation of nanoscale materials as new chemicals under TSCA section 5. The NIEHS briefing described the goal of the NTP research program, i.e., to evaluate the toxicological properties of major nanoscale materials classes and use these as model systems to investigate fundamental questions concerning if and how nanoscale materials can interact with biological systems. The NIOSH briefing focused on the impact of nanotechnology on occupational health. The briefing acknowledged that while the prevalence and types of nanoscale particles in the workplace were not yet determined, there were concerns that nanoscale particles could exhibit a high deposition fraction in the respiratory tract, appear to be toxic and inflammatory to the lung, and may migrate to systemic sites. The NIST contribution to the nanotechnology area is to develop needed measurements, data, and standards; develop infrastructure measurement capabilities; provide the metrology tools and techniques; and transfer measurement capabilities to the appropriate communities.

In 2006, the ITC reviewed EPA's nanotechnology white paper and received a briefing on EPA's nanotechnology research programs. Since then, the ITC has discussed the importance of nanotechnology, but questioned how nanotechnology chemicals for which there are very few Chemical Abstracts Service Registry (CAS) numbers should be discussed in ITC reports or added to the ITC's *Priority Testing List*.

In 2009, the ITC reviewed the EPA's interim report on the Nanoscale Materials Stewardship Program (<http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf>). EPA intends to develop a proposed TSCA section 8(a) rule to obtain information on the production, uses, and exposures of existing nanoscale materials. EPA has indicated that it will ensure that the chemicals where there is ITC interest as described in this unit are either included in that action or are otherwise new chemical substances subject to premanufacture notification (PMN) reporting under TSCA. EPA also intends to develop a proposed TSCA section 4 rule to develop needed environmental, health, and safety data. The ITC also noted NIOSH's guidelines, "Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials," that are available at <http://www.cdc.gov/niosh/topics/nanotech/safenano>.

1. At this time, there are several U.S. Government organizations on the ITC that continue to have data needs for nanoscale materials. Many of these nanoscale materials do not have CAS numbers, or have CAS numbers that may be associated with the non-nanoscale chemical.

a. Occupational exposure data needs include:

i. Recent non-CBI estimates of annual production and/or importation volume data and trends, and use information, including percentages of production or importation that are associated with different uses.

ii. Estimates of the numbers of workers associated with production and downstream uses.

iii. Workplace area and/or personal breathing zone concentrations to which workers may be exposed during manufacturing, processing, and downstream use scenarios.

b. Mammalian toxicology data needs include:

i. Human health effects data such as case reports and epidemiological studies of workers.

ii. Acute, subchronic, chronic, pulmonary, reproductive, and developmental animal toxicity data as well as pharmacokinetics, genotoxicity, and carcinogenicity data.

c. Environmental data needs include:

i. Ecological effects data for aquatic and terrestrial organisms, birds, and wild mammals.

ii. Chemical fate data such as biodegradation, photolysis, hydrolysis, oxidation, and reduction.

iii. Physical or chemical property data such as melting and boiling points, partition coefficients as well as metrology data.

2. At this time, the U.S. Government organizations on the ITC have data needs for occupational exposure and mammalian toxicology data for the following nanoscale materials, and are reviewing data submitted in PMNs or in response to the NMSP:

a. Materials having CAS numbers that are only nanoscale at the molecular level:

- C₆₀ fullerenes—CAS No. 135105-52-1 (this is the generic C₆₀ fullerene; many other CAS numbers exist for specific C₆₀ fullerene structural isomers, including, for example, CAS No. 99685-96-8, for [5,6]Fullerene-C₆₀-1h)

- C₉₀ fullerenes—CAS No. 135113-17-6 (this is the generic C₉₀ fullerene; other CAS numbers exist for specific C₉₀ fullerene structural isomers)

b. Materials having CAS numbers that can exist in the nanoscale and bulk forms:

- Carbon black, nano form—CAS No. 1333-86-4

- Titanium oxide (TiO₂) nanowires—CAS No. 13463-67-7

- Titanium oxide (TiO₂) nanoparticles—CAS No. 13463-67-7

- Zinc oxide (ZnO), nano form—CAS No. 1314-13-2

- Silver, nano form—CAS No. 7440-22-4
- Silica [crystalline], nano form—CAS No. 7631-86-9

- Quartz (SiO₂), nano form—CAS No. 14808-60-7

- Cerium oxide (CeO₂), nano form—CAS No. 1306-38-3

- Indium tin oxide, nano form—CAS No. 50926-11-9

- Indium tin oxide (In_{1.69}Sn_{0.15}O_{2.85}), nano form—CAS No. 71243-84-0

- Indium tin oxide (In_{0.01}SnO₂), nano form—CAS No. 212075-26-8

- Indium tin oxide (In_{0.02}Sn_{0.98}O_{1.99}), nano form—CAS No. 180090-96-4

- Dendrimers—there are a number of CAS numbers describing certain compositions of dendrimers

c. Materials with no CAS numbers that either can exist in both the nano and bulk forms or are only nanoscale:

- Single-walled carbon nanotubes
- Multi-walled carbon nanotubes
- Carbon nanofibers
- Quantum dots with Cd core
- Quantum dots with Se core
- Nanoceramic particles
- Nanoclays

III. The TSCA Interagency Testing Committee

Statutory Organizations and Their Representatives

Council on Environmental Quality
Vacant

Department of Commerce

National Institute of Standards and Technology

Dianne Poster, Alternate

National Oceanographic and Atmospheric Administration

Tony Pait, Member, Chair

Environmental Protection Agency

John Schaeffer, Member
Gerry Brown, Alternate

National Cancer Institute
Vacant

National Institute of Environmental Health Sciences

Scott Masten, Alternate

National Institute for Occupational Safety and Health

Gayle DeBord, Member
Dennis W. Lynch, Alternate

National Science Foundation

Margaret Cavanaugh, Alternate

Occupational Safety and Health Administration

Thomas Nerad, Member, Vice-Chair
Maureen Ruskin, Alternate

Liaison Organizations and Their Representatives

Agency for Toxic Substances and Disease Registry

Daphne Moffett, Member
Glenn D. Todd, Alternate

Consumer Product Safety Commission

Jacqueline Ferrante, Member

Department of Agriculture

Clifford P. Rice, Member
Laura L. McConnell, Alternate

Department of Defense

Laurie Roszell, Member

Department of the Interior

Barnett A. Rattner, Member

Food and Drug Administration

Kirk Arvidson, Member
Ronald F. Chanderbhan, Alternate

Technical Support Contractor

Syracuse Research Corporation

ITC Staff

John D. Walker, Director
Carol Savage, Administrative Assistant

TSCA Interagency Testing Committee (7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; e-mail address: savage.carol@epa.gov; url: <http://www.epa.gov/opptintr/itc>.

[FR Doc. E9-18469 Filed 8-3-09; 8:45 am]

BILLING CODE 6560-50-S



Federal Register

**Tuesday,
August 4, 2009**

Part VI

Department of Education

**Privacy Act of 1974; System of Records—
Erma Byrd Scholarship Program (EBSP)
System; Notice**

DEPARTMENT OF EDUCATION**Privacy Act of 1974; System of Records—Erma Byrd Scholarship Program (EBSP) System**

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) publishes this notice of a new system of records entitled “Erma Byrd Scholarship Program (EBSP)” system (18–12–08).

The EBSP system contains a variety of information relating to a student's application for, and participation in, the EBSP. The Department collects this information to determine the qualifications and eligibility of scholarship recipients under the EBSP, which provides scholarships to individuals pursuing a course of study that will lead to a career in industrial health and safety occupations, including mine safety. The information in the EBSP system will also be used to ensure compliance with program requirements and to demonstrate program effectiveness. The Department seeks comment on the new system of records described in this notice, in accordance with the requirements of the Privacy Act.

DATES: We must receive your comments about this new system of records on or before September 3, 2009.

The Department filed a report describing the new system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on July 30, 2009. This system of records will become effective at the later date of—(1) the expiration of the 40-day period for OMB review on September 8, 2009; or (2) September 3, 2009, unless the system of records needs to be changed as a result of public comment or OMB review.

ADDRESSES: Address all comments about this new system of records to Lauren Kennedy, Erma Byrd Scholarship Program Office, Office of Postsecondary Education, U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8510. If you prefer to send comments through the Internet, use the following address: comments@ed.gov.

You must include the term “Erma Byrd Scholarship Program” in the subject line of your electronic message.

During and after the comment period, you may inspect all comments about this notice at the U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Lauren Kennedy, Erma Byrd Scholarship Program Office. Telephone number: (202) 502–7630. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION:**Introduction**

The Privacy Act (5 U.S.C. 552a(e)(4)) requires the Department to publish in the **Federal Register** this notice of a new system of records maintained by the Department. The Department's regulations implementing the Privacy Act are contained in the Code of Federal Regulations (CFR) in part 5b of title 34.

The Privacy Act applies to a record about an individual that is maintained in a system of records from which individually identifying information is retrieved by a unique identifier associated with each individual, such as a name or Social Security number. The information about each individual is called a “record,” and the system, whether manual or computer-based, is called a “system of records.”

Whenever the agency publishes a new system of records or makes a significant change to an established system of records, the Privacy Act requires each agency to publish a system of records notice in the **Federal Register** and to submit a report to the Administrator of the Office of Information and Regulatory Affairs, OMB. Each agency is also

required to send copies of the report to the Chair of the Committee on Oversight and Government Reform of the House of Representatives, and to the Chair of the Committee on Homeland Security and Governmental Affairs of the Senate.

Electronic Access to this Document

You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: <http://www.ed.gov/news/fedregister/index.html>.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara>.

Delegation of Authority: The Secretary of Education has delegated authority to Daniel T. Madzellan, Director, Forecasting and Policy Analysis for the Office of Postsecondary Education, to perform the functions and duties of the Assistant Secretary for Postsecondary Education.

Dated: July 30, 2009.

Daniel T. Madzellan,

Director, Forecasting and Policy Analysis.

For the reasons discussed in the preamble, the Office of Postsecondary Education, U.S. Department of Education publishes a notice of a new system of records, to read as follows:

SYSTEM NUMBER: 18–12–08**SYSTEM NAME:**

Erma Byrd Scholarship Program (EBSP).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Postsecondary Education, U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8510.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records on students who apply for EBSP scholarships to pursue a course of study that will lead to a career in industrial health and safety occupations, including mine safety. To be eligible for EBSP scholarships, applicants must be United

States citizens, nationals, or permanent residents who are enrolled or planning to enroll in an accredited institution of higher education in a degree program that will prepare them for a career in industrial health and safety occupations, including mine safety. Individuals must be enrolled or planning to enroll in an associate's degree program, or be within two years of completing a degree at the bachelor's or graduate level.

In selecting undergraduate applicants to receive an EBSP scholarship, the Department will give priority first to students who are eligible to receive a Federal Pell Grant. The Federal Pell Grant Program provides need-based grants to low-income undergraduate and certain postbaccalaureate students to promote access to postsecondary education. In addition, the Department will evaluate eligibility for the EBSP scholarships based on an applicant's course of study.

CATEGORIES OF RECORDS IN THE SYSTEM:

The EBSP system contains a variety of information relating to a student's application for, and participation in, the EBSP. Information on an applicant in the system includes the student's name, the student's Social Security number, the student's address, the student's phone number, the student's e-mail address, the student's course of study, and the name of the institution of higher education in which the student is enrolled or intends to enroll. The Department is collecting the student's Social Security number in order to verify the Federal Pell Grant eligibility of EBSP undergraduate applicants through the U.S. Department of Education's National Student Loan Data System. If the applicant receives an EBSP scholarship, the system also includes information about the amount and period of the student's scholarship, the student's agreement to the terms of the scholarship, verification of the institution's agreement to disburse the scholarship, and verification of the student's employment in a career related to industrial health and safety occupations, including mine safety, for a period of at least one year, beginning no more than six months after completion of the degree. The Department is also collecting the student's Social Security number in order to facilitate conversion of the scholarship into a Federal Direct Loan should the recipient fail to comply with the terms and conditions of the scholarship.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Division F, Title III of the Omnibus Appropriations Act, 2009 (Pub. L. 111–8) and the Government Performance Results Act of 1993 (Pub. L. 103–62).

PURPOSE(S):

The Department is establishing this system of records for the following purposes:

(1) To determine the qualifications and eligibility of EBSP scholarship applicants, including the determination of Pell eligibility (for undergraduates).

(2) To ensure compliance with program requirements.

(3) To demonstrate program effectiveness.

(4) To ensure that an EBSP scholarship recipient fulfills the service obligation associated with this program by obtaining employment in a career related to industrial health and safety occupations, including mine safety, for at least one year after completion of the degree.

(5) To ensure the repayment of the amount of the scholarship if the student is not employed in a career related to industrial health and safety occupations, including mine safety, for at least one year after completion of the degree.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. The Department may make these disclosures on a case-by-case basis, or, if the Department has complied with the computer matching requirements of the Computer Matching and Privacy Protection Act of 1988, as amended, under a computer matching agreement.

(1) *Program Disclosures.* The Department may disclose records to an institution of higher education to verify that the scholarship recipient is enrolled in an eligible program at that institution and to facilitate the disbursement of scholarship funds under this program. In addition, the Department may disclose records to the scholarship recipient's employer to verify that the scholarship recipient is employed in a career position related to industrial health and safety, including mine safety, for at least one year after completion of the degree.

(2) *Disclosure for Use by Other Law Enforcement Agencies.* The Department may disclose information to any

Federal, State, local, or foreign agency, or other public authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility within the receiving entity's jurisdiction.

(3) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statutory, regulatory, or legally binding requirement, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, Tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive order, rule, regulation, or order issued pursuant thereto.

(4) *Litigation and Alternative Dispute Resolution (ADR) Disclosure.*

(a) *Introduction.* In the event that one of the parties listed below is involved in litigation or ADR, or has an interest in litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department or any of its components.

(ii) Any Department employee in his or her official capacity.

(iii) Any Department employee in his or her individual capacity if the U.S. Department of Justice (DOJ) has been requested to or has agreed to provide or arrange for representation for the employee.

(iv) Any Department employee in his or her individual capacity where the Department has agreed to represent the employee.

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to DOJ.* If the Department determines that disclosure of certain records to DOJ is relevant and necessary to litigation or ADR, the Department may disclose those records as a routine use to DOJ.

(c) *Adjudicative Disclosure.* If the Department determines that it is relevant and necessary to the litigation or ADR to disclose certain records to an adjudicative body before which the Department is authorized to appear, to an individual, or to an entity designated by the Department or otherwise empowered to resolve or mediate disputes, the Department may disclose

those records as a routine use to the adjudicative body, individual, or entity.

(d) *Disclosure to Parties, Counsel, Representatives, or Witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(5) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records to DOJ or OMB if the Department concludes that disclosure would help in determining whether particular records are required to be disclosed under the FOIA or the Privacy Act.

(6) *Contract Disclosure.* If the Department contracts with an entity to perform any function that requires disclosing records to the contractor's employees, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) with respect to the records in the system.

(7) *Congressional Member Disclosure.* The Department may disclose the records of an individual to a member of Congress or the member's staff in response to an inquiry from the member made at the written request of that individual. The member's right to the information is no greater than the right of the individual who requested the inquiry.

(8) *Disclosure in the Course of Responding to Breach of Data.* The Department may disclose records to appropriate agencies, entities, and persons when: (a) The Department suspects or has confirmed that the security or confidentiality of information in the EBSP system has been compromised; (b) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of the EBSP system or other systems or programs (whether maintained by the Department or by another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise

and prevent, minimize, or remedy such harm.

DISCLOSURE TO CONSUMER REPORTING AGENCIES

Disclosures pursuant to 5 U.S.C. 552a(b)(12): The Department may disclose to a consumer reporting agency information regarding a claim by the Department which is determined to be valid and overdue as follows: (1) The name, address, taxpayer identification number and other information necessary to establish the identity of the individual responsible for the claim; (2) the amount, status, and history of the claim; and (3) the program under which the claim arose. The Department may disclose the information specified in the preceding sentence in accordance with 5 U.S.C. 552a(b)(12) and the procedures contained in 31 U.S.C. 3711(e). A consumer reporting agency to which these disclosures may be made is defined in 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE

The hard copy records will be stored in locked filing cabinets, and the electronic copy records will be maintained in a database on the Department's secure servers and in other electronic storage media.

RETRIEVABILITY

Records are retrieved using an individual's name, Social Security number, or institution of higher education in which the applicant is enrolled.

SAFEGUARDS

Access to the records is limited to authorized personnel only. All physical access to the Department's site where the data is collected and this system of records is maintained is controlled and monitored by security personnel who check each individual entering the buildings for his or her employee or visitor badge.

The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This security system limits data access to Department and contract staff on a "need-to-know" basis, and controls an individual user's ability to access and alter records within the system. All users of this system of records are given a unique user identification. The Department's Privacy

Policy requires the enforcement of a complex password policy. In addition, users are required to change their passwords at least every 60 to 90 days in accordance with the Department's information technology standards.

RETENTION AND DISPOSAL

In accordance with the Department's Records Disposition Schedules, part 10, Item 3a, records will be destroyed five years after final payment to grantee, or after audit, whichever is sooner.

SYSTEM MANAGER(S) AND ADDRESS

Lauren Kennedy, Erma Byrd
Scholarship Program Office, Office of
Postsecondary Education, U.S.
Department of Education, 1990 K Street,
NW., 6th Floor, Washington, DC 20006-
8510.

NOTIFICATION PROCEDURE

If you wish to determine whether a record exists regarding you in the system of records, contact the system manager. Your request must meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURE

If you wish to gain access to your record in the system of records, contact the system manager at the address listed under **SYSTEM MANAGER AND ADDRESS**. Requests should contain your full name, address, and telephone number. Your request must meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURE

If you wish to contest the content of a record regarding you in the system of records, contact the system manager. Your request must meet the requirements of the regulations in 34 CFR 5b.7, including proof of identity.

RECORD SOURCE CATEGORIES

Information maintained in this system of records is obtained from applicants, institutions of higher education, and employers of scholarship recipients. In addition, information from the U.S. Department of Education's National Student Loan Data System will be used to verify information maintained in this system of records.

EXEMPTIONS CLAIMED FOR THIS SYSTEM

None.

[FR Doc. E9-18615 Filed 8-3-09; 8:45 am]

BILLING CODE 4000-01-P

Reader Aids

Federal Register

Vol. 74, No. 148

Tuesday, August 4, 2009

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.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at <http://www.regulations.gov>.**CFR Checklist.** Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at <http://bookstore.gpo.gov/>.

FEDERAL REGISTER PAGES AND DATE, AUGUST

38323-38502..... 3
38503-38884..... 4

CFR PARTS AFFECTED DURING AUGUST

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.

4 CFR	124.....38342
202.....38503	126.....38342
Proposed Rules:	129.....38342

200.....38363
201.....38366

7 CFR

925.....38323
932.....38324
944.....38323
948.....38504
959.....38505

9 CFR

145.....38326

10 CFR

26.....38326

Proposed Rules:

31.....38372

12 CFR

1229.....38508
1291.....38514

Proposed Rules:

914.....38559
985.....38564
989.....38564
1235.....38559
1273.....38564
1274.....38564
1282.....38572
1732.....38559

14 CFR

25.....38328
39.....38340
135.....38522

Proposed Rules:

39.....38381

17 CFR

232.....38523

21 CFR

510.....38341
524.....38341
872.....38686

22 CFR

123.....38342

124.....38342
126.....38342
129.....38342

26 CFR

1.....38830
31.....38830
602.....38830

29 CFR

Proposed Rules:

471.....38488

33 CFR

100.....38524
147.....38524
165.....38524, 38530

37 CFR

351.....38532

39 CFR

Proposed Rules:

111.....38383
3020.....38533

40 CFR

52.....38536
62.....38344, 38346
141.....38348

Proposed Rules:

62.....38384, 38385

44 CFR

64.....38358

Proposed Rules:

67.....38386

47 CFR

Proposed Rules:

73.....38388, 38389

50 CFR

300.....38544
679.....38558

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 "PLUS" (Public Laws Update Service) on 202-741-6043. This list is also available online at <http://www.archives.gov/federal-register/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.

S. 1513/P.L. 111-43

To provide for an additional temporary extension of

programs under the Small Business Act and the Small Business Investment Act of 1958, and for other purposes. (July 31, 2009; 123 Stat. 1965)

Last List July 30, 2009

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.